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PARTNERSHIP AND BIOBANK GOVERNANCE

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Abstract

The forward march of biobanking creates the need for an alternative approach to biobank governance. Biobanking encourages medical advancement by making the conduct of health-related research more efficient, by minimising physical harms to participants, and by facilitating personalised medicine and greater understandings of disease. Nonetheless, its characteristics that distinguish it from general health-related research often give rise to many ethical and social issues. For example, multiple and unexpected uses of biobank resources can render conventional informed consent inadequate for safeguarding participants and maintaining public trust and confidence. Also, because the size of a biobank cohort is normally large, biobanking usually requires considerable management resources and this can mean that biobanks can likely be financially dependent upon for-profit entities. This dependency can cause concern among participants and publics about commercial exploitation. These issues suggest that a new approach to biobank governance is required to address them. Indeed, their complexity and the sheer longevity of biobanking itself also suggest that it is relatively feasible and coherent to address them by focusing on a *relationship* between participants and biobankers. This involves many aspects of interaction and reflects an element of continuity, which is crucial to biobanking success, as opposed to one-off measures. Consequently, with the aim of addressing issues that arise from biobanking, this thesis offers an analysis of the participant-biobanker relationship that can deal with these issues. Such a relationship constitutes an authentic research relationship in biobanking ("**ARR**").

Based on this premise, the main research question of my thesis is to ask: What form of research relationship is appropriate for effective and ethical biobanking practices? Three sub-questions are raised to solve this top-level research question. They start with a normative question of why the ARR proposed in this thesis is desirable for biobanking. The next sub-question asks what this ARR should look like from a conceptual perspective. For a practical respect on my proposals, the last sub-question concerns the ways in which the ARR can be fostered in practice.

To address these research questions, my thesis first establishes the main characteristics of the proposed ARR as the fundamental notion thereof. These main characteristics are used to answer the first sub-question. For the second sub-question, the thesis suggests that the ARR should be based on the concept of partnership, as opposed to solidarity, mainly because partnership can exhibit the main characteristics of the ARR – as argued – and can also be prescribed in a governance manner. The thesis then uses partnership as a basis for proposing the key features of the ARR, which are deemed to be a conceptual framework for the ARR. To answer the last sub-question, the thesis uses this conceptual framework to propose a partnership model for biobank governance that can be used to develop the ARR in practice.

My original contribution is to propose a novel approach to an ARR, and this ARR is based on the concept of partnership. In other words, my thesis argues that the pursuit of the ARR, which looks like a partnership relationship, is an important element of biobanking success. In this respect, my thesis is about a sociologically informed role for partnership in biobank governance. It also provides a nuanced epistemological grounding for a participant-biobanker relationship in both conceptual and practical ways. From a philosophical perspective, my thesis proposes an ethical framework for biobank governance that perceives partnership as a virtuous trait for biobankers and provides rules for acquiring this trait through biobanking practices. Notably, it is argued that this partnership is not – nor need it be – the legal paradigm of partnership, which fundamentally refers to for-profit business association. While law might have a role to play in facilitating the development of the ARR, it cannot prescribe the ARR nor should it attempt to do so.

Lay Summary

Medical advances are generally made through health-related research. Recently, there is a trend towards facilitating this research by establishing biobanks: collections of tissue samples and/or information that serve as resources for research. One substantial benefit of biobanks is that their resources can be used in multiple research studies and so they help researchers avoid the need for participant recruitment in every research study, thus enabling researchers to conduct research studies more conveniently and efficiently. Moreover, biobank resources are usually so rich that they allow research studies on diseases or treatments that cannot be made if the amount and variety of research resources are not sufficient, like multifactorial diseases and personalised treatments.

Notwithstanding, some issues could arise from using biobanks as research resources, and these issues possibly make participation in biobanks unappealing to some potential participants, who would otherwise be crucial contributors by providing biobanks with tissue samples and information as research resources. One example arises from the fact that uses of biobank resources in research studies are in the future and sometimes unforeseeable. This means that, when being recruited in biobanks, participants cannot know exactly how their samples and information are to be used. As a result, they cannot know whether such uses will cause any harms to them. Such uses might, for example, disclose their health condition that can cause emotional injury to them or their families. This disclosure might even expose them to discrimination and stigmatisation. In this respect, they cannot realise all risks involved when giving consent to participation in biobanks. Occurrence of such harms without their anticipation might render participation in biobank unacceptable to them and might even lead them to withdraw from any biobanks in which they have previously agreed to participate. This implication could undermine the viability of biobanks or even discourage biobanking practices in the long run.

Given the complexity of the issues arising from biobanking practices and the long-term nature of biobanks, it can be difficult to simply suggest one or more one-off measures as solution to these issues. Rather, it is argued in this thesis that it is preferable, feasible and coherent to address them by focusing on the nature of a *relationship* between participants and biobankers. This is because it involves many aspects of interaction and reflects an element of continuity, which is crucial to biobank success. Thus, with the aim to address the issues arising from biobanking, this thesis argues for a participant-biobanker relationship that can appropriately deal with these issues and such a relationship is considered as an authentic research relationship in biobanking ("**ARR**"). In other words, the thesis proposes one approach to an ARR so as to render participation in biobanks more appealing to participants and publics as well as to encourage and facilitate biobanking practices. As a result of my research, my thesis suggests that an ARR should look like a partnership relationship. The thesis justifies why an ARR should be based on partnership and how so? It then suggests how an ARR can be fostered in biobanking practice.

Declaration

I declare as follows:

a) the thesis has been composed by myself;

b) the work is my own;

c) the work has not been submitted for any other degree or professional qualification; and

d) no publications are included, except quotations excerpted from other people's publications indicated throughout the thesis.

Tarmphong Chobisara

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Chapter 1

Introduction and Fundamental Notion of the ARR

This thesis is interested in pursuing a participant-biobanker relationship that can be considered authentic. As for the reason behind this interest, there has been a trend towards establishing research biobanks to facilitate health-related research. When compared with conventional research conduct, biobanking is proving to be relatively beneficial to making medical advances by making research conduct more convenient and efficient, as well as allowing researchers to acquire more in-depth knowledge on medical science. Despite these advantages, my literature review suggests that many characteristics of biobanking also raise many issues and challenges that can render biobanking unattractive to participants or weaken their relationship with biobankers, thereby undermining biobanking together with its benefits. Accordingly, with the aim of encouraging biobanking, this thesis seeks to argue for a participant-biobanker relationship that can deal effectively with those issues and challenges. Such a relationship is considered here to be an authentic research relationship in biobanking ("**an ARR**"). The contribution of my thesis is therefore to provide one approach to an authentic research relationship ("**the ARR**") and, as explained in the following chapter, it should look like a *partnership* relationship. Note that, with the expression 'one approach', this thesis is based on the assumption that there are many types of relationship that can be considered 'authentic' for biobanking, and it merely proposes one of them, which is based on the concept of partnership. This implies that there may be other types of relationship that can also be considered authentic in a biobanking context.

This chapter is primarily aimed at explaining the context of this thesis as well as establishing some basic notions regarding the ARR that are per se part of the proposals of this thesis and are necessary for understanding other proposals developed in subsequent chapters. In so doing, its structure can be illustrated as follows. The first section outlines the background problems of this thesis by illustrating how the

distinctive characteristics of biobanking raise many issues and challenges in biobanking practice. It then justifies why this thesis ultimately focuses on proposing a participant-biobanker relationship, as opposed to suggesting one or more one-off measures for biobank governance. The second section explains the principal research question of this thesis together with three sub-questions that need to be addressed to answer this principal question. This section also explains how this thesis is structured and the research methods used in this thesis. The third section clarifies the contribution of this thesis by highlighting some aspects of this contribution in order to define the scope thereof. The fourth section establishes the fundamental notion of the ARR by proposing two main characteristics of it. The last section summarises the contents of this chapter and draws a tentative conclusion regarding the contribution of this thesis.

Three words should first be defined here. First, as far as an ARR is concerned, the term 'authentic' is used in an instrumental manner: an ARR is not claimed to be genuine, in a literal sense, for a participant-biobanker relationship in general; instead, this term is used to make a reference to a participant-biobanker relationship that is capable of tackling issues and challenges arising in biobanking practice. Second, as further explained in Sub-section 1.3.1 below, a biobank refers to a collection of tissue samples and/or data related to tissue samples that is organised or held with an intention to use for health-related research. Finally, in this thesis, biobankers mean all persons who work as part of biobanks. In this respect, they are those involved in organising and/or conducting biobanking activities in certain biobanks, regardless of their professions. They include nurses who collect tissue samples and data from participants, persons who have a role in communicating with participants about biobanking, lawyers who are tasked with tackling legal issues arising from biobanking activities, and principal investigators who facilitate biobanking activities in general. In this sense, biobankers here exclude participants, funders who merely provide financial support for biobank projects, and scientists who only use biobank resources in their research projects.

1.1 Background Problems

The need for medical advances has prompted efforts to make the process of health-related research more efficient and be better positioned to investigate complicated diseases and develop innovative treatments. In recent decades, these efforts have resulted in the establishment of biobanks: organised collections of biological tissue samples and data, which serve as research resources for multiple research studies.[1] Undeniably, the benefits of biobanking are noticeable. Particularly as researchers can use research resources in biobanks, they do not need to recruit participants for every research study. As a result, their administrative burdens and need for management resources significantly decrease, making their research more convenient and efficient. Indeed, the risk of an insufficient cohort is also substantially reduced. Moreover, biobanks usually contain various types of research resources, including tissue samples and a variety of information related to the samples. Some biobanks, such as national and population-based ones, even have large participant cohorts. These characteristics offer many advantages to research conduct. For example, they allow the risks associated with common genetic variations to be generalised and quantified, enabling researchers to understand genetic influence on common multifactorial or complex diseases. Also, these characteristics make it possible to innovate personalised treatments, whereby medical treatment is tailored to individual patients. Other than the benefits to researchers, biobanking is also claimed to entail minimal risks of physical or emotional harm to participants.[2] Given all these

[1] J Kaye et al, "From an Idea to a Project" in J Kaye, SM Gibbons, C Heeney, M Parker and A Smart (eds), *Governing Biobank: Understanding the Interplay between Law and Practice*, (Oxford: Hart Publishing, 2012) 3-29, at 14-15.

[2] LM Beskow et al, "Informed Consent for Population-Based Research Involving Genetics" (2001) 286 *JAMA* 18 2315-2321; S Eriksson and G Helgesson, "Potential Harms, Anonymization, and the Right to Withdraw Consent to Biobank Research" (2005) 13 *European Journal of Human Genetics* 9 1071-1076; UK Biobank, *Information Leaflet*, (2010) 11. Notably, this claim is not widely accepted. See TK Baumann, "Proxy Consent and a National DNA Databank: An Unethical and Discriminatory Combination" (2001) 68 *Iowa Law Review* 2 667-701.

benefits, it is understandable why many countries have recently established their own national biobanks, including Estonia,[3] Taiwan,[4] Sweden,[5] Denmark[6] and the UK.[7]

Biobanking Issues

Nevertheless, biobanking presents a number of issues in practice. According to my literature review, these issues essentially result from the distinctive characteristics of biobanking and they might render biobanking unappealing to potential participants due to, inter alia, nullifying many conventional safeguards for research participants or making participants feel uneasy about biobanking. These issues will now be briefly explained according to the characteristics of biobanking.

For issues regarding participant safeguards, the foremost characteristic is multiple and unforeseen uses of biobank resources, which intrinsically nullify the conventional safeguard of informed consent.[8] In particular, as biobank resources can be used multiple times in the future and these uses are sometimes unexpected, there is not sufficient information available to prospective participants for them to know exactly how their samples and information will be used after recruitment. In this respect, they cannot be sufficiently informed in a conventional sense. Consequently, they might not know whether or not future uses will be in accordance with their expectations and biobanking goals. More importantly, they might also be unable to realise or anticipate any harm resulting from those uses, thus preventing them from assessing the risks and benefits of their participation properly. This is especially the case when genetic materials are involved, as genetic research can have far-reaching implications.[9] It can therefore be said that this characteristic of biobanking renders

[3] University of Tartu, "Estonian Genome Center" available at http://www.geenivaramu.ee/en (accessed 15 July 2016)
[4] Taiwan Biobank, available at http://www.twbiobank.org.tw/ (accessed 15 July 2016)
[5] Biobanking and Molecular Resource Infrastructure of Sweden, available at http://bbmri.se/en/ (accessed 15 July 2016)
[6] Danmarks Nationale Biobank, available at http://nationalbiobank.dk/ (accessed 15 July 2016)
[7] UK Biobank, available at http://www.ukbiobank.ac.uk/ (accessed 10 July 2016)
[8] H Widdows and S Cordell, "The Ethics of Biobanking: Key Issues and Controversies" (2011) 19 *Health Care Analysis* 3 207-219; KJ Maschke, "Alternative Consent Approaches for Biobank Research" (2006) 7 *The Lancet Oncology* 3 193-194.
[9] Council for Responsible Genetics, *Genetic Discrimination: A Position Paper Presented by the Council for Responsible Genetics*, (January 2001) 5.

informed consent ineffective in terms of safeguarding participants from harm resulting from their participation in biobanking.

The next characteristic is the variety of research resources. Biobanks usually contain tissue samples and many types of related data other than health information, including medical histories, genotypes, lifestyles and behaviours. These data are collected by asking participants questions, performing measurements on them and/or acquiring information collected from other existing databases. While this characteristic makes biobanking distinctively beneficial to health-related research, as explained above, it may render anonymisation unable to safeguard participants from harm to their confidentiality and privacy since a concealed identity might be uncovered by researchers using certain genetic information.[10] This exposes participants to risks of discrimination and stigmatisation.[11] As an example, if it is revealed to participants' insurance companies that they are part of a cohort with a high chance of suffering heart disease, they might have to pay a higher premiums although they are actually healthy and do not eventually contract the disease. Indeed, provided that genetic material or information is involved, this implication might also affect other people who are genetically related to them, such as their families or genetic communities. One can therefore say that the richness of biobank resources might render anonymisation unable to protect biobank participants' identity from unauthorised disclosure.

Other than issues regarding these participant safeguards, biobanking might raise other issues that implicitly cause participants to feel uneasy about biobanking. These issues mainly stem from the size of biobank cohorts, which are normally large. Particularly, in practice, this characteristic increases the cost and the administrative burden of biobanking activities. On the one hand, this increase usually causes

[10] Z Lin et al, "Genomic Research and Human Subject Privacy" (2004) 305 *Science* 5681 183-183.

[11] R Ashcroft, "Should Genetic Information Be Disclosed to Insurers? No" (2007) 334 *BMJ* 7605 1197-1197; C Heeney et al, "Assessing the Privacy Risks of Data Sharing in Genomics" (2011) 14 *Public Health Genomics* 1 17-25. However, some authors say that this concern might be exaggerated. See HT Greely, "The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks" (2007) 8 *Annual Review of Genomics and Human Genetics* 1 343-364, at 350; MA Hall and SS Rich, "Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination" (2000) 66 *American Journal of Human Genetics* 1 293-307.

biobanking to rely upon financial support from the private sector,[12] thereby allowing for-profit companies to become influential in biobanking. Indeed, this probably makes biobanking prone to the accusation of commercial exploitation, which is opposed to participants' altruism and can provoke public disapproval. This probability is supported by extensive literature[13] and empirical studies[14] revealing concerns about commercial involvement in biobanking. On the other hand, the aforesaid increase in cost and administrative burden makes it difficult for biobankers to implement some measures that help make participants feel content with biobanking. An example of such measures is the provision of individual feedback: while many empirical studies suggest that individual feedback is generally desirable,[15] it might be unfeasible for large-scale biobanks to provide feedback, especially when it involves careful and complicated analysis. One can therefore say that the large cohort size of biobanks might indirectly render biobanking unattractive to participants. Indeed, this might also be the case for small-scale biobanks that do not have limited resources.

It can be concluded from the explanations above that, while many characteristics of biobanking are distinctively beneficial to health-related research,

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[12] This is supported by a survey revealing that funding shortage is a main concern for biobanking. See RJ Cadigan et al, "Neglected Ethical Issues in Biobank Management: Results from a U.S. Study" (2013) 9 *Springer-Verlag* available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228790/ (accessed on 14 July 2016).

[13] M Anderlik, "Commercial Biobanks and Genetic Research: Ethical and Legal Issues" (2003) 3 *American Journal of Pharmacogenomics* 3 203-215; D Budimir et al, "Ethical Aspects of Human Biobanks: A Systematic Review" (2011) 52 *Croatian Medical Journal* 3 262-279.

[14] G Haddow et al, "Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal" (2007) 64 *Social Science & Medicine* 2 272-282; Wellcome Trust and MRC, *Public Perceptions of the Collection of Human Biological Samples*, (October 2000) 130, at 63-64; *Biobank UK: A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust* (March 2002) 46, at 20-21; SB Trinidad et al, "Genomic Research and Wide Data Sharing: Views of Prospective Participants" (2010) 12 *Genetics in Medicine* 8 486-495.

[15] J Murphy et al, "Public Expectations for Return of Results from Large-cohort Genetic Research" (2008) 8 *The American Journal of Bioethics* 11 36-43; AA Lemke et al, "Biobank Participation and Returning Research Results: Perspectives from a Deliberative Engagement in South Side Chicago" (2012) 158A *American Journal of Medical Genetics Part A* 5 1029-1037; D Wendler and E Emanuel, "The Debate over Research on Stored Biological Samples: What Do Sources Think?" (2002) 162 *Archives of Internal Medicine* 13 1457-1462; NL Allen et al, "Biobank Participants' Preferences for Disclosure of Genetic Research Results: Perspectives from the OurGenes, OurHealth, OurCommunity Project" (2014) 89 *Mayo Clinic Proceedings* 6 738-746.

they might raise many issues that make biobanking unappealing to participants. To encourage biobanking, these issues need to be properly addressed in order to make biobanking more acceptable to participants. In so doing, however, there are many practical challenges to be overcome.

Practical Challenges

The first one is the inevitable trade-offs between different values and interests. This is particularly the case for commercial involvement in biobanking and possibilities of re-identification: as explained above, while the richness of biobank resources allows scientifically-valid and ground breaking research studies, the large size of biobank cohorts might heighten the risk of commercial exploitation, and the variety of information about participants might allow their identity to be disclosed despite anonymisation. Indeed, even if complete anonymisation is possible, it will prevent the provision of individual feedback, which is considered generally desirable and might be clinically beneficial to participants. Given these trade-offs, it can be said that direct solutions to these biobanking issues might not be feasible in practice. Particularly, while a decrease in the range of biobank resources and the prohibition of commercial involvement might address those two issues, those measures could reduce the intrinsic value of biobanking and make it practically unviable, respectively. One can, therefore, say that the attempts to address these biobanking issues can create tension between biobanks' and participants' interests – i.e. the capabilities of biobank resources versus the potential harms to participants' privacy and other personal interests, and the sufficiency of financial support versus participants' unease about commercial exploitation.[16]

Another practical challenge stems from the longevity of biobanking, because this characteristic renders many one-off measures inappropriate for addressing biobanking issues. An obvious example is the issue regarding consent procedure in biobanking. Particularly, as explained above, multiple and unexpected uses of biobank

[16] Note that other trade-offs in biobanking are also pointed out in the academic literature, such as degrees of privacy versus facilitation of research and individual control of samples versus consideration of community risks and benefits. See KC O'Doherty and MM Burgess, "Engaging the Public on Biobanks: Outcomes of the BC Biobank Deliberation" (2009) 12 *Public Health Genomics* 4 203-215, at 203.

resources make informed consent impractical for safeguarding participants. As a result, alternative approaches to consent have been proposed to replace this conventional one,[17] such as tiered consent,[18] implied consent[19] and broad consent.[20] My literature review suggests that the latter approach seems to be preferable and has become the mainstream choice in practice, as it has generally been adopted in many biobank initiatives.[21] While these alternatives are, in practice, more suitable for handling unexpected uses of biobank resources when compared to informed consent, it is still questionable whether they provide participants with sufficient safeguards against any harm caused by future uses, since participants do not know how biobank resources will *actually* be used, let alone the probable dynamics of and uncertainty in biobanking caused by changes in policies and the direction of biobanking activities, if any. One can therefore doubt whether these one-off consent approaches can be solutions to this biobanking issue. This also implies that they are unable to deal properly with the longevity of biobanking, and so they might not be able to make biobanking attractive to participants.

Appropriate Solutions?

These practical challenges indicate that it is not straightforward to address the aforementioned issues in biobanking. To make biobanking attractive to participants, one solution to these issues might be to consistently engage them in making decisions

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[17] AL McGuire and LM Beskow, "Informed Consent in Genomics and Genetic Research" (2010) 11 *Annual Review of Genomics and Human Genetics* 361-381.
[18] AL McGuire and RA Gibbs, "No Longer De-Identified" (2006) 312 *Science* 5772 370-371; MA Rothstein, "Tiered Disclosure Options Promote the Autonomy and Well-Being of Research Subjects" (2006) 6 *The American Journal of Bioethics* 6 20-21.
[19] P Furness, "Consent to Using Human Tissue: Implied Consent Should Suffice" (2003) 327 *BMJ* 7418 759-760; JWW Coebergh et al, "One-time General Consent for Research on Biological Samples: Opt Out System for Patients is Optimal and Endorsed in Many Countries" (2006) 332 *BMJ* 7542 665-667; L Johnsson et al, "Opt-out from Biobanks Better Respects Patients' Autonomy" (2008) 337 *BMJ* a1580-a1580.
[20] D Wendler, "One-time General Consent for Research on Biological Samples" (2006) 332 *BMJ* 7540 544-547; MG Hansson et al, "Should Donors Be Allowed to Give Broad Consent to Future Biobank Research?" (2006) 7 *The Lancet Oncology* 3 266-269.
[21] German Ethics Council, *Human Biobanks for Research: Opinion*, (2010) 57, at 18; *Icelandic Biobanks Act (No. 110/2000)*, art 7; *Estonian Human Genes Research Act 2000*, s 12; *Norwegian Health Research Act 2008*, s 14; Norwegian Institute of Public Health, *Protocol: The Norwegian Mother and Child Cohort Study*, (June 2002) 63. Both UK Biobank and ALSPAC use broad consent to recruit their participants. See ch 4 and 5 below.

about biobanking. In principle, this solution is arguably promising because it has the element of continuity, which can deal with the longevity of biobanking, and it might enable participants to know about and deal with any possible harm to them, including possible disclosure of their identity, and/or commercial involvement in biobanking. Examples of this engagement that are usually proposed in the academic literature, are dynamic consent and ongoing participant involvement. Nevertheless, when considering these examples in more detail, one can say that they raise additional practical issues that can undermine biobanking practices, as explained below.

Dynamic consent allows participants to decide whether their samples and information will be used in certain research studies throughout biobanking endeavours. In this respect, they can directly control every use of biobank resources at an individual level.[22] While this approach can deal well with unexpected uses of biobank resources, as well as the long-term nature of biobanks, it is probably undesirable in practice. One reason is that it can impose substantial administrative and financial burdens on biobankers. Moreover, even though some proposals for dynamic consent that use either opt-outs[23] or an information technology interface[24] could avoid these burdens to some extent, it remains doubtful whether participants really prefer dynamic consent as some empirical studies indicate that some people consider the complicated information in consent material cumbersome, and some feel unqualified to make decisions about the uses of biobank resources,[25] let alone their actual capabilities for doing so.[26] Furthermore, this consent approach might also raise the practical issue of insufficient cohorts, since participants can decide not to participate in certain studies. This issue

[22] J Kaye et al, "From Patients to Partners: Participant-Centric Initiatives in Biomedical Research" (2012) 13 *Nature Reviews: Genetics* 5 371-376; J Kaye et al, "Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks" (2015) 23 *European Journal of Human Genetics* 2 141-146.
[23] J Kaye, "Abandoning Informed Consent the Case of Genetic Research in Population Collections" in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, (London: Routledge, 2004) 117-138.
[24] See note 22 above.
[25] CM Simon et al, "Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models" (2011) 13 *Genetic Medicine* 9 821-831; AL McGuire et al, "DNA Data Sharing: Research Participants' Perspectives" (2008) 10 *Genetics in Medicine* 1 46-53.
[26] KS Steinsbekk et al, "Broad Consent versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?" (2013) 21 *European Journal of Human Genetics* 9 897-902.

can significantly discourage biobanking practices, especially when the reasons behind those decisions might be based on conscience – not reasonable grounds. It can therefore be said that the use of dynamic consent can raise additional practical issues that might hinder biobanking. Note that there are some academic controversies about whether participants should have control over biobanking at all, as explained below.[27]

As regards ongoing participant involvement, participants are continuously involved in biobank management by, inter alia, being appointed to working groups or committees dealing with biobank governance. In some circumstances, participants' communities are involved in organising biobanks as well.[28] Accordingly, participants are allowed to know about and deal with biobanking issues directly by collaborating with biobankers or influencing decisions about biobanking activities at a collective level. Nonetheless, there might be some other issues that arise with such involvement in practice. On the one hand, it is questionable whether involvement procedures employed are meaningful or just tokenistic, as participant involvement can be executed in many forms – ranging from merely being informed about biobanking activities to having actual control over biobanking.[29] Thus, it is possible for participants to be involved in biobanking but not actually able to help address any biobanking issues. On the other hand, this involvement usually leads certain participants to represent other participants or a whole cohort, thereby causing the interests of some participants to be overlooked.[30] It can therefore be said that there may be some practical issues arising from measures employed to involve participants in biobanking.

Given these two examples, the conclusion drawn here is that measures for engaging participants in biobanking could raise additional issues in practice. That is, to the extent that these measures might provide some solutions, they only do so for other practical issues that this thesis is concerned about. One might therefore ask whether they really can be appropriate solutions to biobanking issues.

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[27] See 6.4.1 in ch 6 below.
[28] AA Lemke et al, "Community Engagement in Biobanking: Experiences from the eMERGE Network" (2010) 6 *Genomics, Society, and Policy* 3 35-52.
[29] See 2.2.3 (b) in ch 2 below.
[30] See 6.3.1 in ch 6 below.

Focus on Research Relationships

All the explanations above reveal the complexity of the issues arising in biobanking: those issues involve trade-offs between different values and interests; some measures for addressing them might raise additional issues in practice. These explanations also suggest that one or more one-off measures might not be the best solution to these biobanking issues. A relatively holistic solution is therefore required to maintain the viability and acceptability of biobanking.

Nonetheless, one might question whether this requirement is really necessary, as many empirical studies indicate a high level of trust in a biobanking context.[31] Despite such evidence, the answer to this question is arguably positive[32] since it is still vital to ensure the ethicality of biobanking practices. This is especially the case when considering many circumstantial factors that might potentially hamper biobanking, such as public mistrust in science[33] and the erosion of trust caused by the supposed untrustworthiness of professional actors.[34] These factors also include some scandals that could diminish the public's trust in health-related research, such as the unexpected commercial uses of research results in the *Greenberg* case, the unauthorised removal and retention of human tissues in the *Alder Hey* case, the suspicious exploitation of the Icelandic people's genetic make-up[35] and the introduction of an opt-out model into the sharing of sensitive health information with commercial companies in the care.data

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[31] AK Rahm et al, "Biobanking for Research: A Survey of Patient Population Attitudes and Understanding" (2013) 4 *Journal of Community Genetics* 4 445-450; W Lipworth et al, "Tissue Donation to Biobanks: A Review of Sociological Studies" (2011) 33 *Sociology of Health & Illness* 5 792-811.

[32] Some authors argue for securing participants' trust in a biobanking context. See M Levitt and S Weldon, "A Well Placed Trust?: Public Perceptions of the Governance of DNA Databases" (2005) 15 *Critical Public Health* 4 311-321; LM Beskow and E Dean, "Informed Consent for Biorepositories: Assessing Prospective Participants' Understanding and Opinions" (2008) 17 *Cancer Epidemiol Biomarkers Prev* 6 1440-1451;

[33] UK House of Lords, "Science and Technology - Third Report" (March 2000) available at http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3801.htm (accessed 25 April 2012); B Wynne, "Public Engagement as a Means of Restoring Public Trust in Science--Hitting the Notes, But Missing the Music?" (2006) 9 *Community Genetics* 3 211-220.

[34] O O'Neill, *Autonomy and Trust in Bioethics*, (Cambridge: Cambridge University Press, 2004), at 3.

[35] HT Greely, "Iceland's Plan for Genomic Research: Facts and Implications" (2000) 40 *Jurimetrics* 153-191.

initiative.[36] Accordingly, an appropriate solution to biobanking issues is still essential. Otherwise, biobanking might not only directly erode participants' and the public's trust and confidence in biobanks, but also eventually hinder research practices as a whole, with implications for medical advances in the long run.

When considering the aforesaid complexity of biobanking issues together with the sheer longevity of biobanking, it is reasonable to suggest that it is a viable proposition to address these issues by focusing on a participant-biobanker *relationship*, as opposed to proposing certain one-off measures. One reason is that this method intrinsically reflects the element of continuity, which is crucial to biobanking success. Indeed, this element could deal well with the aforesaid inadequacy of participant safeguards stemming from one-off consent approaches. Furthermore, focusing on a relationship generally allows many aspects of interaction to be taken into consideration and could thereby provide ways to properly address any complicated issues or challenges. In this circumstance, one might say that this focusing can properly deal with the dynamics and uncertainty in biobanking, as well as the aforementioned trade-offs, by allowing different values and interests to be considered and providing contextually appropriate solutions. Given these reasons, it can be said that the focus on a participant-biobanker relationship may provide a more systemic and coherent solution here, since it may be able to deal with many issues and challenges arising in biobanking practice.

This thesis therefore aims to pursue a participant-biobanker relationship that can handle these issues and challenges, in order to make biobanking appealing to participants as well as to encourage biobanking practices. Notably, such a relationship is considered as an authentic relationship between biobankers and participants, or an ARR, in this thesis and, as emphasised below, this relationship is the core contribution of this thesis.

[36] Department of Health, "Review of Health and Care Data Security and Consent" (6 July 2016) available at https://www.gov.uk/government/speeches/review-of-health-and-care-data-security-and-consent (accessed 15 July 2016); National Data Guardian for Health and Care, *Review of Data Security, Consent and Opt-Outs*, (June 2016) 58; T-P van Staa et al, "Big Health Data: The Need to Earn Public Trust" (2016) 354 *BMJ* available at http://www.bmj.com/content/354/bmj.i3636 (accessed on 19 July 2016).

1.2 Research Questions and Methodology

From the previous sub-sub-section, it can be seen that this thesis pursues an ARR, i.e. a participant-biobanker relationship that can address issues and challenges arising in biobanking practice. As the distinctive characteristics of biobanking are beneficial to research conduct but these same characteristics render biobanking less appealing to participants, there seem to be two different values that need to be underlined when pursuing this relationship: one is the ethical acceptability of biobanking to participants, which makes biobanking attractive to them, and the other is the effectiveness of biobanking, which allows biobanking to fully benefit health-related research. Based on this premise, my principal research question asks: **What form of research relationship is appropriate for ethical and effective biobanking practices**? To address this top-level question, three sub-questions need to be dealt with.

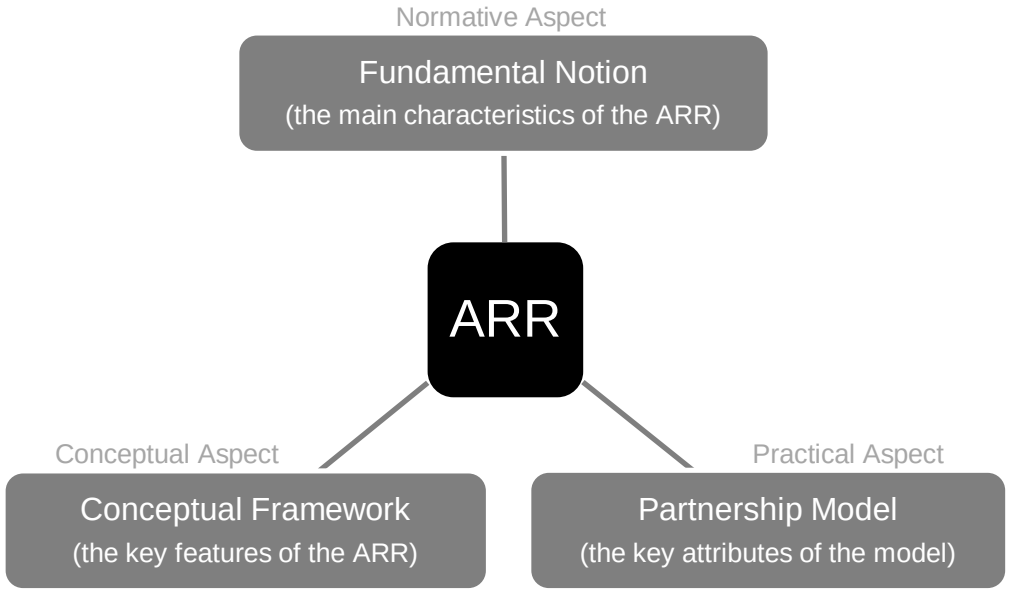
1.2.1 Three Sub-questions

The first sub-question concerns why the ARR proposed here is desirable for biobanking. This sub-question aims to provide a normative basis for the ARR. In so doing, this thesis first takes into account the issues and challenges in biobanking outlined in the previous section and then lays down the broad and basic criteria of the ARR. These criteria are considered to be the main characteristics that the ARR is expected to have. It can therefore be said that the ARR is normatively justified by illustrating how the background problems of this thesis are translated into the main characteristics of the ARR. **The second sub-question concerns what the ARR should look like from a conceptual perspective**. This sub-question aims to provide more details about the ARR that can be applicable in practice, by proposing the key features that conceptually characterise it. To do so, this thesis seeks for a concept in the field of social science that complies with the main characteristics of the ARR, so as to use the concept to underlie the ARR. As suggested in the title of this thesis, such a concept is partnership. Based on this, the thesis then develops a conceptual framework for the ARR by proposing four key features thereof. For a practical aspect

of my proposals, **the last sub-question concerns how the ARR can be developed in biobanking practice**. This sub-question suggests how to develop the ARR in practice by devising a partnership model for biobank governance that can incorporate the ARR's key features into biobanking activities. This model consists of four key attributes, and each key attribute requires biobankers to implement certain measures and mechanisms in biobank governance so as to manifest that key attribute.

Based on all these research questions, the main proposals of this thesis can be explained with the aid of a diagram, as shown in Box 1.1 below.

Box 1.1: The main proposals of the thesis



Two points should be noted here. The first point concerns the relation between these proposals. In particular, the main characteristics of the ARR, which are used to normatively justify it, stem from the background problems of this thesis and they are basic criteria for seeking the concept underlying the ARR. Then, this concept becomes a basis for developing the conceptual framework of the ARR, which consists of the key features of the ARR. This framework is eventually used as a guide when proposing the partnership model for biobank governance, and thereby this model basically entails biobanking activities that can reflect the ARR's key features. Based on this relation, it is worth emphasising that the main characteristics of the ARR differ

from its key features, in that the former stem from the issues and challenges arising in biobanking while the latter are established by translating the former into relatively specific criteria that can be applied to biobanking practices.

On the second point, the aim of the proposed model is in particular to foster the ARR, which is expected to deliver ethical and effective biobanking practices. This aim is different from those of other models for biobank governance that have been proposed in other academic literature. For example, Campbell proposes a model that has the aim of safeguarding trust and altruism in biobanking.[37] Prainsack and Buyx's model aims to incorporate solidarity into biobanking.[38] Winickoff suggests a shareholder model for engaging participants in managing UK Biobank.[39] Notably, regarding the relationship between the proposed model and these examples, it can be said that the former serves as an alternative to the latter since the former has different basic notions, as suggested in the explanations below.[40]

1.2.2 Structure of the Thesis

This thesis has six chapters. Chapter 1 illustrates the problems behind this thesis, how they inform the top-level research question of this thesis, and what sub-questions need to be addressed to answer this question, as is evident above. This chapter also defines the scope of the contribution of this thesis, and devises the main characteristics of the ARR, which are used to answer the first sub-question. Chapter 2 deals with the second sub-question by first examining the concepts of solidarity and partnership, and then justifying why partnership is selected to underlie the ARR. This chapter eventually proposes the ARR's key features as its conceptual framework. Chapter 3 answers the last sub-question by devising a partnership model that biobankers can use to foster the ARR in biobanking practice. In doing so, this chapter outlines the key attributes of this model and explains what practical measures are

[37] AV Campbell, "The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust" (2007) 18 *King's Law Journal* 2 227-245.
[38] B Prainsack and A Buyx, "A Solidarity-Based Approach to the Governance of Research Biobanks" (2013) 21 *Medical Law Review* 1 71-91.
[39] DE Winickoff, "Partnership in U.K. Biobank: A Third Way for Genomic Property?" (2007) 35 *The Journal of Law, Medicine & Ethics* 3 440-456.
[40] See 2.2.3 c) in ch 2 and 6.4.1 in ch 6 below.

required to implement these key attributes. It also illustrates how these key attributes and practical measures can reflect the key features of the ARR. In Chapters 4 and 5, the partnership model proposed in Chapter 3 is tested against two biobank initiatives, namely UK Biobank and ALSPAC, respectively, in order to demonstrate how the model can be put into practice. The last chapter clarifies the extent of the contribution of this thesis by first summarising its core proposals as well as the lessons learnt from the aforesaid testing. Next, it describes the types of literature to which this thesis contributes. It then highlights the limitations of the contribution. Finally, it explains how the proposals of this thesis deal with issues that commonly arise in a biobanking context, such as the provision of individual feedback, financial incentives and commercial involvement in biobanking.

1.2.3 Research Methods

All the discussions in this thesis are based on documentary research. There are three main categories of materials involved in these discussions. The first category is the academic literature, which encompasses many fields of study. For example, articles and books regarding legal, ethical and social controversies over biobanking practices were reviewed to determine biobanking issues that need to be addressed as well as to acknowledge existing arguments on certain biobanking issues. The literature on sociology was also examined to acquire basic knowledge about many concepts that might be used to underlie the ARR, such as partnership, solidarity and participation. The second category is reports on the results of empirical studies, which are used to support many of the arguments and proposals in this thesis. It is, however, worth emphasising that I have not conducted my own empirical study, while doing research for this thesis. The last category is materials illustrating activities of certain biobanks, which are used to identify and analyse activities that have been practically performed in those biobanks, such as reports on annual reviews of biobanking activities, participant newsletters and biobank websites. These materials are particularly crucial when testing the proposed partnership model against practical biobank initiatives in Chapters 4 and 5. Note that almost all of the materials in the latter category are publicly

accessible, i.e. they are readily available on biobank websites. Only one internal document is used in this thesis, the communication plans of UK Biobank.[41]

1.3 Scope of the Contribution

It can be seen from the previous discussions that this thesis attempts to pursue an ARR, a participant-biobanker relationship that can deal with issues and challenges arising in biobanking practice (as explained in Section 1.1). The reason is that this relationship is deemed to be able to encourage and facilitate biobanking by delivering ethical and effective biobanking practices. In doing so, this thesis first establishes the main characteristics of the proposed ARR as a fundamental notion of what this ARR is expected to achieve. These main characteristics are then used to suggest the key features of the ARR, which are considered as its conceptual framework. Finally, the thesis proposes a partnership model that can be used to foster the ARR in practice by incorporating the ARR's key features into biobanking activities.[42] It can therefore be said that the contribution of this thesis is an approach to an ARR; and to make this contribution, the thesis proposes the main characteristics of the ARR, its conceptual framework and a model for developing the ARR in practice. As explained below, this contribution can be categorised in the area of applied ethics in a biobanking context.[43]

Before suggesting the fundamental notion of the ARR – which can be used to address the first sub-question of this thesis – it is necessary to discuss some aspects of the contribution of this thesis in order to further clarify the scope of this contribution. Thus, this section deals with three issues, namely the meaning of a biobank in this thesis, the level of relationship that the ARR involves and the ethicality of this contribution. These issues are addressed separately in three sub-sections, as follows.

[41] This document was provided by a UK Biobank staff member who produced it, with his knowledge that it would be used in this thesis.
[42] The proposals of this thesis are concluded in the form of a diagram in Chapter 6 (Box 6.1) below.
[43] See 6.2.1 in ch 6 below.

1.3.1 Meaning of a Biobank

As there are many types of biobanks, it is important to clarify the types of biobanks to which the proposals of this thesis are applied. To do so, this sub-section first reviews the literature and regulatory instruments that offer definitions of the term biobank, and then it gives the definition of a biobank that will be used in this thesis.

My literature review suggests that two parameters have usually been used to classify biobanks: purposes of biobanking and types of biobank resources. The former can be broadly categorised into medical purposes (e.g. pathology, organ transplants and reproductive technology) and non-medical purposes (e.g. insurance premiums, criminal intelligence and employment).[44] The medical purposes can be either for research or non-research. Biobank resources can be categorised into two main types. One is tissue samples, which encompass any human tissues that consist of or include human cells. The other is data related to tissue samples, e.g. family and medical history, lifestyle and phenotype. Two points should be noted here. First, while tissue samples contain genetic information within their DNA, they are not treated as data in law.[45] Nevertheless, genetic sequences are considered as data.[46] Second, other characteristics of biobanking are also mentioned in some definitions of a biobank. An example is the length of preservation: in the Icelandic Biobanks Act, a biobank is defined as 'a collection of biological samples which are permanently preserved';[47] in contrast, under the Swedish biobank law, biobanks can preserve biological samples for

[44] SMC Gibbons, "Regulating Biobanks: A Twelve-point Typological Tool" (2009) 17 *Medical Law Review* 3 313-346.
[45] *UK Human Tissue Act 2004*, s 45(5); *Estonian Human Genes Research Act 2000*, s 2(2); *Swedish Biobanks in Medical Care Act (2002:297)*, s 2; *Norwegian Health Research Act 2008*, s 4(b).
[46] *Estonian Human Genes Research Act 2000*, s 2(9); *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation)*, available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679 (accessed 16 July 2016).
[47] *Icelandic Biobanks Act (No. 110/2000)*, art 3(5).

either an indefinite or a limited period.[48] Indeed, the origins of tissue samples in Swedish biobanks need to be traceable to individuals.[49]

As regards the meaning of a biobank in this thesis, it can be inferred from the discussions above that this thesis focuses only on biobanks for health-related research. That includes biobanks that were originally established for other purposes but later used for research purposes. It can therefore be said that, as long as biobanks currently serve as resources for health-related research, they fall within the scope of this thesis. As regards types of biobank resources, this thesis does not differentiate between physical and informational resources. This is because the thesis basically deals with interactions between participants and biobankers, and so types of biobank resources do not matter here. Indeed, this absence of differentiation renders the proposals of this thesis more widely applicable in that it does not limit their application to biobanks that only have certain types of biobank resources. It can be concluded from this sub-section that the term 'biobank' in this thesis refers to a collection of tissue samples and/or data related to tissue samples that is organised or held with an intention to use for health-related research.

1.3.2 Level of Relationship

Given that the proposed ARR concerns a participant-biobanker relationship and, in practice, participants can interact with biobankers as either collectives or individuals, a question arises as to whether the ARR involves a meso- or micro-level of relationship. This question is important as it helps to clarify what forms of interaction between participants and biobankers are of interest to this thesis, as well as what measures can be suggested in the proposed partnership model. For example, to receive input about biobanking from participants, this question will indicate whether biobankers can merely receive input from participants who represent participant collectives, or they need to receive input from every cohort participant. Another example concerns participants' control over uses of biobank resources: when focusing on a micro-level of relationship, biobankers might be required to allow all participants

[48] *Swedish Biobanks in Medical Care Act (2002:297)*, ch 1, s 2.
[49] *Ibid*.

to make decisions on the uses through, inter alia, dynamic consent, whereby each participant can decide whether his/her own sample and information will be used in certain research studies; by contrast, a focus on a meso level of relationship might lead biobankers to either involve some participants in making decisions about such uses on behalf of a whole participant cohort, or adopt Winickoff's shareholder model, where the decisions made by participants at general meetings represent those of all cohort participants.[50]

The answer to this question is that the ARR involves a micro-level of relationship, i.e. biobankers' relationship with *individual* participants. The reason is that the ARR aims to make biobanking ethically acceptable to participants, who are of course vital contributors to biobanking, and so it is necessary to give weight to the interests of every participant. By contrast, a focus on a meso-level of relationship usually results in the interests of some participants being neglected, thereby possibly undermining the ethical acceptability of biobanking to these participants. For this reason, the ARR should therefore focus on biobankers' interaction with individual participants, as opposed to participant collectives or other parties in biobanking such as members of the public and participants' communities. While this answer is justifiable in principle, some might raise the practical issues of how to take into account the interests of every participant in certain biobanks and how to address conflicts between these interests. In this thesis, these practical issues are to be discussed and addressed when proposing the partnership model in Chapter 3. In short, the model addresses these issues by only requiring biobankers to give all participants opportunities to give their input about biobanking, not to receive input from all of them; in case of conflicts between their input, biobankers need to provide sufficient justifications for not acting on certain input.[51] Notably, the focus on a micro-level of relationship also imposes some limitations on the contribution of this thesis and addresses the issue of representation in a biobanking context. This will be explained further in the last chapter of this thesis.[52]

[50] DE Winickoff, see note 39 above.
[51] See 3.2.1 b) (Disregard for Participants' Input) in ch 3 below.
[52] See 6.3 in ch 6 below.

1.3.3 Ethicality of the Proposals

Since the proposed ARR stems from an attempt to deliver ethical (and effective) biobanking practices, the contribution of this thesis arguably contains the element of ethicality.[53] Thus, it can generally be said that the proposals of this thesis can be considered to be an ethical framework for biobank governance. A question subsequently arises as to what approach to ethical reasoning these proposals employ.

In general, there are three main moral theories of modern philosophy in the field of bioethics.[54] The first theory is consequentialist. This theory bases the morality of certain actions on the consequences of those actions. When applying this theory, all the consequences of possible actions are compared, and moral actions are actions that would result in better consequences than the other ones.[55] The second theory is deontological ethics, where the means and features of actions are major considerations in terms of morality. This theory uses moral rules, obligations or duties to determine the morality or rightness of certain actions. This morality might also be explained in terms of prohibitions or constraints.[56] The last relevant school of thought is virtue ethics. Unlike the other two theories, this moral theory determines morality by mainly considering the character traits or virtues of actors – e.g. courage, justice, honesty and temperance. It seeks to answer the question of how persons should be, as opposed to that of what persons should do.[57] Based on this classification, this sub-section takes into account the research questions of this thesis together with these three moral theories, and then determines which theories will be used to ethically justify the proposals of this thesis.

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[53] The term 'ethical' here has a broad meaning in that it refers to the state of being correct, right or acceptable according to those of certain professions or groups. In this respect, it is not limited to ethics, a system of philosophical principles or moral values that influence how people make decisions and deal with certain issues.

[54] M Talbot, *Bioethics: An Introduction*, (Cambridge: Cambridge University Press, 2012), at 32.

[55] Note that, among consequentialists, the ways in which this moral theory is applied are different. See JF Childress, "Methods in Bioethics" in B Steinbock (ed) *The Oxford Handbook of Bioethics*, (Oxford: Oxford University Press, 2007) 15-45, at 17-20.

[56] D McNaughton and P Rawling, "Deontology" in D Copp (ed) *The Oxford Handbook of Ethical Theory*, (Oxford: Oxford University Press, 2009) 424-458.

[57] AV Campbell, *Bioethics: The Basics*, (Oxon: Routledge, 2013), at 32.

Given the explanations about the three sub-questions that need to be dealt with to address the main research question,[58] it can be said that two of these three moral theories will be adopted as approaches to ethical reasoning in this thesis. One is deontological ethics, which bases the rightness of certain actions on rules or features of actions when making moral decisions about those actions. This stems from the third sub-question, which concerns how to develop the ARR in practice. Particularly, this sub-question seeks to propose measures that biobankers need to implement in biobank governance. As these measures aim to develop the ARR, which in turn encourages biobanking by enhancing the ethical acceptability (and effectiveness) of biobanking, they can be taken as rules for biobankers who need to make their biobanking ethical. It can therefore be said that the proposals of this thesis consider the features of actions to be a source of ethicality. The other moral theory is virtue ethics, where morality is based on the character traits of actors. This moral theory is applied when addressing the second sub-question, which aims to propose the concept underlying the ARR. As the practical aspect of the ARR involves biobankers' interactions with participants, this proposed concept intrinsically characterises these interactions, and thus it can be considered to define the character of biobankers. In this respect, the ethicality of the proposals of this thesis stems from the character traits of actors as well.

Given these explanations, it is therefore arguable that the proposals of this thesis use deontological ethics and virtue ethics as their approaches to ethical reasoning. Notably, this aspect of these proposals is to be explained further in the last chapter of this thesis.[59] This is because the content of these proposals in the following chapters is required to explain it properly.

To summarise, this section has explained that the contribution of this thesis is one approach to an ARR, a participant-biobanker relationship that can deal with the issues and challenges arising in biobanking practice; and this contribution is applied only to biobanks for health-related research, no matter what types of resources they contain. The proposed ARR involves a micro-level of relationship, i.e. a biobankers'

[58] See 1.2.1 above.
[59] In Chapter 6, the explanations on this matter include the questions of how these two moral theories are related to each other from the perspective of this thesis and why consequentialist is ruled out. See 6.2.1 in ch 6 below.

relationship with individual participants. Also, this thesis uses deontological ethics and virtue ethics as methods for justifying its proposals ethically. Two additional points can be noted here. First, this thesis focuses on proposing a novel approach to an ARR. Even though this ARR is expected to address issues that commonly arise in biobanking, such as commercial involvement in biobanking and the provision of individual feedback, the thesis does not seek to solve these issues *directly*. Nevertheless, it is acknowledged that these issues are important and can potentially affect a participant-biobank relationship. Thus, they are to be addressed in the last chapter of this thesis, which demonstrates how the proposals of this thesis deal with them.[60] Second, while this thesis focuses on a micro-level of participant-biobanker relationship, its contribution basically address the questions of what biobanking activities in biobank governance should look like and how biobankers should behave towards participants. It can therefore be said that this thesis deals with a micro-and-meso-level of a management approach to biobank governance. In other words, this focus is directed at a micro-level of interaction but does not necessarily involve only face-to-face interactions.

1.4 Main Characteristics of the ARR

As this thesis aims to address the issues and challenges arising in biobanking practice by proposing one approach to an ARR, it is necessary to establish the fundamental notion of the proposed ARR so as to provide the main criteria for the ARR, which can be used to develop a conceptual framework for the ARR and a partnership model for fostering it in the following chapters. Also, this notion inherently paints a broad picture of what the contribution of this thesis will look like. Thus, this section provides such a notion by proposing main characteristics that the ARR should have. Given the background problems of this thesis, one can say that there are two major challenges. One is that the distinctive characteristics of biobanking raise many issues and challenges in biobanking practice. The other is that, as suggested by the principal research question of this thesis, there are two values that need to be promoted

[60] See 6.4 in ch 6 below.

in biobanking, i.e. the ethical acceptability of biobanking to participants and the effectiveness of biobanking;[61] and as explained below, these two values might conflict with each other. To deal with these two major challenges, it is suggested that the ARR should have two main characteristics: (1) the ability to deal with the distinctive characteristics of biobanking and (2) the ability to strike a balance between participants' and biobanks' interests. The details of these main characteristics are explained in the next two sub-sections, as follows.

1.4.1 Ability to Deal with Biobanking

The first main characteristic of the ARR stems from the fact that the distinctive characteristics of biobanking raise many practical and ethical issues and challenges, which can make biobanking unappealing to participants. Consequently, the ARR must be able to help participants and biobankers to address these issues and challenges. For example, as explained above, multiple and unexpected uses of biobank resources render the conventional safeguard of informed consent ineffective for protecting participants from harm resulting from these uses. Thus, the ARR might need either to offer additional safeguards for participants or to enable them to handle such harms directly. As another example, the long-term nature of biobanks results in the practical challenge of maintaining the viability of biobanking, due to the dynamics and uncertainty of a participant-biobanker relationship. The ARR should therefore be able to handle this challenge by, inter alia, enabling participants to anticipate any changes in biobanking activities or allowing them to negotiate changes that do not conform to their expectations. Notably, while Section 1.1 demonstrates many other characteristics of biobanking that result in issues and challenges in biobanking practice, this sub-section merely focuses on these two characteristics since they cannot be dealt with by the other main characteristic of the ARR.

[61] See 1.2 (first paragraph) above.

1.4.2 Ability to Balance Participants' and Biobanks' Interests

The other main characteristic of the ARR is the ability to strike a balance between participants' and biobanks' interests. This main characteristic is based on the aforesaid attempt to support two key values that this thesis aims to enhance, namely the ethical acceptability of biobanking to participants and the effectiveness of biobanking. With the aims of describing and justifying this main characteristic, this sub-section first explains the meanings of participants' and biobanks' interests in this context. Next, it illustrates the possible conflicts between these two interests. Ultimately, it explains why the ARR should be able to strike a balance between these two interests and how.

a) Participants' and Biobanks' Interests

By defining the term 'interests' as benefits or advantages for somebody or something, participants' interests refer to benefits or advantages that individuals have as biobank participants, as opposed to those of biobanks or participant collectives.[62] They can be equated with individuals' interests in a participant-biobanker relationship. The list of what these interests are is non-exhaustive, but it is worth citing those usually mentioned in many ethical guidelines: health, well-being, confidentiality, privacy, right to self-determination and dignity.[63] In general, these interests are promoted and protected when engaging in ethical conduct. As an example, according to the moral theory of principlism,[64] there are four basic principles that underlie the character of ethical actions, i.e. respect for individual autonomy, beneficence, non-maleficence and justice.[65] These principles basically encourage measures that can promote

[62] See 1.3.2 above.
[63] World Medical Association, *Declaration of Helsinki*, (2013) 8, art 9; The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*, (18 April 1979) 697; *European Clinical Trials Directive 2001/20/EC*.
[64] This is one of the moral theories that underpin ethical conduct in the area of bioethics. This theory is also called 'pluralistic principlism'. See JF Childress, see note 55 above. Note that other moral theories are to be dealt with in the last chapter of this thesis. See Sub-section 6.2.1 in ch 6 below.
[65] TL Beauchamp and JF Childress, *Principles of Biomedical Ethics*, 7th ed (New York: Oxford University Press, 2013); R Gillon, *Philosophical Medical Ethics*, (Wiltshire: Antony Rowe, 1994); The Belmont Report, see note 63 above; RJ Levine, *Ethics and Regulation of Clinical Research*, (London: Yale University Press, 1986).

participants' interests. For example, based on the principle of respect for autonomy, biobankers need to obtain consent from participants at recruitment and allow them to withdraw their consent at any time without giving any reason. Also, participants should be given opportunities to be involved in biobank management, as well as access to information about biobanking activities, so that they are capable of making decisions about biobanking. Conceptually, all these measures enable participants to safeguard their own interests. Regarding the principle of non-maleficence, biobankers are required to protect participants' identity by anonymisation in order to safeguard them against any harm to their privacy or confidentiality. Given these explanations, it can be said that the promotion of participants' interests can intrinsically indicate the enhancement of ethicality. That is, promoting the interests of biobank participants can make biobanking more ethically acceptable to them.

For biobanks' interests, since biobanks generally have the goal of advancing medical science, medical advances are in biobanks' interest. Indeed, because this goal is conceptually shared by all parties in biobanking – including every individual participant – medical advances amount to a collective interest in a relationship between participants and biobankers. This implies that medical advances can also be considered as being in participants' interest. There are a number of ways to promote biobanks' interests, such as maintaining the viability of biobanking, increasing the availability of biobank resources, and improving the effectiveness and efficiency of biobanking.

Two points should be noted here. First, biobankers' interests are not taken into account here since biobankers are considered as constituents of biobanks. In this respect, they share the same interests with biobanks and have an instrumental role in promoting biobanks' interests in practice. Second, it can be concluded from the explanations in this sub-sub-section that the promotion of participants' interests can make biobanking more ethically acceptable to participants, and the promotion of biobanks' interests involves improving the effectiveness and efficiency of biobanking. Based on this conclusion, the two values that the ARR is expected to enhance, i.e. the ethical acceptability of biobanking to participants and the effectiveness of biobanking, can be equated with participants' and biobanks' interests, respectively. It can therefore be said that the ARR should be able to promote both of these two interests.

b) Conflict between Two Interests

Given the nature of participants' and biobanks' interests, it might be said that there is a constant risk that these two interests might come into conflict. Particularly in health-related research, the interests of research participants have always been important. The reason is that research participants are exposed to various threats to their interests – including physical discomfort, emotional injury, discrimination and stigmatisation – for the benefit of others.[66] As a result, health-related research may be accused of exploiting research participants by seeing them as a means to another end, i.e. making medical advances. To allow research to proceed and dismiss this accusation, many safeguards have been introduced to protect and promote their interests, such as risk-benefit assessments, informed consent and anonymisation. These safeguards are therefore crucial to justifying the conduct of health-related research on research participants, whether healthy or ill. However, the promotion of their interests might conflict with medical advances, since these safeguards might discourage research practices by, inter alia, introducing additional costs and administrative burdens. This might also be the case for biobanking: as explained above, biobanking has many characteristics that facilitate health-related research but might undermine many safeguards for biobank participants; for example, multiple and unforeseen uses of biobank resources may boost the efficiency of research conduct, but this characteristic may prevent participants from understanding and assessing all the risks and benefits of their participation.[67] Thus, it can be said that, while both participants' and biobanks' interests are crucial here, these two interests might conflict with each other.

Furthermore, there appear to be many arguments that are in favour of biobanks' interests overriding those of biobank participants, especially in the context of public-oriented initiatives. For example, Chadwick and Berg argue for solidarity in the context of genetic research, and then they ask for a rethink about measures to

[66] D Evancs and M Evans, *A Decent Proposal: Ethical Review of Clinical Research*, (West Sussex: John Wiley & Sons, 1996); See also note 11 above.
[67] See 1.1 above.

emphasise individuals' rights, such as consent and the right of withdrawal.[68] Likewise, Prainsack and Buyx propose a solidarity-based model for the governance of publicly funded biobanks, whereby participants agree to accept certain costs for the benefit of biobanking and thus biobankers should, inter alia, embrace broad consent instead of informed consent, refrain from unnecessary re-contacting, and adopt an actual-harm compensation strategy as opposed to a risk-prevention one.[69] One reason behind these arguments is that, while the benefits of biobanking are arguably immense, the risks to biobank participants are fairly low when compared to conventional health-related research because biobanking involves negligible levels of direct physical harm to biobank participants.[70] For some authors, the same reasoning is also applied to the harm resulting from accidental identification.[71] It is also argued that the risk to confidentiality and the potential for genetic discrimination are controversial and unclear.[72] Some even argue for 'a duty to facilitate research progress and to provide knowledge that could be crucial to the health of others'.[73] Note that these arguments are normally based on the concept of solidarity, which generally refers to a state where individuals exhibit beneficial behaviour towards others who share the same social connectedness with them.[74]

Despite these arguments, it is arguable here that participants' interests still need to be given importance to in biobanking, especially when accentuating a participant-biobanker relationship. Particularly, given the long-term nature of biobanks, a healthy relationship with participants is crucial for maintaining the viability of biobanking since it can help to guarantee their ongoing disposition, commitment and contribution to biobanking. One way to build such a relationship is to promote their interests in order to make biobanking ethically acceptable and appealing to them. This also prevents abusing the well-evidenced trust that harm to

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[68] R Chadwick and K Berg, "Solidarity and Equity: New Ethical Frameworks for Genetic Databases" (2001) 2 *Nature Reviews: Genetics* 4 318-321.
[69] B Prainsack and A Buyx, *Solidarity: Reflections on an Emerging Concept in Bioethics*, (November 2011) 111; B Prainsack and A Buyx, see note 38 above.
[70] S Eriksson and G Helgesson, see note 2 above.
[71] B Prainsack and A Buyx, see note 69 above, at para 6.22
[72] KE Ormond et al, "Assessing the Understanding of Biobank Participants" (2009) 149A *American Journal of Medical Genetics Part A* 2 188-198, at 195. See also note 11 above.
[73] R Chadwick and K Berg, see note 68 above, at 320.
[74] See 2.1.2 in ch 2 below.

participants' interests is sufficiently prevented in biobanking.[75] For these reasons, it can therefore be argued that the proposed ARR needs to promote participants' interests as well. This argument is supported by some authors[76] as well as the fact that the aforementioned authors who favour biobanks' interests do not entirely neglect the interests of participants. Particularly, Chadwick and Berg say, as a caveat, that participants still need to be sufficiently safeguarded against discrimination.[77] Prainsack and Buyx suggest providing participants with information about the biobanks in which they participate (e.g. biobanking goals, funding and governance structures), in addition to risks and potential benefits.[78]

It can therefore be concluded from the discussions above that there might be a tension between participants' and biobanks' interests in biobanking, and thus it is questionable which interests should be prioritised by the ARR.

c) Balance between Two Interests

The conclusion drawn at this stage is that, while it is important to promote both participants' and biobanks' interests in biobanking, they might conflict with each other. With the aim of encouraging biobanking, it is arguably promising to seek a balance between these two interests. Such a balance is not only the best way to promote biobanking in the short and the long run, but it might also be able to deal with the aforesaid trade-offs between different values and interests.[79] It can thus be said that this balance should be a main characteristic that the ARR needs to have.

Nonetheless, the strict criteria for this balance cannot be defined here as they should be circumstantial in practice. This is supported by many empirical studies revealing discrepancies in the preferences regarding biobanking activities, such as the

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[75] W Lipworth et al, "An Empirical Reappraisal of Public Trust in Biobanking Research: Rethinking Restrictive Consent Requirements" (2009) 17 *Journal of Law and Medicine* 119-132.
[76] C Lenk et al, *Biobanks and Tissue Research: The Public, the Patient and the Regulation*, (London: Springer, 2011), at 30.
[77] R Chadwick and K Berg, see note 68 above.
[78] B Prainsack and A Buyx, see note 69 above, at para 6.23.
[79] See 1.1 above.

consent procedure[80] and the provision of individual feedback.[81] In this respect, it is uncertain as to the ways in which participants' interests can be promoted or balanced with biobanks' interests in practice and, consequently, the consideration of this balance should be on a case-by-case basis. As is evident in the following chapters, this thesis does not lay down any strict criteria regarding the evidence for the ARR or when the ARR already exists; rather, it merely suggests ways in which biobankers can develop the ARR through biobanking activities. However, one certain thing that can be inferred from this explanation is that the ARR needs to involve allowing participants to provide their input in order to know what their interests actually are in certain circumstances. This will be reflected in the last chapter of this thesis, which suggests that communication should be a crucial mechanism when fostering the ARR in practice.[82]

To summarise, this section has established that, to address the issues and challenges arising in biobanking practice, the ARR should have two main characteristics. First, it needs to be able to deal with the distinctive characteristics of biobanking that result in practical and ethical issues and challenges, such as the longevity of biobanking and unexpected uses of biobank resources. Second, the ARR should be able to strike a balance between participants' and biobanks' interests. The reason is that this balance is arguably appropriate for encouraging biobanking, given that both of these two interests are crucial for biobanking but they might conflict with each other. These main characteristics of the ARR are to be used as a guideline for proposing a conceptual framework for the ARR in Chapter 2. Indeed, they can also be used to address the first sub-question, which concerns normative justification for the ARR. In particular, the reason why the ARR is desirable for biobanking is that it is designed to deal with the distinctive characteristics of biobanking, which potentially make biobanking unappealing to participants. Also, the ARR can properly enhance the ethical acceptability of biobanking to participants as well as the effectiveness of biobanking, as it requires participants' interests to be balanced with those of biobanks.

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[80] CM Simon et al, see note 25 above.
[81] J Murphy et al, "Public Expectations for Return of Results from Large-cohort Genetic Research" (2008) 8 *The American Journal of Bioethics* 11 36-43; NL Allen et al, "Biobank Participants' Preferences for Disclosure of Genetic Research Results: Perspectives From the OurGenes, OurHealth, OurCommunity Project" (2014) 89 *Mayo Clinic Proceedings* 6 738-746.
[82] See 6.1.2 b) (Communication with Participants) in ch 6 below.

One can therefore say here that the ARR is desirable because it is designed to solve the background problems of this thesis and to create a situation where the attractiveness of biobanking to participants is in harmony with its benefits to health-related research. Notably, the ARR's capability to promote participants' interests reflects the element of ethicality in the ARR, and this element will be echoed within the other proposals relating to the ARR (i.e. its conceptual framework and the partnership model for fostering it), as further emphasised below.[83]

1.5 Tentative Conclusion of the Thesis

As the conclusion of this chapter, the central problem of this thesis is that the distinctive characteristics of biobanking render some conventional safeguards for research participants ineffective and can also cause participants unease by necessitating commercial involvement in biobanking and hindering some desirable measures. These become practical and ethical issues and challenges in biobanking, which can make biobanking unappealing to participants. With the aim of encouraging biobanking, this thesis proposes an approach to an ARR, i.e. a participant-biobanker relationship that can deal with these issues and challenges. The proposed ARR aims to enhance the ethical acceptability of biobanking to participants and the effectiveness of biobanking. This suggests that the ARR contains the element of ethicality. It involves a micro-level of participant-biobanker relationship and it is only applied to biobanks for health-related research. This premise brings up the principal research question of this thesis: What form of relationship is appropriate for effective and ethical biobanking practices? Three sub-questions need to be addressed to answer this principal question: (1) Why is the proposed ARR desirable for biobanking? (2) Conceptually, what should this ARR look like? (3) How can the ARR be developed in practice? This chapter has already addressed the first sub-question by outlining the main characteristics of the proposed ARR and explaining how they can deal with the background problems of this thesis.

[83] See 2.3.2 (last paragraph) in ch 2, Conclusion (fourth paragraph) in ch 3 and 6.2.1 in ch 6 below.

It can be said that this chapter has outlined what the context of this thesis topic is and how it leads to the research questions of this thesis. It also highlights the contribution of this thesis and provides a broad picture thereof by explaining the scope of this contribution and the fundamental notion of the ARR.

The following chapters deal with the second and third sub-questions. As a rough picture of my proposals, Chapter 2 outlines the conceptual framework of the ARR, which is based on the ARR's main characteristics (proposed in this chapter). In so doing, it first establishes that the concept of partnership should be used to underlie the ARR mainly because it allows the ARR to give importance to the interests of individual participants, unlike solidarity, which focuses more on collective interests. By using common partnership attributes explained in the academic literature, Chapter 2 outlines five key features of the ARR, namely respectfulness, cooperation with negotiability, support, continuity in relationship and collectiveness in goals. These key features become the conceptual framework of the ARR. This framework answers the second sub-question of this thesis, which concerns what conceptually the ARR should look like. In the light of this framework, Chapter 3 addresses the last sub-question of how to develop the ARR in practice by proposing a partnership model for biobank governance that can be used to foster the ARR through biobanking activities. This model has four key attributes, i.e. emphasis on collective goals, collaboration, reciprocation and control sharing; and it can incorporate the key features of the ARR into a participant-biobank relationship. In Chapters 4 and 5, the proposed model is tested against two biobanks, namely UK Biobank and ALSPAC, respectively, in order to demonstrate how this model is applied in practice.

Chapter 2

Conceptual Framework of the ARR

Chapter 1 concluded that an authentic research relationship in biobanking ("**an ARR**") generally refers to a participant-biobanker relationship that can deal with the practical and ethical issues and challenges created by the distinctive characteristics of biobanking. With the aim to encourage and facilitate biobanking, this thesis pursues one approach to an ARR ("**the ARR**"). The ARR is expected to enhance both the ethical acceptability of biobanking to participants and the effectiveness of biobanking. As its fundamental notion, it should have **two main characteristics**. First, it should be able to deal with the distinctive characteristics of biobanking, such as multiple and unexpected uses of biobank resources and the longevity of biobanking. Second, it should also be able to strike a balance between participants' and biobanks' interests. These main characteristics are considered to be the fundamental notion of the ARR proposed in this thesis. The first chapter also established that the ARR is only applied to biobanks for health-related research and it focuses on a micro-level relationship – i.e. it involves biobankers' interactions with individual participants but these interactions are not necessarily face-to-face. Given the explanations about the ARR in Chapter 1, a question subsequently arises as to what the ARR should look like from a conceptual perspective.

This chapter addresses this question by proposing the key features of the ARR as its conceptual framework. Two steps are taken to do so. First, this chapter seeks the underlying concept of the ARR. Such a concept must satisfy **two criteria**: first, it is applicable to biobank governance because it is to be used as a basis for governing biobanks; second, it reflects the two main characteristics of the ARR. In this chapter, two concepts, namely partnership and solidarity, are examined because they are both considered to be desirable in biobanking according to the extensive literature in this area. This examination is conducted in the first two sections, each of which deals with one concept. In these sections, the literature explaining these two concepts is reviewed and their working notions for this thesis are proposed. To refine the understanding of

them, the same procedures are also applied to other related concepts that also feature heavily in the literature, such as collaboration and participation, and the relationships between all these concepts are also described. The first step ends with justifying why partnership should be used for underlying the ARR. In a second step, the common attributes of partnership are translated into key features that the ARR should have. This will be done in the last section.

Two points need to be made here. First, the working definitions and attributes of all the concepts proposed in this chapter are extracted from the academic literature, and they serve as the basis for analysis in subsequent discussions in this thesis. In this respect, this chapter does not intend to make any original contributions to these concepts; rather, these working definitions and attributes aim to illustrate the kinds of insights that each concept can bring according to the academic literature, so as to avoid confusion that might arise from multiple, overlapping definitions. Second, the main characteristics and key features of the ARR, proposed in Chapters 1 and 2, respectively, are different. In particular, the former are merely broad criteria that the ARR is expected to fulfil after considering the background problems of this thesis, while the latter amount to the conceptual framework of the ARR, which results from the translation of partnership attributes into features that the ARR should have in order to exhibit the former. Indeed, the latter are to be used to inform the partnership model for biobank governance proposed in the following chapter ("**the Model**"), as well as discussions and explanations regarding the ARR later in this thesis.

As for a tentative conclusion to this chapter, partnership is considered appropriate to underlie the ARR, rather than solidarity. The main reason is that partnership can be utilised in a governance manner and can better echo the two main characteristics that the ARR is expected to have. In contrast, this is not the case for solidarity. Thus, although solidarity can be deemed promising for a relationship between participants and biobankers, it is considered to be merely the aspirational concept of the ARR. With the expression 'aspirational concept', it is possible for the ARR to develop solidarity, but this is not necessarily the case. Based on the premise that partnership and solidarity are the underlying and aspirational concepts of the ARR, respectively, the ARR should have five key features: (i) respectfulness, (ii) cooperation

with negotiability, (iii) support, (iv) continuity in relationship and (v) collectiveness in goals. These key features basically stem from the common attributes of partnership that are translated in a way that befits a participant-biobanker relationship, and they might also encourage solidarity in biobanking. They are considered to be the conceptual framework of the ARR, which becomes an important basis for proposing the Model. Notably, it is this cumulative account (i.e. the argument for partnership as an underlying concept and that for those key features as a conceptual framework for the ARR) that is an original contribution concerning the conceptual aspect of the ARR. In this respect, the engagement with different concepts is per se not original, because it mainly aims to propose the working notions of those concepts for this thesis.

2.1 Solidarity

Solidarity has increasingly been embraced by many authors when attempting to move away from individualism and autonomy. Extensive literature attempts to apply this concept to a situation where individualism and autonomy might not be suitable or where collective benefits are at stake, including genetic research[1] and public health.[2] This is also the case for biobanking: many authors say that the introduction of solidarity to biobanking is advantageous in that it generally helps reinforce the trend towards collective benefits.[3] It is therefore intriguing to first explore this concept by examining the literature on it, and then answer the question of whether it is appropriate for this concept to underlie the ARR. Notably, the literature examined is in the field of

[1] BM Knoppers and R Chadwick, "Human Genetic Research: Emerging Trends in Ethics" (2005) 6 *Nature Reviews. Genetics* 75-79; R Hoedemaekers et al, "Solidarity and Justice as Guiding Principles in Genomic Research" (2007) 21 *Bioethics* 6 342-350.
[2] Nuffield Council on Bioethics, *Ethical Challenges in Bioscience and Health Policy for the New UK Parliament*, (July 2015) 3; M Krishnamurthy, "Political Solidarity, Justice and Public Health" (2013) 6 *Public Health Ethics* 2 129-141; A Dawson and B Jennings, "The Place of Solidarity in Public Health Ethics" (2012) 34 *Public Health Ethics* 5 65-79.
[3] B Prainsack and A Buyx, *Solidarity: Reflections on an Emerging Concept in Bioethics*, (November 2011) 111; R Chadwick and K Berg, "Solidarity and Equity: New Ethical Frameworks for Genetic Databases" (2001) 2 *Nature Reviews: Genetics* 4 318-321; H Machado and S Silva, "Public Participation in Genetic Databases: Crossing the Boundaries between Biobanks and Forensic DNA Databases through the Principle of Solidarity" (2015) 41 *Journal of Medical Ethics* 10 820-824.

the social sciences, and this examination focuses on literature that explicitly defines and explains this concept.

As for the structure of this section, four issues are to be dealt with in four different sub-sections. The first sub-section reviews the academic literature on solidarity and discusses definitional issues of this concept. The second sub-section explains the fundamental nature of solidarity, which eventually becomes the working notion of this concept for this thesis. The third sub-section then illustrates how solidarity might be applied to a biobanking context. The last sub-section addresses the question of whether the ARR should be based on solidarity. As implied from the thesis topic, solidarity is not the underlying concept of the ARR; rather, it is considered as the aspirational concept thereof because it is still appealing to biobanking. The main aim of this section is therefore to explain why solidarity should not be used to underlie the ARR, despite some authors arguing for solidarity in biobanking.

2.1.1 Definitional Issue

It is worth first noting that solidarity has been used either to explain social facts or as an ethical value. The former approach is adopted by many authors, such as Lindenburg and Durkheim, who use solidarity to explain social phenomena[4] and social bonds between people in society,[5] respectively. By contrast, some consider solidarity to be an ethical value. For example, Harmon explores this concept and argues for using it as a value that allows community and interconnectedness to be used to inform solutions to social or legal problems and to underpin derivative legal rules for evaluating legal and quasi-legal instruments.[6] Benatar also argues that solidarity is the most important value that needs to be promoted for improving global health,

[4] S Lindenberg, "The Microfoundations of Solidarity: a Framing Approach" in P Doreian and T Fararo (eds), *The Problem of Solidarity: Theories and Models*, (Pennsylvania: Gordon and Breach Publishers, 1998) 61-112, at 62-64.
[5] A Giddens, *Capitalism and Modern Social Theory: An Analysis of the Writings of Marx, Durkheim and Max Weber*, (Cambridge: Cambridge University Press, 1971), at 117.
[6] SHE Harmon, "Solidarity: A (New) Ethic for Global Health Policy" (2006) 14 *Health Care Analysis* 4 215-236.

well-being and meaningful development.[7] However, my impression is that these two approaches seem to be two sides of the same coin: there is still a single notion of solidarity, which involves connectedness between people and a disposition to benefit others, but this notion can be used either for explaining social phenomena or as a value to be promoted. Since this section aims to investigate the basic nature of this concept, these two approaches are not treated separately here.

My review of the extensive literature on solidarity reveals some discrepancies in the definitions of this concept. Nonetheless, it can be said that this concept does not suffer a definitional problem since its common nature can be identified from those definitions. Particularly, these discrepancies simply result from differences in the contexts to which solidarity is applied or in the aspects in which certain authors are interested, not in the basic nature of this concept. For instance, the application of solidarity in the context of biofuels involves *protecting* vulnerable people and *sharing benefits* fairly with them, since development in biofuels usually impose unjust burdens on them.[8] By contrast, Jaeggi considers solidarity to be one type of *cooperation,* as he compares it with compassion and altruism, which normally involve a one-sided dependency.[9] Despite this difference, these definitions echo the common nature of solidarity, which involves a willingness to be of benefit to others, as is explained in more detail below. It is therefore arguable that solidarity has its fundamental nature but, in practice, it has been variously defined depending on how it is used or which aspects of it are considered. This argument implies that its working notion for this thesis should be based on its fundamental nature, rather than on the definitions proposed by different authors.

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[7] SR Benatar, "Bioethics and Society: A View from South Africa" in MP Neves and M Lima (eds), *Bioética ou bioéticas na evolução das sociedades,* (Coimbra: Gráfica de Coimbra, 2005) 377-380.
[8] Nuffield Council on Bioethics, *Biofuels: Ethical Issues,* (April 2011) 187, at para 4.14-15.
[9] R Jaeggi, "Solidarity and Indifference" in RT Meulen, W Arts and R Muffels (eds), *Solidarity in Health and Social Care in Europe,* (Dordrecht: Kluwer Academic Publishers, 2001) 287-308.

2.1.2 Fundamental Nature

To understand solidarity and settle on its working notion for this thesis, its descriptions in the academic literature were reviewed. This literature review indicates that there are three main aspects of solidarity that are usually used to define this concept, i.e. solidaristic bases, expression and attitudes. This sub-section therefore explains the fundamental nature of solidarity by outlining these three aspects. Some points should be noted here. First, in the academic literature, these aspects of solidarity are also used to compare solidarity with other related concepts, such as communality, compassion and loyalty.[10] Second, the literature reviewed does not always use all three aspects to describe this concept. Finally, it is worth emphasising again that the explanation of solidarity in this sub-section stems from analysing the descriptions of this concept provided in the academic literature. In this respect, it does not attempt to make any sociological contribution to this concept; rather, it only aims to provide a working notion of solidarity for this thesis.

a) Solidaristic Bases

The first aspect is solidaristic bases. Some literature refers to this aspect as solidaristic property[11] or sources.[12] My literature review indicates that solidaristic bases are social conditions of connectedness that can inform and develop a solidaristic relationship, such as collective purposes, shared interests, common sets of values and interdependence between people. With the term 'connectedness', these conditions can connect individuals with others, and thereby form a solidaristic relationship between them. My analysis classifies these social conditions into two categories: social bonds and collectiveness between individuals. The former refer to interpersonal relations that can bring about solidarity, regardless of whether or not individuals have any social conditions in common. These relations might be in the form of either interdependence

[10] *Ibid*.
[11] R Ashcroft et al, "Solidarity, Society and the Welfare State in the United Kingdom" (2000) 8 *Health Care Analysis* 4 377-394.
[12] J Hawdon et al, "Crime as a Source of Solidarity: A Research Note Testing Durkheim's Assertion" (2010) 31 *Deviant Behavior* 8 679-703; J Goldberg, "Trauma as a Potential Source of Solidarity" (2013) 28 *Tikkun* Winter 2013 38-42; KP Rippe, "Diminishing Solidarity" (1998) 1 *Ethical Theory & Moral Practice* 3 355-373.

between people or other interpersonal relationships, such as ties within a family or a village.[13] Durkheim's organic solidarity, the solidarity in society with complex division of labour and substantial variation,[14] is a classic example of the solidarity based on interdependence between individuals.

The other category of solidaristic bases is collectiveness between individuals, which refers to a situation where individuals share some conditions with others. According to my literature review, this form of solidaristic bases is embraced by many socialist theories – e.g. the classic Marxist and the Leninist concepts of solidarity, where the recognition of sameness between people is the foundation of solidarity.[15] It is also adopted by many authors; for example, Bayertz considers the actual common ground between people to be a factual aspect of solidarity.[16] There are various types of this collectiveness. A classic example is the collectiveness in conscience explained in Durkheim's mechanical solidarity, which refers to social integration where all members share common sentiments and beliefs.[17] Another example is the state of being faced with the same situation, such as missing a flight because of a delayed departure, surviving colon cancer[18] and suffering from a large-scale natural disaster.[19] The state of sharing a common interest,[20] goal, set of values,[21] or occupation[22] is also in this category. It can therefore be concluded from these examples that collectiveness in certain areas of life can form social conditions of connectedness that may culminate in solidarity. It is worth noting that this category plays an important role in a

[13] KP Rippe, *ibid*, 356-357.
[14] A Giddens, see note 5 above; S Lukes, *Émile Durkheim: His Life and Work*, (Middlesex: Penguin Books, 1973).
[15] S Stjernø, *Solidarity in Europe*, (Cambridge: Cambridge University Press, 2005), at 58-59.
[16] K Bayertz, "Four Uses of "Solidarity"" in K Bayertz (ed) *Solidarity: Philosophical Studies in Contemporary Culture*, (London: Kluwer Academic Publishers, 1999) 3-28, at 3.
[17] A Giddens, see note 5 above.
[18] B Prainsack and A Buyx, see note 3 above, at para 5.8.
[19] TE Drabek, *Human System Responses to Disaster: An Inventory of Sociological Findings*, (London: Springer-Verlag, 1986), at 179-182.
[20] R Ashcroft et al, see note 11 above, at 378; J Feinberg, *Doing & Deserving: Essays in the Theory of Responsibility*, (New Jersey: Princeton University Press, 1970), at 234.
[21] D Gunson, "Solidarity and the Universal Declaration on Bioethics and Human Rights" (2009) 34 *The Journal of Medicine and Philosophy* 3 241-260, at 245.
[22] R Chadwick, "Euroscreen 2: Towards Community Policy on Insurance, Commercialization and Public Awareness" (2001) 26 *Journal of Medicine and Philosophy* 263-272.

biobanking context, since all parties in biobanking basically share the same goal, which is to advance medical science, as explained in 2.1.3 below.

A key finding from my literature review is that solidarity is based on social conditions of connectedness between individuals, and these conditions can be either collectiveness in some areas of life or some social bonds between them. This finding can help in understanding this concept, in that it suggests what social conditions are necessary for developing a solidaristic relationship and also how solidarity, which is to be used here as the aspirational concept of the ARR, can be encouraged in a biobanking context. Indeed, it also helps to explain the relationship between solidarity and partnership in the following section.[23] Note that the definitions of solidarity proposed by some authors do not explicitly mention solidaristic bases. For example, Prainsack and Buyx define solidarity as 'shared practices reflecting a collective commitment to carry 'costs' (financial, social, emotional, or otherwise) to assist others', but they explain that solidaristic expression stems from the recognition of sameness or similarity between individuals.[24]

b) Solidaristic Expression

The next aspect of solidarity is solidaristic expression, which refers to the ways in which individuals show their solidarity through their behaviours. According to my literature review, many authors say that this form of expression usually shows a willingness to be of benefit to others. For example, Bayertz describes solidarity as acts that at least show a disposition to help others.[25] As explained by Knoppers and Chadwick, some bioethicists believe that, in the context of genetic research, solidarity may be expressed as 'a willingness to share information for the benefit of others'.[26] Indeed, this willingness might be passively expressed by way of sacrificing benefits or accepting burdens for the benefits of others. An example is Prainsack and Buyx's definition of solidarity, which involves a willingness to accept cost – whether financial,

[23] See 2.2.3 c) below.
[24] A Buyx and B Prainsack, "Lifestyle-related Diseases and Individual Responsibility Through the Prism of Solidarity" (2012) 7 *Clinical Ethics* 79-85, at 80.
[25] K Bayertz, "Staat und Solidarität" in K Bayertz (ed) *Politik und Ethik,* (Stuttgart: Reclam, 1996) 305-330, at 308, quoted in B Prainsack and A Buyx, see note 3 above, at para 3.7.
[26] BM Knoppers and R Chadwick, see note 1 above, at 76.

social, emotional or otherwise.[27] Given these examples, it can be said that the display of a willingness to be of benefit to others is a typical characteristic of solidaristic expression. This implicitly suggests that there are no specific forms of solidaristic expression in practice. As is evident in the vast literature, solidarity encompasses many forms of action or activity, such as engagement,[28] blood donation to soldiers,[29] transfusion[30] and cooperation.[31] It can be concluded here that solidaristic expression generally shows a willingness to be of benefit to others and can be found in various forms of action. This conclusion suggests that participants and biobankers can express their solidarity through biobanking activities if those activities can show a willingness to be of benefit to other parties in biobanking, as further explained in 2.1.3 below.

c) Solidaristic Attitudes

The last aspect is solidaristic attitudes, i.e. psychological processes inside solidaristic individuals' minds. My literature review suggests that solidaristic attitudes are explained in two patterns. First, solidaristic individuals *accept* or *recognise* social connectedness that amounts to solidaristic bases. For example, Prainsack and Buyx[32] as well as Jaeggi[33] explain that solidarity only emerges among people who recognise their connectedness to others, i.e. the sameness and any connections that link their and others' situations together, respectively. Similarly, some authors say that feelings of connectedness with others are an ingredient for solidarity.[34] Likewise, Bayertz explains that people will express their solidarity with others in particular groups to

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[27] B Prainsack and A Buyx, "A Solidarity-Based Approach to the Governance of Research Biobanks" (2013) 21 *Medical Law Review* 1 71-91, at 75.
[28] C Calhoun, "Imagining Solidarity: Cosmopolitanism, Constitutional Patriotism, and the Public Sphere" (2002) 14 *Public Culture* 1 147-171.
[29] C Waldby and R Mitchell, *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism*, (London: Duke University Press, 2006).
[30] P Rabinow, *French DNA: Trouble in Purgatory*, (London: University of Chicago Press, 1999), at 84.
[31] A Wildt, "Solidarity: Its History and Contemporary Definition" in K Bayertz (ed) *Solidarity: Philosophical Studies in Contemporary Culture*, (London, Dordrecht: Kluwer Academic Publishers, 1999) 209-220, at 216.
[32] B Prainsack and A Buyx, see note 3 above, at para 5.8.
[33] R Jaeggi, see note 9 above, at 291.
[34] KP Rippe, see note 12 above, at 358; SE Komter, *Social Solidarity and the Gift*, (Cambridge: Cambridge University Press, 2005), at 115.

which they believe they belong.[35] For the second pattern, solidaristic individuals have feelings of a mutual obligation to benefit others. This pattern is mentioned by Bayertz, who explains that solidarity involves an obligation to help others as a normative level of mutual attachment between individuals, and feelings of such an obligation are an emotional dimension of solidarity that emerges from common ground.[36] Given these explanations, it can therefore be said that solidarity has a psychological element and this element plays a role in fostering a solidaristic relationship.[37] Note that this aspect of solidarity is to be used below for justifying why this concept cannot be used to underlie the ARR: in brief, this element suggests that it is difficult to prescribe solidarity and confirm its existence in practice, and thus it is arguably not applicable to biobank governance.[38]

To summarise, there are three aspects of solidarity that have been widely used in the academic literature to define this concept. The first aspect is solidaristic bases, i.e. social conditions that constitute connectedness between solidaristic individuals. Solidaristic bases can be classified into two categories: collectiveness in certain aspects of life and social bonds between individuals. The second aspect is solidaristic expression. This expression has no specific form, but generally it shows a willingness to be of benefit to others. The last aspect is solidaristic attitudes, which refer to either the recognition/acceptance of solidaristic bases or feelings of a mutual obligation to benefit others in the same group. As these explanations can reflect the fundamental nature of solidarity, they are considered as the working notion of this concept for this thesis. As is evident in the following sub-sections, these explanations are to be used to describe how solidarity can be present in a biobanking context and then to address the question of whether solidarity can be used for underlying the ARR. Notably, the literature reviewed does not specifically explain how these three aspects interact with one another, and so it is difficult to draw any conclusions about the relationship between them.

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[35] K Bayertz, *Solidarity*, (Dordecht, The Netherlands: Kluwer Academic Publishers, 1999), at 4, cited in D Gunson, see note 21 above, at 245.
[36] K Bayertz, see note 16 above, at 3.
[37] Mayhew and Wildt are among authors who give a detailed description of solidaristic attitudes. See SE Komter, see note 34 above; A Wildt, see note 31 above, at 216-217.
[38] See 2.1.4 a) below.

2.1.3 Solidarity and Biobanking

Based on this working notion of solidary, it can be said that solidarity may exist in biobanking, since all three aspects of solidarity can be applied to a biobanking context. Particularly for solidaristic bases, every research biobank normally has the goal of advancing medical science, and thereby all participants and biobankers can be assumed to share this goal. Thus, collectiveness in biobanking goal is one solidaristic basis that exists in any research biobanks. Moreover, biobanking intrinsically reflects interdependence between individuals: biobankers need participants' samples and information as biobank resources, while participants have to rely on biobankers' skills and management to make their samples and information beneficial to research studies. Accordingly, the social bond of interdependence between individuals is another solidaristic basis found in any research biobanks. Some biobanks might also involve other social connectedness that constitutes additional solidaristic bases, such as a similarity in diseases from which participants are suffering and a sameness in participants' nationality.

As for solidaristic attitudes, whilst it is admittedly very difficult in practice to know precisely the actual thoughts of both parties in biobanking, it can be assumed from the acts of joining biobanking and recruiting participants that, in general, both participants and biobankers at least recognise and accept the collectiveness in their goals to advance medical science and the aforesaid interdependence. For some authors, such acts might also stem from feelings of a mutual obligation to promote the health of others.[39] Regarding solidaristic expression, there are a number of biobanking activities that can be used to express solidarity, because they can demonstrate a willingness to benefit other parties in biobanking. For example, participants may express their solidarity by providing additional samples and information, or helpful input about biobanking. Biobankers may show their solidarity by, inter alia, accepting the burdens created by communication about biobanking activities or reciprocating participants' contributions with feedback of incidental findings. All these activities can, to some extent, reflect the willingness of participants and biobankers to be of

[39] R Chadwick and K Berg, see note 3 above.

benefit to each other. Indeed, they also allow these two parties to help each other in managing and facilitating biobanking.

Given these explanations, it can therefore be argued that solidarity can exist or be embodied in a biobanking context. There are two notable points here. First, this argument merely means that solidarity is possible in a biobanking context. The ways in which this concept is beneficial to biobanking are to be described in the following sub-section. Second, the aforesaid explanations are based on the premise that the contribution of this thesis focuses on a research relationship between participants and biobankers.[40] In this respect, members of the public and communities are not involved here because these parties are beyond the scope of this contribution. Accordingly, collective interests in a solidaristic relationship here refer to the interests of biobanks, not those of the public or communities. This point will be revisited when explaining the limitations on the proposals of this thesis in the last chapter.[41]

2.1.4 Solidarity and the ARR

A subsequent question arises as to whether solidarity can be a concept that underlies the ARR. To address this question, it must be evident that solidarity can satisfy two criteria: as explained in the introduction above, (1) it needs to be applicable to biobank governance and (2) it should be able to reflect the two main characteristics of the ARR, established in Chapter 1, i.e. the ability to tackle the distinctive characteristics of biobanking and to achieve a balance between participants' and biobanks' interests. Given the working notion of solidarity above, the answer to this question is arguably negative, because this concept cannot meet both of these criteria, as explained below.

a) Inapplicability to Biobank Governance

For the first criterion, it can be said that solidarity cannot be applied to biobank governance mainly because, based on the explanations of solidaristic attitudes

[40] See 1.3.2 in ch 1 above.
[41] See 6.3 in ch 6 below.

given above,[42] solidarity has a psychological element and this element renders this concept incapable of being used in a governance manner for two reasons. First, the occurrence of solidarity is uncertain. Particularly, as explained above, solidarity depends on individuals accepting, recognising, feeling solidaristic bases, or having feelings of a mutual obligation to benefit others. Based on this explanation, one might say that the perception of individuals is crucial for developing a solidaristic relationship.[43] This suggests the possibility that, although there are solidaristic bases, individuals may not have solidaristic attitudes or become solidaristic. It can therefore be said that the presence of solidaristic bases does not always result in solidarity. This is supported by Jaeggi, who considers the psychological aspect of solidarity to be a practical difficulty in forming solidaristic bonds.[44] Second, it might be very difficult, or even impossible, to confirm the existence of solidarity in practice, because it is not feasible to know precisely whether certain behaviours are actually informed by solidaristic motivations. Behaviours of consideration might mainly, or purely, result from other motivations in this respect.

Given this explanation, it can therefore be said that it is in practice difficult to arrange solidarity as well as confirm its existence, and thereby this concept is not suitable as a governance instrument nor a goal to be pursued. Accordingly, solidarity is arguably not applicable to biobank governance and, thereby this concept cannot satisfy the first criterion for the underlying concept of the ARR, which is established in the introduction of this chapter.

Nonetheless, this argument might be countered by some scholars who explain that solidarity can be based on a legal relationship by citing solidarity within the welfare state as an example.[45] To rebut this counter-argument, it seems that any legal arrangements for social welfare and acts conforming to them are considered solidaristic simply because solidarity conceptually underlies them. Such arrangements and acts might per se not be solidaristic in this respect. As for a reason, people

[42] See 2.1.2 c) above.
[43] This is supported by Gunson, who explains that solidarity might be based on the perception of some commonality. D Gunson, see note 21 above.
[44] R Jaeggi, see note 9 above, at 301.
[45] B Prainsack and A Buyx, see note 3 above, at para 5.13.

performing those acts might not actually have solidaristic attitudes: they do so only because those arrangements are legally binding. Thus, their acts might not really stem from their own recognition of solidaristic bases nor their feelings of a mutual obligation to benefit others. One can therefore argue that, although those arrangements may be based on solidarity, those actors may not actually be solidaristic. This rebuttal is supported by many authors who are sceptical about solidarity within the welfare states by citing the coercive character of those arrangements.[46] In reality, it would indeed be difficult to assert that every person in the welfare states pays high taxes with the primary aim of helping people living on a pension, although this taxation is undoubtedly based on solidarity. My impression is that while the notions behind certain arrangements are solidaristic, these arrangements themselves do not necessarily constitute solidarity in practice. One might also say that, in this case, solidarity is only used to justify arrangements that target the public good, but it is not always the result of such arrangements.[47]

b) Silence about Participants' Interests

For the second criterion regarding the two main characteristics of the ARR, it is arguable that solidarity cannot reflect one of them, namely the ability to strike a balance between participants' and biobanks' interests. This is because, essentially, solidarity tends to accentuate collective benefits: its explanations usually stress why and how individuals commit themselves to collectives, but they are silent about the role of individuals' interests in a solidaristic relationship. Even though solidaristic expression might practically promote individuals' interests, the extent to which these interests are given importance to is unclear from a conceptual perspective. Accordingly, it is questionable whether, in a biobanking context, solidarity can be used to promote participants' interests when using this concept to underlie the ARR. As an

[46] K Bayertz, see note 16 above, at 22-25; Rt Meulen et al, "Solidarity, Health and Social Care in Europe: Introduction to the Volume" in Rt Meulen, W Arts and R Muffels (eds), *Solidarity in Health and Social Care in Europe*, (Dordrecht: Springer, 2001) 1-12, at 7-8.
[47] Notably, Arts and Verburg say that it is typical for modern welfare states to impose solidaristic obligations on their members in order to promote the common good. W Arts and R Verburg, "Modernisation, Solidarity and Care in Europe: The Sociologist's Tale" in Rt Meulen, W Arts and R Muffels (eds), *Solidarity in Health and Social Care in Europe*, (Dordrecht: Springer, 2001) 15-39, at 25.

example, biobankers sharing useful information with participants could be considered solidaristic if this sharing evidently stems from their recognition of connectedness with participants and their willingness to benefit participants. However, this consideration does not require the evidence that this sharing is actually beneficial to those participants. Thus, it is doubtful whether solidarity can be used conceptually to strike a balance between participants' and biobanks' interests.

The conclusion here is that solidarity cannot meet the two main criteria for the underlying concept of the ARR, established in the introduction of this chapter, i.e. (1) the applicability to biobank governance and (2) the ability to reflect the two main characteristics of the ARR. For the former, it is difficult to arrange solidarity as well as confirm its existence, and thus it cannot be used comprehensively in a governance manner. For the latter, since solidarity does not provide a clear enough account of how to promote participants' interests, it is unclear whether this concept can reflect one main characteristic of the ARR, namely the ability to balance participants' and biobanks' interests. Given this explanation, it is therefore arguable solidarity cannot be used to underlie the ARR.

Solidarity as an Aspirational Concept

Although solidarity should not be used to underlie the ARR, it is still desirable in biobanking. The reason is that, based on the explanation of how this concept can exist in a biobanking context (in Sub-section 2.1.3), it can be beneficial to a relationship between participants and biobankers when considering every aspect of it. Particularly for solidaristic bases, since solidarity is based on social connectedness between individuals that is voluntarily established, solidarity – where it exists – helps to emphasise and encourage a genuine relationship between participants and biobankers. Regarding solidaristic attitudes, feelings of a mutual obligation to benefit others, which is one pattern of solidaristic attitudes, probably lead participants and biobankers to have a positive disposition towards, and commit themselves to, biobanking and each other. This can be favourable to both a participant-biobanker relationship and biobanking activities. As for solidaristic expression, solidarity can lead participants and biobankers to perform many biobanking activities that can improve a relationship between them and might also facilitate biobanking, such as

contributing more biobank resources, providing helpful input about biobank governance and reciprocating participants' contributions with individual feedback. Given all these benefits, it can be said that solidarity can strengthen a participant-biobanker relationship, and it can also lead these two parties to dedicate themselves to biobanking. One can therefore argue that this concept is promising for biobanking.

Based on this argument, although solidarity cannot be the underlying concept of the ARR, it should be considered to be the aspirational concept of it when proposing its key features. With the expression 'aspirational concept', the ARR attempts to encourage solidarity by providing the best chance for solidarity, but it does not necessarily foster a solidaristic relationship in biobanking. In other words, solidarity is not a goal to be achieved by design, albeit that it might emerge during the course of cultivating the ARR. This attempt is similar, in terms of methodology, to some forms of arrangements that are considered by some authors to be social engineering towards certain normative values. One example is the system of voluntary blood donation, which Titmuss believes to be intrinsic to fostering altruistic attitudes in individuals and thereby can be used to institutionalise altruism.[48] Another example is organisational mechanisms (and cultural contexts), which – according to Healy – can be used to forge altruism because they can help provide reasons and opportunities to give to others.[49] Indeed, this attempt is also similar to many legal regimes (e.g. criminal law) that theoretically target certain consequences, although these might not actually be achieved in practice (e.g. deterrence).

It is, however, worth emphasising again that the ARR proposed in this thesis is based on partnership, not solidarity. One can therefore say that this thesis proposes a partnership relationship between participants and biobankers that might develop a solidaristic relationship in biobanking. In this respect, it is not the case that any attempt to build this partnership can always mandate the existence of, and a role for, solidarity in biobanking.

[48] RM Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, (London: LSE, 1997).
[49] K Healy, *Last Best Gifts*, (London: The University of Chicago Press, 2006).

2.1.5 Conclusion on Solidarity

Solidarity is used either to describe social phenomena or as an ethical value to be promoted, particularly when collective benefits are an important consideration. Although this concept has been variously defined by different authors, it has its own fundamental nature, which can be outlined in three aspects: solidaristic bases, expression and attitudes. The former refer to social conditions of connectedness between individuals, and these conditions can be either certain social bonds or collectiveness in certain aspects of life between individuals. Solidaristic expression refers to individuals' behaviours that reflect their solidarity. There is no specific form of this expression but it must show a willingness to be of benefit to others. Solidaristic attitudes refer to the psychological processes inside solidaristic individuals' minds. These attitudes have been explained in two ways: (i) the recognition or acceptance of solidaristic bases and (ii) feelings of a mutual obligation to benefit others. **All these explanations are to be used as the working notion of solidarity for the discussions that follow in this thesis.** Note again that these explanations result from my analysis of the academic literature on solidarity, and thereby they are not intended to make any contributions to the sociological literature on this concept.

Based on this working notion of solidarity, although it is possible for solidarity to be embodied in biobanking, it is arguably impractical to use this concept as the underlying concept of the ARR for two main reasons. First, solidarity involves a psychological element, and thereby it is difficult to prescribe this concept and to assure the existence thereof in practice. This makes this concept not feasible to be used as a governance instrument or a goal to be attained. Second, solidarity is silent about the role of individuals' interests in a solidaristic relationship. In this respect, it is unclear how this concept can strike a balance between participants' and biobanks' interests, the former of which amount to individuals' interests in the ARR. As the ability to strike this balance is one of the two main characteristics of the ARR, as established in Chapter 1, one can therefore question whether this concept can really reflect both of the ARR's main characteristics. For these two reasons, it can be argued that solidarity should not be used to underlie the ARR. Despite this argument, it is still evident that solidarity is promising for biobanking: it can strengthen a relationship

between participants and biobankers and also lead these two parties to dedicate themselves to biobanking. Accordingly, it is suggested that solidarity should be seen as the aspirational concept of the ARR.

The conclusion here is that solidarity is not to be used as the underlying concept of the ARR, but instead as the aspirational concept of it. In this respect, solidarity is neither a basis nor a benchmark for the development of the ARR in practice. As will be shown below, this thesis instead uses partnership to inform the key features of the ARR. Notably, the context of the discussion here is different from those in other literature that argues for introducing solidarity into biobanking.[50] In particular, this thesis focuses on the ARR, which basically involves a relationship between participants and biobankers,[51] and thereby its discussion excludes other parties that might engage in biobanking, such as members of the public, participants' communities and family members. This is the reason why collective interests in the ARR amount to biobanks' interests. By comparison, other literature does not have such exclusion and thus it usually takes the interests of the public or communities as collective interests in biobanking. This exclusion will be further emphasised below because it imposes a limitation on the contribution of this thesis.[52]

2.2 Partnership

Partnership generally refers to a state where two or more parties work together to achieve their shared goals within a special relationship.[53] By the term 'special relationship', a group of individuals working together does not of itself constitute a partnership, unless those individuals additionally have certain responsibilities and attitudes towards one another. This concept seems to be promising for this thesis, because it involves a strong interpersonal relationship between individuals and thus it might be used to underlie the ARR, which aims to deal with, inter alia, the longevity

[50] See note 3 above.
[51] See 1.3.2 in ch 1 above.
[52] See 6.3 in ch 6 below.
[53] Tunnard and Ryan argue that partnership is not about equality of power, but rather involves working together to fulfil common goals. J Tunnard and M Ryan, "What Does the Children Act Mean for Family Members?" (1991) 5 *Children & Society* 1 67-75, at 67.

of biobanking. Moreover, partnership involves cooperation between individuals and an aim to achieve collective goals, and thereby it seems to be applicable to biobanking, where participants and biobankers work together to pursue the shared goal of advancing medical science. It is therefore interesting to examine this concept to find out whether it can really be the underlying concept of the ARR.

To do so, this section first explores the definitions and common attributes of partnership provided in the academic literature that explicitly define and describe this concept, in order to propose its working notion for this thesis. This section then examines its relationships to other related concepts – like collaboration, participation and solidarity – so as to refine its working notion. This section eventually justifies why it becomes focal in this thesis. It is note-worthy that the term partnership in this thesis refers to the general notion of partnership, which is widely used in the social-science field. It encompasses, but is not limited to, the legal paradigm of partnership in this respect.[54]

2.2.1 Definitional Issue

My literature review suggests that there are two difficulties when using the definitions of partnership provided in the academic literature as a working notion of this concept for this thesis.

First, it is difficult to decide on a common definition of partnership from the academic literature. The reason is that this concept basically involves many aspects of relationship and thereby its definitions proposed in the literature are fairly diverse, depending upon what aspect of relationship is focused on. For example, some authors define it from the aspect of control power. Arnstein, in her typology of participation, describes partnership as one form of participation that allows power to be redistributed through negotiation with power holders.[55] In a social-work context, Miley defines

[54] Partnership is defined in Partnership Act 1890 as 'the relationship which subsists between persons carrying on a business in common with a view of profit.' See *Partnership Act 1890*, s 1.
[55] SR Arnstein, "A Ladder of Citizen Participation" (1969) 35 *Journal of the American Institute of Planners* 4 216-224.

partnership as a 'collaborative process whereby the social worker and client work as equals'.[56] By contrast, other authors focus on other aspects of relationship. Macaulay et al define partnership as 'a mutually respectful relationship based on sharing responsibilities, costs, and benefits'.[57] In social care settings, Carnwell and Carson perceive partnership to be 'a shared commitment, where all partners have a right and an obligation to participate and will be affected equally by the benefits and disadvantages arising from the partnership'.[58] Given the range of these definitions, it is arguably difficult to find parameters that the academic literature commonly uses to define this concept, let alone the content of its definitions.

Second, even if a common definition of partnership is possible, it might not be applicable in practice. This is because this concept fundamentally involves ongoing interaction between equal parties. It basically has the elements of continuity, cooperation and negotiability in this respect. As a result, the characteristics of a partnership relationship can in certain circumstances be influenced and changed by involved parties as well as by other contributory factors, rendering this relationship dynamic in nature. This is supported by Carnwell and Carson, who explain that partnerships (in health and social care settings) are significantly informed by social policy – which changes quickly – and thereby they can change across time and place.[59] Thus, it can be said that, in practice, the definition of partnership can change over time.

Given these two difficulties, it is arguably inappropriate to use the definitions of this concept provided in the academic literature to propose its working notion for this thesis, which should be able to reflect its true nature. Otherwise, this working notion would be neither sufficiently inclusive nor practically applicable. Accordingly, this section instead proposes a working notion of partnership by considering partnership attributes that are commonly explained in the academic literature. In other

[56] A Scheyett and MJ Diehl, "Walking Our Talk in Social Work Education: Partnering with Consumers of Mental Health Services" (2004) 23 *Social Work Education* 4 435-450, at 436.
[57] AC Macaulay et al, "Participatory Research Maximises Community and Lay Involvement" (1999) 319 *BMJ* 7212 778-774, at 775.
[58] R Carnwell and A Carson, "The Concepts of Partnership and Collaboration" in R Carnwell and J Buchanan (eds), *Effective Practice in Health Social Care and Criminal Justice*, 2nd ed, (Berkshire: Open University Press, 2009) , at 7.
[59] *Ibid*, at 6.

words, the working notion of partnership to be used herein stems from an amalgam of attributes commonly found in academic accounts of this concept, rather than an attempt to offer a definitive definition of this concept.

2.2.2 Working Attributes

With the aim of settling on a working notion of partnership for this thesis, this sub-section reviews the academic literature that illustrates the common attributes of partnership, and then suggests partnership attributes that are suitable for a relationship between participants and biobankers. These attributes will become the working notion of partnership for this thesis.

Two points need to be clarified here. First, as suggested above, my literature review focuses on partnership in a general sense, i.e. partnership that is generally used in the field of the social sciences. In this respect, the term partnership here is not limited to legal partnership, which refers to business associations established for generating profits.[60] Nor is it limited to partnership in Arnstein's ladder of citizen participation, which focuses on redistributing decision-making power.[61] The reason is that the ARR, by considering its main characteristics, is not merely about profitability or equality of control in a biobanking context, although either of these two factors might be involved in practice. Second, a partnership between professionals and non-professionals is of interest here, as opposed to a partnership among professionals, since this partnership is analogous to the ARR, which is based on a relationship between participants (non-professionals) and biobankers (professionals). Still, this sub-section discusses both forms of partnership so as to underline the differences between them. Note that these differences will inform one key feature of the ARR, as further emphasised below.

Among the literature that explains partnership attributes, two approaches are worthy of consideration here: Bidmead and Cowley's and Carnwell and Carson's explanations of partnership attributes, as summarised in Table 1 below. The reason for highlighting these two approaches is that they both result from an attempt to propose

[60] *Partnership Act 1890*, s 1.
[61] SR Arnstein, see note 55 above.

partnership attributes in a general context, and this was done by reviewing other literature on partnership.[62] Indeed, they also cover different aspects of partnership relationship, ranging from ethical attributes (e.g. trust and respect) to procedural ones, such as negotiation, participation and communication. These two approaches are therefore arguably robust, and thus they should be used to propose a working notion of partnership for this thesis.

Table 1: Summary of two approaches to defining partnership attributes

Bidmead and Cowley[63]	Carnwell and Carson[64]
• a genuine and trusting relationship • sharing and respect for the other's expertise • working together with negotiation of goals, plans and boundaries • reciprocity • empathy • honest and open communication and listening • information giving • participation and involvement • *praise and encouragement* • *support and advocacy* • *enabling choice and equity*	• trust and confidence in accountability • respect for specialist expertise • joint working and teamwork • agreement about objectives and common goals • members of partnerships have the same vested interests • reciprocity • empathy • transparent lines of communication within and between partner agencies • appropriate governance structures • blurring of professional boundaries

As for the question of which approach is more suitable for the ARR, Bidmead and Cowley's approach is embraced here since, as suggested above, it basically

[62] Bidmead and Cowley perform a concept analysis of partnership by reviewing the literature explaining this concept in different contexts, e.g. health visiting, paediatric care and general nursing. See C Bidmead and S Cowley, "A Concept Analysis of Partnership with Clients" (2005) 78 *Community Practitioner* 6 203-208. Carnwell and Carson propose partnership attributes by reviewing the definitions of partnership provided in dictionaries, websites and other academic literature. See R Carnwell and A Carson, see note 58 above.
[63] C Bidmead and S Cowley, *ibid*, at 206.
[64] R Carnwell and A Carson, see note 58 above, at 11.

concerns a partnership between professionals and non-professionals. In this respect, this partnership is analogous to the ARR, which involves a relationship between biobankers and participants. By contrast, Carnwell and Carson's approach is about partnership in any context and thus it encompasses a partnership among professionals, which has fewer defining attributes (as further explained below). Accordingly, the former approach is taken as a working notion of this concept for this thesis.

For the content of these two approaches, one can generally say that they are essentially similar. Nonetheless, differences between them are evident and should be noted here, since these differences help suggest what should be incorporated into a conceptual framework for the ARR. As italicised in the table, Bidmead and Cowley's approach has some partnership attributes that are additional to Carnwell and Carson's approach, such as encouragement, support and equity. Although my literature review does not clearly reveal the reasons behind these differences, it might be inferred from the nature of these additional attributes that these differences are based on an attempt to achieve equality in the capabilities of partners. Particularly when a partnership consists of professional and non-professional partners, there are likely to be discrepancies between partners in their capability to handle certain matters. Thus, there should be some measures in place for dealing with these discrepancies properly, and these additional attributes can be deemed to be such measures. In other words, provided that such discrepancies exist in a partnership, partners are generally required to support and encourage each other. This requirement could therefore be considered important in a partnership between professionals and non-professionals. As seen below, this requirement is translated into one key feature of the ARR, i.e. support, as the ARR involves a partnership relationship between participants (non-professionals) and biobankers (professionals).[65]

To facilitate the following discussion, Bidmead and Cowley's partnership attributes can be classified into two categories: attributes of values and procedures. The former concerns important values that reside in a partnership relationship, including a genuine and trusting relationship, respect for others' expertise, reciprocity, empathy, encouragement and equity. The latter concerns the processes or measures

[65] See 2.3.1 below.

that are normally implemented in a partnership, such as participation, involvement, working together via negotiation, honest and open communication and information giving. This categorisation is useful for this thesis in that it highlights two broad aspects of partnership that need to be considered when building a partnership in practice. As evident in Sub-section 2.2.3 below, this is particularly helpful when explaining how partnership differs from other related concepts that involve only one of these categories, such as empowerment and participation.

2.2.3 Other Related Concepts

To further the understanding of partnership, this sub-section delineates its relationships to other related concepts that need to be clarified or clearly distinguished from it. These concepts are as follows: (1) collaboration, which is generally similar to, or even used interchangeably with, partnership, (2) empowerment, which can have more than one meaning, (3) participation, which is variously defined in different literature, and (4) solidarity, which has been increasingly suggested in the literature on biobanking. In doing so, this sub-section first examines the meanings of these concepts that are explained in the academic literature, then assigns their working notions for this thesis, and finally explains their relationships to partnership.

As for the structure of this sub-section, these four concepts are dealt with separately in three different sub-sub-sections, according to their roles in this thesis. Particularly, the first sub-sub-section explains collaboration, which is to become a key attribute of the Model, as outlined further in Chapter 3. The next sub-sub-section deals with participation and empowerment, which will be used to explain and justify many practical measures proposed in the Model. The last sub-sub-section compares solidarity with partnership, in order to confirm whether partnership is more suitable to underlie the ARR than solidarity.

a) Collaboration

In general, collaboration refers to the act of working together to do something. Nonetheless, the act of helping the enemy during war is also defined as collaboration,[66] but this meaning is arguably not applicable to this thesis since the focus here is on biobanking – which involves mutual co-operation and contributions to medical science, not rival relationship and a goal to occupy another party's territory. My literature review reveals that the forms of collaboration vary depending upon how this concept is put into practice. For example, Himmelman considers the acts of exchanging information, altering activities, sharing resources and enhancing others' capacity, to be instances of collaboration.[67] Mailick and Jordan also include the act of sharing responsibility for outcomes within the meaning of collaboration.[68] Involvement in discussions and decision-making processes might also amount to collaboration in some circumstances.[69] These examples indicate that collaboration encompasses various types of action, and thereby it is arguably difficult to define this concept strictly without considering the context of application. This is supported by many authors: Henneman et al explain that the definition of collaboration is vague or highly variable;[70] D'Amour et al explain in detail how the conceptualisation of collaborative processes is influenced by environmental factors.[71] **The act of 'working together'** is therefore, albeit vague, suitable to be used as the working notion of collaboration for this thesis.

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[66] AS Hornby, *Oxford Advanced Learner's Dictionary*, 8th ed (Oxford: Oxford University Press, 2010); An Encyclopedia Britannica Company, "Merriam-Webster Dictionary: Collaborate" (2013) available at http://www.merriam-webster.com/dictionary/collaboration (accessed 29 January 2014).

[67] AT Himmelman, "On the Theory and Practice of Transformational Collaboration: From Social Service to Social Justice" in C Huxham (ed) *Creating Collaborative Advantage*, (London: Sage Publications, 1996) 19-43.

[68] M Mailick and P Jordan, "A Multimodel Approach to Collaborative Practice in Health Settings" (1977) 2 *Social Work Health Care* 445-454, cited in EA Henneman et al, "Collaboration: A Concept Analysis" (1995) 21 *Journal of Advanced Nursing* 1 103-109, at 104.

[69] National Health & Medical Research Council, *Statement on Consumer and Community Participation in Health and Medical Research*, (December 2001) 45, at 18.

[70] EA Henneman et al, see note 68 above, at 103.

[71] D D'Amour et al, "The Conceptual Basis for Interprofessional Collaboration: Core Concepts and Theoretical Frameworks" (2005) 19 Suppl 1 *Journal of Interprofessional Care* 116-131, at 127-128.

Collaboration and Partnership

According to my literature review, the difference between collaboration and partnership is unclear mainly because, as implied above, these two concepts have been variously defined and explained according to contexts and goals of application. Indeed, the relationship between them is differently described as well. For instance, some consider partnership to be an attribute of collaboration[72] while others consider the opposite.[73] Indeed, it is also said that collaboration and partnership are often used interchangeably,[74] and the former is frequently equated with the latter.[75]

Nevertheless, in the light of their working notions assigned in this thesis, the working distinction between them for this thesis can be explained, as follows. In this thesis, collaboration merely refers to the act of working together, while partnership has a wide range of attributes and its attributes can be classified into the attributes of values and procedures. Based on these working notions, it can be said that, for this thesis, collaboration merely refers to certain actions, while partnership encompasses not only actions and activities but also values to be promoted, such as empathy, a trusting relationship, honesty and respectfulness. Accordingly, from the perspective of this thesis, a focus only on action can be used to distinguish collaboration from partnership. Notably, this distinction is supported by Carnwell and Carson, who – with the aim of distinguishing between these two concepts – state that collaboration is about 'what we do', but partnership is about 'who we are'.[76]

Based on the working notions of and the working distinction between collaboration and partnership explained above, it is arguable that collaboration is related to partnership, in that the former is used to develop the latter. In other words, individuals need to collaborate with each other to foster a partnership relationship between them. This argument is supported by many authors who offer similar

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[72] B Hudson et al, *The Integration of Localised and Collaborative Purchasing: A Review of the Literature and a Framework for Analysis*, (Leeds: Nuffield Institute for Health, 1998), cited in R Carnwell and J Buchanan, *Effective Practice in Health, Social Care and Criminal Justice.*, 2nd ed (Berkshire: Open University Press, 2009), at 15.
[73] See note 77 and 78 below.
[74] R Carnwell and A Carson, see note 58 above, at 3.
[75] EA Henneman et al, see note 68 above, at 104.
[76] R Carnwell and A Carson, see note 58 above, at 10-11.

explanations of this matter. Cahil, for example, illustrates that there is a hierarchical relationship between collaboration and partnership, and the former must be achieved to develop the latter.[77] Likewise, Apostolakis describes collaboration as a mechanism for developing strategy for multi-organisational partnerships.[78]

The conclusion regarding collaboration for this thesis is as follows: this concept refers to the act of working together with others; it only has a procedural aspect, unlike partnership – which also involves the aspect of values; as regards its relationship to partnership, this thesis considers it to be a measure for developing a partnership relationship. It is worth emphasising that this conclusion might not agree with the literature that offers different explanations of collaboration.[79]

b) Participation and Empowerment

As explained above, this thesis uses participation and empowerment as concepts that justify some practical measures proposed in the Model. It is therefore necessary to explore these two concepts, to find the relationships between them as well as their relationships to partnership. In doing so, this sub-sub-section first explores their meanings that are explained in the academic literature, and then proposes their working notions for this thesis. Finally, based on these working notions, the relationships between participation, empowerment and partnership are outlined.

Participation or Involvement

Participation generally refers to the act of taking part in something. A question subsequently arises as to what the term 'taking part' exactly means. My literature review suggests that participation does not actually have particular forms of action. Indeed, its definition normally varies depending upon what purposes it is expected to serve in certain circumstances. As explained by Brager et al, there are many of such purposes, including being a means to educate citizens and increase their

[77] J Cahill, "Patient Participation: A Concept Analysis" (1996) 24 *Journal of Advanced Nursing* 3 561-571, at 567.
[78] C Apostolakis, "Citywide and Local Strategic Partnerships in Urban Regeneration: Can Collaboration Take Things Forward?" (2004) 24 *Politics* 2 103-112.
[79] Some authors explain that collaboration involves some values, such as trust and respect. See B Hudson et al, see note 72 above.

competence; a mechanism for ensuring sensitivity and accountability of services to consumers; a vehicle for influencing decisions that affect the lives of citizens; and an avenue for transferring political power.[80] Undoubtedly, its definitions proposed in the academic literature are diverse. For example, Brager et al refer to participation as 'the means by which people who are not elected or appointed officials of agencies and of government influence decisions about [programmes] and policies that affect their lives'.[81] Richardson defines this concept as the ways in which ordinary citizens can or do take part in decision-making processes.[82] For Armitage, citizen participation is a process whereby citizens act in response to public concerns, voice their opinions about decisions that affect them, and take responsibility for changes to their community.[83] Westergaard refers to participation as a collective effort to increase and exercise control over resources and institutions.[84] It can be inferred from these examples that participation can take various forms of action and its definition is contextually diverse. It is therefore difficult to assign an exact meaning to it.

Moreover, a question might arise as to whether or not participation necessarily involves perceptible action. In other words, when people participate in something, do they need to be actively involved in it by performing certain perceptible actions, such as voicing their opinions or making decisions, as opposed to imperceptible ones, e.g. receiving information or realising something? My literature review suggests that it is difficult to answer this question due to discrepancy in the definitions of participation provided in the academic literature. Particularly for some authors, this concept only refers to the act of receiving information that leads to, inter alia, sensitisation, an increase in receptivity, an increase in an ability to get involved,[85]

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[80] G Brager et al, *Community Organizing*, 2nd ed (New York: Columbia University Press, 1987), at 62.
[81] *Ibid*, at 63.
[82] A Richardson, *Participation (Concepts in Social Policy 1)*, (London: Routledge & Kegan Paul, 1983), at 8.
[83] A Armitage, *Social Welfare in Canada : Ideals and Realities*, 2nd ed (Toronto: McClelland and Stewart, 1988), cited in GM Mathbor, *Effective Community Participation in Coastal Development*, (Chicago: Lyceum Books, 2008), at 8.
[84] KB Westergaard, *An Economic and Social Analysis of a Village in Bangladesh*, (Bangladesh: Rural Development Academy, 1986).
[85] UJ Lele, *The Design of Rural Development: Lessons from Africa*, (London: Johns Hopkins University Press, 1975).

an increase in knowledge[86] or an active concern.[87] In this sense, participation does not require perceptible action. This is, however, not the case for some authors who equate this concept with an increase in control over objects of participation, as illustrated below. Given this discrepancy, one can say that participation can range from the act of being informed about objects of participation, to the act of having control over them. It can therefore be concluded, as the working notion of participation for this thesis, that this concept refers to **the act of taking part in something** that might involve the act of receiving information about it.

It can be inferred from this working notion that participation here does not necessarily involve control over objects of participation. Admittedly, this does not agree with the literature that considers such control to be central to the nature of this concept. For example, the World Bank Participation Sourcebook, which defines participation as 'a process through which stakeholders influence and share control over development initiatives, and the decisions and resources which affect them'.[88] Another example is Arnstein's ladder of citizen participation, a classic typology of participation, where the act of taking part without actual control over decisions is considered to be either non-participation or tokenistic participation.[89] To recognise this disagreement, participation in this thesis is classified into three types, as follows: mere 'participation' includes the act of being informed about objects of participation; 'active participation' calls for active or perceptible action related to objects of participation; and 'meaningful participation' requires participants to have some control over objects of participation. It is worth emphasising here that this classification is aimed at coining the working terms of participation used *in this thesis*, not making any theoretical contribution or constructing any argument about this concept.

Notably, in general, the expression 'participation in biobanking/biobanks' specifically refers to the act of joining a biobank, which involves the acts of giving consent and providing a biobank with tissue samples and information, and the word 'participant' is usually used to refer to a person who performs such acts. In this respect,

[86] G Brager et al, see note 80 above, at 62.
[87] A Richardson, see note 82 above, at 9.
[88] World Bank, *The World Bank Participation Sourcebook*, (1996) 259, at xi.
[89] SR Arnstein, see note 55 above.

the meaning of the term 'participation' in this context is different from the concept of participation explained above: from a conceptual perspective, the former amounts to the act of following the processes which people normally take part as ordinary procedure, while the latter refers to the act of taking part in the processes that are not deemed ordinary procedure. This difference is also highlighted by Rifkin et al, who explain in a healthcare context that 'the mere receiving of services does not constitute participation'.[90] As this thesis revolves around biobanking practices, this explanation implies that there is likely to be some confusion between the former and the latter when the word 'participation' is used in this thesis. To avoid such confusion, afterwards, **this thesis uses the term 'involvement' to refer to the concept of participation**, which is explained in this sub-sub-section, and uses the term 'participation' to refer to the act of joining a biobank. This is also applied to the aforesaid classification: the terms 'active involvement' and 'meaningful involvement' are used for recognising the disagreement as to the meanings of participation explained by different authors.

Empowerment

It can be argued that the meanings of empowerment vary according to individuals' perceptions and contexts of application.[91] They are even ambiguous in some circumstances.[92] This is evident from some of its definitions proposed in the academic literature. Adam, for example, defines empowerment as 'the means, by which individuals, groups and/or communities become able to take control of their circumstances and achieve their own goals, thereby being able to work towards helping themselves and others to maximise the quality of their lives'.[93] For Fawcett et al, empowering physically-disabled people refers to 'the process of gaining some control

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[90] SB Rifkin et al, "Primary Health Care: On Measuring Participation" (1988) 26 *Social Science & Medicine* 9 931-940, at 933.
[91] CC Ellis-Stoll and S Popkess-Vawter, "A Concept Analysis on the Process of Empowerment" (1998) 21 *Advances in Nursing Science* 2 62-68, at 62; B Humphries, "Contradictions in the Culture of Empowerment" in B Humphries (ed) *Critical Perspectives on Empowerment*, (Birmingham: Venture Press, 1996) 1-16; CH Gibson, "A Concept Analysis of Empowerment" (1991) 16 *Journal of Advanced Nursing* 3 354-361, at 355.
[92] T Gilbert, "Empowerment: Issues, Tensions and Conflicts" in M Todd and T Gilbert (eds), *Learning Disabilities: Practice Issues in Health Settings*, (London and New York: Routledge, 1995) 83-102, at 84-85.
[93] R Adams, *Social Work and Empowerment*, 3rd ed (Hampshire: Macmillan Distribution, 2003), at 8.

over events, outcomes, and resources of importance to an individual or group',[94] while community empowerment is defined as 'the process of gaining influence over conditions that matter to people who share neighbourhoods, workplaces, experiences, or concerns'.[95] In poverty-reduction initiatives, the World Bank sees this concept as 'the expansion of assets and capabilities of poor people to participate in, negotiate with, influence, control, and hold accountable institutions that affect their lives'.[96] These definitions suggest that the meaning of empowerment depends on the context of application, which – according to these examples – involves whom is to be empowered and what is to be achieved as a result of empowerment. One can therefore say that the definitions of empowerment are contextually diverse.

However, the theme underlying the definitions of empowerment can be identified: they all refer to processes by which people/entities gain either additional control over, or extra capability to control, matters that affect them. This theme is similar to Rappaport's definition of empowerment, where empowerment is the process by which people, organisations and communities gain mastery over their own lives.[97] Two elements can be extracted from this theme. The first element is the enhancement of control or of capability to control. Those empowered either might not originally have any or sufficient control or capability to control, such as elderly people (less capability to live by themselves),[98] physically disabled people (less capacity to work),[99] and ethnic minorities (less ability to decide about their lives).[100] Second, those empowered are directly affected by matters of interest. For this element, the context must be taken into consideration. For example, provided that a poverty reduction

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[94] SB Fawcett et al, "A Contextual-behavioral Model of Empowerment: Case Studies involving People with Disabilities" (1994) 22 *American Journal of Community Psychology* 471-496, at 472.
[95] SB Fawcett et al, "Using Empowerment Theory in Collaborative Partnerships for Community Health and Development" (1995) 23 *American Journal of Community Psychology* 5 677-697, at 679.
[96] World Bank, *Empowerment and Poverty Reduction: A Sourcebook*, (May 2002) 272, at vi.
[97] J Rappaport, "Studies in Empowerment - Introduction to the Issue" (1984) 3 *Prevention in Human Services* 2 1-7, cited in CH Gibson, see note 91 above, at 355.
[98] P Lloyd, "The Empowerment of Elderly People" (1991) 5 *Journal of Aging Studies* 2 125-135.
[99] SB Fawcett et al, see note 94 above.
[100] MS Chen, Jr., "Informal Care and the Empowerment of Minority Communities: Comparisons between the USA and the UK" (1999) 4 *Ethnicity & Health* 3 139-151.

programme aims to provide individuals with opportunities to improve their economic status, empowerment should involve an increase in their capabilities to, inter alia, negotiate with financial institutions. However, information-sharing among financial institutions is not considered to be empowerment because, although such sharing can enhance those institutions' capability to tackle poverty, those institutions themselves are not directly affected by it. It can be concluded from the academic literature that empowerment generally refers to processes or measures for enhancing one's control over or one's capability to control matters affecting them.

In this thesis, however, this concept focuses only on the enhancement of *capability to control*, not control itself, since the thesis deals with the aspect of control in a participant-biobanker relationship separately.[101] Thus, to avoid any confusion, an increase in control needs to be differentiated from an increase in capability to control. As an example in a biobanking context, participant involvement in management boards is considered as empowerment here only because participants have access to information about biobanking activities, which enables them to deal with biobanking by giving meaningful input about biobanking. The reason is not that they have some degree of control over decisions about biobanking. Thus, the term 'empowerment' in this thesis refers to **processes or measures that allow ones to enhance their capability to control matters affecting them**. In a biobanking context, it amounts to measures that allow biobank participants to improve their capability to deal with biobanking, such as giving input about biobank governance and providing samples and information properly. In practice, it mainly involves information and knowledge sharing, because this sharing basically increases such capability. Notably, it can be assumed that any biobanking issues affect participants, because participants can be considered to be part of biobanking and thereby those issues inherently affect them.

Relationships Between Three Concepts

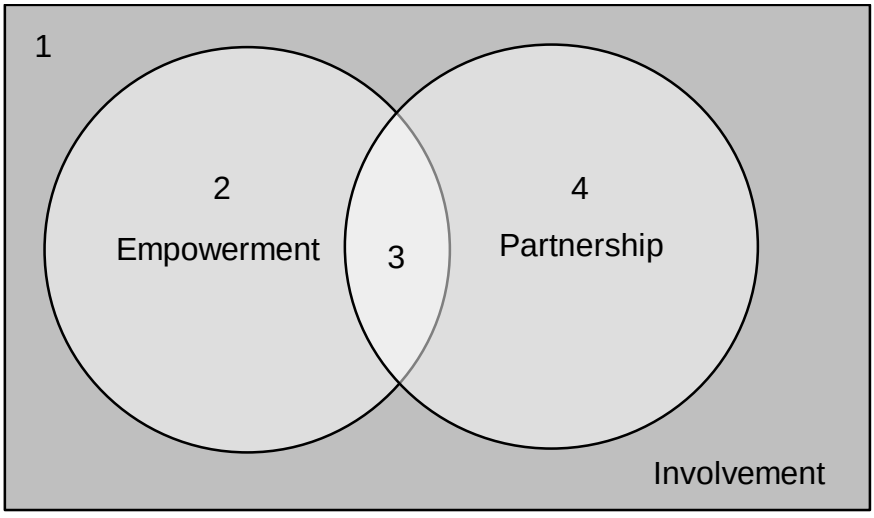
Before describing the relationships between involvement, empowerment and partnership, their working notions for this thesis are first noted: **partnership** refers to the state of having a relationship between professionals and non-professionals, and its

[101] See 3.4 in ch 3 below.

attributes are based on Bidmead and Cowley's explanation of partnership attributes, which is concluded in Table 1 above; **involvement** (or participation) refers to the act of taking part in something, ranging from merely the act of receiving of information to the act of having control over objects of participation; **empowerment** refers to processes or measures for increasing ones' capability to control matters affecting them.

Based on these working notions, one can say that, in general, the nature of partnership is different from that of the other two concepts. This is because partnership refers to a state or relationship and so it involves the aspect of values; by contrast, empowerment and participation are only about measures or processes.[102] This difference implies that merely implementation of certain measures cannot build a partnership if certain values – e.g. trust, openness and equity – are not concurrently encouraged. Other than the nature of these three concepts, when considering the content of their working notions in more detail, the relationships between them can be demonstrated in a Venn diagram (see Figure 1 below) and described as follows:

Figure 1: Venn diagram illustrating the relationship between partnership, empowerment and involvement



[102] In practice, empowerment and participation can be used to enhance certain values, such as autonomy and equity, respectively. However, the working notions of these two concepts for this thesis do, per se, not involve any values.

For involvement [**1-4**], this concept is a basis for both partnership and empowerment, as two or more parties need to take part in performing empowerment or forming a partnership. On the other hand [**2, 3, 4**], involvement may result in empowerment and/or partnership. As an example, people who take part in certain projects may acquire knowledge or information that renders them capable of dealing with problems they need to handle. Alternatively, these people might become part of those projects, establish open and honest communication with project organisers, and even help to pursue the goals of those projects, thereby making them become partners with project organisers. Notwithstanding [**1**], involvement does not always result in partnership and empowerment as it might lead to mere awareness of something. For example, healthy people might be involved in disease prevention programmes in order to receive information about disease which they are interested in but are not suffering from. As a result, their involvement merely leads them to being aware of it, not enhancing their capability to deal with disease that they are suffering from or building a partnership between them and programme organisers.

As for the empowerment circle, although it is said that empowerment and involvement are closely related and indivisible,[103] these two concepts are in fact arguably distinguishable here: based on their working notions explained above, empowerment accentuates the consequences of measures (i.e. an increase in capability to control) while involvement focuses on the methods involved in measures (i.e. the act of taking part). As for the relationships between empowerment and partnership, [**2**] empowerment does not always result in a partnership relationship. As an example, the sharing of knowledge about financial management might only aim to increase ones' capability to deal with their financial problems. This sharing can be considered to be empowerment, but it might not build a partnership since it might not develop any special relationships. On the other hand [**3**], empowerment and partnership can be concurrent. For example, in a case where people engage in a pollution-reduction project and can voice their opinions on the strategy of this project, the sharing of information about environmental science not only helps them to deal with environmental problems they face, but also enables them to collaborate properly with

[103] A Sidorenko, *Empowerment & Participation in Policy Action on Ageing*, (2006) 9, at 2.

organisers of this project by, inter alia, making useful contributions to this project. In this case, the sharing of information can be deemed to be both empowerment and a means to exhibit or build a partnership.

When considering the partnership circle [**4**], the key question is whether it is possible for a partnership to be developed without empowerment. From a conceptual perspective, the answer to this question can be positive: non-professionals and professionals might work together to form a partnership, and they both have capability to control the issues they are responsible for. A possible example is where a service provider forms a partnership with clients with the aim of improving the quality of its services, and they both agree to deal single-handedly with particular aspects of those services by using their own skills and resources. In this case, they do not both need to be empowered to achieve this aim. In practice, however, it is questionable whether this form of partnership actually exists because it might be difficult to find a partnership that does not involve any empowerment at all. Particularly, the sharing of information or expertise is conceptually a common attribute of partnership. Also, from a practical perspective, this sharing is usually used to help other partners to pursue the goals of partnerships. Moreover, in reality, individuals/entities are unlikely to team up with others to do something if they are already capable of dealing with it by themselves. It can therefore be concluded that partnership is normally intertwined with empowerment, but a partnership without empowerment is – albeit theoretically possible – rarely existent in reality.

There are some limitations to the above description of the relationships between these three concepts. First, this description is not applicable if any of these three concepts is defined differently from their working notions for this thesis. For example, provided that involvement is considered to require control, this description – where involvement also includes the act of being educated – is not applicable. Second, this description is only applied to a situation where two or more parties are involved and these parties consist of at least one non-professional and one professional. The reason is that, in this description, partnership is between professionals and non-professionals. Thus, this description might not be suitable for situations that do not involve such parties. An example is a situation where 'have-nots'

empower themselves by gaining financial knowledge and skills: this situation does not have any involvement and thus this description, whereby empowerment stems from involvement, is not applicable. Finally, this description does not concern the aspect of values because, here, empowerment and involvement merely have the aspect of procedure. As can be seen above, when considering partnership, this description focuses only on its procedural attributes, such as working together, information sharing and negotiation.

To summarise, the relationships between involvement, empowerment and partnership can be concluded, based on their working notions for this thesis, as follows. Involvement is a basic concept or precursor to the other two concepts. Empowerment and partnership are interrelated. In particular, partnership can lead to empowerment since it involves the sharing of information or expertise. On the other hand, empowerment can be considered as a means to develop a partnership relationship because all partners should have sufficient capability to pursue the goals of partnerships. Notably, as empowerment can be considered inseparable from partnership in practice, this concept is inherently essential for partnership-building processes. This is echoed in the Model, as explained and emphasised in the following chapters. Particularly, according to Chapter 3, almost all of the key attributes of the Model require implementing measures that result in empowering biobank participants. These measures involve communicating general knowledge about biobanking and information about biobanking activities to biobank participants, so as to enhance their capability to exercise their right of withdrawal,[104] negotiate policies on tangible reciprocation[105] and provide useful input about biobank governance.[106] As emphasised in Chapter 6, these measures are considered crucial for the Model.[107]

c) Solidarity

The previous section has already explored the concept of solidarity by discussing its definitional issues, outlining its fundamental nature and explaining its

[104] See 3.1.1 b) (Changes to Participants' Goals) in ch 3 below.
[105] See 3.3.1 b) (Negotiation over Policies) in ch 3 below.
[106] See 3.2.1 b) (Insufficiency of Capability) in ch 3 below.
[107] See 6.1.2 b) (Communication with Participants) in ch 6 below.

applicability to biobanking. That section eventually argues that solidarity cannot be used to underlie the ARR because it cannot be used in a governance manner and cannot exhibit one of the ARR's main characteristics. However, because this concept is deemed desirable for biobanking, it is considered to be the aspirational concept of the ARR. In other words, the ARR does not aim to achieve solidarity in biobanking, but a solidaristic relationship might emerge during the course of fostering the ARR.

With the aim of finding the underlying concept of the ARR, it is useful to understand how partnership is conceptually related to solidarity, in order to know whether and how partnership is more suitable to underlie the ARR when compared with solidarity. This sub-sub-section therefore examines the relationship between these two concepts by examining the similarities and differences between them. Notably, this sub-sub-section only performs a comparison between partnership and solidarity. In this respect, the question of whether partnership can be considered as the underlying concept of the ARR will be answered in the following sub-section.

Similarities

There are many similarities between solidarity and partnership. First, both concepts refer to certain forms of connectedness between individuals. Second, the natures of solidarity and partnership both have various aspects of relationship other than the aspect of procedure: partnership requires some values to be encouraged, such as equity, empathy and a trusting relationship; solidarity theoretically stems from social connectedness and requires individuals to have certain attitudes. One can therefore say that partnership and solidarity both involve psychological and social aspects, and thus the mere presence of certain processes or actions cannot prove their existence. Participant involvement alone, for example, can verify neither a partnership nor a solidaristic relationship in biobanking, unless it is also evident that this involvement allows participants to help biobankers pursue biobanking goals or is based on a willingness to be of benefit to biobanking, respectively. The last similarity concerns the content of these two concepts, which can be separated into four points: (1) both concepts involve two or more people voluntarily joining together; (2) these people have a disposition to be of benefit to each other; (3) they share similar internal motivations that stem from certain forms of connectedness; and (4) they express their

motivations through perceptible behaviours, whether active (e.g. assisting others) or passive (e.g. accepting burdens). Given these similarities, one can therefore say that partnership and solidarity largely share the same features.

Differences

Despite these similarities, there are three differences between these two concepts. First, they have different functions. Partnership basically concerns interactions between individuals that express or develop a partnership relationship between them, and thereby its attributes focus on suggesting how to treat those with whom one is in partnership or want to build a partnership, respectively. By contrast, solidarity is basically used to justify and explain the interactions between solidaristic individuals. Thus, its explanation rather focuses on describing why individuals become solidaristic (solidaristic bases and attitudes) and how they express their solidarity (solidaristic expression).[108]

Second, these two concepts give importance to individuals' interests differently. When building a partnership, individuals' interests remain an important consideration. This is evident from many partnership attributes that enable individuals' interests to be acknowledged, respected and even influential in a partnership relationship, such as open communication, listening and openness to negotiation. In contrast, solidarity is usually silent about the importance of individuals' interests, since it is normally used to explain a situation where collective interests are paramount.[109] Indeed, it is sometimes used to justify limiting individuals' interests, e.g. Prainsack and Buyx's solidarity-based model for biobank governance, where a risk-prevention strategy can be replaced with an actual-harm compensation one as participants presumably agree to accept some costs for the benefit of biobanking.[110]

The last difference is that a partnership can be intentionally established, while this is not the case for solidarity. Particularly, it is arguably difficult to prescribe solidarity in practice. As already illustrated above, according to the psychological

[108] See 2.1.2 above.
[109] See 2.1.4 b) above.
[110] See 1.4.2 b) in ch 1 and 2.1.2 b) above.

aspect of solidarity (i.e. solidaristic attitudes), individuals need to accept, recognise or feel something so as to become solidaristic, and thereby the occurrence of solidarity essentially depends on individuals' perception. One can therefore say that, despite the presence of solidaristic bases, it is uncertain whether a solidaristic relationship is to be developed afterwards, let alone the difficulty in confirming the existence of solidarity in practice.[111] By contrast, in partnership, partners basically share the same goals and have an inherent willingness and intention to develop a partnership relationship with others.[112] Also, a partnership can be built or expressed through certain arrangements. Accordingly, partnership does not raise theoretical doubts about whether partners recognise their connectedness with others, whether they really want to be of benefit to each other, or whether a partnership actually exists. It can therefore be said that, unlike solidarity, a partnership can be built intentionally.

The relationship between solidarity and partnership can be concluded as follows: it can be argued that solidarity is essentially similar to partnership, since they both refer to connectedness between individuals and involve various aspects of relationship, not only a procedural aspect. Furthermore, both of them concern a situation where two or more people share similar internal motivations and have a disposition to be of benefit to each other. The crucial difference between these two concepts is that a partnership can be built intentionally, while solidarity cannot, since the occurrence of solidarity relies on individuals' perception. Moreover, it is arguable that partnership emphasises individuals' interests relatively and also better suggests ways to promote these interests. By contrast, solidarity is fundamentally silent about the importance of individuals' interests, and it accentuates justifying and explaining a social phenomenon where individuals have dispositions and commitments to collectives. Note that the similarities and differences between these two concepts will be used in the following sub-section, which discusses why partnership (rather than solidarity) should be used to govern biobanking and to underlie the ARR.

[111] See 2.1.4 a) above.
[112] Common characteristics of partnership include voluntariness and common purposes. Theoretically, individuals cannot be coerced to enter into partnerships.

2.2.4 Partnership and the ARR

This sub-section addresses the questions of whether and why partnership should be used to underlie the ARR. Given all the above explanations about partnership, the answers to these questions are arguably positive. The main reason is that partnership does not suffer the two issues that prevent solidarity from being used to underlie the ARR, i.e. the inapplicability to biobank governance and the silence about participants' interests.[113] For the former, unlike solidarity, a partnership can be built intentionally through making certain arrangements, as explained above.[114] Indeed, its existence can be confirmed by the presence of measures that are implemented for exhibiting or developing a partnership relationship, thereby allowing its use to be recognised and benchmarked. One can therefore say that it can be used as a governance instrument, and so it is arguably applicable to biobank governance. For the latter issue, as illustrated above, partnership gives importance to individuals' interests better than solidarity does.[115] Indeed, since a partnership is normally built to achieve the goals shared by certain persons, it can also lead individuals to assist others and/or contribute towards collectives. Accordingly, one can say that partnership can be used to balance individuals' with collectives' interests, making it possible for this concept to strike a balance between participants' and biobanks' interests.[116] Given that partnership can resolve these two issues, one can say that partnership is more suitable to underlie the ARR than solidarity.

In addition, partnership is, per se, promising for biobanking. In general, partnership attributes suggest how to treat individuals properly, and so they can be used to advise how to behave towards participants in order to strengthen a relationship between participants and biobankers. Indeed, many of its attributes can deal well with the distinctive characteristics of biobanking. For example, reciprocity can be used to respect participants' contributions to biobanking and can help encourage their ongoing commitment to biobanking, thereby corresponding to the longevity of biobanking.

[113] See 2.1.4 above.
[114] See 2.2.3 c) above.
[115] See 2.2.3 c) above.
[116] See 1.4.2 in ch 1 above.

Also, honest and open communication can enhance the transparency and accountability of biobanking, which can cope with multiple and unexpected uses of biobank resources. Given all these reasons, it can therefore be said that partnership can satisfy both of the main criteria for the underlying concept of the ARR.[117] Furthermore, a partnership might build solidarity, which is an aspirational concept here.[118] Particularly, a partnership can be used to establish solidaristic bases by leading individuals to share the same goals. This is applicable to a biobanking context, where all parties normally share the same goal of advancing medical science. Accordingly, a solidaristic relationship might be fostered when building a partnership in biobanking, thereby allowing a participant-biobanker relationship to be additionally strengthened by the occurrence of solidarity.[119] Given all the explanations in this sub-section, it can therefore be argued that partnership should be used as a basis for the ARR.

2.2.5 Conclusion on Partnership

To summarise, this section does not propose the working notion of partnership for this thesis by using its generic definition extracted from the academic literature. Instead, Bidmead and Cowley's explanation about its attributes is adopted as its working notion here because this explanation is generally applied to a partnership between professionals and non-professionals, making it suitable for the ARR – which involves a relationship between biobankers and participants. This section then proposes the working notions of other related concepts and explains the relationships of these concepts to partnership, all of which can be concluded as follows: Collaboration, the act of working together, can be used for developing a partnership relationship. Involvement refers to the act of taking part, which ranges from the act of receiving information to the act of having control over something. It is a basis for a partnership relationship, since a partnership involves two or more parties working together. Empowerment, the measures for increasing ones' capability to control the matters affecting them, is interrelated to partnership since both concepts can be used

[117] See the introduction of this chapter above.
[118] See 2.1.4 (Solidarity as an Aspirational Concept) above.
[119] See 2.1.3 above.

to achieve each other. Solidarity is essentially similar to partnership. It does however differ from partnership, in that it can be neither intentionally prescribed nor proven in practice and it does not clearly demonstrate how important individuals' interests are when they are balanced against collective interests.

After considering the nature of partnership and its relationship to solidarity, this section has argued that partnership should be used as the concept underlying the ARR. The main reason is that it does not raise the issues that solidarity does if being used to underlie the ARR – that is, partnership is applicable to biobank governance and it can be used to balance participants' interests with biobanks' ones. This renders it relatively suitable to underlie the ARR when compared with solidarity. Moreover, when considering partnership itself, its attributes are arguably beneficial to biobanking, and it can indirectly encourage the occurrence of solidarity, which is desirable in biobanking. For these reasons, this thesis therefore adopts partnership as the underlying concept of the ARR. This means that this concept is to be used as a basis for both the conceptual framework of the ARR and the Model.

It is worth noting again that the working notions of all concepts and the relationships between them, explained in this chapter, are not intended to make any original contribution or to construct theoretical argument concerning them. Rather, these explanations are only provided for use as working bases for the following discussions in this thesis.

2.3 Conceptual Framework of the ARR

The previous two sections establish that partnership should be used to underlie the ARR because it is applicable to biobank governance and can also reflect both of the main characteristics of the ARR, proposed in Chapter 1, namely the ability to deal with the distinctive characteristics of biobanking and the ability to strike a balance between participants' and biobanks' interests. Also, solidarity is merely the aspirational concept of the ARR, whereby a solidaristic relationship might be fostered when developing the ARR but this is not necessarily the case.

Based on this premise, this section outlines the conceptual framework of the ARR, which is fundamentally based on partnership but aspires to solidarity. In doing so, its first sub-section takes into account partnership attributes proposed by Bidmead and Cowley, and translates them into key features of a partnership relationship in biobanking ("**a PRB**"). Then, the following sub-section explains how these key features can reflect the two main characteristics of the ARR, in order to justify why these key features should be considered as the conceptual framework of the ARR. Note that, as explained at the end of this section, this conceptual framework can also be used to answer the second sub-question of this thesis concerning what the ARR should look like from a conceptual perspective, as well as to demonstrate how virtue ethics is adopted as an approach to ethical reasoning in this thesis.

2.3.1 Partnership in Biobanking

When considering Bidmead and Cowley's partnership attributes together with biobanking practices, a PRB should have five key features as follows. The first one is **respectfulness**, whereby biobankers treat participants with due respect. This key feature is embraced as the psychological aspect of a PRB because it is echoed in many partnership attributes, such as respect for others' expertise, equity, and honest and open communication. The second key feature is **cooperation with negotiability**, which requires biobankers to work together with participants as well as to allow them to influence biobanking activities or the direction of biobanking. This key feature amounts to the procedural aspect of a PRB, which encompasses the partnership attributes of collaboration, negotiation and involvement. It is noteworthy that, since these first two key features are partnership attributes that are commonly found in partnership initiatives, it can be said that they incorporate the fundamental attitudes and procedures that normally exist in a partnership relationship into a relationship between participants and biobankers. In this respect, they help reflect the basic nature of partnership in a biobanking context.

The third key feature is **support**, whereby biobankers need to help participants to make contributions towards biobanking via empowerment, advocacy and encouragement, amongst others. In practice, this key feature normally involves the

sharing of general knowledge about biobanking and information about biobanks, the latter includes background information about biobanks and updates on biobanking activities. This key feature is important here, since the ARR is based on a relationship between participants and biobankers, and support is a partnership attribute that is particularly necessary in a partnership between non-professionals and professionals.[120] The fourth key feature is **continuity in relationship**, which requires biobankers to maintain their relationship with participants. This key feature is echoed in some partnership attributes that can be used to continue the relationship between partners, such as reciprocation and ongoing communication.

The last key feature is **collectiveness in goals**, whereby participants and biobankers need to share the same biobanking goals throughout biobanking endeavours. Collectiveness in goals can be considered as a fundamental attribute of a partnership relationship, and thereby this key feature incorporates another common attribute of partnership into a participant-biobanker relationship. Indeed, this key feature is applicable to biobanking, as all parties in biobanking generally share the same goal, which is to advance medical science. This suggests that collective goals here generally refer to medical advances. In practice, they might be specific to a certain disease and/or cohort population, and they might also include non-research goals, such as profitability and benefit sharing. Furthermore, this key feature can indirectly encourage solidarity, the aspirational concept of the ARR, in biobanking: as explained above, collectiveness in goals is a partnership attribute that can establish solidaristic bases, and so it allows a partnership to foster a solidaristic relationship.[121] Given these explanations, it can be said that this collectiveness not only underlines partnership but also expresses an attempt to encourage solidarity in biobanking, and thereby it should be another key feature of a PRB.

To summarise, a PRB should have five key features: (i) respectfulness, (ii) cooperation with negotiability, (iii) support, (iv) continuity in relationship, and (v) collectiveness in goals. These key features stem from partnership attributes that are translated to suit a participant-biobanker relationship and to encourage the occurrence

[120] See 2.2.2 (the second last paragraph) above.
[121] See 2.2.4 (last paragraph) above.

of solidarity in biobanking. In the following sub-section, they are to be tested against the main characteristics of the ARR, in order to answer the question of whether they really can be taken as the conceptual framework of the ARR. It is noteworthy that these key features might not be clearly differentiated from each other in practice. For example, the collaboration with negotiability and the support could be considered as ways to respect participants. Also, the respectfulness could in practice maintain the continuity of a relationship between participants and biobankers. Still, this lack of clear differentiation does not raise any theoretical issues. The reason is that this sub-section is not intended to categorise the key features of a PRB precisely. Rather, it merely offers them as conceptual criteria for what a partnership between participants and biobankers should look like, as well as working bases for the following discussions.

2.3.2 From Partnership to the ARR

The previous sub-section suggests how the concept of partnership can be incorporated into a participant-biobanker relationship by proposing the key features of a PRB. A subsequent question arises as to whether these key features can be used as a conceptual framework for the ARR. The answer to this question not only underlines the aforesaid argument for partnership as the underlying concept of the ARR, but also resolves the second sub-question of this thesis concerning what the ARR should look like from a conceptual perspective. To address this question, this sub-section explains whether and how the key features of a PRB can reflect the two main characteristics of the ARR, proposed in Chapter 1, i.e. the ability to deal with the distinctive characteristics of biobanking and the ability to strike a balance between participants' and biobanks' interests. These two main characteristics are dealt with separately in two different sub-sub-sections, as follows.

a) Ability to Deal with Biobanking

It is arguable that the key features of a PRB can address many issues and challenges resulting from the distinctive characteristics of biobanking, especially the longevity of biobanking and unexpected uses of biobank resources. Particularly, the key feature of continuity in relationship, which involves reciprocation and ongoing

communication, can handle these two distinctive characteristics of biobanking. For example, participants might be provided with individual feedback in order to encourage their continuing commitment to biobanking. Also, regular communication might be established to keep them up-to-date with biobanking activities, so that they can know how their samples and information are actually used. Also, the key feature of cooperation with negotiability enables biobankers and participants to cope with unwelcome changes and unanticipated harm to participants, both of which may occur as a result of those two distinctive characteristics of biobanking. Moreover, the key feature of collectiveness in goals can deal with unexpected uses of biobank resources and any dynamics in biobanking, by highlighting the commitment that biobanking activities will conform to participants' expectations. In addition, the key feature of respectfulness can generally maintain the good quality of a participant-biobank relationship from a psychological perspective, and so it helps maintain the continuity and viability of biobanking. Given these explanations, it can therefore be said that the key features of a PRB can deal with the distinctive characteristics of biobanking, and thereby they can arguably reflect one main characteristic of the ARR.

b) Ability to Strike a Balance between Interests

It is also arguable that the key features of a PRB can be used to balance participants' interests with biobanks' ones. According to the key features of respectfulness and cooperation with negotiability, biobankers are required to treat participants respectfully as well as to allow them to engage in and influence biobanking. This implies that their interests and attitudes are given due importance and consideration. Indeed, this also prevents them from being treated as a mere means to another end. One can therefore say that these two key features allow participants' interests to be promoted in a participant-biobanker relationship. On the other hand, biobanks' interests are also promoted, especially through the key feature of collectiveness in goals. Particularly, this key feature emphasises the connectedness between participants and biobankers. This emphasis helps reaffirm the commitment of both parties to biobanking and, as explained above, encourage the occurrence of

solidarity in biobanking.[122] Consequently, this key feature not only strengthens a participant-biobanker relationship, but also allows a positive disposition and helpful contributions towards biobanking, thus promoting biobanks' interests. Indeed, one can also say that this key feature inherently promotes participants' interests: biobanks' interests normally include medical advances, which are in participants' interest too.[123]

These explanations indicate that the key features of a PRB can be used to promote participants' and biobanks' interests differently, and thereby they allow these two interests to be variously and flexibly promoted. Accordingly, it is possible to use these key features to strike a balance between these two interests. One can therefore say that these key features have the ability to strike such a balance, which is another main characteristic of the ARR.

It is notable that the PRB's key feature of support can promote both of these two interests. In particular, this key feature can further participants' interests, in that it renders participants capable of dealing with biobanking by allowing them to, inter alia, understand biobanking, keep up-to-date with biobanking progress and be aware of possible harm to them. On the other hand, it also indirectly promotes biobanks' interests, in that it enables participants to help improve biobanking by allowing them to properly collaborate with or provide useful input for biobankers. For example, the sharing of knowledge and information about biobanking activities with participants allows them to have a good understanding of biobanking and to realise possible harm to their interests. As a result, they can protect themselves from such harm as well as suggest how to prevent it and make biobanking attract more participation. Given this explanation, it can therefore be said that the key feature of support can promote both participants' and biobanks' interests.

To summarise this sub-section, it can be said that the key features of a PRB, proposed in the previous sub-section, can exhibit the two main characteristics of the ARR since they can deal with some distinctive characteristics of biobanking and can also be used to balance participants' interests with biobanks' ones. It is therefore arguable that these key features, which are based on partnership, can be considered as

[122] See 2.2.4 (last paragraph) above.
[123] See 1.4.2 a) in ch 1 above.

the conceptual framework of the ARR. As mentioned above, this argument reinforces the above argument that partnership should be used to underlie the ARR.[124] Furthermore, it also answers the second sub-question of this thesis, regarding what the ARR should conceptually look like: the ARR should look like a partnership relationship and it should have these five key features as its conceptual framework. It is noteworthy that, in terms of ethicality, this argument also suggests that this thesis uses the moral theory of virtue ethics, which determines morality by considering the character traits of actors, to justify its proposals ethically.[125] Particularly, as the ARR involves biobankers' interactions with participants in practice, this argument implies that biobankers should treat participants in the same ways that partners do towards each other. Partnership can therefore be considered to underlie the desirable character of biobankers. This means that this thesis perceives partnership as a virtue that biobankers need to have for fostering the ARR. In other words, partnership is used to define the character trait of virtuous biobankers. Accordingly, the ethicality of the proposals of this thesis is arguably based on the character traits of actors.[126]

Conclusion

This chapter has explored the concepts of solidarity and partnership in order to find the underlying concept of the ARR, which needs to (1) be applicable to biobank governance and (2) echo the two main characteristics of the ARR, outlined in Chapter 1. Other related concepts – i.e. collaboration, participation and empowerment – have also been explored to refine the understanding of partnership as well as propose their working notions for this thesis.

As a result of this exploration, this chapter first argues that solidarity cannot be used to underlie the ARR. However, since solidarity is arguably desirable in biobanking, it should be considered as the aspirational concept of the ARR. This chapter then argues for using partnership as the concept that underlies the ARR. One

[124] See 2.2.4 above.
[125] See 1.3.3 in ch 1 above.
[126] Notably, this aspect of the proposals of this thesis will be explained further in the last chapter. See 6.2.1 in ch 6 below.

reason is that partnership can be used in a governance manner and thus it is arguably applicable to biobank governance. Moreover, it can reflect the two main characteristics of the ARR: it acknowledges the importance of both individuals' and collectives' interests, and so it can be used to balance participants' with biobanks' interests; it also has many attributes that can deal with the distinctive characteristics of biobanking. These reasons suggest that partnership is more suitable to underlie the ARR, especially when compared with solidarity. Other than these two reasons, partnership might also encourage solidarity, which can further strengthen a participant-biobanker relationship and encourage participants to dedicate themselves to biobanking. Given all these reasons, one can say that partnership can be used to introduce the main characteristics of the ARR into a participant-biobanker relationship as well as to encourage the occurrence of solidarity in biobanking. It is therefore arguable that this concept should be used as the underlying concept of the ARR.

Based on this argument, this chapter then translates common attributes of partnership into the key features of a PRB that befit a participant-biobanker relationship. These key features are respectfulness, cooperation with negotiability, support, continuity in relationship and collectiveness in goals. Finally, with the aim of explaining why these key features should be considered as the conceptual framework of the ARR, this chapter demonstrates that they can exhibit both of the main characteristics of the ARR, as follows. First, almost all of them can deal with the longevity of biobanking and unexpected uses of biobank resources. Second, they can be used to strike a balance between participants' and biobanks' interests, because they can promote either of these two interests: on the one hand, the key features of respectfulness and cooperation with negotiability allow participants' interests to be given due importance and consideration; on the other hand, the key feature of collectiveness in goals essentially promotes biobanks' interests by reaffirming the commitment to biobanking and encouraging solidarity in biobanking. Given these explanations, it can be concluded that the ARR should have these five key features as its conceptual framework. These key features are considered to be conceptual criteria that need to be satisfied when developing the ARR in practice. In this respect, they will be used to underpin the Model in the next chapter.

Two important arguments in this chapter can be summarised as follows: first, partnership should be the underlying concept of the ARR, and solidarity should only be an aspirational concept when developing the ARR; second, the ARR should have five key features, namely respectfulness, cooperation with negotiability, support, continuity in relationship, and collectiveness in goals. These two arguments answer the second sub-question of this thesis, regarding what the ARR should look like from a conceptual perspective: the ARR should look like a partnership relationship and it should have those five key features as its conceptual framework. Also, as far as ethicality is concerned, these arguments suggest that partnership should be considered to be the character trait of virtuous biobankers. In the following chapter, this conceptual framework will be used as a working basis when proposing the Model, which suggests how the ARR can be fostered in biobanking practice. The Model consists of four key attributes, i.e. emphasis on collective goals, collaboration, reciprocation and control sharing. To apply these key attributes in practice, biobankers need to implement certain practical measures. These key attributes and measures can foster the ARR because they can reflect all the key features of the ARR through biobanking activities.

Chapter 3

Partnership Model for Developing the ARR

By considering a participant-biobanker relationship that can deal with the practical and ethical issues and challenges created by biobanking as an authentic research relationship in biobanking ("**an ARR**"), this thesis pursues one approach to an ARR ("**the ARR**"), one which can enhance both the ethical acceptability of biobanking to participants and the effectiveness of biobanking. The previous chapter concluded that partnership is the underlying concept of the ARR, while solidarity is merely taken as the aspirational concept thereof. Based on this premise, that chapter establishes the conceptual framework for the ARR by suggesting that the ARR should have five key features, namely: (1) respectfulness, (2) cooperation with negotiability, (3) support, (4) continuity in relationship and (5) collectiveness in goals. With the aim to suggest ways to foster the ARR, this chapter addresses the last sub-question of this thesis, regarding how to develop the ARR in practice. In doing so, it proposes a partnership model for biobank governance that can reflect all of the ARR's key features ("**the Model**").

This chapter explains the Model by proposing the key attributes that biobank governance needs to embody. Each key attribute is explained separately in four different sections, each of which has three main sub-sections. In each case, the first sub-section explains the general meaning and characteristics of a key attribute in a biobanking context. The second sub-section outlines the practical application of that key attribute. To do so, it first proposes practical *measures* as essential requirements for applying that key attribute, and then suggests some *mechanisms* for implementing those measures. Note that the latter are considered to be exemplars of how to put the former into practice and so, unlike the former, they are actually not the proposals of this thesis. Finally, the last sub-section justifies that key attribute by showing how it can reflect the key features of the ARR, proposed in the previous chapter. The measures and mechanisms for applying that key attribute may also be specifically justified in the same fashion, if they additionally reflect other ARR's key features.

Two points need to be noted here. First, this chapter mainly aims to propose the Model. In this respect, it does not deal with controversial issues that might arise from these proposals, such as participants' control, the provision of individual feedback and commercial involvement. These issues will be addressed in Chapter 6. Second, in an attempt to make the proposals of this thesis practically applicable in a range of biobanking settings, the Model intentionally does not lay down overly stringent requirements so as to make its practical application somewhat flexible.

As an interim conclusion, the Model consists of four key attributes, namely: (i) emphasis on collective goals, (ii) collaboration, (iii) reciprocation and (iv) control sharing. It is arguable that the Model can be used to foster the ARR in practice because its key attributes, as well as the measures and mechanisms proposed for applying them, can reflect all the key features of the ARR, outlined in the previous chapter. It is worth emphasising that the Model is primarily aimed at suggesting the ways in which the ARR can be developed in practice. In this respect, the more biobank governance conforms to the Model, the more likely the ARR is to be fostered in that governance. This does not mean that biobanks whose governance does not conform to the Model can be *judged* ineffective, unacceptable or unsuccessful. Rather, such non-conformity merely *tentatively suggests* that the participant-biobanker relationship in those biobanks is unlikely to be fully beneficial to biobanking or that their biobanking activities might not be effective and ethically acceptable to participants.

3.1 Key Attribute 1: Emphasis on Collective Goals

Emphasising collective goals as a key attribute of the Model conceptually requires participants and biobankers to share the same biobanking goals. Also, this goal sharing must be consistent throughout biobanking endeavours, and thus continuity is an important element here. Accordingly, this key attribute basically reflects the ARR's key features of collectiveness in goals and continuity in relationship. As for the question of what biobanking goals are of consideration, biobanks have diverse purposes – whether research or non-research ones. Research biobanks generally have the goal to advance medical science. In practice, their goals

may differ or vary depending upon, inter alia, types of biomaterials they collect, participant cohort, forms of knowledge they pursue and/or degree of commercial involvement. Some research biobanks, for example, focus on a particular disease in a certain population, while others function otherwise and collect various types of tissue samples and information for epidemiological purposes. Given this diversity, this key attribute requires the sharing of biobanking goals that are specific to certain biobanks, as opposed to merely the general goal to advance medical science. The main reason is that, based on the underlying concept of partnership, participants as partners should – or at least should be allowed to – know exactly how their tissue samples and information will be used.

Nonetheless, when applying this key attribute, factual evidence on the sharing of specific biobanking goals is not required. This is based on the assumption that participants might not have a comprehensive understanding of biobanking goals. More importantly, it may also not be feasible in practice to gather such evidence as this evidence requires careful assessment of participants' understanding, which may be too resource-consuming. One might therefore say that the requirement for such evidence is likely to make the Model impractical and thereby this requirement is not enforced here: to apply this key attribute, biobankers do not have to prove that all participants fully understand and actually share biobanking goals at this level of specificity. Instead, this specificity level is used as a standard for the quality of the measures used to apply this key attribute. For example, the information on biobanking goals that is communicated to participants needs to include details that are specific to biobanks in which they participate. It can therefore be concluded that this specificity is not required when determining the extent to which participants actually understand and share biobanking goals; rather, this specificity needs to be applied to the practical application of this key attribute – i.e. it is used to determine the adequacy of the information about biobanking goals that biobankers offer to participants.

3.1.1 Practical Application

To put this key attribute into practice, biobankers need to implement measures that emphasise biobanking the goals shared with participants, i.e. collective goals.

These measures stem from two major issues in biobanking practice. The first one concerns participants' understanding of biobanking goals, which is highlighted in the academic literature.[1] Admittedly, misunderstandings of biobanking goals seem unlikely, since uses of biobank resources are generally unanticipated and so biobanking goals do not usually involve detailed and complicated information.[2] These misunderstandings are, however, possible in practice, especially given that participants do not usually have any professional expertise in this area.[3] Thus, this issue should not be overlooked, especially for the ARR, where collectiveness in goals is one of its key features. As for the second issue, biobanking activities might not conform to the goals shared with participants. This might result from errors in managing biobanks or the dynamics of biobank governance, such as changes to management boards. Some extrinsic factors may also result in this non-conformity. One example is incremental commercial involvement, whereby biobankers might be enticed to incline more towards profitability – as opposed to healthcare necessity – and this might result in uses of biobank resources that are undesirable and not in accordance with the goals shared with participants.

These two issues may result in uses of biobank resources that go beyond participants' expectations, thereby eroding their relationship with and trust in biobankers. More importantly, since both issues might involve the discrepancy between participants' and biobankers' actual biobanking goals, they might preclude the ARR's key feature of collectiveness in goals. Given these implications, one can

[1] LM Beskow et al, "Informed Consent for Biobanking: Consensus-Based Guidelines for Adequate Comprehension" (2015) 17 *Genetics in Medicine* 3 226-233; AK Rahm et al, "Biobanking for Research: A Survey of Patient Population Attitudes and Understanding" (2013) 4 *Journal of Community Genetics* 4 445-450.

[2] KE Ormond et al, "Assessing the Understanding of Biobank Participants" (2009) 149A *American Journal of Medical Genetics Part A* 2 188-198; CA McCarty et al, "Informed Consent and Subject Motivation to Participate in a Large, Population-Based Genomics Study: The Marshfield Clinic Personalized Medicine Research Project" (2007) 10 *Public Health Genomics* 1 2-9.

[3] M Dixon-Woods et al, "Beyond "Misunderstanding": Written Information and Decisions about Taking Part In a Genetic Epidemiology Study" (2007) 65 *Social Science & Medicine* 11 2212-2222; G Moutel et al, "Bio-Libraries and DNA Storage: Assessment of Patient Perception of Information" (2001) 20 *Medicine and Law* 2 193-204; V Toccaceli et al, "Research Understanding, Attitude and Awareness towards Biobanking: A Survey among Italian Twin Participants to a Genetic Epidemiological Study" (2009) 10 *BMC Medical Ethics* 1 1-8.

therefore say that these two issues might undermine a participant-biobanker relationship as well as the viability of biobanking. To avoid such setbacks, this key attribute proposes two measures that aim to tackle these issues by way of reinforcing the ARR's key feature of collectiveness in goals. These two measures are (a) the clarification of biobanking goals and (b) the reinforcement of collectiveness in biobanking goals. The former focuses on the recruitment stage, while the latter emphasises following stages of biobanking. The details of these two measures are explained separately in two sub-sub-sections, as follows:

a) Clarification of Biobanking Goals

For the first measure, this key attribute requires biobankers to clarify their biobanking goals. This clarification emphasises collectiveness in biobanking goals by attempting to achieve genuineness in this collectiveness at an early stage of biobanking. In particular, as this measure essentially makes biobanking goals clear when participants are recruited, it assists participants in having an accurate understanding of biobanking goals and thereby enables them to verify whether they actually share the same goals with biobankers before participating. Given this explanation, this measure can address the above issue concerning misunderstanding of biobanking goals. Indeed, a proper understanding of biobanking goals can inherently enhance participants' capability to deal with biobanking. They can, for example, give meaningful consent and provide useful input on the direction of biobanking. In this respect, this measure could be seen as empowerment, which echoes the ARR's key feature of support. In addition, this measure can help participants to have a better understanding of the implications of their participation, thereby allowing them to avoid misguided participation and foreseeable harm as well as promoting their exercising of autonomy. Thus, it is arguable that this measure can improve a participant-biobanker relationship. It is notable that the focus of this measure is on the recruitment stage. In contrast, the other measure, proposed below, serves to accentuate collective goals during the course of biobanking.

Effective Communication

For the practice of this clarification, the focus should generally be on good communication with participants during recruitment. Given the aim of making biobanking goals clear to participants, **the quality of communication should be an important consideration** – that is, communication with participants should be sufficiently effective for delivering an accurate understanding of biobanking goals. To have such communication, many factors need to be taken into account. The foremost one is the characteristics of participants, including age, education level and cognitive ability. For example, information about biobanks should be presented differently to adult and young participants. The nature of information is another factor to be considered: sensitive or potentially confusing information – e.g. policies on individual feedback, commercial involvement and the fact that research biobanks do not provide medical treatment[4] – needs to be carefully explained and sufficiently justified. Biobank design can also inform this communication. An example is a consent approach, which intrinsically indicates the amount of information to be communicated and the level of understanding to be achieved.[5] It can be argued from these factors that the ways to implement this measure are contextual. One can therefore say that, without considering the contributory factors, merely to offer a deluge of detailed technical information about biobanking cannot amount to the implementation of this measure.

Three points are noteworthy here. First, the implementation of this measure should in practice focus on the methods of communication, rather than the consequences thereof. Particularly, this implementation does not call for evidence of a sufficient level of participants' understanding, which is arguably impractical to gather given the probable non-activeness of participants and the need for excessive resources to carefully assess participants' understanding of biobanking goals. Rather,

[4] FG Miller and S Joffe, "Evaluating the Therapeutic Misconception" (2006) 16 *Kennedy Institute of Ethics Journal* 4 353-366; AA Lemke et al, "Biobank Participation and Returning Research Results: Perspectives from a Deliberative Engagement in South Side Chicago" (2012) 158A *American Journal of Medical Genetics Part A* 5 1029-1037; CA McCarty et al, see note 2 above; KE Ormond et al, see note 2 above.

[5] In the model proposed, the consent procedure has a role in sharing control over biobanking with participants at an individual level, according to the Model's key attribute of control sharing. See Section 3.4 below.

it suggests looking for evidence demonstrating biobankers' attempts to facilitate such understanding. An example is the fact that biobankers involve prospective participants in preparing recruitment materials. Another example is recruitment documents having content that is easily comprehensible to cohort participants by design. On the second point, when determining the extent of information to be communicated, the aforesaid level of specificity is applied – that is, this communication should allow participants to access the information about biobanking that is sufficiently specific to certain biobanks. For the last point, the information provided for participants needs not be only about the purposes of biobanks. It might include information concerning other aspects of biobanking that can help them to understand biobanking goals, such as types of research studies using biobank resources and researchers who have access to biobank resources. Indeed, it is necessary for biobankers to notify participants of any commercialisation that might be involved in biobanking, such as possible patenting and access to biobank resources by for-profit companies, since this indicates a commercial aspect of biobanking goals.[6]

Re-contacting

In some circumstances, collectiveness in biobanking goals between participants and biobankers does not exist in the first place, or become non-existent. This might result from the fact that participants are originally recruited to biobanks for different purposes, such as a criminal investigation or organ donation, or there are changes to biobanking goals originally agreed with participants. As an example of the latter, a long-standing biobank did not have the goal of commercialising its resources when recruiting participants but, afterwards, it comes to need and involve this commercialisation. In these circumstances, the suggestion of re-contacting is added: biobankers should re-contact participants and also explain current biobanking goals to them. The reason behind this suggestion is simply that such re-contacting allows biobankers to make current biobanking goals clear to participants. Furthermore, this re-contacting is of practical benefit to biobanking, in that it intrinsically enables

[6] The notification of commercial involvement in biobanking is considered to be one of the ways that this proposed model uses for dealing with this involvement. See 6.4.3 b) in ch 6 below.

biobankers to obtain consent as well as more samples and information from participants if needed. Conceptually, this re-contacting can reflect the ARR's key feature of respectfulness. Particularly, it involves respectful gestures towards participants by valuing their autonomy through individual contact and not exploiting their original intent. This re-contacting could indeed amount to allowing them to agree to become partners in current biobanks. For these reasons, **this re-contacting should therefore be done in these circumstances**. This also implies that, if those participants cannot be re-contacted, they should not be recruited to current biobanks.

It can be concluded from this sub-sub-section that this key attribute requires biobankers to recognise the importance of participants' understanding of biobanking goals, rather than ensuring that participants achieve a certain level of understanding of biobanking goals. To satisfy this requirement, biobankers need to clarify biobanking goals. In practice, they should establish communication that effectively allow participants to have an accurate understanding of biobanking goals. There are no criteria for what such communication should look like as this needs to be contextual. Alternatively, this requirement might be fulfilled with evidence of biobankers' attempts to make information about biobanking goals easily comprehensible, such as involving prospective participants in preparing recruitment documents and differentiating between the content of recruitment leaflets for adult and young cohorts. In a case where collectiveness in biobanking goals does not exist to begin with or becomes non-existent, biobankers should re-contact participants. Notably, as this clarification involves the provision of information during the recruitment stage, one can say that this measure is complementary to the consent procedure.

b) Reinforcement of Collectiveness in Goals

For the second measure, **this key attribute requires biobankers to reinforce collectiveness in biobanking goals by establishing mechanisms for continuously encouraging participants and biobankers to share the same biobanking goals**. The reason for this measure is that biobankers' or participants' goals might deviate from the goals already agreed, and thereby there must be mechanisms in place to discourage such deviation in order to maintain collectiveness

in biobanking goals throughout biobanking endeavours. Given this reason, this measure conceptually emphasises collectiveness in goals as well as continuity of this collectiveness, and so it arguably reinforces the ARR's key features of collectiveness in goals and continuity in relationship. Moreover, this measure can address the issue regarding non-conformity of biobanking activities to collective goals, which is explained at the beginning of this sub-section: in this case, biobankers' goals, reflected through non-conforming biobanking activities, are considered to deviate from the goals shared with participants; and this measure, which aims to discourage such deviation, could be implemented to hinder those activities. Indeed, one can also say that this measure could help develop trusting relationships with participants by encouraging the uses of biobank resources that accord with their expectations.

It can be inferred from the above explanation that this reinforcement measure requires biobankers' goals (or biobanking activities) and participants' goals to be constantly monitored, and if any of these goals deviate from collective goals, there must be some mechanisms in place for identifying and hindering such deviation (unless new consent is sought). In practice, however, it is arguably not feasible for biobankers to constantly monitor participants' goals. This is because such a monitoring task requires the continuous examination and careful assessment of participants' thoughts and thereby can be considered excessively burdensome and resource consuming, let alone the possibility of non-active participants.[7] The focus of this measure should therefore be on biobankers' goals, which can be assumed to be reflected in biobanking activities. Accordingly, this reinforcement measure needs to have **two crucial elements. The first one is ongoing oversight of biobanking activities**. This oversight basically allows biobankers' goals to be regularly identified from biobanking activities and, as suggested below, this identification allows any deviations from collective goals to be detected. **The second element is the capability to discourage deviations from collective goals**. This element basically plays a role in maintaining collectiveness in biobanking goals. To give examples of how to implement this measure, this sub-sub-section suggests mechanisms for resisting the

[7] Non-active participants here refer to participants that are not actively involved in biobank governance, such as those who are apathetic or unwilling to interact with biobankers other than providing their samples and information.

changes to participants' and biobankers' goals that deviate from collective goals. The details of these suggested mechanisms are as follows.

Changes to Participants' Goals

The first suggestion is for a situation where participants themselves change their original goals, which have already been agreed with biobankers. Here, biobankers' goals, reflected in biobanking activities, are perceived as collective goals, while participants' goals are considered to deviate from collective goals. Accordingly, changes to participants' goals need to be recognised and resisted in order to maintain collectiveness in biobanking goals. Conceptual consideration aside, it is, however, not feasible in practice for biobankers to constantly monitor participants' thoughts and recognise such changes, as explained above. Such changes should therefore be dealt with by participants themselves. As a result, the task of reinforcing collectiveness in biobanking goals in this situation should be entrusted to participants, with the proviso that biobankers have an ongoing responsibility to keep them suitably informed.

Based on this premise, there should be two mechanisms, which stem from the aforesaid two crucial elements: (1) communication about biobanking progress ("CBP") and (2) the right to withdraw consent. CBP provides participants with information about biobanking activities and thereby allows them to recognise biobankers' goals, which are collective goals here, through such information. In this respect, CBP enables them to determine whether or not they still have the same goals as biobankers. Provided that the answer is negative, they can prevent deviation of their goals from collective goals by withdrawing their consent. Other than reinforcing collectiveness in goals in this model, these suggested mechanisms are also of practical benefit in general. Particularly, as CBP facilitates the exercising of the right of withdrawal by enabling participants to know whether and/or when to withdraw their consent, these mechanisms arguably promote this right as well as empowering them by enhancing their capability to exercise this right. Indeed, these mechanisms can be used in a case where their goals do not actually change but they perceive that biobankers' goals are deviating from the goals they originally agreed.

Three points can be noted here. First, these mechanisms are basically for active participants: they require participants to actively maintain collectiveness in biobanking goals through a self-checking method. This is based on the presumption that they will become active if their biobanking goals change. Second, the fact that participants might not be able to withdraw their contributions from research that has already used their samples and information does not undermine these mechanisms,[8] because they are based on the assumption that their biobanking goals change after previous uses. That is, previous uses are justifiable because they conform to participants' original goals or collective goals. Finally, these two mechanisms together inherently allow participants to have some control over biobanking at an individual level, as further illustrated in the fourth key attribute of control sharing below.[9]

Changes to Biobankers' Goals

The second suggestion aims to deal with a situation where biobanking activities are not in accordance with the goals shared with participants. In assuming that biobanking activities are generally a reflection of biobankers' goals, this situation equates to the deviation of biobankers' actual goals from collective goals. Accordingly, with the aim of reinforcing collectiveness in biobanking goals, there should be mechanisms in place for recognising and hindering biobanking activities that do not conform to participants' goals so as to discourage the changes to biobankers' goals that deviate from collective goals. It is noteworthy that, in contrast to the aforesaid suggestion, where biobankers' goals are taken as collective goals, participants' goals are perceived as collective goals in this situation because they are goals that are originally agreed between participants and biobankers.

As for the question of who should have a role in implementing these mechanisms, one straightforward answer might be participants, since they are partners, who know well about collective goals and indeed share those goals. However, when

[8] Normally, it is not feasible to retrieve or destroy participants' information that has already been used in research studies or released as part of research results. See T Caulfield et al, "Research Ethics Recommendations for Whole-Genome Research: Consensus Statement" (2008) 6 *PLoS Biology* 3 0430-0435, at 0432; UK Biobank, *UK Biobank Ethics and Governance Framework Version 3.0*, (October 2007) 20, at 8.
[9] See 3.4.1 a) (Right of Withdrawal) below.

considering the nature of this role and the characteristics of participants, this answer is not entirely sensible for many reasons. First, this role normally requires specialised knowledge of this area, not merely personal experience and reflection.[10] Thus, participants, who are usually not experts, are unlikely to have adequate capability for this role. Second, as the identification of non-conforming activities involves ongoing oversight of biobanking activities, this role calls for a certain level of dedication to biobank governance. When considering that participants are not always active, it is doubtful whether they will have a sufficient level of such dedication. Finally, this role basically requires the ability to hinder or inhibit non-conforming activities. Given that the ARR is limited to biobankers' relationship with individual participants,[11] it is not feasible in practice for each participant to have such ability, let alone dealing with practical challenges of doing so. These reasons suggest that participants are probably unable to assume this role properly in practice and, consequently, they should not single-handedly take on this role.

This model therefore suggests establishing an oversight body, a fully or semi-professional entity that is assigned to monitor biobanking activities and encourage the conformity of those activities to collective goals.[12] This mechanism not only avoids the above issues, but also conceptually helps participants to inhibit biobanking activities that go against their goals or beyond their expectations. To adopt this suggestion, this body should interact with both biobankers and participants. The details of these two interactions are explained separately, as follows:

For interactions with biobankers, the oversight body should (1) have access to information about biobankers' activities and (2) be able to hinder or inhibit activities that do not conform to participants' goals. These interactions are based on the two aforesaid crucial elements, namely the ongoing oversight of biobanking activities and the discouragement of any deviation from collective goals, respectively. There are no criteria for what this discouragement should look like so as not to limit the

[10] Note that the model proposed here is not based on the Information Deficit Model, but it recognises the reality that specific knowledge and understanding are required to deal with biobanking practices.
[11] See 1.3.2 in ch 1 above and 6.3 in ch 6 below.
[12] More detail about this oversight body will be explained in the last chapter of this thesis. See 6.1.2 b) (Establishment of an Oversight Body) in ch 6 below.

implementation of this measure to certain forms of governance structure. In this respect, discouragement mechanisms might either directly enable the oversight body to hinder non-conforming activities or involve other entities in doing so; these may range from simple practical sanctions to complicated legal mechanisms. Still, the effectiveness of discouragement mechanisms is an important consideration – that is, they should be able to hinder, or even impede, activities that the oversight body considers not to be in conformity with participants' goals. One practical example is financial sanctions by funders:[13] although these sanctions might not per se be considered powerful, they can amount to discouragement mechanisms if it is evident in practice that funders can use funding to effectively hinder activities that are considered not to conform to participants' goals.

As for interactions with participants, two tasks should be fulfilled by the oversight body. First, the body should know participants' biobanking goals so that they can know what collective goals actually are. This task helps to make the body eligible to reinforce collectiveness in biobanking goals. In practice, the body can simply derive participants' goals from their consent to biobanking. It might also adopt other mechanisms if their consent does not suffice, such as communication and focus groups. Notably, the body does not necessarily know precisely what biobanking goal each participant actually has, due to the impracticality of doing so. Given the likelihood of non-active participants, it is possible that the body will take participants' consent as their overall goals and establish a communication channel that enables them to voice their thoughts about biobanking. For the second task, the body should make information about its interactions with biobankers (explained above) accessible to participants, because they (as partners) share collective goals and so should be allowed to know whether collective goals are being pursued. In practice, this task can be fulfilled by establishing communication with them. In the light of these two tasks, it can be concluded that the oversight body should generally establish mechanisms for understanding participants' biobanking goals and informing them of its own activities.

[13] These sanctions are a common mechanism that is used for governing biobanks in the UK, and there is the view that funders should be involved in overseeing biobanking activities. See WW Lowrance, *Access to Collections of Data and Materials for Health Research: A Report to the Medical Research Council and the Wellcome Trust,* (March 2006) 36.

Note that these mechanisms can arguably reflect the ARR's key features of respectfulness and support, since these mechanisms render the body's activities transparent to participants and assist participants in dealing with biobanking by allowing them to know when to exercise their right of withdrawal, respectively.

In summary, to implement the measure for reinforcing collectiveness in biobanking goals, there must be mechanisms for resisting the changes to participants' and biobankers' goals that deviate from collective goals. To deal with changes to participants' goals, CBP and the right of withdrawal should be available for participants to verify this collectiveness and to inhibit the deviations from collective goals that are caused by themselves, respectively. As for changes to biobankers' goals, an oversight body might be established to perform this resistance task by monitoring biobanking activities and hindering or inhibiting biobanking activities that do not conform to collective goals. In addition, the body should have mechanisms for realising collective goals through participants' biobanking goals, and informing them of its own activities. Note that the mechanisms for dealing with changes to biobankers' goals are similar to those suggested for applying the key attribute of reciprocation. The reason is that the Model uses the fact of biobankers committing themselves to the goals shared with participants to reciprocate participants' contributions to biobanking.[14]

3.1.2 Reflection on the ARR

As explained at the beginning of this section, overall, this key attribute reflects the ARR's key features of collectiveness in goals and continuity in relationship, since it requires participants and biobankers to share the *same* biobanking goals *throughout* biobanking endeavours. The other key features of the ARR are also reflected in the measures and mechanisms proposed for applying this key attribute. In particular, the ARR's key feature of respectfulness is echoed in both the clarification of biobanking goals, which recommends that biobankers respect participants' autonomy by re-contacting them in the absence of collectiveness in biobanking goals, and the reinforcement of collectiveness in biobanking goals, where the oversight

[14] See 3.3.1 a) below.

body's activities are made transparent to them. The ARR's key feature of support can be exhibited through communication about biobanking goals and progress, as this communication inherently empowers participants by enhancing their capability to deal with certain biobanking activities, i.e. giving consent to biobanking and withdrawing their consent. The establishment of this oversight body can also assist participants in reinforcing collectiveness in biobanking goals and maintaining continuity of this collectiveness. It can therefore be concluded that this key attribute can help develop the ARR by reflecting almost all of the ARR's key features, namely collectiveness in goals, continuity in relationship, support and respectfulness.

3.1.3 Interim Conclusion

The key attribute of emphasis on collective goals conceptually requires biobankers and participants to share the same biobanking goals. To apply this key attribute, biobankers need to implement two main measures. For the first measure, biobanking goals need to be clarified so as to encourage genuine collectiveness in biobanking goals. If this collectiveness does not exist or becomes ambiguous, biobankers should re-contact participants to initiate or verify it. For the second main measure, this collectiveness needs to be reinforced by hindering any deviations from collective goals. To implement this measure, there must be mechanisms that allow biobanking activities to be continuously monitored and hinder the changes to participants' or biobankers' goals that deviate from collective goals, e.g. the right of withdrawal, communication about biobanking progress and establishment of an oversight body that is assigned to monitor biobanking activities and resist such changes. Notably, the clarification measure focuses on the recruitment stage, while the reinforcement one emphasises subsequent stages of biobanking. Thus, these two measures can help maintain continuity of collectiveness in goals throughout the course of biobanking. In terms of the ARR, this key attribute helps develop the ARR by reflecting many of its key features: not only does this key attribute generally echo the ARR's key features of collectiveness in goals and continuity in relationship, but its practical application also reflects those of respectfulness and support.

3.2 Key Attribute 2: Collaboration

The term collaboration generally refers to the act of working together.[15] Collaboration in the Model, however, additionally encompasses respect for participants, because respectfulness is one of the ARR's key features and participants are considered to be partners here, as explained in Chapter 2.[16] Thus, this collaboration does not just refer to cooperation, which basically focuses on working together by fulfilling ones' own responsibilities;[17] rather, it also requires a psychological element of respectfulness. In this respect, this element renders this collaboration different from mere collaboration in a general sense. Notably, while collaboration generally involves bilateral commitment and action, this key attribute only focuses on those of biobankers since the Model basically concerns the ways in which biobankers should behave towards participants. In this respect, the Model is not arguing that collaboration in biobanking should be unilateral. Based on this premise, this second key attribute should have two elements: one is cooperation, or a state of working together, with participants; the other is respectful gestures towards them. These elements are to be used as bases for the practical application of this key attribute.

3.2.1 Practical Application

In the light of the aforesaid elements, one feasible way to cooperate with and also show respect to participants in biobanking, is to provide them with *opportunities* to *meaningfully* influence biobanking activities. Particularly, via the term 'opportunities', all participants are not required to actively engage in biobanking. This recognises the reality that some participants are interested in actively engaging in biobanking, while others prefer to be inactive and thus do not want to take part in biobanking activities other than providing their samples and information. As for the term 'meaningfully', the call for meaningful influence incorporates an element of

[15] See 2.2.3 a) in ch 2 above.
[16] See 2.3 in ch 2 above.
[17] It is explained that cooperation refers to the state of individuals working together to achieve shared goals, while collaboration additionally involves respect for each individual's contributions. See O Kozar, "Towards Better Group Work: Seeing the Difference between Cooperation and Collaboration" (2010) 2 *English Teaching Forum* 16-23.

genuineness into the aforesaid opportunities, thereby preventing such opportunities from being tokenistic in practice. Accordingly, the provision of these opportunities can be considered both practical for biobanking practice and respectful to participants, making it promising for a participant-biobanker relationship. Based on this premise, this sub-section therefore proposes two measures that are required to apply this key attribute: measures that (a) give participants opportunities to provide input about biobanking and (b) ensure the meaningfulness of their input.[18] As for the structure of this sub-section, these two measures are dealt with separately in two different sub-sub-sections.

a) Opportunities to Provide Input

For the first measure, this second key attribute requires biobankers to **give participants opportunities to provide input about biobanking**. The main reason is that this measure can reflect the ARR's key features of (1) cooperation with negotiability and (2) respectfulness: it indicates biobankers' willingness to cooperate with participants and, as further explained below, allows them to negotiate about biobanking; also, it intrinsically shows respect for their opinions and attitudes as well as their interests. In practice, biobankers need to implement mechanisms that allow all participants to voice their thoughts, including opinions and attitudes, about biobanking. They might, for example, establish some communication channels that enable participants to provide their input or feedback about biobanking activities, such as participant meetings with Q&A sessions and hotlines for general enquiries.

Two points are noteworthy here. First, as the ARR concerns biobankers' relationship with individual participants and every participant is deemed to be a partner in the Model,[19] it is important to offer these opportunities to all participants, regardless of whether they choose to be active or not. Second, this measure accentuates opportunities to contribute, not actual input from participants. In this respect, it does

[18] The term 'input' in this chapter is limited to intangible contributions to biobanking, including opinions, attitudes and concerns about biobank governance. In contrast, the term 'contributions' encompasses such input as well as other forms of contributions to biobanking, such as participants' tissue samples and information. The latter term has a wider meaning in this respect.
[19] See 1.3.2 in ch 1 above and 6.3.1 in ch 6 below.

not require biobankers to seek input from every participant. As suggested above, this can address the likelihood of inactive participants.

b) Assurance of Meaningfulness

For the second measure, biobankers are required to ensure the meaningfulness of participants' input. To achieve this, they need to ensure that **participants' input actually has the possibility to influence biobanking activities**. This does not mean that biobankers always have to put participants' input into practice; rather, they must give participants a real chance to influence biobanking activities substantially. This requirement indicates that the genuineness of the aforesaid opportunities and the quality of participants' input are main considerations here. Given these considerations, this measure is arguably crucial here because it can prevent those opportunities suffering from tokenism, which can arise in any participatory mechanisms[20] and indeed could undermine a participant-biobanker relationship. Also, in terms of the ARR, the measure can help reinforce the ARR's key features that are reflected in the previous measure, namely respectfulness and cooperation with negotiability, by making these key features more prominent and likely.

To explain how to ensure this meaningfulness, this sub-sub-section separately deals with three forms of tokenism that could arise in biobanking, i.e. insignificance of the issues under consideration, insufficiency of participants' capability to provide input, and disregard for participants' input. For each possible form of tokenism, its nature is first delineated and then mechanisms for addressing it are suggested.

Insignificance of Issues

The first possible form of tokenism is that issues on which participants can provide input are not sufficiently significant, thereby preventing their input from influencing biobanking activities. Examples of such issues might be the theme colour of newsletters and the frequency of non-biobanking activities. **Biobankers are thus required to give participants opportunities to provide input on sufficiently**

[20] The term 'tokenism' here refers to the practice of making non-genuine attempts to achieve something or not doing something meaningfully.

significant issues. It is however difficult to define criteria for 'sufficiently significant issues', since the level of significance varies depending upon the aspects and contexts under consideration. As an example, the issue regarding monetary offers can be considered significant for the question of whether to have monetary offers as participation incentives, while this is unlikely to be so for the question of whether offers should be cash vouchers or cinema tickets. Thus, determination of this matter should be on a case-by-case basis. Nonetheless, one might say that, in general, the issues affecting the quality of a participant-biobanker relationship or the direction of biobanking activities can be considered significant, since they are influential in the management and viability of biobanking. Examples of these issues are policies on individual feedback, priorities in use of biobank resources and the degree of commercial involvement in biobanking. These characteristics should therefore be used as approximate guides to determine what issues should be considered sufficiently significant according to this second key attribute.

Insufficiency of Capability

The second possible form of tokenism is a situation where participants' capability is not sufficient to give useful input about biobanking. As an example, participants may not have adequate knowledge about access to biobank resources and implications of this access, and so they are probably unable to voice useful opinions on priorities in it. As a result, their input might be unhelpful for biobanking and thereby not worthy of consideration. This can prevent their input from influencing biobanking activities and thus, in terms of the ARR, undermine the ARR's key features of cooperation with negotiability and respectfulness. This insufficiency is likely to be the case, since participants are usually not professionals in this area and might not have access to knowledge about biobanking or much information about biobanking activities. **Biobankers are therefore required to address this insufficiency by empowering participants.**

To fulfil this requirement, the suggestion is that biobankers should generally give participants access to such information and knowledge, because this access enables participants to enhance their capability to provide input about biobanking. Indeed, the level of this access should be sufficient in terms of both the amount and

type of information. It should be noted from this suggestion that the major concern here is the accessibility of such information and knowledge, as opposed to the extent to which participants actually access or absorb such information and knowledge. Also, no specific mechanisms are suggested – i.e. to address this possible form of tokenism, biobankers can use any mechanisms that allow participants to have sufficient access to such information and knowledge. In practice, biobankers might establish mechanisms for sharing such information and knowledge with participants. These mechanisms might be in the form of communication or participatory activities, such as issuing participant newsletters, arranging participant meetings, conducting workshops on certain issues, and responding to participants' enquiries. Indeed, these mechanisms might be performed among participants. Biobankers might, for example, arrange meetings that enable cohort participants to share their experiences of data-collecting sessions with one another, so as to increase their capability to express their opinions about these sessions or recruitment procedures in general.

It is noteworthy that mechanisms for addressing this possible form of tokenism can fundamentally exhibit the ARR's key feature of support, in addition to the ARR's key features of respectfulness and cooperation with negotiability. The reason is that these mechanisms intrinsically empower participants by enhancing their capability to deal with certain aspects of biobanking:[21] the aforesaid access enables them to know about, inter alia, the nature of biobanking activities, actual problems with biobanking and possible solutions to these problems, all of which assist them in making useful contributions towards biobanking.

Disregard for Participants' Input

The last possible form of tokenism is present when participants' input is not given serious consideration. This prevents participants from having any real chance of influencing biobanking, thereby making their opportunities to provide input tokenistic. To address this possible form of tokenism, **biobankers are required to take participants' input into consideration seriously**. To fulfil this requirement in practice, there should be mechanisms that can help to verify actual consideration of

[21] See 2.2.3 b) (Empowerment) in ch 2 above.

participants' input, so as to assure participants that their input is not neglected by biobankers. These mechanisms may vary contextually depending upon, inter alia, the design of biobank governance and the availability of management resources. For example, participant representatives might be appointed to certain working groups or management committees and be assigned a role to observe how biobankers deal with participants' feedback.[22] As another example, after every meeting with participants, biobankers might be obliged to write a public report that documents participants' feedback, discusses it and, if necessary, responds to it. In this case, biobankers should also be obliged to justify adequately why they put certain feedback into practice while ignoring other feedback.

Three points are noteworthy here. First, the solution to this last possible form of tokenism merely accentuates actual consideration of participants' input. In this respect, it is not necessary for biobankers to always put participants' input into practice. This implies that this possible form of tokenism could be addressed even without any changes resulting from participants' input. Second, the mechanisms for verifying biobankers' consideration are especially important in a situation where input from certain participants is not put into practice or in conflict with that from other participants or other stakeholders in biobanking, such as members of the public and participants' communities.[23] This is because these mechanisms help demonstrate that the former input is not overlooked, thereby reinforcing the ARR's key feature of respectfulness. In practice, biobankers might, for example, provide explanations or justifications for not acting upon that input. Finally, one might say that the requirement for giving participants' input serious consideration implicitly introduces some extent of negotiability here, in the sense that it is possible for participants to trigger changes to certain biobank activities by voicing their attitudes or preferences about those activities. However, unlike negotiation in a general sense, this negotiation does not involve formal negotiation procedures and participants (as individuals) hold limited negotiation power in practice.

[22] However, if appointed participants provide any input on behalf of other participants as well, this appointment is prone to the issue of representation, which is not desirable for the ARR. See 6.3.1 in ch 6 below.
[23] See 6.3 (last paragraph) in ch 6 below.

To summarise this sub-section, the practical application of this key second attribute generally requires measures that (1) give participants opportunities to provide input on biobanking and (2) assure the meaningfulness of their input. The former, by conceding the research reality that participants are not always active, merely calls for mechanisms that allow all participants to provide input on biobanking, as opposed to receiving actual input from them. The latter aims to deal with any possible forms of tokenism, given that those mechanisms might be tokenistic, and so biobankers are required to ensure the following: first, the issues of participants' consideration are sufficiently significant; second, participants are able to have sufficient capability to provide useful input; and finally, their input is given serious consideration. There are two notable points here. First, these measures are also employed in the key attribute of reciprocation, particularly when allowing participants to negotiate about policies on tangible reciprocation.[24] Second, no specific collaborative mechanisms are required, since these mechanisms should vary contextually depending on many factors, such as the design of biobank governance, the availability of management resources and the activeness of participants. Thus, the Model is open to any innovative methods for applying this key attribute. Web-based applications,[25] for example, might be used to receive participants' input on individual feedback, and this input will be submitted to and eventually considered by management boards.

3.2.2 Reflection on the ARR

In general, the two measures required for applying the second key attribute of collaboration can arguably help develop the ARR. Particularly, the measure to give participants opportunities to provide their input about biobanking can indicate biobankers' willingness to work with participants and, to some extent, allow them to negotiate about biobanking; also, as this measure allows participants to collaborate with biobankers and possibly influence biobanking, it can be seen to treat them with

[24] See 3.3.1 b) (Negotiation over Policies) below.
[25] It is suggested that some information technology interfaces should be applied to biobanking. See J Kaye et al, "From Patients to Partners: Participant-Centric Initiatives in Biomedical Research" (2012) 13 *Nature Reviews: Genetics* 5 371-376; J Kaye et al, "Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks" (2015) 23 *European Journal of Human Genetics* 2 141-146.

due respect. Accordingly, this measure can arguably exhibit the ARR's key features of cooperation with negotiability and respectfulness, respectively. Indeed, the measure for assuring the meaningfulness of participants' input incorporates an element of genuineness into such opportunities, thereby additionally reinforcing these ARR's key features. One can therefore say that, overall, these two measures can help foster the ARR. Furthermore, the mechanisms suggested for implementing these measures can per se reflect other key features of the ARR. One example is the sharing of information and knowledge, which is suggested to address the insufficiency of participants' capability to give their input. This mechanism can reflect the ARR's key feature of support in that it empowers participants to deal with biobanking activities by enhancing their capability, inter alia, to provide useful input about biobanking activities. It can be concluded from these explanations that this second key attribute can exhibit at least three key features of the ARR, i.e. respectfulness, support and cooperation with negotiability.

3.2.3 Interim Conclusion

To summarise, the second key attribute of collaboration in the Model refers to the act of working together that involves an element of respectfulness. The practical application of this collaboration involves two main measures, i.e. measures to (1) give participants opportunities to provide input and (2) assure the meaningfulness of their input by addressing any forms of tokenism that might arise in a biobanking context. These two measures generally reflect the ARR's key features of cooperation with negotiability and respectfulness, because they enable participants to collaborate with biobankers and to have a real chance of influencing biobanking activities substantially. Also, the mechanisms suggested for implementing these two measures can reflect the ARR's key feature of support. It is therefore arguable that this key attribute can help foster the ARR. In addition, this key attribute is arguably promising for biobanking practices. In particular, as this collaboration enables participants to make useful contributions towards biobanking, it could indirectly help improve some biobanking activities and even tackle some challenging issues arising from biobanking. This might also improve participants' perception and acceptability of those biobanking activities.

Accordingly, one can say that this key attribute can be beneficial not only to a participant-biobanker relationship but also to biobanking practices themselves.

Three points are notable here. First, the appointment of some participants to working groups or committees in biobank governance could enhance this collaboration, in that this would provide those participants with more opportunities to provide input and can inherently prevent biobankers from disregarding the input from appointed and other participants. However, in practice, this appointment is likely to lead those appointed to represent other participants, or even a whole participant cohort, and thus it is prone to the issue of representation, which does not comply with the ARR because the interests of some participants are disregarded.[26] Thus, this appointment is not desirable for the Model in general. Second, the collaborative measures and mechanisms proposed for this key attribute might be employed when applying other key attributes of the Model. Particularly, an oversight body might use them to collaborate with participants so that it can learn about participants' biobanking goals when reinforcing collectiveness in biobanking goals.[27] Biobankers could use them to allow participants to negotiate about policies on tangible reciprocation.[28] Finally, the collaborative measures might give participants some control over biobanking, because they give participants a real chance to influence biobanking activities by giving participants' input serious consideration, as illustrated in the last key attribute of control sharing below.[29] However, this key attribute accentuates a state of working together and revolves around participants' input, and thus the aspect of control in biobanking is not discussed in this section.

3.3 Key Attribute 3: Reciprocation

For the third key attribute of reciprocation, biobankers are required to reciprocate participants' contributions that result from their participation in biobanking. As the premise underlying this requirement, it is assumed that participants

[26] See 6.3.1 in ch 6 below.
[27] See 3.1.1 b) (Changes to Biobankers' Goals) above.
[28] See 3.3.1 b) (Negotiation over Policies) below.
[29] See 3.4.1 a) (Meaningful Involvement) below.

have to bear additional burdens and expose themselves to many risks in order to make contributions to biobanking. Given that the ARR is intended to be ethically acceptable to them,[30] they need to be properly compensated for these burdens and risks, and their contributions should also be sufficiently valued. One way to do so is to reciprocate their contributions. This is supported by many studies that reveal a preference for an opportunity for reciprocation.[31] Thus, with the aim of fostering the ARR, biobankers should make participants feel satisfied with their participation by providing them with reciprocation. This rationale introduces this key attribute into the Model.

In terms of methods, it is proposed that reciprocation in biobanking can be in either tangible or intangible form. Tangible reciprocation involves offers of tangible benefits to participants, such as monetary benefits and individual feedback (including individual research results, incidental findings and analysed health information). Intangible reciprocation refers to the commitment to do something obliquely beneficial to participants, namely the provision of participant safeguards and the pursuit of collective goals. These two forms of reciprocation will be explained further below.

It is questionable whether intangible reciprocation is actually important here, since the benefits it offers can be considered barely perceptible in practice. The answer to this question is positive, mainly because tangible reciprocation cannot be used to foster the ARR in some circumstances. Particularly, tangible reciprocation might not be possible for some biobanks due to their design and/or characteristics. Biobanks that use complete anonymisation, for example, are unable to provide individual feedback. Indeed, even if individual feedback is possible, it might be undesirable for some participants and thereby cannot be used as reciprocation.[32] In contrast, intangible reciprocation involves two activities that are commonly required to conduct ethical research and thereby can generally be used as reciprocation. In terms of the ARR, tangible reciprocation is prone to some issues that can undermine the ARR: as discussed below, the incentives it offers might be so financially strong that some

[30] See 1.2 (first paragraph) in ch 1 above.
[31] AA Lemke et al, see note 4 above; J Murphy et al, "Public Expectations for Return of Results from Large-cohort Genetic Research" (2008) 8 *The American Journal of Bioethics* 11 36-43.
[32] See 6.4.2 a) in ch 6 below.

participants may be enticed to further their own personal ends, not the collective goal of medical advances,[33] thereby hindering the ARR's key feature of collectiveness in goals. In contrast, this is unlikely to be the case for intangible reciprocation, which merely involves making certain commitments, and thus it better helps to develop the ARR. It can therefore be said that, without intangible reciprocation, the ARR might not be fostered through reciprocation in some biobanking contexts and so intangible reciprocation is arguably crucial for this key attribute.

3.3.1 Practical Application

To explain the practical application of this third key attribute, intangible and tangible reciprocation are dealt with separately in two different sub-sub-sections. In these sub-sub-sections, the meanings of these two forms of reciprocation are first explained. Then, the ways to provide them are described by proposing measures required for doing so, and then mechanisms for implementing these measures are suggested as practical examples.

a) Intangible Reciprocation

Conceptually, intangible reciprocation in the Model refers to reciprocation where biobankers are committed to conduct activities that can offer participants cognitive satisfaction in return for their participation, with the aim of showing them that their contributions to biobanking are valuable. Given this meaning, the ways to provide such reciprocation can be diverse, depending on, inter alia, participants' goals of and expectations from participation. For example, sharing the benefits of research findings with third parties could be acceptable in some biobanks, but it might not please participants of other biobanks. Nonetheless, to make the Model generally applicable, two fundamental activities are suggested for this reciprocation, since they can be assumed to be desirable for participants in any biobanks: (1) the pursuit of collective goals, and (2) the provision of sufficient safeguards for participants. The reason is that these two activities can generally be considered to be ethical, or even

[33] See 6.4.4 a) in ch 6 below.

legal, responsibilities towards participants in biobanking. More importantly, they can also exhibit some key features of the ARR: the former can emphasise collectiveness in goals and the latter can be used to show participants due respect by demonstrating that their interests are important and taken into consideration. It is therefore arguable that these two activities can help to develop the ARR in general, and thus they should be used as intangible reciprocation in the Model.

Based on this argument, in principle, biobankers need to give participants commitments to pursue collective goals and to provide sufficient safeguards for them, in order to intangibly reciprocate their contributions to biobanking. In practice, two main measures are required to make such commitments. **The first measure is to encourage fulfilling these two commitments**. This measure adds genuineness and firmness to these commitments. In practice, it can also prevent biobankers from being accused of paying lip service to those two activities. **For the second measure, participants need to be informed of these commitments and the fulfilment thereof**. This latter measure is specifically important for intangible reciprocation. In particular, as those two activities might not be perceived by participants in practice, those activities need to be clearly communicated to them in order to allow them to realise what biobankers commit to do and whether or not these commitments are actually fulfilled. This communication aims to make participants feel satisfied with their participation in this respect. One can therefore say that the second measure plays a role in making those two activities act as intangible reciprocation in the Model, and thereby this measure is considered crucial here.

In practice, the mechanisms suggested for implementing these two measures may be similar to those suggested for reinforcing collectiveness in biobanking goals, which are explained in the first key attribute,[34] since they all basically require the ongoing oversight of biobanking activities and the encouragement to conduct certain activities properly. Accordingly, the mechanisms suggested here can be explained again as follows: an oversight body should be established to monitor biobanking activities, and to encourage the pursuit of collective goals and the provision of sufficient safeguards for participants; this body should also have communication with

[34] See 3.1.1 b) (Changes to Biobankers' Goals) above.

participants in order to know what collective goals actually are and whether they consider existing safeguards sufficient, as well as to inform them of its own overseeing activities; there should be mechanisms that allow participants to see those activities, such as communication about biobanking progress. It can be concluded from this explanation that the mechanisms proposed in the first key attribute can be adopted to encourage the fulfilment of the aforesaid commitments and to inform participants of such fulfilment. What is additionally required for intangible reciprocation here is merely to inform participants explicitly about those commitments. It is noteworthy that the involvement of an oversight body can arguably help to make this intangible reciprocation workable in practice, since this body consists of professionals in this area,[35] and thus it can determine the sufficiency of participant safeguards properly.

In summary, the Model intangibly reciprocates participants' contributions to biobanking by making commitments to pursue collective goals and to provide safeguards for participants. Giving these two commitments involves measures for (1) encouraging the actual fulfilment of these commitments and (2) informing participants of these commitments and the fulfilment thereof. The mechanisms suggested for implementing these two measures are as follows: for the first measure, biobankers should establish an oversight body that (a) is assigned to encourage two activities, i.e. the pursuit of collective goals and the provision of participant safeguards and (b) can realise participants' attitudes towards these two activities; as for the second measure, there should be the communication with participants that (i) explicitly informs them of these commitments and (ii) enables them to realise the fulfilment of these commitments. It is notable that this third key attribute requires encouraging the provision of safeguards for participants, and thus this requirement can inherently address risks resulting from their participation in biobanks. It is worth emphasising that this key attribute does not propose any criteria for the sufficiency of participant safeguards, because such criteria need to be contextual and thus the determination of this sufficiency should be on a case-by-case basis.

[35] See 6.1.2 b) (Establishment of an Oversight Body) in ch 6 below.

b) Tangible Reciprocation

Tangible reciprocation in the Model refers to offering tangible benefits to participants in return for their contributions to biobanking, with the aim of compensating participants for the burdens and risks resulting from their participation in biobanking as well as to showing them that their contributions are valuable to biobanking. These tangible benefits include individual research results, access to analysed health information and monetary offers. As explained above, tangible reciprocation might not be possible in some circumstances and could cause some issues that hinder the ARR, unlike intangible reciprocation.[36] Accordingly, this third key attribute does not necessitate this reciprocation, in order to make this partnership model more widely applicable and able to foster the ARR effectively.

Based on this premise, to provide tangible reciprocation, this key attribute merely requires measures for (1) clarifying policies on tangible reciprocation and (2) allowing participants to negotiate about these policies. These proposed measures attempt to avoid the aforesaid setbacks by introducing negotiability into this equation. That is, they render tangible reciprocation in certain biobank governance contextually flexible. Also, as further explained below, these two measures can help foster the ARR by additionally exhibiting the ARR's key features of respectfulness, support and cooperation with negotiability. The details of these two measures are explained separately as follows.

Clarification of Policies

For the clarification measure, biobankers are required to clarify their policies on tangible reciprocation in order to enable participants to know and understand about this aspect of biobanking. In doing so, **they need to have clear policies on whether and how this reciprocation is provided, and such policies – or any changes thereto – must be clearly notified and justified to participants**. In practice, this measure might be implemented through communicative mechanisms that inform participants

[36] See 3.3 (third paragraph) above together with 6.4.2 a) and 6.4.4 a) in ch 6 below.

of current policies on this matter, including the actual extent of tangible reciprocation and justifications for this extent.

As for the reasons behind these proposals, this measure is intended to assist participants in dealing with the negotiation over these policies, which will be proposed below. Furthermore, this measure is beneficial to a relationship with participants in practice: it promotes their autonomy since it allows them to make informed decisions on this matter by enabling them to appreciate, inter alia, biobanks' actual capability to provide tangible reciprocation and the factors that might affect their preferences on this matter (such as the nature and implications of tangible reciprocation); also, this measure can handle issues about therapeutic misconception and misunderstandings,[37] which may undermine a relationship between participants and biobankers. Likewise, some authors support this measure by citing the benefit of transparency in research processes.[38] In terms of the ARR, this measure can reflect the ARR's key features of respectfulness and support, since it can be perceived as offering open communication and empowerment, respectively. It is notable that this measure is supported by some authors[39] and adopted as guidelines.[40]

Negotiation over Policies

For the second measure, **participants must be allowed the possibility of negotiating about policies on tangible reciprocation**. As explained above, the reason behind this measure is that the availability of this reciprocation is uncertain and varies depending on many factors, e.g. the design and characteristics of biobanks. This availability might also be limited in practice by contextual factors, such as the financial vulnerability of participants or the insufficiency of management resources. Another crucial factor is participants' actual desire for this form of reciprocation. These factors

[37] See note 4 above.
[38] E Clayton and L Ross, "Implications of Disclosing Individual Results of Clinical Research" (2006) 295 *JAMA* 1 37-38.
[39] V Ravitsky and BS Wilfond, "Disclosing Individual Genetic Results to Research Participants" (2006) 6 *The American Journal of Bioethics* 6 8-17; LM Beskow, "Considering the Nature of Individual Research Results" (2006) 6 *The American Journal of Bioethics* 6 38-40.
[40] Medical Research Council, *Human Tissue Series and Biological Samples for Use in Research: Operational and Ethical Guidelines*, (April 2001) 11, at para 8.1.

indicate a need for contextualisation when considering whether to provide tangible reciprocation, and thereby an openness to negotiation is necessary to make policies on this matter feasible for and favourable to all parties in biobanking. Furthermore, this negotiation can deal with such practical challenges as possible changes to biobank governance and unpredictability in the uses of biobank resources, through the notions of mutual learning and reflexivity.[41] Most importantly, this negotiation is also arguably promising for the Model since it directly reflects the ARR's key features of cooperation with negotiability. It can therefore be concluded that room for negotiation over policies on tangible reciprocation is required. This inherently implies that the Model advocates neither a duty to disclose nor a right to access in particular.[42]

In practice, biobankers are required to give participants' opportunities to negotiate about policies on tangible reciprocation. This does not mean that formal negotiation processes are necessary; rather, biobankers should at least allow participants to voice their preferences on this matter and give their preferences serious consideration. This process allows negotiation in that it gives participants a real chance of influencing policies on tangible reciprocation, although these policies might not eventually change in accordance with their preferences. Given this process, measures for applying the key attribute of collaboration[43] can be adopted here since those measures can be used to repeat this process. Particularly, the collaborative measures call for providing participants with opportunities to give input, and thus they can be used to allow participants to voice their preferences about tangible reciprocation. Also, those measures require biobankers to consider participants' input seriously, and so they can be used to lead biobankers to do the same for these preferences. Moreover, as those measures ask biobankers to address the insufficiency of participants' capability to provide input about biobanking, they inherently require biobankers to adequately

[41] The notion of reflexivity in a biobanking context is explained and discussed elsewhere. See G Laurie, "Reflexive Governance in Biobanking: on the Value of Policy Led Approaches and the Need to Recognise the Limits of Law" (2011) 130 *Human Genetics* 3 347-356.
[42] There are a lot of discussions about the duty to disclose and the right to access. See SM Wolf et al, "Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets" (2012) 14 *Genetics in Medicine* 4 361-384; FA Miller et al, "Duty to Disclose What? Querying the Putative Obligation to Return Research Results to Participants" (2008) 34 *Journal of Medical Ethics* 3 210-213.
[43] See 3.2.1 above.

provide participants with the information that is useful for this negotiation. This not only reflects the ARR's key features of, inter alia, respectfulness and support, but also addresses the issue regarding an asymmetry of information during this negotiation, which might arise in practice. Based on this explanation, it can therefore be said that the mechanisms suggested for implementing the collaborative measures could also be employed here. For example, communication channels should be established to gather participants' preferences for tangible reciprocation and biobankers should also be required to write reports that discuss and/or respond to those preferences.[44]

To summarise, tangible reciprocation is possible but not required in the Model. If it is to be provided, two measures need to be implemented. First, policies on this matter need to be clear as well as clearly communicated and justified to participants. Second, biobankers need to allow participants to negotiate about these policies. The mechanisms for applying the key attribute of collaboration could be embraced to introduce negotiability into this aspect of biobanking. Two points are notable here. First, the clarification measure intrinsically enhances participants' capability to deal with the negotiation measure by providing them with information about policies on tangible reciprocation, including the actual extent of tangible reciprocation in the biobanks in which they participate and the practical limitations imposed by the design and characteristics of those biobanks. Thus, it can be said that this measure complements the negotiation measure. Second, the Model neither suggests nor requires any particular approaches to tangible reciprocation. Rather, it merely requires biobankers to clarify their policies on this matter and provide participants with opportunities to negotiate about these policies. Accordingly, this key attribute might be fulfilled without any tangible reciprocation.

[44] Notably, this negotiation might be conducted via electronic communication, such as a web-based interface with a filter setting which allows participants to indicate what forms of reciprocation they prefer. See N Anderson et al, "Participant-Centric Initiatives: Tools to Facilitate Engagement in Research" (2012) 1 *Applied & Translational Genomics* 25-29.

3.3.2 Reflection on the ARR

Given the practical application of reciprocation in the Model, it is arguable that this third key attribute can foster the ARR since it exhibits many key features of the ARR. In general, as this key attribute is used conceptually to value participants' contributions to biobanking and compensate them for any burdens and risks resulting from their participation, it accords them respect and can consequently encourage ongoing involvement as well as further contributions. Thus, overall, this key attribute reflects the ARR's key features of respectfulness and continuity in relationship. Particularly for intangible reciprocation, the commitments to pursue collective goals and to provide participant safeguards inherently show that biobankers share the same goals as participants and attach importance to participants' interests. This echoes the ARR's key features of collectiveness in goals and respectfulness, respectively. As regards tangible reciprocation, since this key attribute involves negotiation over policies on tangible reciprocation, it echoes the ARR's key feature of cooperation with negotiability. Furthermore, the measure to clarify those policies can exhibit the ARR's key features of respectfulness and support. This is because it allows those policies to be openly communicated and justified to participants, and it empowers them to deal with this aspect of biobanking (including the negotiation measure), respectively. Thus, it can be concluded from these explanations that this key attribute arguably helps to develop the ARR, since it can reflect all of the ARR's key features.

3.3.3 Interim Conclusion

The key attribute of reciprocation requires biobankers to reciprocate participants' contributions to biobanking. This reciprocation might be in either tangible or intangible form. The former is provided by making commitments to pursue collective goals and to provide participant safeguards. In practice, intangible reciprocation involves measures and mechanisms that are similar to those for applying the key attribute of emphasis on collective goals, as it similarly requires encouraging the performance of certain activities. Tangible reciprocation refers to offering participants tangible benefits, such as individual feedback and monetary offers. This

reciprocation is not required here and needs to be negotiable, since it might be impossible for some biobanks or unfavourable to the ARR. It might even be undesirable for some participants. Accordingly, the practical application of tangible reciprocation consists of measures to (1) clarify policies on this reciprocation and (2) provide opportunities to negotiate about these policies. In terms of the ARR, this key attribute generally reflects the ARR's key features of respectfulness and continuity in relationship. Also, the measures for applying it additionally echo the other ARR's key features, i.e. collectiveness in goals, cooperation with negotiability, and support. Thus, it is arguable that this key attribute can help develop the ARR.

Three points should be noted here. First, this third key attribute also echoes other key attributes of the Model. Particularly, it requires encouraging biobankers to pursue collective goals, similarly to the reinforcement of collectiveness in biobanking goals in the key attribute of emphasis on collective goals. Also, this key attribute recommends that biobankers receive participants' input on tangible reciprocation and take that input into consideration, similarly to the collaborative measures in the key attribute of collaboration. This explains why this key attribute uses similar mechanisms to those two key attributes. Second, extensive literature can be used to support this key attribute being incorporated into the Model. From a practical perspective, many partnership initiatives and proposals consider reciprocation to be an important attribute.[45] Also, many authors argue for reciprocation in biobanking. For example, Levitt and Weldon argue that when donations are made to 'large organisations, some multinational and profit-making, a free gift with no expectations of reciprocity seems less appropriate'.[46] Also, after examining the public perception of biobanks in Europe, Gaskell et al conclude that 'successful biobanking is a matter of creating reciprocity' and, indeed, reciprocity can be in form of appreciation and personal benefits.[47] Finally, this key attribute involves some controversial issues that have been raised in a biobanking context, such as the desirability of individual feedback and the implications

[45] See 2.2.2 (Table 1) in ch 2 above.
[46] M Levitt and S Weldon, "A Well Placed Trust?: Public Perceptions of the Governance of DNA Databases" (2005) 15 *Critical Public Health* 4 311-321, at 320.
[47] G Gaskell et al, *Publics and Biobanks in Europe: Explaining Heterogeneity*, (5 October 2011) 16, at 12.

of financial incentives for participants' decisions to participate. These issues will be explained and discussed in the last chapter of this thesis.[48]

3.4 Key Attribute 4: Control Sharing

Based on the notion that the term 'control' refers to power that someone has to make decisions about something, the fourth key attribute of the Model, namely control sharing, considers participants as equal co-contributors with biobankers, as opposed to leaders and followers. Thus, it requires biobankers to ensure that control over biobanking is appropriately shared with individual participants. For the reasons behind this key attribute, control sharing is a common attribute of partnership, where partners are generally equal in status, and the Model uses this sharing to exhibit the ARR's key feature of respectfulness, as further explained below. However, this is not to say that control over biobanking must be *shared equally* between participants and biobankers; rather, it means that participants as *equal co-contributors* should be allowed to have some extent of control over biobanking. Notably, by requiring appropriate sharing of control over biobanking, this key attribute asks biobankers to take into account separately the aspect of control in biobank governance, and then only to ensure that, overall, control over biobanking is shared with participants in a contextually appropriate fashion. In this respect, this key attribute neither proposes nor directly suggests any particular forms of control-sharing mechanisms. Notably, the question of how to fulfil this requirement is addressed in 3.4.1 b) below.

There are some points to be noted as **the working notion of control** for the Model.[49] First, as the ARR accentuates biobankers' relationship with individual participants,[50] the explanations and proposals in this fourth key attribute involve control over biobanking when considering from the perspective of *participant individuals*. With the aim of showing respect for those individuals, this control

[48] See 6.4.2 and 6.4.4 in ch 6 below.
[49] It is noteworthy that this section does not make any theoretical contributions to the concept of control in a biobanking context. This paragraph only aims to establish the working notions of control for this thesis.
[50] See 1.3.2 in ch 1 above and 6.3.1 in ch 6 below.

basically allows participants to make decisions about biobanking at an individual level. It is opposed to control that participants collectively have over biobanking, as further emphasised below.[51] In practice, this control allows participants to make decisions about biobanking activities that can be personalised, such as the uses of their own samples and information (through the consent procedure and the right of withdrawal) and the provision of individual feedback (if any). One can say that this control gives individual participants only slight influence on biobanking activities that cannot be personalised. Second, here, control over biobanking fundamentally stems from biobanking activities or certain mechanisms within biobank governance. In this respect, this key attribute does not involve control exercised through ownership over biobank resources. It is notable that the issue of ownership over biobank resources is dealt with in the last chapter of this thesis.[52] Finally, some authors use the term power to refer to control, such as Foucault, who uses the term bio-power to refer to control over a population in a political sense.[53] This thesis, however, avoids such a term because it might be confused with 'power' as used in the word 'empowerment', where 'power' might also refer to the capability to deal with something.

3.4.1 Practical Application

To ensure appropriate sharing of control over biobanking, **biobankers need to first take into consideration existing control-sharing mechanisms in biobanking**, in order to gauge the overall level of control that participants currently have over biobanking. Then, they are required to determine whether or not such a level of control is contextually appropriate. If that is not the case, **biobankers need to share more or less control over biobanking with participants in order to strike an appropriate balance of control between the two parties**. These two tasks are considered to be two measures required for applying this key attribute. In the light of this requirement, this sub-section deals separately with these two measures in two different sub-sub-sections. The first one addresses the questions of what mechanisms

[51] See 3.4.1 a) (last paragraph) below.
[52] See 6.4.5 b) in ch 6 below.
[53] M Foucault, *The History of Sexuality: The Will to Knowledge*, (London: Penguin Books, 1998).

are taken into consideration and how to determine the level of control over biobanking that these mechanisms provide. The second sub-sub-section suggests how to determine whether control over biobanking is appropriately shared between participants and biobankers.

a) Control-sharing Mechanisms

For the question of what mechanisms are to be considered, it is arguable that there is no definite answer to this question since there are diverse types of mechanisms that directly or indirectly give individual participants control over biobanking. Accordingly, biobankers are required to take into account any mechanisms that can give individual participants some control over biobanking. To determine the level of control that certain mechanisms provide, biobankers need to focus on the actual level of control that mechanisms under consideration allow individual participants to have. That is, biobankers are required to consider the extent of control over biobanking that individual participants will eventually have as a result of those mechanisms. In this respect, all factors that can increase or decrease the level of this control in practice are taken into account, such as the forms of those mechanisms, how they are implemented and the aspects of biobanking they involve. For example, biobankers can use the consent procedure to allow participants to have various levels of control over the uses of biobank resources by adopting different approaches to this procedure. Thus, the ways in which this procedure is implemented need to be taken into consideration when determining the level of control that it actually provides for participants.

It can be concluded from the above explanations that, when determining the overall level of control that individual participants have in biobanking, biobankers are required to take into account all control-sharing mechanisms as well as any contextual factors affecting the level of control that these mechanisms actually provide. Given this conclusion, it is helpful to give some examples of control-sharing mechanisms here by discussing those that are commonly found in biobanking, namely the consent procedure, the right of withdrawal and meaningful involvement. One reason for this discussion is that it inherently outlines the nature and characteristics of the mechanisms to be considered as well as explains how to determine the level of control over

biobanking that participants are actually provided by those mechanisms. Indeed, it is also useful for the following sub-sub-section: these examples will be used when demonstrating how control over biobanking is appropriately shared in a relationship between participants and biobankers. As for the structure of this sub-sub-section, it deals with these three common control-sharing mechanisms by explaining how they give participants control over biobanking as well as how they provide different levels of this control. Note that these explanations will be used in the following sub-sub-section for delineating ways to determine the appropriateness of this control sharing.

Consent Procedure

The first example is the consent procedure, which is a fundamental requirement for any biobanking and based on the ethical principle of respect for autonomy. In the Model, this procedure is considered to give individual participants some control, particularly over uses of biobank resources, by allowing them to determine the scope of how their samples and information will be used. In a biobanking context, many approaches to consent have been developed, such as presumed consent, broad consent,[54] tiered consent[55] and dynamic consent.[56] Some also propose alternative measures, such as authorisation,[57] to replace the consent procedure. Indeed, these approaches allow participants to have different levels of the control over biobanking. This could be described as the spectrum of control. Particularly, at the high end of this spectrum is dynamic consent, where consent is required for every use of biobank resources, thereby giving participants the highest level of control. At the

[54] MG Hansson et al, "Should Donors Be Allowed to Give Broad Consent to Future Biobank Research?" (2006) 7 *The Lancet Oncology* 3 266-269; D Wendler, "One-time General Consent for Research on Biological Samples" (2006) 332 *BMJ* 7540 544-547.
[55] AL McGuire and RA Gibbs, "No Longer De-Identified" (2006) 312 *Science* 5772 370-371; MA Rothstein, "Tiered Disclosure Options Promote the Autonomy and Well-Being of Research Subjects" (2006) 6 *The American Journal of Bioethics* 6 20-21.
[56] J Kaye, "Abandoning Informed Consent the Case of Genetic Research in Population Collections" in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, (London: Routledge, 2004) 117-138; J Kaye et al, "Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks", see note 25 above.
[57] B Hofmann, "Broadening Consent—and Diluting Ethics?" (2009) 35 *Journal of Medical Ethics* 2 125-129.

other end is presumed consent, or an 'opt-out' approach, whereby consent is presumed and thus not required in practice when recruiting participants. Blanket consent, broad consent and categorical consent are along this spectrum from a low to a high level of control. In the Model, the consent procedure is therefore considered to provide participants with various levels of control over biobanking at an individual level. Note that the conventional 'informed consent' is not mentioned here since, in general, information about the uses of biobank resources is not sufficiently available to allow participants to become 'informed' in the conventional sense.[58]

It is important to consider presumed consent. In general, this approach raises many ethical issues, including non-conformity to the principle of respect for autonomy.[59] For the Model, this approach should arguably not be adopted since it does not help develop the ARR. Particularly, when using this approach, participants are not contacted or recruited directly in practice since their consent is presumed. This raises the question of whether they, as partners in the Model, are treated with sufficient respect. Indeed, those who are inactive might not even be aware of their recruitment. Furthermore, the lack of direct contact can raise the question of whether participants really share the same biobanking goals as biobankers, casting doubt on the genuineness of collectiveness in biobanking goals. One can therefore say that presumed consent does not reflect and might hinder the ARR's key features of respectfulness and collectiveness in goals, respectively.

Given all the explanations about the consent procedure, it can be concluded that the Model considers this procedure to be one of control-sharing mechanisms in biobanking and uses its approaches to determine the level of control that participants actually have over uses of biobank resources. This suggests that there are no consent approaches that are particularly preferred or suggested here but, as explained above, presumed consent is not desirable for the Model.

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[58] J Kaye, see note 56 above; H Widdows and S Cordell, "The Ethics of Biobanking: Key Issues and Controversies" (2011) 19 *Health Care Analysis* 3 207-219, at 208.
[59] HT Greely, "Iceland's Plan for Genomic Research: Facts and Implications" (2000) 40 *Jurimetrics* 153-191, at 179-181.

Right of Withdrawal

The second example is the right to withdraw one's consent, which biobank participants normally have as an ethical requirement. In terms of the ARR, this right can be used to express respectful gestures towards participants by allowing them to leave biobanks at will. For this key attribute, this right gives individual participants control over biobanking by, inter alia, allowing them to prevent their samples and information from being used by researchers or prevent their information in other databases from being accessed. Indeed, this right might also influence the direction of biobanking as it may reduce the availability of biobank resources, or might even undermine the viability of biobanking in the case of mass withdrawal. Notably, in some biobanks, this right also allows participants to prevent further communication with and/or further data collection from them.[60] However, this right itself cannot be effectively exercised without CBP: CBP allows participants to know about biobanking activities, including how biobank resources are actually used,[61] and thereby it assists them in determining whether and when to withdraw their consent. One can therefore say that this right cannot be considered to be an effective control-sharing mechanism unless biobank governance has proper CBP in place for participants.

Other than complementing the right of withdrawal, CBP can also be used to regulate the level of control over biobanking that this right provides for participants. Particularly, this right itself can be perceived as an on-off switch that can prevent certain biobanking activities, such as uses of biobank resources. However, CBP can be used in practice to enable this right to provide gradations of control over biobanking by regulating the quality and quantity of CBP. For example, informing participants about all uses of biobank resources gives them a higher level of this control than providing them with annual reports that only give rough indications of these uses. It can therefore be said that CBP can make this right able to provide different levels of control over biobanking.[62] In addition to CBP, biobankers might provide gradations of

[60] See 4.4.1 in ch 4 and 5.4.1 in ch 5 below.
[61] Notably, Kaye considers the communication about research studies using biobank resources to be a moral obligation when adopting broad consent. J Kaye, see note 56 above, at 31.
[62] Notably, the quality and quantity of CBP should be regulated cautiously since, as suggested above, CBP is also used for applying other key attributes of the Model. Otherwise,

control over biobanking through this right by offering various withdrawal options as well. An example is the withdrawal options offered in UK Biobank governance, whereby participants can (i) merely prevent UK Biobank from contacting them directly, (ii) forbid such contact as well as any access to their health records in other databases, or (iii) forbid such contact and access together with forbidding researchers from using their samples and information afterwards.[63] In this case, participant individuals can be considered to have different levels of control over biobanking through their right of withdrawal.

Given these explanations, one can therefore say that the right of withdrawal can be considered to be another control-sharing mechanism that can be used for balancing overall control that participants have over biobanking. It is noteworthy that biobank governance that adopts the Model does not raise any problems with regard to the effectiveness of this control-sharing mechanism since CBP is inherently required for applying the other key attributes of the Model. In particular, CBP is required to enable participants to reinforce collectiveness in biobanking goals, to empower them in order to facilitate meaningful collaboration, and to provide them with intangible reciprocation. It is therefore arguable that, for the Model, the right of withdrawal is always deemed legitimate as a control-sharing mechanism in biobanking.

Meaningful Involvement

The last example is meaningful involvement, which refers to the act of taking part that provides participants with some control over biobanking activities.[64] For the Model, this involvement refers to the participatory mechanisms in biobanking that allow participants to influence biobanking activities. Based on this meaning, the focus of this involvement is on the actual possibilities of influencing biobanking activities

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such regulation might hinder the application of other key attributes and thereby discourage development of the ARR. For example, if CBP is excessively limited, participants might not be able to reinforce collectiveness in biobanking goals effectively or collaborate properly with biobankers.

[63] UK Biobank, *UK Biobank Ethics and Governance Framework Version 3.0*, (October 2007) 20, at 9-10.

[64] As established above, 'meaningful involvement' in this thesis refers to involvement that gives participants some control over objects of involvement. See 2.2.3 b) (Participation or Involvement) in ch 2 above.

that participants are allowed. In this respect, any participatory mechanisms can be considered as this involvement if they give participants a genuine chance to influence biobanking activities. One illustrative example is the measures for applying the key attribute of collaboration, which were explained above: biobankers give participants opportunities to provide input about biobanking and that input is given serious consideration.[65] As these collaborative measures enable participants to influence biobanking activities in practice, they can be equated with meaningful involvement here and thereby can be deemed to be a control-sharing mechanism according to this last key attribute. Notably, the fact that these collaborative measures can amount to a control-sharing mechanism, does not render the key attributes of collaboration and control sharing repetitive. Rather, these two key attributes perceive these measures from different perspectives, as explained in 3.4.3 below.

For the level of control over biobanking that this involvement gives to participants, two types of biobanking activities can be dealt with separately. One is biobanking activities that can be personalised, such as the provision of individual feedback, where participants can decide whether to receive individual feedback.[66] It can be said that participants can control these activities properly. The level of this control depends upon the extent to which participants are allowed to personalise these activities. As for biobanking activities that cannot be personalised, the level of control that participants have over these activities is basically low. Particularly, as the Model deals with biobankers' relationship with individual participants,[67] this involvement refers to a situation where biobankers allow each participant to engage in biobanking and have a real chance of influencing these activities. In practice, one possible way to allow this involvement is to enable every participant to voice input and to give this input serious consideration. As participants' voices regarding biobanking activities that cannot be personalised can be diverse, some of those voices do inevitably not produce any changes to these activities. It is also possible that those voices cannot trigger any changes at all. Thus, it is arguably uncertain whether participants can

[65] See 3.2.1 above.
[66] Note that this example is used for explaining what biobank activities can be personalised. The questions of whether and why individual feedback should be provided are addressed in Sub-section 6.4.2 (Chapter 6) below.
[67] See 1.3.2 in ch 1 above.

influence these activities through this involvement. One can therefore say that, in practice, meaningful involvement gives individual participants little chance of influencing biobanking activities that cannot be personalised.

It can be concluded that, in practice, meaningful involvement in the Model gives individual participants a good chance of influencing biobanking activities that can be personalised, but not those that cannot be personalised. It is worth mentioning other forms of participatory mechanisms that might be implemented in biobanking and can be considered to be meaningful involvement in the Model. One is the formal inclusion of participants on management boards with voting power in the decisions about biobanking activities. Another example is participant bodies that are established to collaborate with biobankers or to deal single-handedly with certain aspects of biobanking. Despite that these mechanisms give participants a real chance of changing biobanking activities, they are not considered to be control-sharing mechanisms from the perspective of the Model, which focuses a participant-biobanker relationship at a micro level. The reason is that these mechanisms do not basically give such a chance to every participant, only to those appointed to management boards or participant bodies. In this respect, they might be considered to give control over biobanking to participants at a collective level. Indeed, they might also lead some participants to represent others or even a whole participant cohort, thereby raising the issue of representation, which is undesirable for the ARR.[68] Thus, these forms of participatory mechanisms are not taken into account when applying this fourth key attribute.

To summarise this sub-sub-section, biobankers are required to take into account any mechanisms that give some control over biobanking to individual participants. To illustrate this requirement, this sub-sub-section gives three examples of control-sharing mechanisms that are commonly found in biobanking, i.e. the consent procedure, the right of withdrawal and meaningful involvement. It explains how these mechanisms give participants control over biobanking and then how they can provide different levels of this control. In short, the consent procedure allows participants to have control over the uses of their own samples and information, and the level of this control varies depending upon the approaches to consent that are used.

[68] See 6.3.1 (Representation) in ch 6 below.

It is however noted that presumed consent is not desirable for the Model as it might undermine the ARR. The right to withdrawal gives participants control over some biobanking activities, such as communication with them and future uses of their samples and information, and the level of this control can be regulated through the quality and quantity of CBP. Ultimately, meaningful involvement conceptually allows participants to have control over biobanking through participatory mechanisms. In practice, this involvement mainly allows participants to control biobanking activities that can be personalised, and the level of this control depends on the extent to which participants are allowed to personalise these activities.

Two points can be inferred from these explanations. First, as control in the Model is based on the individual level of a participant-biobanker relationship, this control is unlikely to allow participants to directly or immediately cause changes to the biobanking activities that cannot be personalised, as suggested above. This control differs from the control based on the collective level of a participant-biobanker relationship, where it is more likely for participants to influence those biobanking activities. For the Model, it is therefore difficult in practice for participants to shape the general direction of biobanking activities, except for the unusual case of mass withdrawal. As emphasised further in the last chapter, this aspect of the Model can be considered to be a limitation on the proposals of this thesis.[69] Second, since there are no stringent criteria for control-sharing mechanisms in the Model, this key attribute is open to any innovative mechanisms that can give individual participants some control over biobanking. One example is the automated Web-based platform in the Genomera project, which grants participants a certain level of control over biobanking by allowing them to initiate, design and operate health studies by themselves.[70]

b) Appropriate Control Sharing

To suggest how to determine the appropriateness of certain control sharing, biobankers should **determine whether that control sharing can conceptually accommodate respectful gestures to participants**. A basis for this suggestion is the

[69] See 6.3.1 in ch 6 below.
[70] Genomera, "Genomera" (2016) available at http://genomera.com/about (accessed 20 January 2016).

ARR's key feature of respectfulness: as explained below, this fourth key attribute is basically intended to reflect this ARR's key feature and thus control sharing in the Model should be able to reflect this key feature. That is, the appropriateness of control sharing here relates to respectfulness towards participants. However, it is admitted that this determination is challenging in practice. This is because it is difficult to define criteria for when control sharing can be considered to show respect for participants, due to differences in their perceptions and expectations on this matter. This reason is supported by many empirical studies demonstrating the variety in a preferred level of the control over uses of biobank resources[71] as well as discrepancies in the preferences vis-à-vis consent approaches.[72] Moreover, in practice, there are many circumstantial factors that can influence these preferences, such as financial sponsors of biobanks, participants' experiences, their characteristics[73] and the possibility of commercial involvement.[74] There are also some factors that inherently limit the extent of this control sharing, such as management resources and the activeness of participants.

Given these reasons, it is arguable that to determine the appropriateness of control sharing in certain biobank governance needs to be contextual. In other words, it is not feasible to define exact criteria for how control is shared appropriately with participants, and thus determination of this matter should be on a case-by-case basis. In practice, biobankers should consider a number of contextual factors, which are already suggested in the previous paragraph. It might also be helpful for this determination if biobankers also receive input from participants on, inter alia, their willingness to control and the level of control they prefer. In doing so, biobankers

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[71] AL McGuire et al, "DNA Data Sharing: Research Participants' Perspectives" (2008) 10 *Genetics in Medicine* 1 46-53; AT Ewing et al, "Demographic Differences in Willingness to Provide Broad and Narrow Consent for Biobank Research" (2015) 13 *Biopreservation and Biobanking* 2 98-106.

[72] CM Simon et al, "Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models" (2011) 13 *Genetic Medicine* 9 821-831; F D'Abramo et al, "Research Participants' Perceptions and Views on Consent for Biobank Research: A Review of Empirical Data and Ethical Analysis" (2015) 16 *BioMed Central* 60 available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4563851/ (accessed on 20 January 2016); J Murphy et al, "Public Perspectives on Informed Consent for Biobanking" (2009) 99 *American Journal of Public Health* 12 2128-2134.

[73] JI Valle-Mansilla et al, "Patients' Attitudes to Informed Consent for Genomic Research with Donated Samples" (2010) 28 *Cancer Investigation* 7 726-734.

[74] E Vermeulen et al, "Obtaining 'Fresh' Consent for Genetic Research with Biological Samples Archived 10 Years Ago" (2009) 45 *European Journal of Cancer* 7 1168-1174.

might establish communication with them to obtain their feedback on this matter. Collaborative measures proposed in the key attribute of collaboration could be used as an example of what this communication should look like. It is worth emphasising again that this last key attribute merely requires biobankers to *ensure* that control sharing is circumstantially appropriate and suggests how to do so, i.e. by taking into consideration all control-sharing mechanisms and determining whether control sharing can be used to show participants respect. In this way, it does not directly suggest the extent to which control over biobanking should be shared with participants nor what mechanisms need to be implemented to apply this key attribute.

Examples

As an example of this determination, broad consent is used to recruit participants to a national biobank which serves as a resource for any types of health research. In this case, participants are considered to have low control over biobanking due to a broad biobanking goal: the resources of this biobank can be used in a wide range of studies and thus the available details about future uses of these resources are few during recruitment; this prevents participants from controlling uses of these resources through their consent. According to the suggestion of this key attribute, biobankers should give participants more control by, inter alia, continuously informing them about how their samples and information are actually used. In doing so, they have incremental control over biobanking: as they have more information about actual uses of biobank resources, they better realise whether and when to withdraw their consent, thereby allowing them to have additional control over the uses of their samples and information through their right of withdrawal. As this increased control enables them to effectively prevent their samples and information from being used against their will, this increase in their control can arguably be considered to show them respect, and thus this control sharing can be deemed appropriate according to this key attribute. Note that, if blanket consent is instead adopted in this circumstance, communication should be more frequent, informative and/or effective, so as to befit the relatively low level of their control which results from this consent approach.

Another example is a biobank where cohort participants all share the same genetic trait. These participants join this biobank with the aim of supporting innovative

treatments that can benefit their genetic community. However, as they share the same genetic trait, any research on the resources of this biobank may have adverse consequences for this cohort as a whole. In this case, control via the right of withdrawal might not be considered sufficient because, if such consequences arise, all the participants could only withdraw their consent, thereby impeding biobanking as well as opposing their goal. In other words, control sharing that is only based on the right of withdrawal might not be considered respectful towards participants. According to this key attribute, more control over this biobanking should be given to participants by, for example, adopting categorical consent rather than broad or blanket consent. For a small cohort, every participant might be allowed to voice his/her preferences regarding uses of biobank resources, and deliberative discussions might also be used to handle any disputes. As a result, the aforesaid mass withdrawal could be avoided, since participants can help decide which uses will not result in such withdrawal. In addition, because their interests and preferences are better valued and their goal can be achieved, biobankers can be considered to treat them with respect. It can therefore be argued from the perspective of the Model that this increase in participants' control could render this control sharing relatively appropriate.

3.4.2 Reflection on the ARR

From a conceptual perspective, control sharing is a common characteristic that is normally found in partnership initiatives, especially where an imbalance in control between partners exists.[75] Accordingly, the fourth key attribute of control sharing is arguably substantial here, since partnership is the underlying concept of the ARR and, in a biobanking context, participants conventionally have relatively less control over biobanking. In terms of the ARR, this key attribute arguably reflects the ARR's key feature of respectfulness: allowing participants to have some control over biobanking can amount to treating participants with respect, regardless of whether or not they actually prefer or need this control. Furthermore, control sharing is intrinsic

[75] AI Hilsen, "Balancing Power - The Give and Take of Tripartism in Transition Economies" in HS Desivilya and M Palgi (eds), *The Paradox in Partnership: The Role of Conflict in Partnership Building*, (Dubai: Bentham Science, 2011) 24-35.

to the ARR's key feature of cooperation with negotiability. Particularly, if biobankers work with participants and also allow them to negotiate about biobanking activities, some control over biobanking is inherently shared with them. Indeed, from a psychological perspective, control sharing might also lead to successful negotiations, as it can lead participants to perceive themselves to have more equal power with biobankers.[76] It can be concluded from these explanations that this key attribute not only reflects the nature of partnership, but can also help develop the ARR.

3.4.3 Interim Conclusion

To summarise, the fourth key attribute of control sharing requires biobankers to take into account separately the aspect of control in biobank governance and to ensure that control over biobanking is shared with participants appropriately. This key attribute does not require any mechanisms in particular, but it does instead suggest ways to determine whether control sharing is appropriate. Regarding this suggestion, biobankers should first take into consideration all mechanisms that can give control over biobanking to individual participants, in order to assess the overall level of control that they actually have over certain biobanking. Examples of these mechanisms are the consent procedure, the rights of withdrawal and meaningful involvement. Then, biobankers should determine if control sharing that results from these mechanisms can be considered appropriate. This determination should be made on a case-by-case basis but, conceptually, control sharing is considered appropriate if it can express respectful gestures towards participants. If this is not the case, biobankers need to share more or less control over biobanking with participants, in order to achieve appropriate control sharing. As for justifications for this key attribute, control sharing not only amounts to a common attribute of partnership, but it also helps foster the ARR by reflecting the ARR's key features of respectfulness and cooperation with negotiability.

It is also worth stressing the relationship between the Model's key attributes of control sharing and collaboration in order to avoid considering these two key attributes repetitive, since certain mechanisms in biobank governance might comply

[76] RJ Wolfe and KL McGinn, "Perceived Relative Power and its Influence on Negotiations" (2005) 14 *Group Decision and Negotiation* 3-20.

with both of these key attributes concurrently. Conceptually, the former emphasises the control over biobanking that participants have as a result of implementing mechanisms, while the latter revolves around input that they provide through mechanisms. From a practical perspective, some mechanisms embody both of these key attributes by giving participants control over biobanking as well as receiving their input and making it meaningful for biobanking. An example is involvement mechanisms that amount to meaningful involvement, as explained above.[77] On the other hand, some mechanisms involve only one of these two key attributes. For example, the right of withdrawal gives participants control over uses of biobank resources, but it does not seek their input about biobanking. By contrast, to receive participants' feedback about their experience of measurement sessions can be considered to be collaboration with participants according to the Model, but it might not be a control-sharing mechanism here because it might not allow participants to influence those sessions directly.

Conclusion

This thesis proposes the ARR, a participant-biobanker relationship that can deliver ethical and effective biobanking practices. The last chapter established that the ARR should be based on partnership and its conceptual framework should consist of five key features, namely respectfulness, cooperation with negotiability, support, continuity in relationship and collectiveness in goals. To explain how to foster the ARR in practice, this chapter proposes the Model, which has four key attributes – i.e. emphasis on collective goals, collaboration, reciprocation and control sharing. To apply the Model, biobankers are required to implement certain measures in biobank governance in order to incorporate these key attributes into biobanking activities. With the aim of facilitating practical application of the Model, this chapter also suggests some mechanisms that can comply with those measures in practice.

Three points concerning the Model need to be emphasised here. First, there are three categories of proposals in this chapter: (i) the Model's key attributes, (ii) the

[77] See 3.2.3 and 3.4.1 a) (Meaningful Involvement) above.

measures for applying those key attributes and (iii) the mechanisms suggested as promising ways to implement those measures. When adopting the Model, those *key attributes* and *measures* are important considerations, while those mechanisms are merely suggestions which do not need to be followed. Second, the Model has the main aim of suggesting ways to develop the ARR, which is expected to deliver ethical and effective biobanking practices, and it is intended to be used for determining the prospect of the ARR in certain biobanks. In this respect, any non-conformity to the Model can diminish such a prospect, but it does not necessarily amount to the unethicality or ineffectiveness of biobanking practices. Finally, some mechanisms can be used to apply more than one key attribute. For example, the establishment of an oversight body that is tasked with encouraging biobankers to pursue collective goals is suggested for applying the key attributes of emphasis on collective goals and reciprocation. Also, the mechanisms for collaborating with participants, which involve allowing them to provide input and ensuring the meaningfulness of their input, are basically for applying the key attribute of collaboration, but these mechanisms can also be used to apply the key attributes of reciprocation and control sharing.

The relationship between the Model's key attributes and the key features of the ARR, proposed in Chapter 2, can be concluded as follows. The key attribute of emphasis on collective goals emphasises the key feature of collectiveness in goals. The key attribute of collaboration allows participants to work with biobankers and to influence biobanking activities, thereby accentuating the key feature of cooperation with negotiability. The key attribute of reciprocation seeks to compensate for participants' burdens resulting from their participation and to value their contributions, and thus it exhibits the key features of respectfulness and continuity in relationship. The key attribute of control sharing, by allowing participants to have some control over biobanking, reflects the key feature of respectfulness. In addition to the key attributes themselves, the measures proposed for applying the key attributes can per se exhibit some key features of the ARR. For example, the measures for applying the first three key attributes exhibit the key feature of support, since they involve the sharing of information about biobanking activities and knowledge about biobanking, which basically empowers participants to deal with biobanking. Moreover, the negotiation about tangible reciprocation in the key attribute of reciprocation reflects the key feature

of cooperation with negotiability. It is also notable that the key feature of respectfulness is echoed in every key attribute of the Model. Given these explanations, it can be argued that the Model can be used to foster the ARR because it can exhibit all key features of the ARR.

Two points regarding this chapter should be noted here. First, the proposals in this chapter reflect that this thesis uses deontological ethics to ethically justify its proposals. Particularly, the Model aims to develop the ARR, which in turn seeks to render biobanking activities ethically acceptable. Thus, the measures for adopting the Model's key attributes can be considered to be rules for determining if biobankers' actions are ethical from the perspective of this thesis. It is therefore arguable that the ethicality of these proposals is based on features of actions.[78] Second, as this chapter is mainly intended to propose the Model, it does not address many issues that might arise in the Model, such as the undesirability of individual feedback, the negative influence of financial incentives, and the acceptability of participants' control over biobanking. There are also some limitations on application of the Model that should be noted. These issues and limitations will be addressed and highlighted, respectively, in the last chapter of this thesis.

Given all the explanations in this chapter, the practical measures required for applying the Model can be concluded, as outlined in the following page.

[78] Notably, this aspect of the proposals of this thesis will be further explained in the last chapter of this thesis. See 6.2.1 in ch 6 below.

Outline of the Partnership Model

Key Attribute 1: Emphasis on Collective Goals

- 1.1 Clarifying biobanking goals
- 1.2 Reinforcing collectiveness in biobanking goals
  - 1.2.1 Overseeing biobanking activities continuously
  - 1.2.2 Resisting any deviations from collective goals

Key Attribute 2: Collaboration

- 2.1 Giving participants opportunities to provide input
- 2.2 Assuring the meaningfulness of input by preventing three possible forms of tokenism:
  - a) Insignificance of issues
  - b) Insufficiency of capability
  - c) Disregard for participants' input

Key Attribute 3: Reciprocity

- 3.1 Intangible reciprocation: Making commitments to pursue collective goals and to provide safeguards for participants
  - 3.1.1 Encouraging the fulfilment of these two commitments
  - 3.1.2 Having communication with participants about these two commitments
- 3.2 Tangible Reciprocation: Offering tangible benefits to participants
  - 3.2.1 Clarifying policies on tangible reciprocation
  - 3.2.2 Allowing negotiation over policies on tangible reciprocation

Key Attribute 4: Control Sharing

- 4.1 Considering all control-sharing mechanisms
- 4.2 Sharing control over biobanking appropriately with participants at an individual level

Chapter 4

Partnership Model and UK Biobank[1]

The first three chapters have outlined the main proposals of this thesis, which revolve around a participant-biobanker relationship that can deal with issues and challenges arising in biobanking practices, aka an authentic research relationship in biobanking ("**an ARR**"). This thesis seeks to propose one approach to an ARR that is based on partnership ("**the ARR**"). Chapter 1 establishes the fundamental notion of the ARR by proposing its main characteristics. Then, Chapter 2 proposes its conceptual framework, which consists of five key features that are considered to exhibit its main characteristics. Ultimately, Chapter 3 proposes a partnership model for biobank governance that can be used to foster the ARR in practice ("**the Model**"). It can be concluded that the main proposals of this thesis involve (1) the fundamental notion of the ARR, (2) the conceptual framework of the ARR and (3) the Model, all of which concern the normative, conceptual and practical aspects of the ARR, respectively. To demonstrate how to put the Model into practice, this and the next chapters are to test it against two practical biobank initiatives, namely UK Biobank and ALSPAC, respectively. To facilitate understanding of the discussions in this chapter, general information about UK Biobank is summarised in Box 4.1 below.

Box 4.1: General information about UK Biobank[2]

Objectives

- UK Biobank is a long-term biorepository that contains tissue samples and related information from people across the UK, with the aim to create national

[1] Appendix 1 lists materials that were accessed and reviewed to set up the discussions and develop the arguments in this chapter. It also demonstrates how the titles of these materials are simplified when being used as references in the discussions and footnotes here.
[2] These explanations are based on publicly-accessible documents, such as EGC annual reports and the UK Biobank website.

health resources for scientists to conduct health-related research on particular diseases.

- The purpose of UK Biobank is to provide research resources for improving prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses as well as promoting health across society for the public's benefit.

Cohort

- The participants of UK Biobank are 500,000 British people aged between 40 and 69 years at the time of recruitment, from across the UK.
- Participants were recruited from 2006 to 2010 by undergoing measurements, providing samples (blood, urine and saliva) and information about themselves, and agreeing to have their health followed through their health records.
- UK Biobank's resources were opened up for research use in March 2012.

Governance Structure

- UK Biobank has four main governing bodies that facilitate, manage and conduct biobanking activities, i.e. the UK Biobank Board, the Steering Committee, the Expert Working Groups and the International Scientific Advisory Board.
- UK Biobank has many governance documents. A key one is the Ethics and Governance Framework (**EGF**), which explains the commitments and standards to which UK Biobank will adhere during creation, maintenance and use of UK Biobank's resources. Basically, this framework deals with UK Biobank's relationships with participants, researchers and society. There are also other guidance documents on certain matters, such as access procedures, re-contacting and de-identification.
- Reviews of access applications involve three bodies. The Principal Investigator (**PI**) and the Co-ordinating Centre determine access applications in terms of scientific leadership and efficiency regarding uses of UK Biobank's resources. On the PI's recommendation, the Access Sub-Committee of UK Biobank Board makes key decisions on access applications.
- The Ethics and Governance Council (**EGC**) was established by the funders of UK Biobank, in 2004, to keep UK Biobank's activities under its ethical and operational scrutiny. The Council is external to and independent from UK Biobank, and its main role is to critically monitor UK Biobank's activities, unlike general ethics committees that ethically review and approve research proposals. As regards the remit of this body, it (1) ensures and reports publicly on the conformity of UK Biobank's activities to the EGF and participants' consent, (2) advises UK Biobank on revisions to the EGF and (3) advises UK

Biobank on the interests of participants and the public. This body is accountable to and, if necessary, provides information to the funders.

Relationship with Participants

- Data collection: At the recruitment stage, participants underwent baseline measurements and provided blood, urine and saliva samples for future analysis. They also provided information about themselves regarding their lifestyle and environment through questionnaires. They agreed to have their health followed by granting UK Biobank access to their health records in other databases, so that all their major health episodes and eventual death could be captured. Their data were additionally collected through repeated baseline assessments and questionnaires on exposures and outcomes that are not available in the records, such as cognitive function, occupational history and mental health outcomes. At present, UK Biobank is collecting imaging enhancements – i.e. pictures of brains, hearts and bones – from participants.
- Active involvement: Participants can normally communicate with biobankers through either channels opened for general enquiries and feedback, or Q&A sessions at meetings arranged by the EGC (2005–2010) and UK Biobank (after 2010). There were also surveys and interviews that allowed them to provide input on certain matters.
- Communication:[3] Other than the above involvement mechanisms, participants can generally receive updates and information about UK Biobank's activities primarily through annual participant newsletters and the UK Biobank website. They can also access detailed versions of such information by accessing various documents provided on UK Biobank's and the EGC's websites, including EGC annual reports, reports on EGC internal meetings, reports on UK Biobank consultations and EGC public meetings, and many policy documents.[4]

UK Biobank is chosen for testing the Model for many reasons. First, this biobank has distinctive biobanking characteristics with which the ARR is intended to

[3] The term 'communication' in this chapter refers to any mechanisms set up to transfer or exchange information between relevant parties, whether one way or two ways. Thus, this term ranges from the transfer of information through newsletters and websites, to information exchanged through dialogues and discussions. Involvement mechanisms can therefore be considered to be one approach to this communication. The difference is that communication focuses on the transfer of information while involvement mechanisms focus on the act of taking part.

[4] There might also be an Annual General Meeting, as suggested by the panel reviewing the EGC's work in 2015, but it was not arranged in 2015 yet. This is further explained in the conclusion to this chapter, below.

deal, i.e. the longevity of biobanking and unexpected uses of biobank resources.[5] Thus, it is compelling to know whether, and if so the extent to which, the Model can contribute towards the governance of UK Biobank. Second, the size of its cohort is so large that it is intriguing to see how the Model, which mainly involves collaboration and communication, can be applied to the governance. Third, many activities in the governance hold the promise of the ARR, such as series of public and participant meetings, critical oversight by the EGC and ongoing communication with participants. Thus, it is interesting to know the extent to which the governance conforms to the Model. For these reasons, testing the Model against governance arrangements in UK Biobank can show how the Model is applied to such circumstances and provide practical examples of biobanking activities that comply with the Model. Also, it might inherently suggest how to further improve a participant-biobanker relationship in UK Biobank. This could be considered important when considering the fact that UK Biobank is open not only to commercial use but also to non-UK use.[6] Accordingly, it is reasonable to use UK Biobank as a case study to test the Model.

This chapter consists of four sections, each of which deals with one of the four key attributes of the Model, i.e. emphasis on collective goals, collaboration, reciprocation and control sharing. The order of these sections is the same as that of the explanations about the practical application of those key attributes, provided in Chapter 3.

Four points are noteworthy here. First, discussions in this chapter purely stem from documentary research that mainly examines publicly accessible sources, such as websites, meeting reports and annual reports,[7] as opposed to personal correspondence and interviews. As further emphasised below, this imposes some limitations on these discussions.[8] Second, these discussions are limited to biobanking activities carried out before 2016, regardless of when information about those activities became available. For example, the latest document used is the EGC's Annual Review 2015, which was available in 2016. Third, although the EGC is part of the governance of UK Biobank,

[5] See 1.4.1 in ch 1 above.
[6] Report on 41st EGC Meeting (December 2014), at 4.
[7] The documents used as sources for the discussion in this chapter are listed in Appendix 1.
[8] See the conclusion of this chapter.

it is intended to be a 'critical friend' of UK Biobank.[9] Thus, as evident below, this body can serve as an oversight body in the governance. Finally, the notion underlying these discussions is that the governance is dynamic and has a mutual learning strategy as its core practice. Accordingly, the arguments here basically aim to make constructive suggestions, rather than making 'right or wrong' judgements.

Box 4.2: Change in communication strategy

It is necessary to explain briefly the development of involvement activities in UK Biobank governance, particularly regarding the change in a body that is responsible for these activities, since many discussions here concern them. During the recruitment stage (2006–2010), the EGC played an important role in engaging with the public by, inter alia, arranging annually public meetings. After recruitment, a communication strategy changed: the series of EGC public meetings ceased in 2010[10] and UK Biobank started to engage with participants by establishing its own communication with participants, i.e. issuing annual participant newsletters (2011), launching its new website (2011),[11] using social media as online communication channels (2014)[12] and starting its own series of participant meetings (2014).[13] The EGC continues to communicate with the public,[14] and it has attended UK Biobank's participant meetings.[15] Two points are notable here. First, it is unclear from accessible documents as to reasons behind this change. However, this change happened after the panel reviewing the EGC's work in 2010 ("**the 2010 Panel**") had implied in its report that a role in

[9] EGC Annual Report 2010, at 6.
[10] Report on 25th EGC Meeting (December 2010), at 2. It is said that EGC public meetings become occasional events, i.e. when certain issues arise. See EGC Communication Strategy (2011), at 3.
[11] The UK Biobank website was re-developed for facilitating communication with participants, including providing updates and information about biobanking activities, receiving general enquiries and feedback, and allowing participants to update contact details. See Communication Plans (2011).
[12] Thus far, Facebook and Twitter have been used as online communication. See EGC Annual Report 2014, at 11-12.
[13] According to the UK Biobank website, six UK Biobank participant meetings have been arranged in three recruitment cities, i.e. Edinburgh (November 2014 and January 2015), Manchester (April, May and September 2015) and Nottingham (November 2015). See also Report on 44th EGC Meeting (September 2015), at 6.
[14] EGC Communication Strategy (2011), at 2, 3.
[15] UK Biobank gave the EGC a standing invitation to attend any participant events. See Report on 43th EGC Meeting (June 2015), at 6. It also invited the EGC to speak at its participant events. See Report on 44th EGC Meeting (September 2015), at 6. Indeed, it is evident from accessible documents that the EGC did speak at those events. See EGC Annual Report 2015, at 1, 16.

engaging with the public and participants was outside the EGC's remit and should be handled by UK Biobank.[16] Second, the panel reviewing the EGC's work in 2015 ("**the 2015 Panel**")[17] implied the same in its report released in June 2015.[18] This panel also suggested arranging an annual general meeting ("**AGM**") for public reporting, discussion and future planning. However, the ways in which the EGC responded to the latest review in practice were unclear in 2015.

The tentative conclusion to be drawn is that the governance of UK Biobank essentially conforms to the Model, and thereby it is likely that the ARR has been developed in UK Biobank to some extent. This conformity mainly results from the work of the EGC, which acts as a 'critical friend' of UK Biobank and a guardian of participants, because the Council plays an important role in helping the governance to has all key attributes of the Model. Moreover, since 2015, this conformity might even increase if certain recommendations made by the 2015 Panel are put into practice, i.e. arranging an AGM and developing an official mechanism for UK Biobank when dealing with the EGC's advice. On the other hand, there are also some concerns raised by the review of the 2015 Panel, particularly regarding a recommendation to arrange an AGM and the understanding of the 2015 Panel that the EGC should not play a role in engaging with participants and the public.

4.1 Emphasis on Collective Goals

As explained in Chapter 3, the key attribute of emphasis on collective goals requires participants and biobankers to share the same biobanking goals throughout biobanking endeavours. To achieve this, there must be measures to (1) clarify biobanking goals and (2) reinforce the collectiveness in biobanking goals between participants and biobankers.[19] Based on this premise, this section deals with the

[16] Review of the EGC 2010, at para 42; EGC Communication Strategy (2011), at 2-3.
[17] EGC Annual Report 2015, at 7.
[18] Review of the EGC 2015. Notably, the EGC seemed to be critical of this review. See Report on 44th EGC Meeting (September 2015), at 10.
[19] See 3.1 in ch 3 above.

questions of whether any mechanisms in UK Biobank governance can be used to implement these two measures, and if so how? As for the structure of this section, these two measures are dealt with separately in two different sub-sections. At first glance, it seems that this aspect of the governance conforms to the Model mainly because of consistent communication with participants in the governance and the establishment of the EGC, but there are some practical issues that may undermine this conformity.

4.1.1 Clarification of Biobanking Goals

> The Model (Chapter 3): The measure to clarify biobanking goals generally involves the communicative mechanisms during recruitment that aim to make biobanking goals clear to participants. It is suggested conceptually that the focus of this measure should be on methods, as opposed to consequences, and thereby the quality of this communication is an important consideration. In practice, there should be evidence of biobankers' attempts to facilitate participants' understanding of biobanking goals, as opposed to evidence of sufficiency in such understanding.

To find out whether UK Biobank's goals have already been clarified, the recruitment documents and documents describing communication mechanisms in the governance of UK Biobank, were examined to determine how the goals were communicated to participants and whether the governance had any mechanisms in place for facilitating their understanding of the goals. As a result of this examination, it can be argued that the goals were adequately clarified since the governance had many communication channels that could facilitate understanding of the goals. These channels include providing participants with the recruitment documents[20] and a leaflet for repeat-measurement visits, both of which clearly explain the purpose of UK Biobank.[21] Also, there were EGC public meetings and UK Biobank participant

[20] The recruitment documents here refer to the consent form, the information leaflet and the further information leaflet. See Appendix 1.

[21] The recruitment documents that are accessible are dated 2010, although UK Biobank started recruiting participants in 2006. It is therefore questionable whether the information that was actually given to participants at recruitment is the same as that contained in these documents.

meetings, which presented information that could help participants (who attended the meetings) to understand the goals, such as the purpose of UK Biobank, its importance, potential uses and actual uses of UK Biobank's resources ("**the Resources**"). Indeed, those meetings had Q&A sessions, which might help verify or improve understanding of the goals. Furthermore, there have been many published documents that explain the goals (e.g. EGC annual reports and the UK Biobank website), and thus participants could use these documents to improve their understanding of the goals. It can therefore by argued from these explanations that UK Biobank's goals were sufficiently clarified because participants were able to acquire an accurate understanding of the goals through many communication channels in the governance.

Furthermore, some might say that, in practice, misunderstanding of UK Biobank's goals is unlikely for three reasons. First, the goals are basically broad and generic, and thereby do not contain detailed or complicated information. Accordingly, participants do not require in-depth or expert knowledge to understand them. Second, it might be assumed from the age range of the participant cohort that participants are unlikely to lack intellectual competence to understand the goals. Finally, it appears that, in general, UK Biobank has attached importance to participants' understanding about UK Biobank, making it reasonable to assume that the goals were well explained to participants. This is based on some documents, such as the EGF[22] and the report on the 44th EGC's meeting,[23] which say that such understanding is one of UK Biobank's concerns. Moreover, in practice, there were some activities suggesting so. One is a post-visit survey (during the pilot phase of recruitment) that examined participants' understanding of their participation and the long-term implications thereof, including UK Biobank's aim of benefiting future generations as opposed to benefitting them.[24] Another is a postal survey that was conducted to deal with participants being unaware of some aspects of participation after this unawareness had been recognised by the

[22] The EGF states that participants' understanding of, inter alia, the purpose of UK Biobank and the expectation of commercial involvement is an important ingredient of consent to participation, and this understanding needs to be assured by UK Biobank. See UK Biobank EGF v3 (2007), at 5-6.
[23] It was said that UK Biobank was well aware of the age of cohort participants and the need to tailor its communication with them. See Report on 44th EGC Meeting (September 2015), at 6.
[24] Report of the Integrated Pilot Phase (2006), at para 4.3.3-4.3.6.

EGC.[25] There was also an empirical study conducted after imaging-assessment visits to assess their understanding of the pilot imaging study, including its aims and the possibility of feedback.[26]

Given these explanations, it can be said that the governance has various communication that facilitates understanding of the goals, although the goals are unlikely to be misunderstood. One can therefore argue that **UK Biobank has made sufficient attempt to clarify its goals** and thus this aspect of the governance conforms to the Model.

There are however two notable points here. First, although the possibility of commercialising the Resources can be implied from the recruitment documents, it is not explicitly stated: the information leaflet briefly explains that the Resources may be used by researchers who work for commercial companies;[27] the consent form merely suggests that the Resources may lead to the commercial development of new treatments.[28] This possibility is instead clarified in detail on the UK Biobank website, particularly in the FAQs section.[29] Accordingly, a question might arise as to whether commercial involvement in UK Biobank was adequately emphasised at recruitment, given the controversy over this matter[30] together with UK Biobank's attempt to attract the commercial sector.[31] Notably, although the answer to this question seems to be negative according to accessible documents, it is admittedly possible that this involvement was already communicated verbally to participants.

Second, it is questionable whether participants actually had sufficient understanding of UK Biobank's goals. This question generally stems from many empirical studies conducted in a general context: these studies reveal that participants

[25] EGC Annual Review 2009, at 12. It is evident that UK Biobank also proposed arranging telephone interviews to address such lack of awareness, but no follow-up is found in accessible documents and thus it is unclear whether these interviews were actually carried out and, if so, how.
[26] Report on 43rd EGC Meeting (June 2015), at 4.
[27] Information Leaflet (2010), at 8; Further Information Leaflet (2009), at 8.
[28] Consent Form (2006).
[29] UK Biobank Website (accessed on 29 April 2016).
[30] See 6.4.3 a) in ch 6 below.
[31] Report on 41st EGC Meeting (December 2014), at 4.

usually had some misunderstandings about certain aspects of biobanking;[32] some studies also show that participants might not read information offered to them.[33] Moreover, while the aforementioned post-visit survey indicates that participants had a good understanding of participation and elements of consent,[34] EGC public meetings revealed that some participants were not fully aware of certain aspects of participation, such as re-contacting by UK Biobank and the linkage between the Resources and NHS records.[35] This fact might raise some doubts as to whether some participants actually had sufficient understanding of UK Biobank, including its goals. However, while such doubts can be considered reasonable, they do not weaken the argument here, since the actual level of participants' understanding is not used as a benchmark for this aspect of the Model. This point is raised here because it is relevant to this aspect of the Model and it will be cited again when discussing how participants' input was not disregarded in 4.2.2 c) below.

[32] M Dixon-Woods et al, "Beyond "Misunderstanding": Written Information and Decisions about Taking Part In a Genetic Epidemiology Study" (2007) 65 *Social Science & Medicine* 11 2212-2222; G Moutel et al, "Bio-Libraries and DNA Storage: Assessment of Patient Perception of Information" (2001) 20 *Medicine and Law* 2 193-204; V Toccaceli et al, "Research Understanding, Attitude and Awareness towards Biobanking: A Survey among Italian Twin Participants to a Genetic Epidemiological Study" (2009) 10 *BMC Medical Ethics* 1 1-8.

[33] P Ducournau and R Strand, "Trust, Distrust and Co-production: The Relationship Between Research Biobanks and Donors" in JH Solbakk, S Holm and B Hofmann (eds), *The Ethics of Research Biobanking*, (London: Springer Science, 2009) 115-130; K Hoeyer, "'Science Is Really Needed—That's All I Know': Informed Consent and the Non-verbal Practices of Collecting Blood for Genetic Research in Northern Sweden" (2003) 22 *New Genetics and Society* 3 229-244; H Busby, "Blood Donation for Genetic Research: What Can We Learn from Donors' Narratives?" in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, (London: Routledge, 2004) 39-56; K Hoeyer, "Ambiguous Gifts: Public Anxiety, Informed Consent and Biobanks" in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, (London: Routledge, 2004) 97-116.

[34] Report of the Integrated Pilot Phase (2006), at para 4.3.3-4.3.6; Report on EGC Public Meeting 2007 (June), at 12.

[35] EGC Annual Report 2009, at 12.

4.1.2 Reinforcement of Collectiveness in Goals

The Model (Chapter 3): This measure aims to encourage participants and biobankers to share the same biobanking goals throughout biobanking endeavours. The reinforcing mechanisms need to have two crucial elements: ongoing oversight of biobanking activities and discouragement of any deviations from collective goals.

Based on this explanation, the governance of UK Biobank was examined to find any mechanisms that can be used to oversee UK Biobank's activities continuously and to discourage any activities that deviate from UK Biobank's goals. In doing so, all accessible documents about the governance were reviewed in order to find out (1) how information about UK Biobank's activities is communicated between different stakeholders – i.e. participants, biobankers and the EGC – and (2) how these stakeholders can deal with undesirable activities, if at all. These documents include the EGF, EGC annual reports and reports on the EGC's internal and public meetings. They also include other materials used to inform participants about UK Biobank's activities, such as participant newsletters and the UK Biobank website. This examination reveals that the governance of UK Biobank has such mechanisms. In this sub-section, explanations of these mechanisms are separated into two sub-sub-sections. One deals with mechanisms for dealing with changes to participants' goals, and the other deals with those for dealing with changes to biobankers' goals.

a) Changes to Participants' Goals

As suggested in the Model, two mechanisms – namely communication about biobanking progress ("**CBP**") and the right of withdrawal – should be available to participants to reinforce collectiveness in biobanking goals. The former enables them to recognise collective goals through information on biobanking activities, and the latter allows them, by themselves, to impede deviations of their own goals from collective goals.

The governance of UK Biobank has both of these mechanisms. Particularly, participants have the right to withdraw their consent 'at any time without having to explain why and without penalty'. The details of this right are clearly explained in the

EGF.[36] Indeed, participants have been informed of this right through many documents, such as the recruitment documents and the UK Biobank website. In terms of CBP, one can generally say that the governance has sufficient CBP, thereby enabling participants to keep properly up-to-date with UK Biobank's activities, including how the Resources are actually used. This might result from UK Biobank's attempt to maintain the validity of participants' broad consent by keeping participants informed about biobanking activities.[37] Explanations of CBP can be separated into two stages of UK Biobank's development, i.e. during recruitment (from 2006 to 2010) and after recruitment (after 2010). The reason behind this separation is the change in communication strategy, which is explained in Box 4.2 above.

During recruitment, the EGC played a major role in communicating with the public, and so it established many publicly accessible communication channels that contain information about UK Biobank's activities, and thereby participants can regularly keep up-to-date with UK Biobank's progress through these channels. They include its series of public meetings, which were arranged annually in the recruitment cities. On its website, it also published its annual reports and reports on its internal meetings, which review and discuss UK Biobank's activities, respectively.[38] In terms of content, these channels provided various information about UK Biobank (such as, background, governance, current and planned activities, and prospective studies), thereby making them eligible to be CBP. Other than this regular communication, participants could get updates about UK Biobank's progress by sending enquiries to the EGC or UK Biobank. One can therefore say that, during the recruitment stage, there were many CBP channels that allowed participants to follow UK Biobank's progress, whether regularly or irregularly. Note that, since the Resources were not open to researchers at that time,[39] these communication channels mainly contained

[36] UK Biobank EGF v3 (2007), at 9-10.
[37] EGC Annual Report 2010, at 13.
[38] The UK Biobank website itself might be another channel for CBP during recruitment (2006-2010). However, it is difficult to confirm this because its previous version, which was used before launching its current version in 2011, is not accessible. See EGC Annual Report 2011, at 12.
[39] The Resources were open for research use in March 2012. See EGC Annual Report 2012, at 2.

information about recruitment and resource management. There was no information about actual uses of the Resources in this respect.

After recruitment, UK Biobank established three main communication channels. The first was a new (or current) UK Biobank website. As this website is intended to be a primary communication channel, it is remarkably informative: it provides not only updates on UK Biobank's activities, such as the management and uses of the Resources, but also relevant information, such as knowledge about genetic research, prospective studies and data-collecting procedures. The second channel is participant newsletters, which started being issued annually in 2011. These newsletters contain similar information to the UK Biobank website, but with more details.[40] The last channel is UK Biobank's participant meetings, which present information about the background and progress of UK Biobank (as similarly as the EGC's public meetings) with more focus on actual uses of the Resources.[41] As for the EGC, its annual reports and reports on its internal meetings still continue to be issued on its website in the same way as occurred during the recruitment stage. Other than these regular communication channels, participants could additionally receive updates about UK Biobank's activities through other occasional communication, such as notifications on controversial issues,[42] individual responses to their enquiries, re-contacting[43] and other mass media (i.e. television and radio broadcasts, newspapers, scientific journals and magazines).[44]

When considering all these communication channels, it can be said that the governance of UK Biobank has had many channels for CBP, and thereby participants

[40] In general, participant newsletters are sent via email. If they are undelivered or participants do not have email addresses, they will be delivered by mail instead. See Communication Plans (June 2011).
[41] These meetings have been arranged in the recruitment cities since November 2014. See note 13 above. However, there are no formal reports on these meetings at the time of writing. Only transcripts, slides and video clips of presentations at these meetings are available on the UK Biobank website.
[42] Report on Public Consultation on Draft Access Procedures (2011), at 10.
[43] Policy on Re-contacting, at para A.3.1.1, B.1.1.1, B.2.
[44] This information was presented by Andrew Trehearne, UK Biobank's Head of Communications, at the EGC's 10-year anniversary conference in 2014 (3-5 November 2014, London). See also Policy on Access, at para A4; EGC Annual Report 2012, at 12; EGC Annual Report 2013, at 11.

have been allowed to properly and continuously keep up-to-date with UK Biobank's activities. In this respect, they are arguably capable of realising UK Biobank's actual goals, which are reflected by its activities. Indeed, this capability might increase as the 2015 Panel recommended that the EGC arranges an AGM, which has the aim of providing the public with updates on UK Biobank's and the EGC's activities.[45] Accordingly, it can be assumed that participants have capability to recognise easily any deviations of their own goals from UK Biobank's goals, the latter being considered to be collective goals in this situation. With their right of withdrawal, they are also able to impede such deviations by withdrawing their consent. It is therefore arguable that **UK Biobank participants are able to help reinforce collectiveness in biobanking goals**, because the governance of UK Biobank has mechanisms that allow them to oversee UK Biobank's activities continuously and to impede changes to their goals that deviate from collective goals.

b) Changes to Biobankers' Goals

The Model suggests that there should be an oversight body that is assigned to reinforce collectiveness in biobanking goals. This body should be capable of monitoring biobanking activities and resisting activities that deviate from collective goals. Also, this body should have mechanisms for recognising what biobanking goals participants actually have and informing them of its own reinforcing activities.

In the governance of UK Biobank, the EGC can be presumed to be such a body since it is generally assigned to monitor UK Biobank's activities critically and to encourage the conformity of those activities to the EGF and participants' consent, as well as to advise UK Biobank on participants' interests.[46] To prove this presumption, this sub-sub-section looks into EGC's activities, particularly its relationships with UK Biobank and participants, in order to find out whether or not it is suitable to be an oversight body that reinforces collectiveness in biobanking goals according to the Model. As for the structure of this sub-sub-section, the EGC's relationships with UK Biobank and participants are dealt with separately.

[45] Review of the EGC 2015, at 8.
[46] See Box 4.1 above.

Relationship with UK Biobank

One can say that the EGC's relationship with UK Biobank is in accordance with the Model's suggestion, since the EGC not only has sufficient access to information about UK Biobank's activities but can also resist activities that deviate from the goals shared with participants.

Regarding sufficient access, the EGC can access information about UK Biobank's activities through its communication with UK Biobank. Particularly, it receives UK Biobank's biannual reports, which summarise many UK Biobank's activities, such as security of data in the Resources, responses to the enquiries and complaints sent to UK Biobank, and linkage between the Resources and NHS records. The EGC normally invites UK Biobank staff to its quarterly internal meetings, usually the UK Biobank PI, to report and answer questions about biobanking activities.[47] Regarding the access-review procedure, the EGC regularly (i) has full access to applications that are considered significant,[48] and (ii) receives quarterly summary reports on access-review processes from UK Biobank.[49] In practice, it also receives minutes of the meetings of UK Biobank's Access Sub-Committee (**ASC**), and these minutes provide information about the access applications that are discussed at ASC meetings.[50] It also had occasional communication with UK Biobank, such as informal meetings between the EGC Chair and UK Biobank's CEO.[51] This amount of communication suggests that the EGC can realise most of UK Biobank's activities, and thus **it arguably has sufficient access to information about those activities**.

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[47] EGC Annual Report 2015, at 6.

[48] When UK Biobank finds certain access applications 'significant', it should notify the EGC of such applications at the earliest opportunity and send a copy of them to the EGC along with its notification. Access applications are considered significant when they involve (1) requests for re-contact; (2) novel and/or important ethical issues; (3) novel and/or important governance issues; (4) making decisions that will set major precedents; or (5) some other matters that, in the judgment of UK Biobank, merit the EGC's attention. See Report on 41st EGC Meeting (December 2014), at Annex A. It was agreed that significant access applications will be escalated for advice to the EGC. See Report on 44th EGC Meeting (September 2015), at 9.

[49] This is a new model for overseeing access procedures, and this model was adopted on 1 January 2015. However, in 2015, it was still being piloted and thus it was not published in the form of a policy document yet. See EGC Annual Report 2014, at Annex A.

[50] Report on 45th EGC Meeting (December 2015), at 4.

[51] EGC Annual Report 2011, at 5; EGC Annual Report 2015, at 6.

As for the capability to resist any deviations from participants' goals – which are deemed to be collective goals in this situation – it is important to note that the EGC can neither directly control nor review any UK Biobank's activities, based on the notion that it generally acts as an advisor, not an arbiter.[52] In the access-review procedure, for example, the EGC only gets involved in certain types of access applications and can merely give advice on them, as opposed to decisions about them.[53] However, one may say that it could resist certain of UK Biobank's activities through some latent sanctions. Particularly, the EGC can either raise any undesirable activities with the funders or express its disapproval of such activities publicly.[54] These mechanisms could result in the withdrawal of funding and/or consent,[55] which might undermine the viability of UK Biobank.[56] Thus, it can use these mechanisms as latent sanctions to hinder any undesirable activities in the governance of UK Biobank. It is therefore arguable that, **in practice, the EGC could resist UK Biobank's activities that deviate from participants' goals through its latent sanctions**. Notably, it seems that possible withdrawal of funding is relatively promising because, in practice, the funders have regularly been involved in the EGC's activities[57] and thereby the EGC can conveniently raise any deviations with them.

It can be concluded that the EGC can oversee UK Biobank's activities and could resist activities that deviate from participants' goals, aka collective goals. One

[52] UK Biobank governance is based on the idea of mutual learning: the EGC is considered as a 'critical friend' who helps reflect the whole picture of UK Biobank governance. See EGC Annual Report 2010, at 6. Notably, this idea is not in line with the 2003 genetics whitepaper, which says that the oversight body of UK Biobank 'will have the power to veto' the use of the Resources. Department of Health, *Our Inheritance, Our Future: Realising the Potential of Genetics in the NHS*, (June 2003) 94, at para 5.37.
[53] See note 48 above.
[54] UK Biobank EGF v3 (2007), at 3, 14-15.
[55] The EGF says that '[c]ompliance with [the EGF] will be a condition of continued funding of UK Biobank by the [f]unders'. See UK Biobank EGF v3 (2007), at 19.
[56] Notably, Cutter et al say that this public denouncement mechanism is deemed powerful from a socio-political perspective, but it may be considered lacking in power when specifically enforcing governance principles. See M Cutter Anthony et al, "Balancing Powers: Examining Models of Biobank Governance" (2004) 1 *Journal of International Biotechnology Law* 5 187-192, at 190.
[57] It is evident that the funders have regularly attended EGC internal meeting as observers and also worked closely with the EGC, such as reviewing the EGC's 2015 report on feedback, assisting the EGC in reviewing the pilot protocol on incidental findings, advising the EGC on the new access oversight model. See Report on 44th EGC Meeting (September 2015).

can therefore argue that this aspect of UK Biobank governance conforms to the Model. Nevertheless, two practical issues might arise regarding this argument. First, it is questionable whether the EGC's knowledge of access applications can be considered sufficient in practice. This is because, while the Council receives summaries vis-à-vis access applications from UK Biobank,[58] it only has full access to access applications that UK Biobank *considers significant* and *escalates* to it for advice.[59] In this respect, its ability to oversee access-review processes relies upon UK Biobank's discretion, let alone the possibility of delayed escalation.[60] Also, its access to the minutes of ASC meetings is not regular and may occur several months after these meetings take place.[61] The second issue concerns the effectiveness of the EGC's latent sanctions. For withdrawal of funding, it is unclear from accessible documents how the funders decide on this matter, thereby raising doubts as to whether this sanction can be used to hinder deviations from participants' goals. For withdrawal of consent, this sanction relies on participants' activeness, which is uncertain and thus cannot be relied on. These two practical issues suggest that, in practice, the EGC might not be able to properly perform the reinforcing role required by the Model, thus undermining the validity of this argument. Nonetheless, discussing these issues require further in-depth information on actual practices, which is not accessible, and thus these issues cannot be addressed here. They are mentioned so as to note that they may weaken this argument.

Relationship with Participants

One can say that the EGC's relationship with participants is also in line with what the Model suggests. The reason is that the Council has mechanisms that, in practice, can be used to realise participants' biobanking goals (or any changes thereto)

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[58] See EGC Annual Report 2015, at 8-9.
[59] See note 48 above. Note that, previously, the EGC could routinely check access applications in UK Biobank's access database. See EGC Annual Report 2015, at 8.
[60] While it is recommended that UK Biobank notifies the EGC of significant access applications at *the earliest opportunity*, the EGC – in practice – received such notification a few months after significant access applications had been submitted to UK Biobank. See Report on 43rd EGC Meeting (June 2015), at 7-8. Indeed, according to accessible documents, there were some applications that the EGC considered to be significant, but they were not reported nor notified to it. See Report on 45rd EGC Meeting (December 2015), at 4.
[61] Report on 45th EGC Meeting (December 2015), at 4. However, it was agreed that, in the future, the EGC will receive these minutes as soon as possible after ASC meetings take place. See EGC Annual Report 2015, at 9.

and inform participants of its own reinforcing activities.[62] Particularly, for the purpose of informing, it has consistently been issuing its annual reports and reports on its internal meetings, both of which are available on its website and explain its oversight activities. The content of these reports includes what UK Biobank's activities it is monitoring or interested in, and how it interacts with UK Biobank or reacts to issues arising in the governance of UK Biobank. Until 2010, it also arranged public meetings in the recruitment cities, where participants could receive updates on its activities. Given these communicative mechanisms, one can say that participants have been able to know about its activities as an oversight body, including its relationship with UK Biobank as explained above. It is therefore arguable that **the EGC has mechanisms that can be used to inform participants of its reinforcing activities**.

As regards mechanisms for understanding participants' current goals, it has two mechanisms that might be used for this purpose, i.e. (1) establishing channels for individual enquiries and feedback and (2) arranging meetings that were attended by participants. The details of these mechanisms are explained separately, as following:

The former refers to channels for individual participants to send their enquiries and feedback to the EGC and UK Biobank. It is evident that the content of these enquiries and feedback can reflect participants' thoughts about biobanking goals and has been considered by the EGC. Particularly, for enquiries and feedback received by the EGC itself, although their details have barely been revealed in publicly accessible documents,[63] it is evident that they involve participants' opinions on uses of the Resources, which could imply participants' expectations and biobanking goals, and these opinions were realised by the EGC.[64] As for enquiries and feedback received by UK Biobank, they also reveal participants' thoughts, such as concerns about commercialisation,[65] which could suggest participants' goals regarding commercial

[62] In general, the EGC aims to provide information for, and gather information from, its key audiences, including UK Biobank participants. See EGC Communication Strategy (2011), at 1.
[63] The EGC's annual reports and reports on its internal meeting rarely reveal the content of these enquiries and complaints as well as the ways in which it dealt with them.
[64] Report on 15th EGC Meeting (June 2008), at 11; Report on 19th EGC Meeting (June 2009), at 14.
[65] EGC Annual Report 2009, at 12.

use. Despite UK Biobank handling them, the EGC can see their content through UK Biobank's biannual reports on enquiries and complaints,[66] which the EGC has been using for monitoring how UK Biobank deals with them.[67] Given how participants' enquiries and feedback have been dealt with by the EGC, it can therefore be argued that the EGC can know participants' goals and realise any changes thereto through UK Biobank's and its channels for individual enquiries and feedback, although this might actually not be the intended use of these channels.

As regards meetings attended by participants, during the recruitment stage, the EGC itself arranged seven public meetings in the recruitment cities and these meetings had Q&A sessions, in which attendees could raise concerns and discuss issues with UK Biobank's staff. In practice, it is also evident that some participants did attend these meetings[68] and issues discussed included commercial use and the possibility of feedback. While it is unclear from accessible documents whether those who raised those issues are participants, these meetings might be assumed to reflect participants' general expectations of biobanking, which could be interpreted as their biobanking goals. It is likely, therefore, that the EGC was able to realise participants' current goals through Q&A sessions at its public meetings. After recruitment, UK Biobank has arranged its own participant meetings in the recruitment cities[69] and these meetings had Q&A sessions too. Indeed, although these meetings were organised by UK Biobank, the EGC was present at these meetings.[70] Thus, one might assume that the EGC could have some insight into participants' biobanking goals through UK Biobank participant meetings as well. Given the meetings and the channels for enquiries and feedback organised by the EGC and UK Biobank, one might therefore argue that, in general, **the EGC has been able to realise participants' goals and any changes thereto**.

There are however three notable points with regard to this argument. First, although the EGC's public meetings were attended by some participants, they were

[66] EGC Annual Report 2007, at 11.
[67] EGC Annual Report 2009, at 4; UK Biobank EGF v3 (2007), at 14-15.
[68] EGC Annual Report 2008, at 9; EGC Annual Report 2009, at 12; EGC Annual Report 2010, at 14.
[69] See note 13 above.
[70] See note 15 above.

not intended to engage with participants specifically. This is echoed in reports on these meetings, which do not differentiate participants from other attendees. Thus, one can question the extent to which the EGC could actually know about participants' goals through its public meetings. Second, some information is not available to confirm the evidence that supports this argument. Particularly, reports on participants' input at UK Biobank participant meetings are not available,[71] making it unclear whether the EGC can actually use these meetings to learn about participants' goals. Also, it is unclear from accessible documents whether the EGC's internal meetings still discuss enquiries and feedback handled by UK Biobank,[72] thereby making it questionable whether those enquiries and feedback still allow the EGC to learn about participants' current goals. Thus, such information is required to confirm the validity of this argument. On the last point, it is evident in the report reviewing the EGC's work in 2015 that the EGC is perceived not to have a role in engaging with participants.[73] So, it is doubtful whether, subsequently, there will be any changes to the governance that hinder the EGC from realising participants' goals and thus undermine the validity of this argument.

4.1.3 Interim Conclusion

This section has argued that biobanking goals shared with participants have been well emphasised in the governance of UK Biobank. One reason is that biobanking goals were sufficiently clarified and are basically unlikely to have been misunderstood. Moreover, the governance has mechanisms that can reinforce the collectiveness in biobanking goals between UK Biobank and participants. Particularly, on the one hand, it has many channels for CBP and also gives participants the right of withdrawal. Thus, participants can maintain such collectiveness by withdrawing their consent if their own

[71] As mentioned in note 41, the UK Biobank website only provides video clips, transcripts and slides of presentations, not Q&A sessions, at these meetings. Also, it is unclear how UK Biobank dealt with the input that participants gave at these meetings. Notably, it is suggested at the EGC's internal meeting that 'there may be value in someone going through the videos of the participants' events to pull out the key issues raised by participants'. See Report on 44th EGC Meeting (September 2015), at 6.

[72] According to accessible documents, UK Biobank's biannual reports on participants' enquiries and complaints started being discussed at the EGC's 13th meeting, and then were merely mentioned briefly at the EGC's 27th meeting for the last time. See Report on 13th EGC Meeting (November 2007), at 8-9; Report on 27th EGC Meeting (June 2011), at 5.

[73] See Box 4.2 above.

goals become different from collective goals, i.e. UK Biobank's goals that they realise through CBP. On the other hand, the governance has the EGC, an oversight body that helps to reinforce such collectiveness by monitoring UK Biobank's activities as well as resisting activities that deviate from collective goals (if any) through latent sanctions imposed by UK Biobank's funders or participants. There have also been mechanisms that enable the Council to inform participants of its oversight activities and to know about participants' goals, which are considered as collective goals in this situation. For these reasons, it is therefore arguable that the governance embodies the Model's key attribute of emphasis on collective goals.

Nonetheless, there are five main practical issues from the perspective of the Model. First, one might question whether commercial involvement in UK Biobank was adequately emphasised at recruitment. Second, it is questionable whether the EGC actually has sufficient access to access applications since such access has to rely on UK Biobank's discretion and notification. Third, some might question the effectiveness of the EGC's latent sanctions, as they depend on uncertain factors, i.e. the discretion of UK Biobank's funders and the activeness of participants. Fourth, it is questionable whether the EGC was able to learn about participants' goals through its public meetings, since these meetings were not intended specifically to engage with participants. Finally, it is unclear whether or not, at present, the EGC can realise participants' goals from UK Biobank participant meetings and from participants' enquiries and feedback handled by UK Biobank. As these issues are related to the EGC's capability to reinforce collectiveness in biobanking goals, they might affect the aforesaid argument about the EGC being an oversight body in the Model. It is not, however, feasible to address these issues here, since more information on actual practices regarding these issues is required. Still, it is worth pointing them out as they help to demonstrate how the Model is applied in practice. Other than these issues, it is notable that the arguments here will be used for the key attribute of reciprocation, since these two key attributes partly share the same practical applications.

4.2 Collaboration

The key attribute of collaboration in the Model requires biobankers to cooperate with participants in a respectful manner by giving participants a chance to influence biobanking activities meaningfully. In doing so, there must be mechanisms that provide participants with opportunities to provide input about biobanking and assure the meaningfulness of their input.[74] Based on this explanation, this section deals with the questions of (1) whether and how the governance of UK Biobank gives participants such opportunities and (2) whether such opportunities suffer from any forms of tokenism, such as the disregard of participants' input and the insignificance of issues under consideration. These two main questions are dealt with separately in two sub-sections. To address these questions, documents illustrating any involvement mechanisms in the governance are reviewed. These documents include EGC annual reports, reports on EGC public meetings, and a report on UK Biobank's consultation on access procedures. As a result of this review, it can be said that the answers to these questions are generally positive, as the governance has mechanisms for receiving participants' input about the governance and their input has a real chance of influencing UK Biobank's activities.

Two points are noteworthy here. First, discussions in this section do not include involvement mechanisms arranged before the recruitment stage, i.e. public consultations before 2006.[75] The reason is that the Model deals with a relationship between participants and biobankers, and thereby it is basically not applicable to mechanisms that do not involve actual participants. In other words, discussions here

[74] See 3.2 in ch 3 above.

[75] UK Biobank, *Ethics Consultation Workshop on 25 April 2002*, (September 2002) 19; UK Biobank, *Minutes of Consultation with Industry Workshop on 4 April 2003*, (2003) 9; People Science & Policy Ltd, *UK Biobank Consultation on the Ethical and Governance Framework*, (June 2003) 50; Opinion Leader Research, *Summary of the UK Biobank Consultation on the Ethics & Governance Framework*, (August 2003) 40. There is copious literature that discusses these consultations, e.g. M Levitt, "UK Biobank: a Model for Public Engagement?" (2005) 1 *Genomics, Society and Policy* 3 78-81; T Wakeford and F Hale, *Generation Scotland: Towards Participatory Models of Consultation*, (2004) 12; HM Wallace, "The Development of UK Biobank: Excluding Scientific Controversy from Ethical Debate" (2005) 15 *Critical Public Health* 4 323-333; A Petersen, "Securing Our Genetic Health: Engendering Trust in UK Biobank" (2005) 27 *Sociology of Health & Illness* 2 271-292; etc.

revolve around input from participants, as opposed to that from the public. The second point concerns difference in the content of discussions between the two following sub-sections. Particularly, the first sub-section of this section only focuses on the opportunities to provide input that participants have, while the possibility of such input influencing UK Biobank's activities will be discussed in the second sub-section.

4.2.1 Opportunities to Provide Input

> The Model (Chapter 3): Biobank governance needs to have mechanisms that allow participants to voice their thoughts about biobanking, so as to give them opportunities to provide their input on biobanking.

In the governance of UK Biobank, when considering some policy documents, it seems that UK Biobank intends to give participants opportunities to provide their input on its governance. Particularly, the EGF says that it might establish a participant panel to voice participants' general views.[76] Its policy on re-contacting also says that it might re-contact participants for the purpose of receiving their opinions.[77] From a practical aspect, although it is unclear from accessible documents whether the mechanisms suggested in these policy documents have already been put into practice, it appears that UK Biobank has implemented other mechanisms that allow participants to provide their input about its governance. Explanations of these mechanisms can be separated into regular and irregular mechanisms, as follows.

For regular mechanisms, both UK Biobank and the EGC have channels for receiving general enquiries and feedback, as explained above.[78] Indeed, UK Biobank also includes an escalation system in its channel for receiving general enquiries and feedback, thereby allowing participants to communicate directly with its senior staffs if necessary.[79] Furthermore, both UK Biobank and the EGC have arranged participant and public meetings, after and during recruitment, respectively. These meetings enable

[76] UK Biobank EGF v3 (2007), at 8.
[77] Policy on Re-contacting (2013), at B.1.1.1.
[78] See 4.1.2 b) (Relationship with Participants) above.
[79] Communication Plans (2011).

participants to provide input about UK Biobank governance by asking and discussing ethics and governance issues.[80]

As for irregular mechanisms, UK Biobank sometimes established one-time communication channels to receive participants' input on certain matters, such as a post-visit survey for obtaining feedback on their experience of recruitment, a postal survey for investigating participants' understanding and expectations of UK Biobank,[81] empirical research on participants' attitudes and understanding about the provision of incidental findings,[82] and a public consultation on access procedures, which participants were notified about and some of them participated in.[83] Also, when reviewing the EGC's work in 2015, the funders held participant focus-group sessions to listen to participants' voices about the EGC.[84]

Given all these regular and irregular mechanisms, one can therefore say that **participants have thus far had many opportunities to provide their input on the governance of UK Biobank**. It is noteworthy that there might be another mechanism for providing such opportunities in the future, i.e. an AGM, and this mechanism will be explained in the conclusion of this chapter.

4.2.2 Meaningfulness of Input

The Model (Chapter 3): Biobankers are required to ensure the meaningfulness of participants' input by allowing their input to have a real chance of substantially influencing biobanking. To fulfil this requirement, they need to address three forms of tokenism that might occur in a biobanking context, i.e. the insignificance of issues under consideration, the insufficiency of participants' capability to provide input, and the disregard of their input.

According to this proposal, this sub-section determines whether participants' opportunities to provide their input about the governance of UK Biobank, explained

[80] See 4.1.2 b) (Relationship with Participants) above.
[81] EGC Annual Report 2009, at 12; UK Biobank Website.
[82] EGC Annual Report 2015, at 13.
[83] Report on Public Consultation on Draft Access Procedures (2011).
[84] Report on 42nd EGC Meeting (March 2015), at 3. Notably, no further detail about these sessions is accessible.

above, can be considered tokenistic. In doing so, the mechanisms presented in the preceding sub-section are examined in order to find out whether or not they suffer from those three possible forms of tokenism. As for the structure of this sub-section, these three possible forms of tokenism are discussed separately in three different sub-sub-sections.

a) Insignificance of Issues

The first possible form of tokenism refers to a situation where issues on which participants are allowed to provide input are not significant for biobanking. The Model does not propose any criteria for what issues are significant, but instead suggests that significant issues should affect the quality of a participant-biobanker relationship or influence the direction of biobanking activities.

Based on this premise, the governance of UK Biobank so far seems not to suffer from this possible form of tokenism, since the main mechanisms for receiving participants' input, i.e. channels for general enquiries and feedback and UK Biobank participant meetings, are not limited to any specific issues. Also, other mechanisms can be considered to address significant issues. In particular, regarding the surveys on participants' experience of recruitment and their expectations about future involvement, it is unclear from accessible documents what aspects of these matters were considered, but these matters can generally be deemed significant since they probably influenced subsequent interactions between UK Biobank and participants. For example, these surveys might lead UK Biobank to improve its measurement procedures or its communication with participants. The public consultation in 2011 was regarding access procedures, which are per se essential for biobanking. Indeed, in practice, responses to this consultation also covered other significant issues, such as data security, communication, and re-contacting.[85] Given issues considered in these mechanisms, one can therefore argue that **the governance has not suffered from this possible form of tokenism**.

[85] Report on Public Consultation on Draft Access Procedures (2011).

b) Insufficiency of Capability

The second possible form of tokenism stems from the insufficiency of participants' capability to give useful input, which renders their input neither helpful nor worthy of consideration. The solution to this form of tokenism is participant empowerment. This empowerment might be performed by way of sharing general knowledge about biobanking and information about certain biobanks with participants. By assuming that some participants prefer to be non-active and thereby do not need such knowledge and information, this sharing accentuates the accessibility of such knowledge and information, not the consequences or methods of this sharing.

As for the governance of UK Biobank, this sub-sub-section examines the extent to which information about UK Biobank and general knowledge about biobanking have been shared with participants, and determines whether this sharing can be considered sufficient to empower them. It is notable that information about UK Biobank basically encompasses updates on UK Biobank's activities. Accordingly, one of the arguments here is analogous with the argument made regarding CBP above,[86] and it can be explained again, as follows: the governance has many CBP channels that enable participants to keep up-to-date with UK Biobank's activities, and thus participants arguably have sufficient access to information on UK Biobank's activities.

The same holds true for the accessibility of other information about UK Biobank and general knowledge about biobanking, as both UK Biobank and the EGC have many communication channels that allow participants to access such information and knowledge. Particularly, UK Biobank has its own website and has issued participant newsletters, both of which explain, inter alia, biobanking practices, genetic research, prospective studies and actual uses of the Resources.[87] Its information leaflets, given to participants during recruitment and assessment visits, provide good background information about UK Biobank. It also arranged participant meetings, which explained recent uses of the Resources and gave participants opportunities to

[86] See 4.1.2 a) above.
[87] See 4.1.2 a) above. Notably, UK Biobank's policy on access procedure says that, to assist participants in providing input, the issues relating to use of the Resources will be highlighted on the UK Biobank website. See Policy on Access (2011), at para A4.4.

glean more information directly from biobankers and researchers. For the EGC, it arranged its own public meetings, which presented background information about UK Biobank and itself, as well as relevant ethics and governance issues. It has also published many documents containing procedural and technical information as well as ethical discussions revolving around UK Biobank's activities, such as annual reports and reports on its internal meetings. Given all of these communication channels, one can say that participants have had sufficient access to information about UK Biobank and knowledge about biobanking. Thus, it is arguable that the sharing of information and knowledge in the governance is adequate to enable participants to give useful input and so **the governance does not suffer from this possible tokenism either.**

c) Disregard for Input

The last possible form of tokenism occurs when participants' input is not given serious consideration by biobankers, thus preventing participants from having a real chance of influencing biobanking activities. To address this concern, biobank governance should have mechanisms that can be used to confirm that participants' input is actually taken into account, regardless of whether or not such input is eventually put into practice.

In the governance of UK Biobank, it can be said that participants' input is not disregarded. At policy level, UK Biobank makes a commitment to take participants' input on access to the Resources seriously, by saying that '[i]nput from the participants … will be taken into account'.[88] This commitment has also been echoed in practice. In particular, it is evident from the report on a public consultation about access procedures that input from attendees (including participants) was taken into account by UK Biobank, as it was well summarised and also responded to properly by UK Biobank.[89] Also, according to the EGC's annual report in 2010, UK Biobank dealt promptly with some procedural issues that participants had voiced through channels for general enquiries and feedback.[90] Furthermore, as explained below, UK Biobank agreed to pay more attention to participants' understanding of the feedback policy when it found that

[88] Policy on Access (2011), at para A3.4.
[89] Report on Public Consultation on Draft Access Procedures (2011).
[90] EGC Annual Report 2010, at 12.

many participants did not clearly understand a certain aspect of this policy.[91] Notably, UK Biobank has also received participants' input about its governance at its participant meetings, but it is unclear whether and how it dealt with that input since there have been no reports on these meetings.[92]

Moreover, in practice, the EGC helps encourage UK Biobank to give participants' input serious consideration. On the one hand, the Council – through biannual reports provided by UK Biobank – routinely monitors how UK Biobank handles and responds to participants' enquiries and feedback.[93] On the other hand, it might indirectly lead UK Biobank to take participants' input into consideration through its advice. This is based on accessible information revealing that it once based its advice for UK Biobank on participants' input that it had received at its public meeting, and UK Biobank was responsive to that advice: after participants' feedback had revealed their unawareness of certain aspects of participation to the EGC, it informed UK Biobank of this issue and UK Biobank subsequently conducted a postal survey to address this issue.[94] Other than this issue, UK Biobank has also evidently been responsive to its advice on other matters,[95] such as including ethics expertise on the access committee[96] and improving lay summaries of access applications.[97] Given these EGC monitoring and advising activities, it can be said that the EGC can help to prevent participants' input from being neglected by UK Biobank. Indeed, the fact that information on these EGC's activities is publicly accessible might spontaneously pressurise UK Biobank to give participants' input serious consideration. Given all of

[91] See 4.3.2 a) below; EGC Annual Report 2015, at 13 (Box 12).
[92] See note 71 above.
[93] EGC Annual Report 2010, at 12. See also note 72 above.
[94] EGC Annual Report 2009, at 12. See also 4.1.1 (last paragraph) above. Note that this evidence is used to support that, in general, the EGC can help lead UK Biobank to take in account participants' input. In this respect, it is per se not an example of such help because, in this case, participants did not aim to give input that influences biobanking activities.
[95] Indeed, this tends to be the case afterwards: the 2015 Panel suggested amending the remits of the EGC, whereby UK Biobank needs to give the EGC's advice serious consideration. See Review of the EGC 2015, at 7. This point will be emphasised again in the conclusion of this chapter.
[96] EGC Annual Report 2010, at 8.
[97] EGC Annual Report 2012, at 8; EGC's Statement on Access (2012), at 1-2.

these UK Biobank and EGC activities, it is arguable that **the governance has so far not suffered from this possible form of tokenism**.

However, two issues that can undermine the strength of this argument might arise from some recent incidents.[98] The first issue is whether the EGC is still monitoring how UK Biobank deals with participants' general enquiries and feedback because, as explained above, its internal meetings no longer discuss UK Biobank's biannual reports on those enquiries and feedback.[99] The second issue concerns whether the Council is still able to realise participants' input and use this input to advise UK Biobank. This issue stems from two incidents that raise doubts about the extent to which the EGC can currently know about participants' input: first, its own public meetings, where participants could provide their input about UK Biobank, are no longer arranged;[100] second, although accessible documents suggest that it has attended UK Biobank participant meetings,[101] there has been no evidence showing what participants' input at these meetings was about and the extent to which it realised or understood that input.[102] These two issues make it questionable whether the EGC still helps encourage UK Biobank to take participants' input into account. However, these issues cannot be addressed here since confirming and discussing them require more information which is not publicly available at the time of writing. These issues are raised to show how to apply the Model by demonstrating what actual incidents can decrease the conformity of the governance to the Model.

4.2.3 Interim Conclusion

Overall, it can be said that collaboration between UK Biobank and participants has been fostered within the governance of UK Biobank to some extent.

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[98] The incidents from which these two issues arise are similar to those mentioned in the last paragraph of Sub-section 4.1.2, but they are discussed from a different perspective. Particularly, this sub-section concerns the EGC's activities that can help ensure participants' input being considered by UK Biobank, while Sub-section 4.1.2 discusses the EGC's ability to know about participants' thoughts about biobanking goals.
[99] See 4.1.2 (last paragraph) above.
[100] See Box 4.2 above.
[101] See note 15 above.
[102] See note 71 above.

The reasons are not only that UK Biobank has offered participants opportunities to provide their input about its governance, but also that their input has a real chance of influencing UK Biobank's activities since the governance has not suffered from the aforementioned three possible forms of tokenism. It is therefore arguable that this aspect of the governance generally conforms to the Model.

However, this argument might be weakened by some incidents that occurred after the change in communication strategy (explained in Box 4.2), i.e. the halt to EGC public meetings and the recent absence of the EGC discussing how UK Biobank deals with participants' general enquiries and feedback. The reason is that these incidents raise the question of whether the EGC still helps encourage UK Biobank to take participants' input into account. Indeed, when considering that UK Biobank has increasingly engaged with participants through various communication channels,[103] some might assume that collaboration in the governance has improved. While this assumption might be correct, no information has been made available to show how UK Biobank deals with participants' input[104] or confirm that it has done so properly in practice, making it difficult to support and accept this assumption. Thus, at present, it is questionable whether the quality of collaboration in the governance remains the same and whether this aspect of the governance still conforms to the Model as before.

It is notable that UK Biobank governance may suffer from the issue of representation, where input from some participants represents that of other participants or a whole participant cohort. This possibility results from two measures that, according to some policy documents, might be implemented within the governance, namely the establishment of a participant panel[105] and participant representation in the EGC.[106] For the ARR, this type of representation is generally not desirable since it is likely to lead biobankers to disregard the interests of some participants.[107] However, this issue is not discussed in this section because these two measures have not been put into practice. Particularly for the former, no participant panel has so far been

[103] See Box 4.2 above.
[104] See note 71 above.
[105] UK Biobank EGF v3 (2007), at 8.
[106] EGC's Terms of Reference, at 2.
[107] See 6.3.1 in ch 6 below.

established within the governance. As for the latter, some participants were actually appointed as members of the EGC, but this appointment took place 'by chance', not with intent to recruit participant representatives[108] – that is, those members did not play any role as participant representatives in the EGC in practice.[109] It can therefore be said that the governance has, to date, not suffered from the issue of representation.

4.3 Reciprocation

As established in Chapter 3, the Model requires biobankers to reciprocate participants' contributions to biobanking, with the aim of making participants feel satisfied with their participation. In practice, this reciprocation can be in either tangible or intangible form.[110] Based on this proposal, this section addresses the questions of whether the governance of UK Biobank provides participants with any reciprocation, and if so how? In doing so, it takes into consideration documents revealing any commitments given and any benefits offered by UK Biobank. These documents include the recruitment documents, participant newsletters, EGC annual reports and some policy documents. As for the structure of this section, two forms of reciprocation, i.e. tangible and intangible reciprocation, are dealt with separately in two different sub-sections. At first glance, this aspect of the governance generally conforms to the Model, but this conformity might decrease due to some practical issues concerning the EGC's activities, which make it doubtful whether the EGC can help provide these two forms of reciprocation in practice.

4.3.1 Intangible Reciprocation

> The Model (Chapter 3): To provide intangible reciprocation, biobankers need to give commitments to pursue collective goals and to provide sufficient safeguards for them. In doing so, biobankers are required to implement measures to (1) encourage the fulfilment of these two commitments and (2) inform participants of them and their fulfilment.

[108] EGC Annual Report 2009, at 14.
[109] Report on 44th EGC Meeting (September 2015), at 12.
[110] See 3.3 in ch 3 above.

Based on the Model, this sub-section explains UK Biobank's activities that can be considered to constitute making commitments to pursue UK Biobank's goals and to provide sufficient safeguards for UK Biobank participants. In doing so, it outlines activities in UK Biobank governance that can be used to (1) encourage the pursuit of UK Biobank's goals and the provision of participant safeguards and (2) notify participants of these two commitments and the fulfilment thereof. This sub-section is divided into two sub-sub-sections, each of which deals with one of these measures. It is notable that, as explained in Chapter 3,[111] the mechanisms suggested for implementing these two measures are similar to those suggested for reinforcing collectiveness in biobanking goals in the first key attribute of emphasis on collective goals. This is because the practical application of these two key attributes similarly requires ongoing oversight of biobanking activities and encouragement to conduct certain activities properly. Thus, some arguments in the first section will be applied here.

a) Encouragement to Fulfil Commitments

According to the Model, the mechanisms suggested for encouraging the fulfilment of those two commitments involve the establishment of an oversight body that is assigned to encourage such fulfilment and which also has communication with participants to elicit their thoughts about what their goals actually are and whether existing safeguards are sufficient.

For UK Biobank, the EGC is arguably eligible to be this oversight body. As the reasons supporting this argument are similar to those supporting the argument regarding the EGC in the first section,[112] the latter can be applied here and explained again, as follows. First, the EGC is able to encourage UK Biobank to pursue collective goals and/or provide participant safeguards, because it can monitor UK Biobank's activities and influence those activities by using some latent sanctions imposed by the funders and participants. Second, the EGC can realise participants' thoughts regarding what biobanking goals participants currently have and whether they are satisfied with

[111] See 3.3.1 a) in ch 3 above.
[112] See 4.1.2 b) above.

existing safeguards within the governance, through UK Biobank's and its own communication. Third, in addition to the reasons given in the first section, the EGC consists of professionals with a wide range of expertise and thus it can be assumed to have adequate capability to determine the sufficiency of participant safeguards. Given all these reasons, it is therefore arguable that **the EGC can encourage the fulfilment of commitments to pursue collective goals and to provide participant safeguards**.

Other than reasoning, the practical issues arising with the similar argument in the first section are also applicable here and can be explained again, as follows: there are some issues that might undermine the strength of this argument; first, one might have doubts about whether the EGC can effectively encourage such fulfilment in practice, since it is questionable whether the EGC actually has sufficient access to access applications and whether its latent sanctions are truly effective; second, one can also question its capability to realise participants' thoughts about collective goals and existing safeguards, because it is unclear whether the EGC can currently do so through UK Biobank participant meetings and UK Biobank biannual reports on participants' enquiries and complaints; also, the EGC was not expected by the 2015 Panel to play a role in engaging with participants; note that all these issues cannot addressed in this chapter since there is insufficient information available to do so.[113]

It is worth mentioning the involvement of Ethox Centre, a multidisciplinary bioethics research centre in the University of Oxford's Department of Public Health, in any ethical review. This involvement is intended to amount to approval of research ethics committees,[114] and thereby it differs from the establishment of the EGC, which seek to oversee the ethicality of all biobanking activities. This involvement can help to fulfil a commitment to provide participant safeguards.[115] However, as the Centre provides merely advice and support, not imposing sanctions against UK Biobank's approvals for access applications, it might not be able to *encourage* UK Biobank to

[113] See 4.1.3 above.
[114] EGC Statement on Access (2012), at 3.
[115] The role of the Ethox Centre is different from, but complementary to, that of the EGC. See EGC Annual Report 2014, at 8.

fulfil this commitment effectively. Accordingly, it cannot be an oversight body according to the Model.

b) Communication about Commitments

The Model suggests that there should be communication with participants to (i) inform them clearly about commitments to pursue collective goals and to provide sufficient safeguards for them and (ii) allow them to realise the fulfilment of these two commitments.

UK Biobank has already informed participants about these two commitments through information leaflets distributed during recruitment.[116] Active participants might also realise these commitments through attending EGC public meetings[117] and seeing certain policy documents as well.[118] Moreover, one can say that UK Biobank governance has many communication channels that allow participants to realise the fulfilment of these two commitments. This is generally supported by explanations of CBP in the governance, which are provided above.[119] To be specific, UK Biobank's communication channels (i.e. its participant meetings and participant newsletters) mainly provide information about potential and actual uses of the Resources, as well as progress and results of actual uses, thus allowing participants to know whether UK Biobank's goals are being pursued. Furthermore, the EGC reports publicly on its oversight activities, which essentially involve promoting the ethicality of UK Biobank's activities, including encouraging UK Biobank to provide sufficient safeguards for participants. This enables participants to realise how their interests are safeguarded in the governance. Given these communication channels, it can therefore be argued that **participants can realise whether and how these two commitments are fulfilled by UK Biobank**.

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[116] UK Biobank's purpose and its participant safeguard, i.e. the protection of participants' confidentiality, are explained and assured in information leaflets provided at recruitment. See Information Leaflet (2010), at 2, 4, 8, 10; Further Information Leaflet (2009), at 4-8.
[117] Report on EGC Public Meeting 2005, at 1, 4-5; Report on EGC Public Meeting 2007 (June), at 1-7; Report on EGC Public Meeting 2007 (December), at 2-13.
[118] UK Biobank EGF v3 (2007); EGC Statement on Access (2012); Policy on Access (2011).
[119] See 4.1.2 a) above.

The conclusion in this sub-section is that UK Biobank has provided participants with intangible reciprocation. One reason is that its governance has the EGC, which is eligible and able to encourage the fulfilment of commitments to (1) pursue goals agreed with participants and (2) provide sufficient safeguards for them. Moreover, participants have already been informed of these two commitments and are able to realise the fulfilment thereof through many communication channels in its governance. It can therefore be argued that, in general, this aspect of UK Biobank governance conforms to the Model.

Two points are notable here. First, in reality, one can question the extent to which participants actually know about the provision of participant safeguards within the governance, since it is evident that some participants could not recall hearing about the EGC,[120] which plays an important role in encouraging and reporting on such provision. Second, this conformity might increase by holding an AGM, which was proposed by the 2015 Panel. Particularly as an AGM aims to disclose publicly the relationship between UK Biobank and the EGC,[121] it might enable participants to realise the EGC's role in encouraging UK Biobank to fulfil those two commitments. In other words, this meeting can be another communication channel that allows participants to realise this fulfilment. Thus, arranging an AGM might make the governance conform more to the Model by facilitating intangible reciprocation.

4.3.2 Tangible Reciprocation

The Model (Chapter 3): Tangible reciprocation refers to offering tangible benefits to participants (e.g. financial benefits, individual research results and analysed health information) in return for their contributions to biobanking. This reciprocation is not necessary due to the uncertainty of its availability. Should it be provided, biobankers are required to (1) clarify policies on this reciprocation, and then (2) allow participants to negotiate on these policies.

[120] Review of the EGC 2015, at 5 (note 2).
[121] Review of the EGC 2015, at 8.

Within the governance of UK Biobank, participants have been provided with two types of tangible reciprocation. One is offers of financial benefits, i.e. travel expenses, which participants are allowed to claim back at a reasonable rate at the end of assessment visits.[122] The other is individual feedback on health information, i.e. incidental findings resulting from imaging assessments, which is going through a pilot phase, as further explained in the next paragraph. To illustrate whether and how this aspect of the governance is in accordance with the Model, this sub-section addresses the questions of whether UK Biobank's policies on tangible reciprocation have been sufficiently clarified and whether participants have been allowed to negotiate on these policies. As for the structure of this sub-section, these two questions are dealt with separately in two different sub-sub-sections.

It is notable that the provision of individual feedback in the governance of UK Biobank is undergoing development. Particularly, UK Biobank originally adopts only a non-feedback policy: participants are only given reports on measurements taken during initial assessment visits[123] together with possible warnings about abnormalities in these measurements; but they do not receive any information produced after these visits, such as laboratory analyses or individual research results.[124] Recently, UK Biobank planned to provide participants with potentially serious incidental findings ("**PSIFs**") stemming from imaging assessments.[125] To test the feasibility of this plan, it piloted a new protocol, namely a limited feedback loop, whereby participants (and their general practitioners) are provided with PSIFs from imaging assessments, if any.[126] With the aim of mainstreaming this protocol, it conducted social science research on the implications of receiving PSIFs over a certain period of time, from the

[122] Information Leaflet (2010), at 5.
[123] These measurements include blood pressure, weight, height, body mass index and lung function. See Report on 15th EGC Meeting (June 2008), at 9.
[124] UK Biobank EGF v3 (2007), at 6-8.
[125] Here, a potentially serious incidental finding is defined as a finding that indicates the possibility of a condition which, if confirmed, carries a real prospect of significantly threatening life span, or of having a substantial impact on major body functions or quality of life. See EGC Annual Report 2014, at 10; EGC Annual Report 2015, at 12 (Box 10).
[126] In practice, any potentially serious findings that are initially noticed by radiographers during imaging visits and subsequently verified by radiologists, will be fed back to participants and their general practitioner. See EGC Annual Report 2014, at 10. It seems to me that this pilot protocol is employed in parallel to the original non-feedback policy, in that the former is only applied to imaging assessments.

perspectives of participants, their families and health professionals involved.[127] It also ran systematic radiology reviews in parallel with this piloting, so as to evaluate the new protocol by assessing the numbers of false positives and false negatives resulting from the use of this protocol.[128] This piloting indicates that UK Biobank is going to provide another approach to tangible reciprocation, i.e. feedback from imaging assessments, in addition. To reflect the dynamics of this aspect of the governance, discussions in this sub-section encompass both the original policy and the pilot protocol. It is however worth emphasising again that discussions here are limited to the development of this piloting in 2015.[129]

a) Clarification of Policies

According to the Model, to clarify policies on tangible reciprocation, biobankers need to have clear policies on tangible reciprocation and then notify and justify those policies, or any changes thereto, to participants.

This premise suggests that this clarifying measure basically involves communication about policies on tangible reciprocation. Accordingly, this sub-sub-section, by examining communicative mechanisms in the governance of UK Biobank, determines the extent to which UK Biobank has communicated its policies on this matter to participants. The two types of tangible reciprocation that it provides for participants are dealt with separately. Regarding the reimbursement of travel expenses, a policy on this reimbursement is clear and was communicated to participants during the recruitment stage.[130] As this policy can be considered self-explanatory, it does not require explicit justification. It can therefore be said that this policy has been

[127] EGC Annual Report 2015, at 13-14. (See also Report on 40th EGC Meeting (September 2014), at 6; Report on 41st EGC Meeting (December 2014), at 6; EGC Annual Report 2014, at 10) Notably, the results of this research are not accessible, but this sub-section does not require such results to determine whether this aspect of UK Biobank governance conforms to the Model.
[128] EGC Annual Report 2015, at 12.
[129] Notably, UK Biobank proposed continuing this pilot protocol, with the EGC's support. See EGC Annual Report 2015, at 13; Report on 43rd EGC Meeting (June 2015), at 4. Ultimately, this proposal was endorsed by the panel that was tasked with reviewing this protocol. See Report on 45th EGC Meeting (December 2015), at 5.
[130] Information Leaflet (2010), at 5; Information Leaflet for Repeat Assessment Visit (2012), at 5.

sufficiently clarified. Likewise, an original policy on individual feedback, i.e. the non-feedback policy, was adequately clarified. Particularly, this policy has been clear since early in the development of UK Biobank.[131] It is also explicitly illustrated and clearly justified in the EGF, which is publicly accessible.[132] Indeed, this policy was notified to participants during recruitment through some of the recruitment documents.[133] Thus, it is arguable that **UK Biobank's policies on tangible reciprocation have been sufficiently clarified**.

As regards the pilot protocol on imaging enhancements, it would be unfair to make any comments on this protocol, since it was yet to be implemented properly in 2015.[134] This might justify why this protocol has not been properly communicated to participants: while the UK Biobank website section for participants and participant newsletters do explain imaging enhancements, they do not mention this protocol; only participants who attended UK Biobank participant meetings in Manchester could realise it;[135] however, this protocol is explained in other publicly accessible sources, i.e. EGC annual reports[136] and the website section for researchers. Nevertheless, it is worth mentioning that, while piloting this protocol, UK Biobank conducted one empirical study on participants who had consented and then undertook imaging assessments, which embodied this protocol, so as to determine their understanding of their consent to imaging assessments. Indeed, after the results of this study had revealed some misunderstandings about this protocol, UK Biobank agreed to pay more attention to this matter.[137] This incident suggests that UK Biobank gave importance to participants' understanding of this protocol by attempting to make this protocol clear to them. Based on this incident, it is likely that this protocol will be sufficiently clarified when being mainstreamed, and thereby this aspect of the governance tends to

[131] UK Biobank EGF v1 (2003), at 11-13.
[132] UK Biobank EGF v3 (2007), at 6-8.
[133] Consent Form (2006); Information Leaflet (2010), at 7.
[134] This pilot protocol was just endorsed at the end of 2015. See note 129 above.
[135] Presentations at UK Biobank's participant meetings did explain the pilot protocol, as is evident from the video clips of those presentations, which are available on the UK Biobank website. See UK Biobank Website (accessed on 4 February 2016).
[136] EGC Annual Report 2014, at 9-10; EGC Annual Report 2015, at 11-13.
[137] UK Biobank and the EGC agreed that more work is required to enhance participants' understanding of the unavailability of an opt-out option in this pilot protocol. See Report on 43rd EGC Meeting (June 2015), at 4; EGC Annual Report 2015, at 13.

conform to the Model. This tendency is also increased by UK Biobank's commitment to prepare notes that explain this protocol and the original non-feedback policy, particularly for participants.[138]

b) Negotiation over Policies

To make policies on tangible reciprocation negotiable, the Model requires biobankers to give participants opportunities to influence these policies by at least allowing them to voice their preferences on these policies and giving their preferences serious consideration.

As this requirement is fundamentally similar to the measures for applying the key attribute of collaboration,[139] the arguments and issues articulated regarding that key attribute are applicable here.[140] They can be described again, as follows. Participants have been provided with opportunities to voice their preferences about policies on tangible reciprocation through many meetings and the channels set up for general enquiries and feedback, both of which have been organised by UK Biobank and the EGC. Also, their preferences have a real chance of being influential because their input appears to be taken into account by UK Biobank, sometimes with the help of the EGC. One might therefore argue that, **in general, UK Biobank participants are allowed to negotiate about policies on tangible reciprocation**, although the governance of UK Biobank has not yet adopted any specific mechanisms for this negotiation. As also explained above, some issues might undermine this argument, since they raise the question of whether the EGC still helps to allow this negotiation by way of preventing participants' preferences on this matter from being disregarded. Nonetheless, these issues cannot be addressed in this chapter because there is insufficient information to do so.

Some might support this argument by citing introduction of the pilot protocol for PSIFs. Particularly, it is evident that participants have consistently voiced their preference for some feedback: despite being informed of the non-feedback policy

[138] EGC Annual Report 2014, at 13.
[139] See 3.3.1 b) (Negotiation over Policies) in ch 3 above.
[140] See 4.2.1 and 4.2.2 c) above.

during recruitment, they have kept asking for more feedback at almost all EGC public meetings,[141] and even during the public consultation on access procedures.[142] The fact that UK Biobank started piloting this protocol might lead some to assume that this piloting resulted from those voices and so UK Biobank's policies on tangible reciprocation are negotiable. While this assumption is reasonable, it is unclear from accessible documents whether this piloting actually originated from those voices. In particular, it is only revealed that the EGC was the body that started discussing the possibility of feeding back PSIFs from imaging assessments to participants, without any reference to participants' voices.[143] Indeed, although UK Biobank received participants' input about the impact of receiving PSIFs,[144] it seems that this input was used for testing the feasibility of this protocol, not allowing negotiation over it. It is therefore difficult to confirm that this introduction actually resulted from negotiation between participants and UK Biobank. Accordingly, this piloting should not be used to prove the negotiability of policies on tangible reciprocation within the governance. It is also notable that, in practice, this introduction might be informed by the trend towards the provision of individual feedback, as further explained below.[145]

4.3.3 Interim Conclusion

It can be concluded that, based on the Model, UK Biobank has provided participants with both intangible and tangible reciprocation. For the former, it can be considered to have given them commitments to pursue the goals shared with them and to provide sufficient safeguards for them, because its governance has mechanisms for informing them about these commitments, encouraging the fulfilment of these commitments, and enabling them to realise this fulfilment. For tangible reciprocation, UK Biobank has already clarified its policies on reimbursing travelling expenses and

[141] According to my research, participants (as attendees) voiced their need for more feedback at five out of six EGC public meetings arranged from 2005 to 2009 (no information is available for the EGC's public meeting in 2006), as well as at the UK Biobank participant meeting in 2014 (I attended this participant meeting).
[142] Report on Public Consultation on Draft Access Procedures (2011), at 11.
[143] Report on 14th EGC Meeting (March 2008), at 6-7.
[144] See 4.3.2 (second paragraph) above.
[145] See the conclusion of this chapter (last paragraph) below.

providing no individual feedback. Also, these policies seem to be negotiable when considering that, in general, participants are allowed to voice their preferences about these policies and their preferences may influence these policies. For example, when there are a number of participants voicing their preferences for other individual feedback at UK Biobank participant meetings, the EGC might – by realising these preferences – use them to advise UK Biobank on this matter. As UK Biobank has normally been responsive to the EGC's advice, it is possible for these preferences to bring about any changes to UK Biobank's policies on individual feedback. Thus, from a conceptual perspective, participants can be considered able to negotiate with UK Biobank about its policy on tangible reciprocation.

Given these explanations, it can therefore be argued that this aspect of the governance of UK Biobank generally conforms to the Model. What might undermine this conformity are issues revolving around the EGC's activities: there are some issues that can raise the question of whether, in practice, the EGC can play roles in (1) encouraging the fulfilment of those two commitments and (2) allowing negotiation over UK Biobank's policies on tangible reciprocation. Note that these issues are similar to those illustrated in the key attributes of emphasis on collective goals and collaboration, respectively. Also, it is noteworthy that the introduction of the pilot protocol for PSIFs should not be used to support the negotiability of policies on tangible reciprocation within the governance. The reason is that it is unclear from accessible documents whether this introduction actually stemmed from the preferences for individual feedback that participants have consistently expressed at many meetings and the public consultation on access procedures.

4.4 Control Sharing

According to the Model, the key attribute of control sharing aims to develop the ARR by sharing control over biobanking with participants. In practice, this key attribute requires biobankers to ensure that this sharing is contextually appropriate. Notably, the term control here refers to capability that participants have to make decisions about their relationship with biobankers at an individual level. In this respect,

it might not allow them to influence the overall direction of biobanking or biobanking activities that cannot be personalised.[146] Based on this premise, this section first identifies mechanisms in the governance of UK Biobank that give participants control over the governance at an individual level, and then determines whether the sharing of control within the governance can be considered appropriate. To carry out these two tasks, all documents that might reveal such mechanisms were reviewed. They include the EGF, which defines UK Biobank's relationship with participants, and other documents that outline the practical aspect of this relationship and the participatory mechanisms in the governance, such as EGC annual reports and reports on EGC internal meetings. This section has two sub-sections, each of which deals with one of these tasks. The tentative conclusion is that the control over biobanking that individual participants have within the governance mainly stems from their right of withdrawal and the level of this control can be considered low. However, control sharing within the governance can be deemed appropriate due to the existence of the EGC.

4.4.1 Control-sharing Mechanisms

> The Model (Chapter 3): Before determining the appropriateness of control sharing, biobankers need to take into account any mechanisms in biobank governance that might give participants control over biobanking at an individual level, such as the consent procedure, the right of withdrawal and meaningful involvement. The ways in which these mechanisms are implemented are also considered, since they help determine the extent to which these mechanisms provide individual participants with control over biobanking.

Based on the Model, all activities in the governance of UK Biobank were examined to identify mechanisms that enable individual participants to influence UK Biobank's activities. As a result of this examination, it can be said that **individual participants may influence UK Biobank's activities through two mechanisms**. One is broad consent, whereby they can limit the use of the Resources to the purpose of health-related research.[147] However, this mechanism gives them a low level of control over the governance because this purpose is quite broad, as further explained

[146] See 3.4 in ch 3 above.
[147] Consent Form (2006).

below. The other mechanism is the right of withdrawal, whereby individual participants have the options of (i) preventing UK Biobank from contacting them directly, (ii) forbidding such contact as well as further access to their health records in other databases, or (iii) forbidding such contact and access together with preventing researchers from using their samples and information afterwards.[148] It is evident from accessible documents that participants have been well informed of this right, as this right was repeatedly communicated through, inter alia, the recruitment documents[149] and EGC public meetings.[150] Also, the options and details of this right are explained in the EGF and on the UK Biobank website.

As regards meaningful involvement, discussions on this involvement can be separated into activities that can and cannot be personalised. For the former, there appear to be very few biobanking activities on which participants have been allowed to make decisions. Thus far, they were only allowed to decide whether to join the piloting about feeding back any PSIFs from imaging assessments; but, in 2015, this piloting was not implemented fully as a routine measure for feeding PSIFs back to participants yet.[151] Accordingly, this piloting cannot be used to discuss whether participants have control over the provision of this feedback within UK Biobank governance. As for non-personalised activities, there is no involvement mechanism in the governance that enables individual participants to directly influence these activities or the direction of UK Biobank's activities. The most likely way for participants to do so is to express their thoughts about certain activities to the EGC, whose advice might be informed by their input and has been well responded to by UK Biobank.[152] In this respect, those activities might be influenced by their thoughts, which are in the form

[148] UK Biobank EGF v3 (2007), at 9-10.
[149] Report of the Integrated Pilot Phase (2006), at para 4.3.4 and figure 4.4c.
[150] Report on EGC Public Meeting 2005, at 3; Report on EGC Public Meeting 2007 (December), at 15.
[151] See 4.3.2 (second paragraph) above.
[152] There is no concrete evidence confirming that this method will work in practice. However, it is likely to be the case according to the evidence that the EGC once based its advice for UK Biobank on participants' input that it had received at its public meeting, and UK Biobank was responsive to that advice. See 4.2.2 c) (third paragraph) above. Note that, although the Council no longer arranges its public meetings, participants still can give their input on this matter to it through its channels for general enquiries and feedback and, possibly, UK Biobank's participant meetings, which it has routinely attended. See 4.1.2 b) (Relationship with Participants) above.

of the EGC's advice. However, this way is far from effective in practice, especially when considering that participants' thoughts probably vary widely, let alone any conflicts between those thoughts. It can therefore be said that individual participants are unlikely to be able to influence UK Biobank's activities that cannot be personalised through meaningful involvement in the governance.

It can be concluded from these explanations that individual participants' control over UK Biobank governance mainly stems from their broad consent and right of withdrawal. It is worth noting the control that participants might have over the governance at a collective level. Particularly, it is evident that the issue of participant involvement was raised and discussed at academic conferences and EGC public meetings.[153] Notwithstanding, participants have been neither directly involved in making decisions about UK Biobank's activities nor included in any committees or working groups within the governance. Some participants were factually appointed as EGC members, who can influence UK Biobank's activities through the EGC's advice to UK Biobank; but this actually occurred by chance and those participants were not involved in the EGC in order to represent cohort participants.[154] Furthermore, while the EGF suggests some mechanisms that allow participants to influence UK Biobank's activities at a collective level, e.g. establishing a participant panel to voice participants' general views and proposing amending the EGF,[155] these mechanisms have not yet been put into practice. Thus, it can be said that participants do not have any control over the governance at a collective level.

[153] EGC Annual Report 2009, at 14.
[154] *Ibid*. Notably, this evidence is not used to argue for participant representation on UK Biobank's management bodies or the EGC; rather, it is used to explain that participants do actually not have control over biobanking at a collective level through this involvement.
[155] UK Biobank EGF v3 (2007), at 8, 19.

4.4.2 Appropriate Control Sharing

The Model (Chapter 3): Control over biobanking needs to be shared appropriately with participants. In doing so, it is suggested that, conceptually, the sharing of control should be able to express respectful gestures towards participants. There are neither mechanisms nor criteria proposed for implementing this suggestion, as this implementation should be contextual.

The previous sub-section explains that UK Biobank shares control over its governance with individual participants through broad consent and the right of withdrawal. A subsequent question arises as to whether or not this sharing can be considered appropriate – i.e. whether it can express respectful gestures towards participants. As there has been no qualitative study that directly answers this question, this sub-section addresses the question by first determining the level of control that individual participants actually have over UK Biobank governance as a result of those two control-sharing mechanisms. It then determines whether or not this level of control can be considered respectful towards participants by considering circumstantial factors that might affect their desire to influence UK Biobank's activities. These two steps are dealt with separately in two different sub-sub-sections, as follows.

a) Actual Level of Control

Between broad consent and the right of withdrawal, one can say that the latter is a main source of individual participants' control over UK Biobank governance. The reason is that, in practice, the former does not provide a high level of this control: it restricts uses of the Resources to the purpose of supporting research studies 'intended to improve the prevention, diagnosis and treatment of illness, and the promotion of health throughout society';[156] this purpose encompasses a diverse range of studies, and thus this consent does not impose stringent restrictions on such uses. By contrast, the right of withdrawal can be considered to give individual participants a high level of this control from their perspective, due to CBP and the withdrawal options offered. In particular, UK Biobank has so many channels for CBP that they can keep up-to-date

[156] Consent Form (2006).

with its activities properly, as illustrated above,[157] and thus they can exercise this right effectively since they know exactly whether and when to do so. Furthermore, this right not only enables them to withdraw their participation in UK Biobank, but also allows them to prohibit certain biobanking activities, namely direct contact with them and access to their health records in other databases, without leaving UK Biobank. Given this explanation, it can be said that the right of withdrawal in the governance can be considered to give participants substantial control over the governance at an individual level. It is therefore arguable that **this right is deemed to be a mechanism that essentially gives individual participants control over the governance**.

b) Circumstantial Appropriateness

Based on accessible documents, there seems to be one important factor that is likely to lead participants to need control over UK Biobank governance, i.e. the possibility of commercial use.[158] In general, commercial use of biobank resources can be considered controversial and, undoubtedly, many empirical studies have revealed widespread scepticism over such use.[159] Based on this premise, one can assume that participants in UK Biobank may need more control over uses of the Resources. One reason is that, while they were informed of this possibility, they did not know how the Resources would actually be used during recruitment. Also, prospective aspects of these uses are not clearly explained in the recruitment documents: the consent form does not provide much detail about prospective uses of the Resources; in two information leaflets provided during recruitment, prospective uses of the Resources are only explained by citing a few illnesses that might involve using the Resources.[160] For these reasons, it is difficult to conclude that participants already had a clear understanding of possible commercial uses. While this amount of explanation can be justified by the use of broad consent in the governance, individual participants might need to make decisions about uses of the Resources on a case-by-case basis, especially

[157] See 4.1.2 a) above. Note that some of channels for CBP, such as EGC annual reports and reports on EGC internal meetings, even provide in-depth information about UK Biobank's activities.
[158] See 4.1.1 (second last paragraph) above.
[159] See 6.4.3 a) in ch 6 below.
[160] Consent Form (2006); Information Leaflet (2010), at 2; Further Information Leaflet (2009), at 4.

given the aforesaid scepticism. Because the right of withdrawal in the governance – a main source of their control over the governance – does not enable them to do so, they are likely to need more control over the governance.

Notwithstanding, this need is likely to be obviated by another circumstantial factor, i.e. the existence of the EGC. In particular, the EGC has properly performed its role in terms of critically monitoring UK Biobank's activities and promoting the interests of participants by, inter alia, encouraging UK Biobank to respect their consent and to provide sufficient safeguards for them.[161] Indeed, it is also evident that, in practice, the Council attempted to retain its ability to perform this role. This attempt is inferred from the fact that the EGC was critical of some of the 2015 Panel's recommendations that could limit such an ability, e.g. reducing its membership and decreasing the frequency of its internal meetings.[162] Thus, it is possible for participants to trust the Council to oversee uses of the Resources and prevent those they find undesirable. One might therefore say that the work of the EGC can fulfil their need for more control over uses of the Resources.

To conclude this sub-sub-section, it can be assumed from these two circumstantial factors that, in spite of the possibility of commercial use, the existence of the EGC potentially makes the control sharing in the governance, which mainly stems from the right of withdrawal, suffice to show respect to participants. It is therefore arguable that, according to the Model, **the sharing of control in the governance can be considered appropriate**, thereby making this aspect of the governance conform to the Model.

4.4.3 Interim Conclusion

In UK Biobank governance, control over the governance is shared with individual participants mainly through the right of withdrawal. The reason is that, while broad consent does not provide them with much of this control, this right can be

[161] See Box 4.1, 4.1.2 b) and 4.3.1 a) above.
[162] Report on 44th EGC Meeting (September 2015), at Annex A (EGC Response to the Report of the Expert Review Panel).

considered to give them a high level of it: the governance has so many CBP channels that they can exercise this right effectively; also, this right allows them to prevent some UK Biobank's activities, such as accessing their health records in other databases or using their samples and information in future research studies. Indeed, this sharing can arguably be considered appropriate according to the Model. Particularly, although the possibility of commercial use might make individual participants desire more control over uses of the Resources, the EGC's oversight activities might obviate this desire. Accordingly, one can say that UK Biobank participants are likely to feel satisfied with the level of control that they have as a result of merely their right of withdrawal, thereby allowing control sharing in the governance of UK Biobank to be considered respectful towards them. It is therefore arguable that, according to the Model, this sharing can be deemed appropriate, and thus this aspect of the governance can be considered to conform to the Model.

It is notable that, as the EGC plays an essential role in this conformity, some recommendations from the 2015 Panel might change this argument because they might change the EGC's role within the governance. However, at the time of writing, it is still unclear whether and how these recommendations are to be acted on.

Conclusion

This chapter has argued that the governance of UK Biobank essentially conforms to the Model. A crucial factor contributing to this conformity is the work of the EGC. In general, the EGC works closely with UK Biobank to monitor UK Biobank's activities critically and reflect on the acceptability of these activities from the perspectives of participants and the public. It also keeps participants informed about those activities and establishes other communication channels that allow them to provide their input on biobanking. In terms of the Model, the EGC helps considerably in making the governance conform to the Model, since it makes the governance embody all the key attributes of the Model, as follows. To emphasise collective goals, the EGC can help reinforce collectiveness in biobanking goals by resisting biobanking activities that deviate from the goals agreed with participants. It

facilitates collaboration by receiving participants' input and helping prevent their input from being disregarded by UK Biobank. In terms of reciprocation, it helps encourage UK Biobank to fulfil commitments to pursue collective goals and to provide participant safeguards, and also helps render policies on tangible reciprocation negotiable in general. Finally, its work can be assumed to render the control sharing within the governance appropriate by obviating participants' need for more control over the governance. One can therefore argue that the EGC plays a crucial role in fostering the ARR in the governance. Notwithstanding, there are a number of issues that might raise the question of whether the governance really conforms to the Model at present, as consistently noted throughout this chapter. Because to discuss these issues would call for more in-depth information, which is not currently accessible, they cannot be confirmed and addressed here.

Possible Changes after 2015

It is worth mentioning recommendations from the 2015 Panel here, as they lead to some changes that might render UK Biobank governance more conformable to the Model. One possible change is the way in which UK Biobank generally responds to the EGC's advice: UK Biobank should seriously consider such advice and clearly indicate whether or not such advice is to be acted on.[163] While UK Biobank has been responsive to the EGC's advice in practice,[164] this change could ensure and certify this responsiveness, thereby making the governance conform better to the Model. For example, this change could reinforce the Model's key attribute of collaboration by preventing participants' input, which the EGC may use to inform its advice to UK Biobank, from being neglected by UK Biobank. Also, as it allows the EGC to better encourage UK Biobank to pursue collective goals and provide participant safeguards, it could reinforce the Model's key attributes of emphasis on collective goals and reciprocation.[165] Another possible change concerns the possibility of an AGM.[166] As this meeting has the aim of formal public reporting, discussion and future planning, it could be another channel for CBP, which is crucial for applying some key attributes

[163] Review of the EGC 2015, at 7 (Recommendation 6).
[164] See 4.2.2 c) (third paragraph) above.
[165] See 4.1.2 b) (Relationship with UK Biobank) and 4.3.1 a) above.
[166] Review of the EGC 2015, at 8 (Recommendation 7).

of the Model.[167] Its aims also suggest that participants could use it as another channel for providing their input, and thus it could help achieve the Model's key attributes that call for allowing participants' input or learning about participants, such as the key attributes of collaboration, emphasis on collective goals and reciprocation.[168]

However, the recommendation for an AGM ironically raises some concerns as well. In particular, the term 'annual general meeting' gives the same impression as general meetings that are arranged within corporate governance, and thereby raises many concerns. In general, this term raises a concern as to whether an AGM would lead many people to perceive UK Biobank to be excessively commercially orientated. More importantly, this term might also introduce corporate governance methods into the governance of UK Biobank. This is similar to Winickoff's proposal, which argues for a shareholder model in UK Biobank: his proposal adopts decision-making procedures that are similar to those used in corporate general meetings, as the way to represent a participant collective in UK Biobank governance.[169] As these procedures might in practice lead some participants to be represented by others, they potentially raise a concern about the issue of representation, which is not desirable for the ARR.[170] From a practical perspective, these procedures also raise concerns about whether UK Biobank plans to grant a participant collective control over its governance, or whether it intends to use an AGM merely to seek tokenistic approval of its activities. Given all these concerns, it is questionable as to what reasons are actually behind this recommendation.[171] Notably this recommendation was not put into practice in 2015.[172]

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[167] See 4.1.2 a), 4.2.2 b) and 4.3.1 b) above.
[168] See 4.1.2 b) (Relationship with Participants), 4.2.1, 4.3.1 a) and 4.3.2 b) above.
[169] DE Winickoff, "Partnership in U.K. Biobank: A Third Way for Genomic Property?" (2007) 35 *The Journal of Law, Medicine & Ethics* 3 440-456, at 449.
[170] See 6.3.1 in ch 6 below.
[171] Notably, Hunter and Laurie argue against applying Winickoff's shareholder model to the context of UK Biobank elsewhere. See KG Hunter and GT Laurie, "Involving Publics in Biobank Governance: Moving beyond Existing Approaches" in H Widdows and C Mullen (eds), *The Governance of Genetic Information*, (Cambridge: Cambridge University Press, 2009) 151-200.
[172] At the time of writing, it is evident from the UK Biobank website that the first AGM was arranged in London on 13 June 2016.

Furthermore, there are some concerns caused by the understanding of the 2015 Panel that it is not appropriate for the EGC to engage directly with participants.[173] Particularly, this understanding raises doubts about whether, in the future, there will be any changes in UK Biobank governance that hinder the EGC from reaching participants. This hindrance could impair some of the EGC's abilities that make the governance conform to the Model, e.g. the ability to realise participants' thoughts about collective goals and the sufficiency of participant safeguards[174] and the ability to receive their input about the governance and take it into UK Biobank's consideration.[175] These abilities might even be more limited by the recommendation from the 2015 Panel that the EGC should reduce its operational scale by, inter alia, reducing its membership and decreasing the work appointment for its secretariat.[176] Indeed, this reduction additionally raises the question of whether the EGC's work will still be sufficiently effective for, as explained in the first paragraph of this conclusion, making the governance conform to the Model or helping develop the ARR in the governance. It is therefore possible that the governance will be less conformable to the Model after 2015.

Given all of these possible changes and concerns, it can be said that the arguments in this chapter might not be applicable to the governance after 2015. Note that, while these changes and concerns cannot be confirmed in 2015, they are explained here so as to show how to apply the Model by demonstrating how the Model responds to the review of the 2015 Panel.

Limitations on the Discussions

It is important to note again that discussions in this chapter are purely based on information in publicly-accessible documents.[177] This implies that other incidents

[173] Review of the EGC 2015, at 7; EGC Annual Report 2015, at 18 (Box 17).
[174] See 4.1.2 b) (Relationship with Participants) and 4.3.1 a) above.
[175] See 4.2.2 c) and 4.3.2 b) above.
[176] Review of the EGC 2015, at 9-10; Report on 44th EGC Meeting (September 2015), at Annex A.
[177] Only one non-published document is used for improving the factual accuracy of discussions in this chapter, namely UK Biobank Communication Plans, which Andrew Trehearne prepared for the EGC in 2011. Note that this document was provided by him with his knowledge that it would be used in this thesis

that are not reported in such documents are excluded from these discussions, although they might actually relate to or even inform these discussions. This also implies that these discussions stem from my own interpretations of such documents, which might admittedly not agree with the reality. These discussions may be deemed sanitised in this respect. An example is the introduction of the pilot protocol for the feedback of PSIFs from imaging assessments.[178] In particular, while accessible documents might lead some to assume that this introduction is informed by the EGC and/or participants' feedback,[179] it is possible that this introduction might be purely or additionally influenced by the recent trend towards the provision of individual feedback. This trend is pointed out by some authors, such as Widdows[180] and Wolf,[181] and is also supported by the recent literature that seeks to pursue a feasible way to provide individual feedback.[182] Given this example, it can be said that the arguments in this chapter might change if information from other sources, such as interviews with participants and UK Biobank staff, is available and taken into consideration as well. However, this does not diminish the value of this chapter since it has the primary aim of demonstrating how to apply the Model in practice, not to make critical arguments concerning or to conduct an evaluation of UK Biobank governance.

[178] See 4.3.2 (second paragraph) above.
[179] See 4.3.2 b) (last paragraph) above.
[180] H Widdows and S Cordell, "The Ethics of Biobanking: Key Issues and Controversies" (2011) 19 *Health Care Analysis* 3 207-219, at 215.
[181] SM Wolf, "Return of Individual Research Results & Incidental Findings: Facing the Challenges of Translational Science" (2013) 14 *Annual Review of Genomics and Human Genetics* 557-577.
[182] SM Wolf et al, "Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets" (2012) 14 *Genetics in Medicine* 4 361-384; LM Beskow and W Burke, "Offering Individual Genetic Research Results: Context Matters" (2010) 2 *Science Translational Medicine* 38 available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3136874/ (accessed on 10 June 2016); I Budin-Ljøsne et al, "Feedback of Individual Genetic Results to Research Participants: Is It Feasible in Europe?" (2016) 14 *Biopreservation and Biobanking* 3 241-248.

Chapter 5

Partnership Model and ALSPAC[1]

The first three chapters have outlined the main proposals of this thesis, which concern a participant-biobanker relationship that can deal with issues and challenges arising in biobanking practices. This thesis considers such a relationship as an authentic research relationship in biobanking ("**an ARR**") and it seeks to propose one approach to an ARR that is based on partnership ("**the ARR**"). These proposals include (i) the fundamental notion of the ARR, which is in the form of its main characteristics, (ii) its conceptual framework, which consists of its five key features that are considered to exhibit its main characteristics, and (iii) the partnership model for biobank governance that is used to develop it in practice ("**the Model**"). With the aim of demonstrating how to put the Model into practice, the previous chapter has tested it against UK Biobank. This chapter is to test it against the Avon Longitudinal Study of Parents and Children (**ALSPAC**), which seems to treat participants as partners (similarly to UK Biobank) but has a different governance structure. To facilitate understanding of the discussions in this chapter, general information about ALSPAC is summarised in Box 5.1 below.

Box 5.1: General information about ALSPAC[2]

Objectives

- ALSPAC is a longitudinal research project aiming to create resources for health-related research that help understand the ways in which physical and social environments interact over time with genetic inheritance to affect health, behaviour and development in infancy, childhood and then into adulthood.

[1] Appendix 2 lists materials that were accessed and reviewed to set up the discussions and develop the arguments in this chapter. It also demonstrates how the titles of these materials are simplified when being used as references in the discussions and footnotes here.
[2] These explanations are based on publicly-accessible documents, such as the recruitment documents, annual reports and the ALSPAC website.

- The main goal of ALSPAC is to help discover the causes of the most important health and social problems facing the world today, so that those problems can be prevented.

Cohort

- More than 14,000 pregnant women with estimated delivery dates between April 1991 and December 1992 were originally recruited.
- These women (**study mothers**) and the children resulting from their pregnancies (**study children, CO90s**) have been followed up intensively for more than two decades, and comprehensive and detailed data have been collected throughout the lives of the children.
- In the last few years, the mothers' partners (**study fathers**), the CO90s' children (**COCO90s**), the CO90s' siblings and the CO90s' grandparents have been enrolled in this project to generate health information covering four generations.

Governance Structure

- ALSPAC is governed by multiple bodies. They include as follows:
  - ALSPAC Executive Committee
  - ALSPAC Independent Scientific Advisory Board
  - ALSPAC Steering Group
  - ALSPAC Ethics and Law Committee
- The remits of these bodies are explained in **Box 5.2**.

Relationship with Participants

- Data collection: Data have been collected by self-administered questionnaires, data extraction from medical notes, linkage to routine information systems and measurements at the research clinics that participants have been invited to attend regularly.
- Active involvement: Participants can be involved in biobanking activities through many mechanisms, such as being members of the Original Cohort Advisory Panel (**OCAP**)[3] or the COCO90s Advisory Panel, joining online parent

[3] The OCAP is the group of study children (CO90s) that was established to help ALSPAC in making decisions about some issues affecting ALSPAC's activities. This panel is representative of the CO90s cohort in terms of age, gender and social class. Its members came from selection of study children who volunteered to be part of this panel. At present, it is a group of 23 participants who meet six times a year and receive no payment for being part of it. Notably, it was first set up in 2006 as the Teenage Advisory Panel (TAP). Because of its members becoming adults, it had become the Young Adult Advisory Panel before it was renamed to the OCAP. In practice, when compared with the TAP, the OCAP is more self-governing and gets less support, in the form of facilitation and advice, from ALSPAC's staff. See Annual Report 2009, appx 1; Annual Report 2011-12, at 1. The detail about the OCAP's activities is further explained below. See 5.2.1 (Regular Mechanisms) below.

advisory forums, attending attrition away days and working with biobankers in some working groups. A Research Partners scheme was introduced to involve participants in designing and making decisions about respective studies.

- Communication: Other than the aforesaid participatory mechanisms, ALSPAC generally communicates with participants through participant newsletters and online media, namely the ALSPAC website, online forums and social networks. Some public events were also organised to communicate with participants.[4]

As for the reason for selecting ALSPAC to test the Model, it is claimed that ALSPAC has attempted to treat its participants 'as partners, rather than merely subjects'.[5] Thus, it is intriguing to know whether or not a participant-biobanker relationship in ALSPAC is comparable to the ARR. On the other hand, ALSPAC has many distinctive characteristics that make it heavily reliant upon the quality of a participant-biobanker relationship. For example, ALSPAC has existed for more than two decades, and so far it has involved four generations of certain families, thus highlighting the need for continuity in this relationship. Also, ALSPAC collects various types of information, including family histories and criminal records, and thus its participants are prone to risks to their privacy and confidentiality. As the Model aims to develop the ARR – which is intended to deal with these characteristics – testing it against ALSPAC could show how well the quality of a participant-biobanker relationship in ALSPAC has been maintained, and could suggest how to maintain the viability of ALSPAC.[6] Accordingly, this testing could arguably not only be an example

[4] The term 'communication' in this chapter refers to any mechanisms set up to transfer or exchange information between relevant parties, whether one way or two ways. Thus, this term ranges from the transfer of information through newsletters and websites, to information exchanged through dialogues and discussions. Involvement mechanisms can therefore be considered to be one approach to this communication. The difference is that communication focuses on the transfer of information while involvement mechanisms focus on the act of taking part.

[5] SE Mumford, "Children of the 90s: Ethical Guidance for a Longitudinal Study" (1999) 81 *Archives of Disease in Childhood - Fetal and Neonatal Edition* 2 F146-F151, at F147.

[6] As established in Chapter 1, one main characteristic of the ARR is the ability to deal with the distinctive characteristics of biobanking that raise issues and challenges in biobanking practice. See 1.4.1 in ch 1 above.

of how to put the Model into practice, but also demonstrate whether and how the Model could contribute to ALSPAC governance.

This chapter consists of four sections, each of which deals with a key attribute of the Model, namely emphasis on collective goals, collaboration, reciprocation and control sharing. The structure within these sections is the same order as that of the explanations about the practical application of these key attributes in Chapter 3.

Three points are noteworthy here. First, similarly to the previous chapter, discussions in this chapter are based on documentary research that examines the governance of ALSPAC through publicly accessible sources, such as websites, annual reports and newsletters, as opposed to personal correspondence and interviews. This suggests that the picture of the governance painted here is purely based on my own interpretation of these sources, which might not depict the reality of the governance. Second, information about many aspects of the governance is not available in those sources, as occasionally noted below, and information about ALSPAC's activities before 2000 is barely accessible. These limitations do noticeably undermine the depth of many discussions and the strength of many arguments in this chapter. Indeed, they also render these discussions unable to reflect the real picture of the governance and a participant-biobanker relationship therein. Thus, from a practical perspective, they may detract from the usefulness of these discussions and arguments. Finally, the notion underlying these discussions and arguments is that the governance is dynamic and has a mutual learning strategy as its core practice. Thus, the arguments here are basically intended to make constructive suggestions, rather than 'right or wrong' judgements.

As a tentative conclusion, ALSPAC governance largely conforms to the Model, mainly because it has many mechanisms for communicating regularly with participants. It also has many involvement mechanisms, which can conform well to the Model's key attribute of collaboration, but it is unclear whether these mechanisms actually suffer from the issue of representation, which is not desirable for the ARR. Nonetheless, the lack of detailed information about some ALSPAC's activities prevents this chapter from conducting an in-depth discussion and reaching a firm conclusion regarding many respects of the governance, as well as confirming the greater extent of this conformity. Despite this situation, this chapter is still useful for

this thesis. This is because the main aim of this chapter is to demonstrate the ways in which the Model is applied in practice, as mentioned above, and this chapter can achieve this aim by explaining what respects of the governance are of interest for the Model and how they affect conformity to the Model, as well as pinpointing issues that might arise within the governance from the perspective of the Model.

5.1 Emphasis on Collective Goals

As explained in Chapter 3, the key attribute of emphasis on collective goals requires participants and biobankers to share the same biobanking goals throughout biobanking endeavours. To achieve this, there must be measures to (1) clarify biobanking goals and (2) reinforce the collectiveness in biobanking goals between participants and biobankers.[7] Based on this premise, this section determines whether any of ALSPAC's activities can be equated with these two measures. As for the structure of this section, these two measures are dealt with separately in two sub-sections. At first glance, the governance of ALSPAC has many mechanisms for communicating with participants, thereby making the governance conform to the Model to some extent. However, it is unclear whether, according to the Model, collectiveness in biobanking goals can properly be reinforced within the governance because the available information is not adequate to confirm that biobanking activities which are not in line with collective goals will be inhibited.

5.1.1 Clarification of Biobanking Goals

The Model (Chapter 3): The measure to clarify biobanking goals generally involves the communicative mechanisms during recruitment that aim to make biobanking goals clear to participants. It is suggested conceptually that the focus of this measure should be on methods, as opposed to consequences, and thereby the quality of this communication is an important consideration. In practice, there should be evidence of biobankers' attempts to facilitate participants' understanding of biobanking goals, as opposed to evidence of sufficiency in such understanding.

[7] See 3.1 in ch 3 above.

For ALSPAC, the measure for clarifying biobanking goals is particularly important because, ever since its inception, part of its participant cohort is children, who probably lack the capability to understand biobanking goals. Also, there are many studies revealing that, in general, participants usually have misunderstandings about some aspects of biobanking[8] and some of them might not read information offered to them.[9] To find out whether ALSPAC's goals are clarified, documents that show how the goals were communicated to participants and how such communication is handled by ALSPAC were examined. These documents include the recruitment documents, i.e. the consent form and two information booklets, and other documents that explain ALSPAC's communicative activities, e.g. annual reports and participant newsletters. After examining these documents, it can be argued that ALSPAC's goals are sufficiently clarified. The reason is that, while the goals are basically broad and generic and thereby do not contain detailed or complicated information, there is evidence of ALSPAC's attempt to facilitate participants' understanding of the goals. This evidence is based on (i) communication with participants during recruitment and (ii) some involvement mechanisms, which can be explained separately, as follows.

Communication at Recruitment

During the recruitment stage, there were many documents explaining ALSPAC's goals to participants. One notable example is the detailed information booklet, which not only explains the goals but also provides other information that could enhance understanding of the goals, such as examples of research studies completed and in progress, the uniqueness of ALSPAC and the direction of ALSPAC's activities.[10] Participant newsletters[11] also indirectly explain the goals by illustrating

[8] See note 32 in ch 4 above.
[9] See note 33 in ch 4 above.
[10] Detailed Information Booklet (2014). Notably, the consent form does, per se, not clearly explain ALSPAC's goals but, during recruitment, participants also received the detailed information booklet, which provides detailed information about those goals. It should also be noted that all these recruitment documents, on which this discussion is based, are dated 2014. In this respect, this discussion might not be applicable to recruitment documents that were previously used before that year.
[11] ALSPAC has recruited different generations at different times, and thereby previous newsletters might be used to inform recent recruits about its goals and direction.

retrospective and prospective uses of ALSPAC's resources ("**the Resources**"), as well as explaining how certain measurements and data collections relate to those uses.

More importantly, the ways in which information in these documents is illustrated can arguably facilitate participants' understanding of the goals. Particularly, the language in these documents is perceptibly simple and their artwork design is clean and readable.[12] There is even a guidelines document that was produced, by the OCAP, to ensure that information sent to participants is presented in a user-friendly manner whilst still including all relevant content.[13] Also, many key issues that can promote such understanding are repeated, such as the aims of ALSPAC and the absence of commercial involvement. ALSPAC even issued participant newsletters separately for adult and young participants, with differences in language and content.[14]

Given these explanations, one can say that ALSPAC has attempted to facilitate participants' understanding of its goals by providing them with information that helps them understand its goals and making this information comprehensible to them. It is therefore arguable that ALSPAC has already clarified its goals.

Involvement Mechanisms

The aforesaid attempt can also be found in some mechanisms that involve participants in improving the communication between ALSPAC and participants. As an example, the OCAP collaborated with the newsletter editor in developing the content and design of some newsletters.[15] Some study fathers were involved in developing a qualitative study that interviewed study fathers with the aim of, inter alia,

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[12] According to accessible information, there is no Crystal Mark certifying that the language is 'plain English'. This claim is based on my own perception, which stems from the difference between the content of participant newsletters issued before 2010 and of documents that were issued recently, including the recruitment documents (2014) and participant newsletters issued after 2010.

[13] YoungHealthParticipation, "Involving Children and Young People in Research – PRWE Forum" (11 December 2013) available at https://younghealthparticipation.com/page/2/ (accessed 20 June 2016).

[14] It should be noted that, since 2013, ALSPAC has issued one participant newsletter per year but each newsletter is divided into sections that provide information and updates about ALSPAC's activities for different cohort groups.

[15] Annual Report 2009, at 1.

identifying information required to make informed decisions.[16] One study father joined the working group for the Fathers' study in order to advise about recruitment.[17] As these mechanisms basically aim to increase the effectiveness of communicating information about ALSPAC to participants, they can be assumed to serve as an important indicator of the attempts to improve participants' understanding of ALSPAC, including its goals. Nonetheless, it is difficult to fully accept this assumption, since accessible information about these mechanisms is limited. Particularly, there are no details about whether or not such understanding is actually part of what those mechanisms seek to achieve. Indeed, their actual purposes are also unclear from accessible sources.[18] Without these details, it is questionable whether, in practice, these mechanisms were actually implemented for improving participants' understanding of ALSPAC's goals.

In addition to the evidence of ALSPAC trying to facilitate participants' understanding of its goals, it can also be argued that, as far as study children are concerned, ALSPAC has mechanisms that helped make its goals clear to them when seeking their (re)consent to participation in it. Particularly, it is evident that its governance has ongoing communication that enables study children, who were originally recruited on the basis of their parents' consent, to have a better understanding of its goals during their childhood: as explained below, its governance has communication about its biobanking progress that allows participants to always keep up-to-date with its activities,[19] and it also provides participants with sufficient access to information about its background;[20] information about its background and biobanking activities can be considered to help participants to better understand its goals during the course of biobanking; indeed, this ongoing communication includes consistently sending newsletters to all participants and, as explained above, the content

[16] Annual Report 2011-12, at 4.
[17] Annual Report 2011-12, at 4.
[18] The establishment of the OCAP was one of two key mechanisms that were introduced for improving the participation rate of study children. See Annual Report 2006, at 2. It might be assumed that this was also the case for the involvement of study fathers in ALSPAC governance, because the participation rates of both cohort groups were low. See Annual Report 2008, at 3; Annual Report 2011-12, at 3, 4.
[19] See 5.1.2 a) below.
[20] See 5.2.2 b) below.

of these newsletters is easily comprehensible to participants. Given this ongoing communication, it is reasonable to believe that, when study children became young adults and gave (re)consent to participation on their own behalf, ALSPAC's goals were sufficiently clarified from their perspective. It is therefore arguable that ALSPAC has mechanisms that helped clarify its goals when it sought (re)consent to participation from study children.

Given these explanations, it is therefore arguable that, in general, **ALSPAC has sufficiently clarified its goals**. This is because it is evident from communication at recruitment that ALSPAC has attempted to facilitate participants' understanding of its goals. This attempt might also be assumed when considering certain involvement mechanisms within its governance, although more information is required to test this assumption. Also, its governance has ongoing communication that could help make its goals clear to study children when it sought their (re)consent to participation.

Notably, one interview study also, at first, seems to show such attempt.[21] This study is part of a project that has a goal to improve the general understanding of ethical issues in epidemiological research, namely the Ethical Protection in Epidemiological Genetic research.[22] The aim of this study is to learn about study children's perceptions of their participation in ALSPAC. During the course of this study, some of study children were asked about ALSPAC, including its overall purpose. So, the results of this study might be used to give more insights into how study children generally understood ALSPAC's goals and to inform any mechanisms for improving their understanding of these goals. However, nothing in accessible documents indicates that the study results had such a use, and thus the conduct of this study cannot be used to support this argument.

[21] T Goodenough et al, "Ethical Protection in Research: Including Children in the Debate" in M Smyth and E Williamson (eds), *Researchers and Their Subjects: Ethics, Power Knowledge and Consent*, (Bristol: The Plicy Press, 2004) 55-72.
[22] Centre for Ethics in Medicine (Unversity of Bristol), "EPEG Project" (October 2000 - September 2003) available at http://www.bris.ac.uk/Depts//Ethics/CEM/epeg.htm (accessed 5 January 2015).

5.1.2 Reinforcement of Collectiveness in Goals

> The Model (Chapter 3): This measure aims to encourage participants and biobankers to share the same biobanking goals throughout biobanking endeavours. The reinforcing mechanisms need to have two crucial elements: ongoing oversight of biobanking activities and discouragement of any deviations from collective goals.

In light of this explanation, the governance of ALSPAC was examined to find any mechanisms that might be used to implement this reinforcing measure. In doing so, all publicly accessible documents were reviewed in order to find out how information about ALSPAC's activities has been communicated between different stakeholders – i.e. participants, biobankers and, if any, oversight bodies – and how these stakeholders can deal with undesirable activities within the governance, if at all. These documents include participant newsletters, annual reports and the terms of reference for different entities in the governance. This examination reveals that the governance has mechanisms for tackling the changes to participants' goals that deviate from collective goals, but it is unclear whether it has measures for dealing with the changes to biobankers' goals that deviate from collective goals. This can be illustrated separately, according to these two different changes, as follows.

a) Changes to Participants' Goals

As suggested in the Model, two mechanisms – namely communication about biobanking progress ("**CBP**") and the right of withdrawal – should be available to participants to reinforce collectiveness in biobanking goals. The former enables them to recognise collective goals through information on biobanking activities, and the latter allows them, by themselves, to impede deviations of their own goals from collective goals.

For ALSPAC, these two mechanisms are both available in its governance. Particularly, participants have the right to withdraw their consent at any time without giving any reason.[23] Indeed, they have been well informed of this right through many

[23] Policy on Withdrawal (2011).

documents – such as the consent form and the information booklets – and these documents as well as a policy document on this matter are also available on the ALSPAC website.[24] In terms of CBP, participants have many opportunities to keep themselves up-to-date with ALSPAC's activities, including how the Resources are used, through many communication channels, as follows.

Participant newsletters can be deemed to be a main channel for CBP, since they are sent individually to participants on a regular basis and are also downloadable from the ALSPAC website. In terms of content, they explain how the Resources have been and will be used in research studies, including what knowledge was derived and will be sought from such uses, how useful participants' contributions are for research studies, and who use the Resources. They also illustrate other biobanking activities, ranging from research-related activities (e.g. progress in recruitment, research studies in progress, and diseases of current and future focus) to management activities (e.g. funding and staff recruitment). The **ALSPAC website** is another CBP channel. This website itself provides background information about ALSPAC as well as updates on its activities, including cohort groups, biobank management, the results of research studies using the Resources. There are also many documents that are available on this website, such as policy documents, annual reports on management activities and scientific publications – the latter provide details on actual uses of the Resources. In addition to these communication channels, there have also been many **involvement mechanisms** that have allowed participants to be updated on ALSPAC's activities and related research findings. These mechanisms are in the form of online communities (i.e. online advisory forums and a Facebook group page) and public events (namely ResearchFest (2012) and the First 21 Years Conference (2012)).

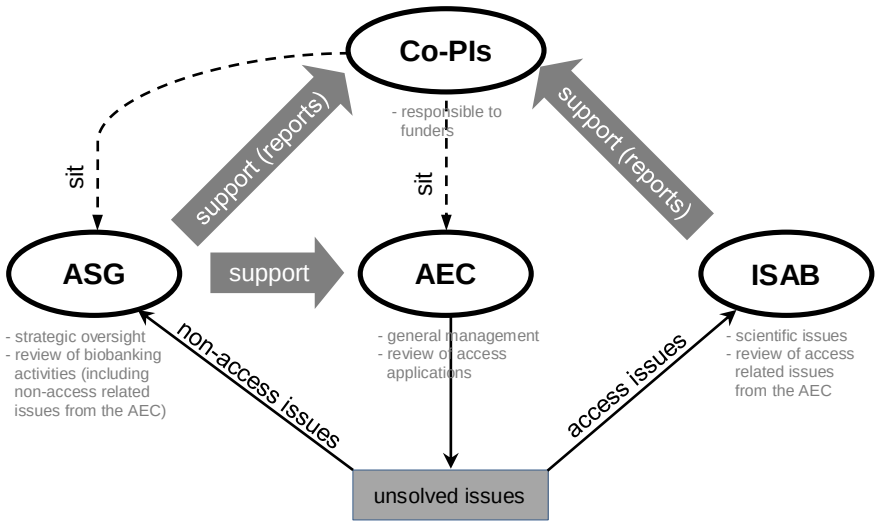
Given all these channels for CBP, it can be said that ALSPAC participants can monitor ALSPAC's activities and progress continuously. Thus, they – by taking into account ALSPAC's activities – are able to identify actual ALSPAC's goals and any changes thereto throughout biobanking endeavours. Indeed, with their right of

[24] According to my research, it is evident that participants have been repeatedly informed about their right of withdrawal through the recruitment documents and many participant newsletters. Indeed, a policy document on this matter is publicly accessible as well.

withdrawal, they are also allowed to withdraw their consent at any time if they find any discrepancies between identified goals and their own biobanking goals. When considering CBP and the right of withdrawal within the governance of ALSPAC, one can say that participants are able to impede the changes to their own goals that deviate from ALSPAC's goals, which are considered to be collective goals in this situation. It is therefore arguable that **the governance has mechanisms that can impede any deviations of participants' goals from collective goals**, and thereby this aspect of the governance conforms to the Model.

b) Changes to Biobankers' Goals

Box 5.2: Governing bodies in ALSPAC governance



- ALSPAC Executive Committee (**AEC**): The AEC generally manages all biobanking activities relating to research studies, including approving requests to access the Resources. It also ensures that biobanking activities are in accordance with any regulatory and ethical requirements, as well as strategic plans developed by the ASG. If any issues arise, it will refer access and non-access related cases to the ISAB and the ASG, respectively.
- ALSPAC Independent Scientific Advisory Board (**ISAB**): The ISAB is a group of scientists who have a role in dealing with any scientific issues, such as providing scientific advice and evaluating scientific output and contributions. It

also reviews access-related cases referred on by the AEC. With the expression 'independent', its certain members will be excluded when considering issues that create conflicts of interests with these members. Reports on the ISAB's meetings are produced for the Co-PIs, the ASG and the funders.

- ALSPAC Steering Group (**ASG**): The main role of the ASG is to provide strategic oversight and to review all activities in the governance, including how participant safeguards are provided and how complaints from participants are handled. It also supports the Co-PI's and the AEC's work regarding research studies, and resolves non-access related issues referred on by the AEC.
- ALSPAC Law and Ethics Committee (**ALEC**): The ALEC comprises clinicians, researchers, people with legal expertise and lay people, including participants. This committee has the aim of providing ethical oversight of ALSPAC as a whole. In practice, it plays a main role in protecting participants' interests by, inter alia, dealing with any legal and ethical issues arising in the governance, establishing guidelines or policy on certain ethical issues and reviewing study proposals that require new data collection from participants.
- Co-Principal Investigator (**Co-PI**): The governance has two Co-PIs of cohort infrastructure and scientific innovation. The former sits on both the AEC and the ASG, while the latter only sits on the ASG. Their work is mainly supported by the ASG and the ISAB through receiving reports from these two bodies. They are responsible to the funders.

According to the Model, it is suggested that there should be an oversight body that is assigned to reinforce collectiveness in biobanking goals. This body should be capable of monitoring biobanking activities and resisting activities that deviate from collective goals. Also, this body should have mechanisms for recognising what biobanking goals participants actually have and informing them of its own reinforcing activities.

As for ALSPAC, its governance employs a multiple-committee model, whereby more than one committee is assigned to govern and manage it. The remits of and relationships between these committees are briefly explained in Box 5.2 above. As regards a role in reinforcing collectiveness in goals, it should first be noted from the remits of these committees that, unlike the Ethics and Governance Council in UK

Biobank (**EGC**),[25] these committees are fundamentally not intended to routinely evaluate the governance of ALSPAC in a critical fashion. Rather, they work together to facilitate biobanking and deal with any issues that hinder ALSPAC's activities or undermine ALSPAC's relationship with participants. Thus, it might be fair to say that this reinforcing task is basically outside their remit, and thus it is arguably unfair to judge them on this matter. Nonetheless, in the attempt to show how the Model is applied to the governance, this sub-sub-section mentions two mechanisms in the governance that might be used to fulfil such a task, as follows:

Reference to the ISAB

The first one concerns a mechanism that refers problematic access applications to the ISAB. This mechanism is triggered during a process of approving applications that request access to the Resources. In general, access applications are handled by the AEC. The conditions of approval are mostly related to scientific acceptability – such as scientific strength, appropriateness of methods and absence of repetition – but they also include whether research proposals are 'within the scope of the consents obtained for the specific samples'.[26] When access applications are considered problematic, they are referred to the ISAB for review. Such applications exist in three circumstances: (1) access applications might significantly deplete stocks of finite samples;[27] (2) access applications are complex or controversial, beyond the AEC's capability to adjudicate;[28] or (3) the AEC's decisions on access applications are contested by applicants or 'significant third parties'.[29] From the perspective of the Model, collectiveness in biobanking goals can be reinforced in a situation where access applications do not conform to participants' consent, which can be analogous to collective goals, and these applications are reviewed by the ISAB because either the AEC decides to send them to the ISAB for review or its decisions on them are

[25] See Box 4.1 in ch 4 above.
[26] Policy on Access (2014), at 11.
[27] Policy on Access (2014), at 11.
[28] Terms of Reference - AEC (2014), at para 3.5 a); Terms of Reference - ISAB (2014), at para 2.1.
[29] Terms of Reference - AEC (2014), at para 3.5 b); Terms of Reference - ISAB (2014), at para 2.1.

contested. In this situation, the ISAB can be considered to play a role as an oversight body, which resists the uses of the Resources that deviate from collective goals.

However, although this mechanism is theoretically possible according to accessible documents, it might not be feasible in practice for reinforcing collectiveness in biobanking goals for two reasons. First, an ISAB review is not routine: it requires either the AEC to 'find itself unable to adjudicate' or someone to contest its decisions on certain access applications, let alone what 'significant third parties' actually include in practice. This infers that access applications that do not conform to collective goals might not be reviewed and rejected by the ISAB. Second, the ISAB is unlikely to perform this reinforcing task in practice since, as assumed from its remit and composition, this body seems to be primarily intended to tackle scientific matters, not the non-conformity of access applications to participants' consent or collective goals. In other words, it is likely that, in practice, only scientific-related issues are left to be addressed by the ISAB. Indeed, it is also unclear from accessible documents how the ISAB knows about participants' actual biobanking goals since it has no regular communication with participants. For these reasons, it can be argued that, in practice, this mechanism cannot properly resist the uses of the Resources that do not conform to collective goals, and thereby it cannot be used as a mechanism for reinforcing collectiveness in biobanking goals according to the Model.

Practical Sanctions by Funders

The second mechanism involves financial sanctions imposed by ALSPAC's funders. Unlike the first mechanism, which focuses on access applications, this mechanism covers biobanking activities in general. This is similar to the governance of UK Biobank, where the EGC can raise undesirable biobanking activities with UK Biobank's funders – who are in a position to use financial sanctions against such activities.[30] In ALSPAC, bodies involved in this mechanism are the Co-PIs of cohort infrastructure and of scientific innovation. One reason is that the Co-PIs have access to information about ALSPAC's activities: both Co-PIs are members of the ASG, which oversees ALSPAC's activities; they receive reports about ALSPAC's activities

[30] See 4.1.2 b) (Relationship with Biobankers) in ch 4 above.

from the ASG and the ISAB; the Co-PI of cohort infrastructure is also a member of the AEC, which manages biobanking activities in general.[31] Another reason is that they are responsible to the funders.[32] Given these two reasons, one can therefore say that the Co-PIs are capable of monitoring ALSPAC's activities and recognising any activities that deviate from the goals shared with participants. Moreover, since they are responsible to the funders, they might resist such activities by raising such activities with the funders, who might use financial sanctions to hinder or inhibit such activities. Accordingly, it is arguably possible for the Co-PIs to play a role in reinforcing collectiveness in biobanking goals in the governance.

However, the lack of information about the Co-PIs' remit and practices prevents investigating this possibility for two reasons. First and foremost, it is unclear whether, in practice, the Co-PIs play a role in enhancing administrative efficiency, scientific justifiability or ethical and social acceptability. Consequently, it is difficult to assert that they will always raise any deviations from participants' goals with the funders. Second, based on the Model, where an oversight body should be able to realise what goals participants actually have, it is unclear how the Co-PIs can realise participants' current goals, due to the absence of information about what data they regularly go through and what activities they are interested in. In practice, they might be able to realise such goals through, for example, public events attended by participants or reports that document participants' feedback about the governance; but this cannot be confirmed from accessible documents. For these reasons, although the Co-PIs possibly recognise and resist any deviations from participants' goals, it is difficult to argue that they will do so in practice. The conclusion here is that **it is unclear whether the Co-PIs can play a role as an oversight body that reinforces collectiveness in biobanking goals in the governance**. In this respect, more information about the Co-PIs' activities is required to determine whether this aspect of the governance actually conforms to the Model.

To summarise this sub-sub-section, given accessible information about the governance of ALSPAC, one might assume that any deviations of ALSPAC's

[31] See Box 5.2 above.
[32] Terms of Reference - ASG (2014), at para 1.3.

activities from collective goals could be resisted within the governance. For one reason, access applications that do not conform to collective goals might be reviewed and rejected by the ISAB. Moreover, biobanking activities that are not in line with collective goals might be hindered through financial sanctions imposed by the funders, with whom the Co-PIs might raise such activities. However, when considering these two mechanisms in more detail, it is difficult to accept this assumption. Particularly, regarding an ISAB review, it can be suggested from accessible documents that, basically, this review is neither performed on a regular basis nor intended to deal with access applications that do not conform to collective goals. As regards financial sanctions, there is not sufficient information to confirm whether the Co-PIs can realise participants' actual goals and whether, if they can, they will raise ALSPAC's activities that do not conform to those goals with the funders. Consequently, it cannot be concluded that collectiveness in biobanking goals can be reinforced by these two mechanisms, and that this aspect of the governance conforms to the Model.

5.1.3 Interim Conclusion

In this section, the overall argument is that collective goals, i.e. goals that ALSPAC and participants originally agreed on, are to some extent emphasised in the governance of ALSPAC. For one reason, it is arguable that ALSPAC has sufficiently clarified its goals. This is supported by the communication with participants during the recruitment stage and some involvement mechanisms within the governance, both of which show that ALSPAC has attempted to facilitate participants' understanding of its goals. As a result of this clarification, participants can have a clear understanding of its goals, and thus they are allowed to genuinely share the same goals with it. Another reason is that participants can properly reinforce collectiveness in biobanking goals in the governance: the governance provides them with the right of withdrawal and has many channels for CBP; consequently, they are allowed to withdraw their consent when their own goals deviate from collective goals, which they can realise through channels for CBP in the governance. For these two reasons, one can say that this aspect of the governance conforms quite well to the Model.

Nonetheless, it is unclear whether or not the governance of ALSPAC can emphasise collective goals by resisting any biobanking activities that deviate from collective goals. This is because, based on accessible information, it seems that the ISAB does not play a role in discouraging the uses of the Resources that do not conform to collective goals. Moreover, the available information is not sufficient to confirm that, in practice, ALSPAC's activities that deviate from collective goals will be resisted or inhibited by other mechanisms within the governance, such as financial sanctions that the Co-PIs might request the funders to impose against these activities. More information is therefore required to confirm that collective goals are emphasised in this fashion as well. In other words, the accessible information is not sufficient to argue for a higher degree of conformity of the governance to the Model.

5.2 Collaboration

The key attribute of collaboration in the Model requires biobankers to cooperate with participants in a respectful manner by giving participants a chance to influence biobanking activities meaningfully. In doing so, there must be mechanisms that provide participants with opportunities to provide input about biobanking and assure the meaningfulness of their input.[33] Based on this proposal, this section deals with the questions of whether and how the governance of ALSPAC provides participants with opportunities to provide input about the governance as well as whether these opportunities suffer from any possible forms of tokenism. With the aim of addressing these questions, documents illustrating involvement mechanisms implemented in the governance were reviewed, in order to find out how ALSPAC has allowed participants to provide input about the governance and how it deals with their input. It first needs to be noted that there are no documents that explicitly explain this aspect of the governance, and thus relevant materials – which include annual reports, participant newsletters and the ALSPAC website – are examined to learn about it. After examining these materials, it is arguable that the answers to those questions are positive. This is because the governance has many communicative and involvement

[33] See 3.2 in ch 3 above.

mechanisms that give participants those opportunities. Also, it seems that those opportunities have not suffered from any possible forms of tokenism, although more information is needed to verify this.

5.2.1 Opportunities to Provide Input

> The Model (Chapter 3): Biobank governance needs to have mechanisms that allow participants to voice their thoughts about biobanking, so as to give them opportunities to provide their input on biobanking.

This sub-section determines the extent to which ALSPAC gives participants opportunities to provide feedback or input about its governance. To do so, all involvement mechanisms in the governance of ALSPAC were examined in order to find out those that allow participants to voice their thoughts about the governance. It is worth emphasising that this sub-section focuses only on participants' opportunities to provide input. In this respect, the possibility that their input will influence ALSPAC's activities will be dealt with in the following sub-section. As a result of this examination, it is arguable that participants have many opportunities to provide input about the governance throughout the course of biobanking, because there are a number of involvement mechanisms within the governance that provide these opportunities. As the structure of this sub-section, such mechanisms can be classified into regular and irregular mechanisms and they can be explained separately, as follows:

Regular Mechanisms

For regular involvement mechanisms, advisory panels should first be mentioned. These panels comprise participants who volunteer to be involved in ALSPAC's management. There are two panels within the governance of ALSPAC: the OCAP[34] and the COCO90s advisory group. The former is the panel of study children that has helped ALSPAC in dealing with many aspects of the governance. It has worked collaboratively with ALSPAC and has thus far been engaged in various

[34] See note 3 above.

matters, ranging from recruitment and communication to research activities.[35] For example, it helped to improve the design and content of some participant newsletters.[36] As for data collection, it was asked to give some advice on the layout and language used in questionnaires and other information documents,[37] as well as to give advice on the clinic environment at focus centres so as to make those centres have a less clinical and more teenage-friendly feel.[38] It got involved in ALSPAC's communication with other participants by setting up the ALSPAC Facebook page and advising on the tone and content of this page.[39] It has also dealt with some ethical questions,[40] such as the disclosure of information to participants.[41] The other panel is the COCO90s advisory group, which is comprised of the children of study children who are eligible to be the COCO90s cohort. Although the detail about this panel is barely revealed in accessible documents, it seems that this panel serves a similar purpose to the OCAP.[42]

In addition to advisory panels, participants can provide input about the governance by being members of some working groups. One example is the ALEC, on which the OCAP,[43] study mothers[44] and study fathers[45] are currently represented. Another is the working group for the Fathers' study, which recruits one study father to give advice on recruitment and study development.[46] There is also the Pre-ALEC, which comprises participant members of the ALEC and works as an additional forum for ethical review by lay members, prior to main ALEC meetings.[47] Other than membership, participants can contribute personally towards the governance through

[35] Annual Report 2006, at 2; Annual Report 2008, at appx 1.
[36] Annual Report 2008, at 2.
[37] Annual Report 2009, at 5.
[38] Annual Report 2008, at 4.
[39] Annual Report 2009, at 5.
[40] Annual Report 2009, at 2.
[41] C Hellmich et al, "Genetics, Sleep and Memory: A Recall-By-Genotype Study of ZNF804A Variants and Sleep Neurophysiology" (2015) 16 *BioMed Central* 96 available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4619339/ (accessed on 10 July 2016), at 6.
[42] Annual Report 2011-12, at appx 5.
[43] C Overy et al, *History of the Avon Longitudinal Study of Parents and Children (ALSPAC), c.1980–2000*, Volume 44 (London: The Trustee of the Wellcome Trust, 2012), at 93.
[44] K Birmingham and M Furmston, "Avon Longitudinal Study of Parents and Children (ALSPAC): Ethical Process" in J Gunning and S Holm (eds), *Ethics, Law and Society Volume II*, (Hampshire: Ashgate Publishing, 2006) 65-74, at 66.
[45] Annual Report 2011-12, at 4.
[46] Annual Report 2011-12, at 4.
[47] ALSPAC, *New Data Collection Review Dates*, (2016) 1.

other involvement activities, such as online parent advisory forums, which were established to engage with study parents.[48] As these forums are used to discuss ideas with and obtain feedback from them, they are provided with opportunities to provide input about the governance, including research areas of interest to them.[49] In addition to these forums, in general, individual participants can provide input about the governance by voicing their thoughts through channels for general enquiries and feedback. These channels exist in various forms, ranging from telephone and email to social media, such as Facebook and Twitter. The details of these channels are provided in participant newsletters and on the ALSPAC website. Indeed, individual participants can also voice their concerns or make complaints about the governance, which will be dealt with systemically by ALSPAC's staff.[50]

Irregular Mechanisms

Other than regular mechanisms, participants additionally have opportunities to provide input about ALSPAC governance through some involvement activities arranged irregularly. Many of these activities were in the form of meetings with biobankers. An example is attrition away days, which allowed participants to voice their opinions on how to improve the participation rate in ALSPAC.[51] Some were arranged as public events, such as ResearchFest in 2012, which enabled participants (as attendees) to provide feedback about the governance.[52] Also, many mechanisms were occasionally implemented to receive participants' input about the governance individually. For example, a 'phone blitz' was initiated to invite missing participants personally to participate again and it also asked those participants to advise on how to make clinic sessions attract more attendance.[53] Some focus groups and interviews were held in father clinics to find an appropriate way to collect samples from study fathers.[54] Some participant newsletters were used to ask participants to give their ideas on certain

[48] Parents Newsletters 2011, at 2.
[49] Parents Newsletters 2011, at 2.
[50] Policy on Complaints (2014).
[51] Annual Report 2006, at 2.
[52] ALSPAC, "Researchfest 2012" (2012) available at http://www.bristol.ac.uk/alspac/events/researchfest2012 (accessed 10 January 2015).
[53] Annual Report 2007, at 3.
[54] Annual Report 2008, at 3.

matters, such as outreach visits[55] and questionnaires for collecting data.[56] Some qualitative studies were also conducted to get participants' perceptions on certain matters, such as study children's perception of their participation[57] and their opinions on some ethical issues.[58]

Given all these involvement mechanisms, one can therefore say that **ALSPAC participants have many opportunities to provide their input about the governance of ALSPAC on a regular basis**. This is even the case for non-biobanking matters. For example, study parents were asked at 'parents evening' meetings to advise how ALSPAC could help their children at school.[59] Study mothers were asked to get involved in producing a series of short books that concern what is most important to women and their well-being.[60] Although these mechanisms are not directly related to the governance, they might help increase the sense of involvement and collaboration, and thereby may strengthen a participant-biobanker relationship within it. It is therefore arguable that this aspect of the governance conforms to the Model. Two points are noteworthy here. First, the governance also has a 'research partners' scheme, which allows participants to get involved in research studies by helping make decisions about research studies.[61] This scheme may enable them to provide input, particularly regarding research studies that use the Resources. However, there are neither details nor updates about this scheme in accessible documents, and so this scheme is not used to support this argument. Second, many of involvement mechanisms in the governance might raise the issue of representation, which is not desirable for the ARR. This issue will be discussed at the end of Sub-section 5.2.2 c) below.

[55] Parents Newsletters 2008, at 3.
[56] Young Participant Newsletters 2012, at 3.
[57] T Goodenough et al, see note 21 above.
[58] E Williamson et al, "Children's Participation in Genetic Epidemiology" in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, (London: Routledge, 2004) 139-160.
[59] Participant Newsletters Issue 26, at 7.
[60] Family Newsletters 2015-16, at 7.
[61] Annual Report 2011-12, at 1.

5.2.2 Meaningfulness of Input

> The Model (Chapter 3): Biobankers are required to ensure the meaningfulness of participants' input by allowing their input to have a real chance of substantially influencing biobanking. To fulfil this requirement, they need to address three forms of tokenism that might occur in a biobanking context, i.e. the insignificance of issues under consideration, the insufficiency of participants' capability to provide input, and the disregard of their input.

Based on the Model, this sub-section addresses the question of whether the opportunities to provide input that ALSPAC participants have can be considered tokenistic. In doing so, ALSPAC's activities revolving around participants' input, including the involvement mechanisms explained in the previous sub-section, were examined in order to find out whether or not the governance suffers from any of those three possible forms of tokenism. As a result of this examination, the answer to this question seems to be negative. To explain this answer, those three possible forms of tokenism are dealt with separately in three different sub-sub-sections.

a) Insignificance of Issues

The first possible form of tokenism refers to a situation where issues on which participants are allowed to provide input are not significant for biobanking. The Model does not propose any criteria for what issues are significant, but instead suggests that significant issues should affect the quality of a participant-biobanker relationship or influence the direction of biobanking activities.

Based on this premise, the governance of ALSPAC seems not to suffer from this possible form of tokenism, as involvement mechanisms in it generally involve biobanking issues that can be considered important. Particularly, many of those mechanisms aim to increase the participation rate, which is basically crucial for the success and viability of ALSPAC. The involvement of the OCAP is a good example: the Panel's input can be considered to help increase the participation rate because it helped make participants have good experiences of ALSPAC's activities by, inter alia, changing the environment of clinics, setting up the ALSPAC Facebook page and

improving the content of ALSPAC's newsletters, questionnaires and website.[62] The same can be said for the involvement of some study fathers. Particularly, one study father has sat on the working group for the Fathers' study to advise on recruitment. Also, some study fathers took part as fathers' ambassadors, who promote the Fathers' study by being involved in a recruitment video and interviews with the media.[63] Another example is attrition away days, which sought to involve participants in finding out how to improve the attrition rate.[64]

Participants have been allowed to get involved in other important issues too. For example, the OCAP engaged in discussing some ethical questions as members of the ALEC[65] and influencing the direction of research studies by advising on new research topics.[66] The COCO90s advisory group was involved in making decisions about clinic measures and the ways to contact the COCO90s cohort.[67] Some study fathers have had opportunities to discuss ethical questions as members of the ALEC, and to give advice on study development as part of the working group for the Fathers' study.[68] Moreover, according to the aforementioned 'research partners' scheme, it might be assumed that participants are allowed to influence research studies by helping make decisions about prospective studies.[69] Above all, communication channels that enable any participants to send general enquiries and feedback, as well as to make complaints about the governance, are not limited to any specific issues. Given all of these involvement mechanisms and communication channels, it can be argued that participants have been allowed to deal with significant issues in the governance, and thus **the governance is not prone to the risk of this possible form of tokenism**.

[62] See 5.2.1 (Regular Mechanisms) above.
[63] Annual Report 2011-12, at 4.
[64] Annual Report 2006, at 2.
[65] Annual Report 2008, at appx 1.
[66] Young Participant Newsletters 2008, at 4.
[67] Annual Report 2011-12, at appx 5.
[68] Annual Report 2011-12, at 4.
[69] Annual Report 2011-12, at 1. Note that further detail about this scheme is not accessible.

b) Insufficiency of Capability

The second possible form of tokenism stems from the insufficiency of participants' capability to give useful input, which renders their input neither helpful nor worthy of consideration. The solution to this form of tokenism is participant empowerment. This empowerment might be performed by way of sharing general knowledge about biobanking and information about certain biobanks with participants. By assuming that some participants prefer to be non-active and thereby do not need such knowledge and information, this sharing accentuates the accessibility of such knowledge and information, not the consequences or methods of this sharing.

Based this premise, this sub-sub-section addresses the question of whether ALSPAC sufficiently share knowledge about biobanking and information about it with participants. Note that, as information about ALSPAC encompasses updates on ALSPAC's activities, part of the arguments here is analogous with the argument made regarding CBP above,[70] and it can be explained again, as follows: there are many communication channels within ALSPAC governance that enable participants to keep themselves up-to-date with ALSPAC's progress; it is therefore arguable that participants have sufficient access to information about ALSPAC's activities. This sub-sub-section focuses on the accessibility of other information, namely background information about ALSPAC and general knowledge about biobanking.

In ALSPAC governance, participants arguably have sufficient access to background information about ALSPAC and general knowledge about biobanking. This argument is supported by the same evidence as that used to support the arguments regarding communication about ALSPAC's goals and activities.[71] Thus, it can be explained again, as follows. The governance has provided participants with such information and knowledge. Particularly, the information about uses of the Resources, which facilitates understanding of ALSPAC's goals, has been provided in the recruitment documents, participant newsletters and public events, as well as on the ALSPAC website. General knowledge about biobanking and the explanations for some biobanking activities (e.g. data linkage and its benefits; procedures for and

[70] See 5.1.2 a) above.
[71] See 5.1.1 and 5.1.2 a) above.

reasons behind collecting certain information and samples; the relations between participants' contributions and medical advances etc.) have been frequently provided in many documents, especially participant newsletters. Participants might also have opportunities to learn about research procedures according to the 'research partners' scheme, whereby biobankers assist them in conducting their own research studies.[72] Given this degree of informational accessibility, one can say that information about ALSPAC and knowledge about biobanking have been sufficiently shared with participants, and thus **this possible form of tokenism is arguably not an issue within the governance**.

c) Disregard for Input

The last possible form of tokenism occurs when participants' input is not given serious consideration by biobankers, thus preventing participants from having a real chance of influencing biobanking activities. To address this concern, biobank governance should have mechanisms that can be used to confirm that participants' input is actually taken into account, regardless of whether or not such input is eventually put into practice.

For ALSPAC, it can be said from accessible information that the governance of ALSPAC only has such mechanisms when handling complaints from participants. Particularly, it is evident that the governance has a systemic procedure for dealing with participants' complaints.[73] Indeed, according to this procedure, these complaints will eventually be resolved by an external body, namely the Management Group of the School of Social and Community Medicine, University of Bristol. Accordingly, this procedure and the involvement of the Management Group can be considered to be mechanisms for ensuring that complaints from participants are given serious consideration by ALSPAC.

As regards other involvement mechanisms in the governance, their details are not available enough to determine conclusively whether participants' input provided via them has been given serious consideration, and whether certain ALSPAC's

[72] See note 69 above.
[73] Policy on Complaints (2014).

activities were truly informed by that input. Still, it might be argued from accessible information that participants' input has actually been taken into account to some extent, as it can be inferred from some statements that certain biobanking activities and some changes thereto were influenced by participants' input. For example, it is explained that, after ALSPAC had realised that some participants deemed questionnaires too lengthy and did not prefer using a paper version of them, it promised to make them shorter and to provide an online version in addition, respectively.[74] It is said that ALSPAC involved the OCAP in making suggestions about the environment of clinics and those suggestions were subsequently implemented.[75] One report says that the establishment of online advisory forums for engaging with study parents resulted from feedback from parents' focus groups.[76] Other than these statements, some facts might also be used to support this argument. An example is the fact that participants have been repeatedly informed of their right of withdrawal:[77] this repetition is in line with the qualitative research on study children which concluded that this right should be reinforced with them constantly.[78] All these statements and facts indicate that ALSPAC has taken participants' input into account.

When considering this indication together with the mechanisms for handling participants' complaints, it is arguable that, **in practice, ALSPAC governance has not, so far, suffered from this possible form of tokenism**.

Despite this argument, it is notable that more information is needed to verify that this aspect of the governance genuinely conforms to the Model. Particularly, it is unclear from accessible documents how ALSPAC actually deals with participants' input received via its involvement mechanisms, and the extent to which such input has actually influenced its activities. On the one hand, this raises the question of whether the governance has routine mechanisms in place for dealing with such input, thus raising doubts as to whether this argument will remain valid afterwards. On the other hand, it is questionable whether the governance has suffered from the issue of

[74] Annual Report 2011-12, at 4; Young Participant Newsletters 2012, at 3.
[75] Annual Report 2008, at 4.
[76] Annual Report 2011-12, at 1, 4.
[77] See 5.1.2 a) (second paragraph) above.
[78] T Goodenough et al, see note 21 above, at 69.

representation, which – as discussed in Chapter 6 – is not desirable for the ARR since the input of some participants is disregarded:[79] most of involvement mechanisms in the governance only involve some participants and so these participants might be considered to represent other participants, thereby making the governance prone to this issue. Admittedly, the governance does have channels for receiving input from every participant and, due to the above statements and facts, it is reasonable to assume that ALSPAC normally takes into account input from other participants, if any. However, accessible information is not sufficient to confirm that this assumption is entirely correct. Thus, more information is required to argue strongly that the governance does not suffer from the issue of representation and genuinely conforms to the Model.

5.2.3 Interim Conclusion

Given all involvement mechanisms in the governance of ALSPAC, it can be said that the collaboration between participants and ALSPAC has been remarkably effective. One reason is that the governance has a number of involvement mechanisms, whether regular or irregular, which have given participants a lot of opportunities to provide their input about the governance. These mechanisms range from establishing the channels for general enquiries and feedback, which provide such opportunities for every participant, to establishing participant panels, such as the OCAP and the COCO90s advisory group, which allow some participants to collaborate closely with ALSPAC's staff. More importantly, their input has had a real chance of substantially influencing the governance, based on the fact that the governance generally has not suffered from the aforesaid three possible forms of tokenism. It is therefore arguable that this aspect of the governance substantially conforms to the Model.[80]

However, it remains to be seen whether this legacy will continue, because it is unclear whether the governance of ALSPAC has any mechanisms for ensuring that

[79] See 6.3.1 (Representation) in ch 6 below.
[80] This degree of collaboration might result from ALSPAC's scientific engagement strategy, which was devised to ensure that all participants are engaged in biobanking. See Annual Report 2006, at 2. However, no further information about this strategy is available in accessible documents, and thus it is difficult to know the extent to which it has underlain involvement mechanisms in ALSPAC governance.

participants' input will always be given serious consideration. Furthermore, it is unclear whether the governance is really free from the issue of representation, which is undesirable for the ARR. In this respect, more information on this matter is required to strengthen this argument.

5.3 Reciprocation

As established in Chapter 3, the Model requires biobankers to reciprocate participants' contributions to biobanking, with the aim of making participants feel satisfied with their participation. In practice, this reciprocation can be in either tangible or intangible form.[81] Based on this premise, this section deals with the questions of whether and how ALSPAC governance provides participants with reciprocation, whether tangible or intangible. To address these questions, documents that reveal any commitments given by ALSPAC and any benefits participants have received from it were reviewed. These documents include the recruitment documents, annual reports and participant newsletters. As a result of this review, it can be argued that this aspect of the governance chiefly conforms to the Model, but accessible information is not sufficient to confirm a higher degree of this conformity. To illustrate this argument, two forms of reciprocation, namely tangible and intangible reciprocation, are dealt with separately in two different sub-sections.

5.3.1 Intangible Reciprocation

> The Model (Chapter 3): To provide intangible reciprocation, biobankers need to give commitments to pursue collective goals and to provide sufficient safeguards for them. In doing so, biobankers are required to implement measures to (1) encourage the fulfilment of these two commitments and (2) inform participants of them and their fulfilment.

Based on the Model, all biobanking activities within the governance of ALSPAC were examined in order to address the question of what mechanisms in the

[81] See 3.3 in ch 3 above.

governance can be used for giving participants commitments to pursue collective goals and to provide safeguards for participants. To answer this question, this sub-section outlines the mechanisms in the governance that can be used as measures (1) to encourage the fulfilment of those two commitments and (2) to inform participants about those commitments and the fulfilment thereof. As for the structure of this sub-section, these two measures are dealt with separately in two different sub-sub-sections. It is noteworthy that, as explained in Chapter 3,[82] the mechanisms suggested for implementing these two measures are in practice similar to those suggested to reinforce collectiveness in biobanking goals in the first key attribute, because they all involve overseeing biobanking activities continuously, encouraging the proper conduct of certain activities, and establishing communication with participants. Thus, some arguments in the first section will be referred to and applied to this sub-section.

a) Encouragement to Fulfil Commitments

According to the Model, the mechanisms suggested for encouraging the fulfilment of those two commitments involve the establishment of an oversight body that is assigned to encourage such fulfilment and which also has communication with participants to elicit their thoughts about what their goals actually are and whether existing safeguards are sufficient.

For ALSPAC governance, those two commitments are considered separately. For a commitment to pursue collective goals, because this pursuit is similar in practice to the reinforcement of collectiveness in biobanking goals, the arguments articulated above[83] are applicable here and can be explained again, as follows: despite that accessible documents suggest that the ISAB can encourage pursing collective goals since it can review access applications that do not conform to collective goals, this review is not routine and seems to essentially involve scientific issues, not conformity to collective goals; the Co-PIs seem to be an oversight body that can encourage ALSPAC to pursue collective goals, with the help of financial sanctions imposed by

[82] See 3.3.1 a) in ch 3 above.
[83] See 5.1.2 b) above.

the funders; however, this role cannot be confirmed since there is not enough information about the Co-PIs to verify whether the Co-PIs can and do play this role in practice; particularly, it is unclear whether they are assigned to critically oversee or only facilitate ALSPAC's activities, and whether they can realise participants' actual goals. Thus, **one cannot firmly say that the governance has mechanisms for encouraging ALSPAC to fulfil a commitment to pursue collective goals.**

Regarding a commitment to provide participant safeguards, a body that can encourage, or even ensure, the fulfilment of this commitment is the ALEC, for many reasons. First, this committee is generally responsible for safeguarding participants by, inter alia, reviewing some research proposals, creating protocols for certain ethical questions, and addressing any ethical or legal issues arising.[84] In practice, these responsibilities cover many aspects of the governance of ALSPAC, such as the provision of individual feedback, hands-on measurements, access to the Resources and the protection for study children during interviews.[85] Second, as this committee is attended by the Co-IP of scientific innovation and the Executive Director, it has access to information about ALSPAC's activities in practice,[86] thus allowing it to recognise any harm to participants' interests, if any. Finally, it can elicit participants' views about the sufficiency of participant safeguards indirectly via the EPEG project,[87] which partly aims to improve understanding of participants' views on appropriate ethical protection as well as to inform the work of ethics committees.[88] Note that, in practice, it can also know about such views from its participant members; but this may raise the issue of representation and thus is not used as supporting evidence here. For these reasons, it can therefore be argued that the ALEC can be an oversight body that

[84] See Box 5.2 above; Terms of Reference - ALEC.
[85] SE Mumford, see note 5 above; K Birmingham and M Furmston, see note 44 above; SE Mumford, "Children of the 90s II: Challenges for the Ethics and Law Committee" (1999) 81 *Archives of Disease in Childhood - Fetal and Neonatal Edition* 3 F228-F231.
[86] K Birmingham and M Furmston, *ibid*, at 66.
[87] Centre for Ethics in Medicine (University of Bristol), see note 22 above.
[88] T Goodenough et al, see note 21 above; E Williamson et al, see note 58 above; E Williamson et al, "Conducting Research with Children: the Limits of Confidentiality and Child Protection Protocols" (2005) 19 *Children & Society* 5 397-409; T Goodenough et al, "'What Did You Think about That?' Researching Children's Perceptions of Participation in a Longitudinal Genetic Epidemiological Study" (2003) 17 *Children & Society* 2 113-125.

supports ALSPAC in providing sufficient safeguards for participants[89] and thereby **the governance has mechanisms for encouraging the fulfilment of a commitment to provide safeguards for participants**.

b) Communication about Commitments

The Model suggests that there should be communication with participants to (i) inform them clearly about commitments to pursue collective goals and to provide sufficient safeguards for them and (ii) allow them to realise the fulfilment of these two commitments.

In the governance of ALSPAC, the former type of communication can be found during the recruitment stage. Particularly, the recruitment documents and the ALSPAC website provide information that helps demonstrate how collective goals have been and will be pursued, such as examples of how the Resources have been and will be used. Also, the same materials and many participant newsletters repeatedly promise to protect participants' privacy and confidentiality, and explain the ways in which this protection is provided and ensured.[90] This is especially the case for study children: certain safeguards were explained to them alongside the development of their capability to understand ethical issues.[91] Indeed, all of these materials are publicly accessible, since they can be downloaded from the ALSPAC website and some of them, i.e. participant newsletters and the recruitment documents, were even sent to participants individually. It can therefore be said that **ALSPAC already informed participants about those two commitments**.

For communication about the fulfilment of those two commitments, CBP in the governance is remarkably effective in terms of both quantity and content, as

[89] It is evident that ALSPAC governance also has the Pre-ALEC, which is comprised of participant members of the ALEC and works as an additional forum for ethical review by lay members prior to main ALEC meetings. See ALSPAC, *New Data Collection Review Dates*, (2016) 1. However, further detail about this body is not available in accessible documents.
[90] Consent Form (2014); Detailed Information Booklet (2014); Summary Information Booklet (2011); Participant Newsletters Issue 25, at 2; Parents Newsletter Issue 33, at 5; Family Newsletters 2014-15, at 3.
[91] K Birmingham and M Furmston, see note 44 above, at 67.

explained above.[92] More importantly, it is indeed evident that CBP allows participants to access information on how the Resources have actually been used[93] and what safeguards have been provided for them.[94] Thus, it is arguable that they can realise whether or not those two commitments have already been fulfilled. However, when looking more closely at communication about participant safeguards, it is questionable if information on this matter is sufficiently accessible. Particularly, this information has only been briefly explained in some participant newsletters.[95] Updates on ethical approvals for ALSPAC's activities have been provided but merely with small details about safeguards for participants.[96] The activities of the ALEC, which has an important role in safeguarding participants, have been explained in a few journal articles, which might be deemed irregularly available and difficult to access for participants.[97] Some participants are members of the ALEC but it is unclear whether information about participant safeguards is normally shared with other participants. Given that this information is used to maintain continuity in a participant-biobanker relationship,[98] one can say that it should be more accessible and more regularly available. The conclusion here is that **ALSPAC participants can realise whether or not those two commitments have actually been fulfilled**, but they should have more access to information about participant safeguards within the governance.

It can be summarised from all analyses in this sub-section that this aspect of ALSPAC governance largely conforms to the Model. Particularly, participants were notified of commitments to pursue collective goals and to provide safeguards for them. They can also check the fulfilment of these two commitments through CBP in the

[92] See 5.1.2 a) and 5.2.2 b) above.
[93] Actual uses of the Resources, as well as interesting research findings resulting from those uses, are normally summarised in participant newsletters. Also, scientific publications about research studies using the Resources are listed in annual reports and downloadable from the ALSPAC website.
[94] After examining many participant newsletters, as listed in Appendix 2, safeguards for ALSPAC participants are explicitly explained in one newsletter. See Family Newsletters 2014-15, at 3. Other newsletters only briefly mention them. See Participant Newsletters Issue 25, at 2; Parents Newsletter Issue 33, at 5.
[95] See note 94 above.
[96] Annual Report 2006, at 1; Annual Report 2008, at 1, 2; Annual Report 2011-12, at 3, 5.
[97] SE Mumford, see note 5 above; SE Mumford, see note 85 above; K Birmingham and M Furmston, see note 44 above.
[98] See 3.3.2 in ch 3 above.

governance. Moreover, the governance has a mechanism in place for encouraging the fulfilment of a commitment to provide participant safeguards, i.e. ethical oversight by the ALEC. Nonetheless, it cannot be confirmed from accessible information that the governance also has a mechanism for encouraging the fulfilment of a commitment to pursue collective goals. The subtle, albeit useful, suggestion here is that information about participant safeguards or information about the ALEC's activities should be more accessible and regularly communicated to participants, so as to enable them to conveniently and continuously realise that their interests are considered important and are properly safeguarded by ALSPAC.

5.3.2 Tangible Reciprocation

> The Model (Chapter 3): Tangible reciprocation refers to offering tangible benefits to participants (e.g. financial benefits, individual research results and analysed health information) in return for their contributions to biobanking. This reciprocation is not necessary due to the uncertainty of its availability. Should it be provided, biobankers are required to (1) clarify policies on this reciprocation, and then (2) allow participants to negotiate on these policies.

In ALSPAC, two types of tangible reciprocation have been provided for participants. One is offers of financial benefits, such as money vouchers, free meals, gifts for study children, opportunities to win monthly prizes, and compensation for travelling and accommodation expenses. These benefits have usually been offered to certain participant groups for their attendance at data-collecting sessions. The other one is the provision of health information, which includes biophysical measurements, questionnaire results and results of tests on samples or genetic materials (excluding measurements taken in the presence of participants). This information shall, as a general rule, not be disclosed to participants, but there are exceptions to this rule, as explained below. To determine whether tangible reciprocation in the governance of ALSPAC is in accordance with the Model, all of ALSPAC's activities were examined in order to address the questions of whether ALSPAC's policies on tangible reciprocation have been clarified and whether participants are allowed to negotiate

about these policies. As for the structure of this sub-section, these two questions are dealt with separately in two different sub-sub-sections.

a) Clarification of Policies

According to the Model, to clarify policies on tangible reciprocation, biobankers need to have clear policies on tangible reciprocation and then notify and justify those policies, or any changes thereto, to participants. As this clarifying measure involves communication about policies on this matter, this sub-sub-section – by examining all communication mechanisms in ALSPAC governance – determines the extent to which ALSPAC participants have been informed of these policies. The two aforementioned types of tangible reciprocation are dealt with separately, as follows.

Regarding financial benefits, incentive schemes were initiated in the governance in order to make ALSPAC more interesting to participants by offering them financial benefits. These schemes have been clearly communicated to them through some participant newsletters.[99] Although there are neither explanations nor justifications for these schemes, they can be considered clear to participants because their nature is understandable: they aim to render data-collecting sessions appealing to participants. It is therefore arguable that incentive schemes in ALSPAC governance have been sufficiently clarified. Note that these schemes might raise the issue of (albeit subtle) coercion, as further discussed below.

As for the provision of health information, the governance can be deemed to have a clear policy on this matter: in general, health information is not disclosed to participants; this disclosure is, however, possible only in exceptional circumstances and it requires both consent from participants and approval from the ALEC; in the absence of such consent, this disclosure might be possible if problems identified are so severe that the argument for disclosing them can outweigh other considerations.[100] As a real-life example of this provision, after participating in ALSPAC, one participant

[99] Young Participant Newsletters 2008, at 3; Parents Newsletters Issue 33, at 1; Young Participant Newsletters 2009, at 6; Family Newsletters 2015-16 at 4.
[100] Policy on Feedback (2011).

whose spine was suffering from scoliosis was referred by ALSPAC to her doctor, and eventually recovered after undergoing an operation on her spine.[101] Indeed, this policy is clearly explained and justified in a policy document, which is available on the ALSPAC website. This website also provides more explanations about this policy, such as when to apply this policy and when health information can be disclosed.[102] Indeed, according to this policy document, the notion that participation in ALSPAC is not for health checks is claimed to have been explicitly stated and frequently repeated to participants.[103]

Based on all of these discussions, one can say that **the governance has clear policies on tangible reciprocation and these policies were clearly justified and notified to participants**. It is therefore arguable that this aspect of the governance is in accordance with the Model.

b) Negotiation over Policies

To make policies on tangible reciprocation negotiable, the Model requires biobankers to give participants opportunities to influence these policies by at least allowing them to voice their preferences on these policies and giving their preferences serious consideration.

As this requirement is fundamentally similar to the measures for applying the key attribute of collaboration, the arguments articulated above[104] are applicable here and can be described again, as follows: ALSPAC participants have many opportunities to voice their preferences about policies on tangible reciprocation through many involvement mechanisms in the governance of ALSPAC; also, their preferences possibly influence such policies, since it is evident that their input on other matters has so far been taken into consideration by ALSPAC. Thus, it is arguable that, **in general, they are able to negotiate about policies on tangible reciprocation**. But still, one

[101] Young Participant Newsletters 2009, at 4.
[102] On 23 June 2016, this information was already removed from the ALSPAC website.
[103] Policy on Feedback (2011), at 1. Notably, my research on accessible documents suggests that this notion was rarely communicated to participants: it is only briefly mentioned in the detailed information booklet. See Detailed Information Booklet (2014), at 14. However, it is possible that, in practice, participants were frequently informed about this notion verbally.
[104] See 5.2.1 and 5.2.2 c) above.

can raise the question of whether this argument is entirely valid. This is because it is unclear whether the governance has any mechanisms for ensuring that participants' preferences on this matter will be taken into account. Nor do accessible materials indicate clearly that those preferences have been and will be influential in the governance. For example, one source says that the OCAP helped develop incentive schemes, but it does not reveal the extent of the OCAP's influence on these schemes,[105] making it questionable whether these schemes were actually informed by the OCAP's input. Accordingly, more information is required to strengthen this argument.

Incentives or Undue Influence?

As financial benefits were offered to ALSPAC participants in return for their involvement in ALSPAC's activities, an issue might arise as to financial involvement in their decisions to participate. That is, it is questionable whether the influence of those offers was so substantial as to impair their capability to make decisions on participation. Again, accessible information is not sufficient to address this question. Particularly, there have not been any empirical studies on this matter. The fact that the OCAP engaged in developing ALSPAC's incentive schemes does not indicate that such influence has been at an acceptable level. Moreover, the fact that the benefits offered have progressively increased[106] might imply a low level of such influence, but it was also possible that this increase resulted from other factors, such as more funding being available and better financial management.[107] It is therefore difficult to answer this question here, due to limited information. More information is required to give an answer, such as the involvement of the ALEC in this matter and empirical evidence on participants' attitudes towards those offers. Note that, from a conceptual perspective,

[105] L Greenwood, "ALSPAC - Lynne Molloy" (30 June 2009) available at http://centreforpublicengagement.blogspot.co.uk/2009/06/alspac-lynne-molloy.html (accessed 13 January 2016).

[106] Monetary benefits offered to study children have constantly increased, from £10 in 2008, £20 plus a free lunch in 2009 and £30 plus travel and accommodation costs in 2015. See Young Participant Newsletters 2008, at 3; Young Participant Newsletters 2009, at 6; Family Newsletters 2015-16 at 4.

[107] No further information on this matter is available: the newsletters issued in 2010, which might reveal the results of ALSPAC's incentive schemes, are not available on the ALSPAC website; the participation rate after implementing these schemes is not explained in any accessible documents.

financial incentives might undermine the ARR: these incentives can hinder the ARR's key feature of collectiveness in goals by enticing participants to pursue financial benefits instead of medical advances as biobankers do, as well as that of respectfulness by exposing participants to undue influence. The issue of financial incentives will be explained and discussed further in the last chapter of this thesis.[108]

5.3.3 Interim Conclusion

To summarise, it is arguable that reciprocation in the governance of ALSPAC does essentially conform to the Model. For tangible reciprocation, policies on this reciprocation were sufficiently clarified, and the governance has mechanisms that allow participants to negotiate about these policies. As for intangible reciprocation, participants have been informed of commitments to (1) pursue collective goals and (2) provide safeguards for them, and they can realise the fulfilment of these commitments essentially through CBP in the governance. However, based on accessible documents, the governance only has a mechanism for encouraging the fulfilment of the latter commitment.

Two points can be noted from this argument. First, as it seems that information on the fulfilment of the latter commitment has not been made sufficiently available to participants, it is suggested that such information should be more accessible and regularly communicated to them. Second, accessible information is not adequate to confirm a higher degree of the conformity of ALSPAC governance to the Model. Particularly, for intangible reciprocation, it is unclear whether the governance has a mechanism for encouraging the fulfilment of the former commitment. As regards tangible reciprocation, it is questionable whether policies on tangible reciprocation are genuinely negotiable, and whether the financial benefits offered to participants under ALPSAC's incentive schemes actually reduced or improved the quality of a participant-biobanker relationship in the governance.

[108] See 6.6.4 in ch 6 below.

5.4 Control Sharing

According to the Model, the key attribute of control sharing aims to develop the ARR by sharing control over biobanking with participants. In practice, this key attribute requires biobankers to ensure that this sharing is contextually appropriate. Notably, the term control here refers to capability that participants have to make decisions about their relationship with biobankers at an individual level. In this respect, it might not allow them to influence the overall direction of biobanking or biobanking activities that cannot be personalised.[109] Based on this premise, this section first identifies mechanisms in ALSPAC governance that give participants control over the governance at an individual level, and then determines whether the sharing of control in the governance can be considered appropriate. To carry out these two tasks, all publicly accessible documents that might reveal such mechanisms were studied. These documents primarily include annual reports, which illustrate overall biobanking activities and management in the governance, and secondarily other communication documents, such as the recruitment documents and participant newsletters. As a tentative conclusion, the governance has many control-sharing mechanisms, and control sharing in it can be considered appropriate.

5.4.1 Control-sharing Mechanisms

> The Model (Chapter 3): Before determining the appropriateness of control sharing, biobankers need to take into account any mechanisms in biobank governance that might give participants control over biobanking at an individual level, such as the consent procedure, the right of withdrawal and meaningful involvement. The ways in which these mechanisms are implemented are also considered, since they help determine the extent to which these mechanisms provide individual participants with control over biobanking.

Based on the Model, the governance of ALSPAC was examined in order to find out mechanisms that enable individual participants to have control over the governance at an individual level. It is notable that the extent to which these

[109] See 3.4 in ch 3 above.

mechanisms give individual participants control over the governance will be discussed in the next sub-section.

As a result of this examination, it can be said that **individual participants in the governance of ALSPAC are allowed to have such control through three mechanisms**. The first mechanism is broad consent, which allows them to restrict the uses of their samples and information to 'research on the causes of the world's most important health and social problems'.[110] As further explained below, this mechanism does not give participants much control since this restriction is arguably not significant. The second one is the right of withdrawal. According to this right, participants are provided with eight options to control different biobanking activities at an individual level, such as sending participants invitations to attend clinic sessions, linking their information in the Resources with their records in other databases and using their samples and information for research purposes.[111] The last one is consent to the feeding back of health information. As explained above, the health information of individual participants might be disclosed to them in some circumstances and this disclosure normally requires their consent.[112] It can therefore be said that they are allowed to control this disclosure personally. Note that, as explained above, some involvement mechanisms in the governance also seem to give individual participants some control over the governance in practice, since their input has evidently influenced ALSPAC's activities (e.g. the development of online advisory forums and the changes to preparation of questionnaires), but there is not sufficient information to confirm that this is routinely the case.[113]

It is worth noting that ALSPAC governance also has many mechanisms that give individual participants control over the governance at a collective level. These mechanisms formally involve some participants in the governance to work with biobankers and influence ALSPAC's activities. An obvious example is the OCAP. This panel has been engaged in many aspects of the governance, ranging from communication with participants to discussions of certain ethical issues. It is also

[110] Summary Information Booklet (2011), at 1.
[111] Policy on Withdrawal (2011).
[112] See 5.3.2 a) above.
[113] See 5.2.2 c) (last paragraph) above.

evident that this panel has influenced many biobanking activities, such as producing participant newsletters, preparing questionnaires and advising on the clinic environment at focus centres.[114] Other than the OCAP, some participants have been appointed to working groups or committees in the governance, thereby allowing them to influence ALSPAC's activities. For example, one study father was recruited to a working group for the Fathers' study to advise on recruitment and study development; study fathers have sat on the ALEC to inform discussions therein.[115] Furthermore, there is also the 'research partners' scheme, whereby participants can get involved in designing and making decisions about research studies.[116] According to accessible information, this scheme seems to allow participants to influence uses of the Resources by helping shape the direction of research activities. However, as the Model focuses on a participant-biobanker relationship at a micro level,[117] these mechanisms are not discussed and used to support the arguments in this section.

5.4.2 Appropriate Control Sharing

> The Model (Chapter 3): Control over biobanking needs to be shared appropriately with participants. In doing so, it is suggested that, conceptually, the sharing of control should be able to express respectful gestures towards participants. There are neither mechanisms nor criteria proposed for implementing this suggestion, as this implementation should be contextual.

The previous sub-section explains that participants can have control over the governance of ALSPAC at an individual level through their broad consent, their right of withdrawal and their consent to the feeding back of health information. A question arises as to whether or not control sharing in the governance is appropriate – i.e. whether it can accord participants respect. As there has been no qualitative study that directly answers this question, this sub-section addresses this question by first determining the level of control that individual participants actually have as a result of

[114] See 5.2.1 (Regular Mechanisms) above.
[115] Annual Report 2011-12, at 4.
[116] See note 69 above.
[117] See 1.3.2 in ch 1 above and 6.3.1 in ch 6 below.

those three control-sharing mechanisms. It then determines whether or not such a level of control can be considered respectful towards participants by considering circumstantial factors that might affect their desire to influence ALSPAC's activities. These two steps are dealt with separately in two different sub-sub-sections, as follows.

a) Actual Level of Control

Among those three control-sharing mechanisms in ALSPAC governance, it can be said that the right of withdrawal is a main source of the control that participants have over the governance at an individual level, since the other two do not grant them much of such control. Particularly, the control resulting from consent to the feeding back of health information is limited only to this aspect of the governance and, indeed, subject to the availability of feedback. Broad consent does not provide a high level of such control: it merely restricts uses of the Resources to supporting 'research on the causes of the world's most important health and social problems';[118] this purpose encompasses a diverse range of studies, even including non-health-related research, and thus this consent imposes very little limitation on those uses in practice.

On the other hand, the right of withdrawal can be considered to provide a high level of such control. One reason is that, as explained above, participants have well been informed of this right and can also exercise it effectively due to CBP in the governance, which allows them to constantly keep up-to-date with ALSPAC's activities.[119] That is, they can know exactly how the Resources are used as well as whether and when they should exercise this right. Also, this right enables them to have control over their participation, as well as other biobanking activities relating to them individually, such as communicating with them, accessing their records in other databases and using their samples and information.[120] Given this explanation, it can be said that the right of withdrawal in the governance can be considered to give participants a high level of control over the governance at an individual level. It can

[118] Summary Information Booklet (2011), at 1.
[119] See 5.1.2 a) above.
[120] Policy on Withdrawal (2011).

therefore be argued that, from the perspective of the Model, **the right of withdrawal is deemed a main control-sharing mechanism for ALSPAC participants**.

b) Circumstantial Appropriateness

A subsequent question arises as to whether control sharing that mainly results from the right of withdrawal can be considered appropriate within the governance of ALSPAC. According to my research, accessible documents do not reveal any empirical studies that might be used to address this question directly.

Still, one can argue that the answer to this question may be positive. The reason is that this control sharing can be considered to show individual participants respect as it seems to give them more control over the governance than their need. Particularly, in the context of ALSPAC, there are a number of factors that can be assumed to reduce their need for such control. One is that ALSPAC does not involve the commercialisation of their samples or information. Another factor is that it is not organised and funded by industrial or commercial entities:[121] based on many empirical studies, this factor could lead participants to have high trust in ALSPAC,[122] and thus they are unlikely to require much control over its activities.[123] Third, it has the ALEC, which is tasked with overseeing and maintaining the ethical acceptability of its activities. Finally, its governance has many involvement mechanisms that allow some

[121] ALSPAC is operated by University of Bristol, and its core funders are this university, UK Medical Research Council and the Wellcome Trust. See ALSPAC, "About" available at http://www.bristol.ac.uk/alspac/about/ (accessed 13 January 2016).

[122] Many empirical studies reveal high trust in non-industrial related entities in a research context. See T Caulfield et al, "Biobanking, Consent, and Control: A Survey of Albertans on Key Research Ethics Issues" (2012) 10 *Biopreservation and Biobanking* 5 433-438; Z Master et al, "Cancer Patient Perceptions on the Ethical and Legal Issues Related to Biobanking" (2013) 6 1 available at http://dx.doi.org/10.1186/1755-8794-6-8 (accessed on 13 January 2016); Wellcome Trust, *Wellcome Trust Monitor Wave 2: Tracking Public Views onScience, Biomedical Research and Science Education*, (May 2013) 143; CR Critchley and D Nicol, "Understanding the Impact of Commercialization on Public Support for Scientific Research: Is It about the Funding Source or the Organization Conducting the Research?" (2011) 20 *Public Understanding of Science* 3 347-366.

[123] The relationship between a high level of trust and the reduced need for control over biobanking is acknowledged in extensive literature. See T Caulfield et al, "A Review of the Key Issues Associated with the Commercialization of Biobanks" (2014) 1 *Journal of Law and the Biosciences* 1 94-110; KB Brothers et al, "Two Large-Scale Surveys on Community Attitudes toward an Opt-Out Biobank" (2011) 155 *American Journal of Medical Genetics Part A* 12 2982-2990.

participants to monitor as well as influence its activities. It can be assumed from all these factors that participants' need for control over the governance is low, and thus it is probable that they feel satisfied with the level of control they have mainly from the right of withdrawal in the governance. It is therefore arguable that **the sharing of control within the governance can be considered respectful towards participants** and thus this sharing can be deemed appropriate according to the Model.

5.4.3 Interim Conclusion

To summarise, the level of control that individual participants actually have over the governance of ALSPAC is mainly based on their right to withdrawal. This is because, given CBP and withdrawal options they have in the governance, this right can be considered to give them a high level of control over the governance at an individual level, while broad consent and consent to the feeding back of health information do not provide much of such control in practice. Also, according to the Model, the extent of this control sharing can arguably be considered appropriate in the context of ALSPAC. The reason is that participants can be assumed to need a low level of such control due to many circumstantial factors within the governance, namely the absence of commercial involvement in the governance (both in terms of the direction of biobanking and the bodies that fund and organise ALSPAC), the ethical oversight of the ALEC and involvement mechanisms in the governance. Thus, one can say that ALSPAC participants are likely to feel satisfied with the level of control that they have over the governance as a result of their right of withdrawal, thus allowing the current control sharing within the governance to be considered respectful towards them. It is therefore arguable that control sharing in the governance can be deemed appropriate according to the Model, and thus this aspect of the governance conforms to the Model.

Conclusion

This chapter has argued that the governance of ALSPAC chiefly conforms to the Model, mainly because the governance has many mechanisms for communicating with participants. Particularly, the governance has established various communication channels for interacting with participants, such as participant newsletters and the ALSPAC website. In terms of content, these channels provide participants with various types of information – ranging from notifications, justifications and summaries of certain biobanking activities, to instructions on how to attend or participate in some activities, such as measurements and data collections. It can therefore be argued that participants are allowed to access both prospective and retrospective information about ALSPAC's activities, understand them, and know how to deal with them. The only suggestion on this point is that information about participant safeguards or the ALEC's activities should be made more accessible and regularly communicated to participants.[124] From the perspective of the Model, this communication helps considerably to make the governance conform to all the key attributes of the Model. First, it helps emphasise collective goals by making ALSPAC's goals clear to participants and allowing them to verify that they still share the same goals with ALSPAC. Second, it facilitates collaboration by allowing participants to provide input about the governance as well as providing them with the information and knowledge that can render their input meaningful. Third, it provides them with reciprocation by allowing clarification of and negotiation over policies on tangible reciprocation as well as enabling them to realise that collective goals are being pursued and safeguards for them are provided. Finally, it gives participants control over the governance at an individual level by assisting them in exercising their right of withdrawal.

It is worth noting that ALSPAC governance also has many involvement mechanisms that formally recruit some participants to work with ALSPAC and to influence its activities. These mechanisms significantly help foster collaboration between participants and ALSPAC: they allow participants to provide input about the governance; also, much of that input has evidently influenced ALSPAC's activities in

[124] See 5.3.1 b) (third paragraph) above.

practice, although it is unclear from accessible information as to the details of how such input was actually dealt with. A notable one is the involvement of the OCAP, which has helped ALSPAC address many issues and influenced many ALSPAC's activities. Indeed, the fact that this panel has existed for a decade reflects not only the success of this mechanism but also ongoing collaboration in the governance. Other examples of these mechanisms are the recruitment of some participants to the ALEC and the working group for the Fathers' study. In practice, these mechanisms can generally be considered to improve a participant-biobanker relationship as well as facilitate ALSPAC's activities. For the Model, they basically strengthen to its key attribute of collaboration. However, they might also raise the issue of representation, which is not desirable. While this issue seems to be unlikely here, there is not enough information to either rule it out or confirm it. It is also notable that, according to the Model, these mechanisms are not deemed to be control-sharing mechanisms. This is because they give participants control over the governance at a collective level, while the Model focuses on the individual level of a participant-biobanker relationship.

Based on all of these explanations, it can therefore be argued that ALSPAC governance largely conforms to the Model, and thus the ARR is likely to have been developed in it. This might justify the longevity of ALSPAC. Notwithstanding, the lack of detailed information about many ALSPAC's activities hinders this chapter from discussing many aspects of the governance. This hindrance not only undermines the robustness and accuracy of many discussions and arguments here, but also prevents this chapter from confirming a higher degree of such conformity, as consistently noted throughout this chapter. As a notable example, information about the Co-PIs is not sufficient to confirm whether they can play a role in encouraging ALSPAC to pursue collective goals, thereby making this chapter unable to confirm whether this aspect of the governance conforms to the Model's key attributes of emphasis on collective goals and reciprocation. Other aspects of the governance that suffer from such lack include the progress on the 'research partners' scheme, the effects of financial incentives on participants' decisions to participate, and the ways in which ALSPAC deals with participants' input. More information is therefore required to increase the depth and accuracy of the discussions in this chapter. This also implies that this chapter's picture

of ALSPAC governance and a participant-biobanker relationship in it might not agree with the reality.

Despite the lack of detailed information about many ALSPAC's activities, this chapter is still useful for this thesis. The reason is that it can achieve the main aim of illustrating how the Model is applied in practice by showing what aspects of the governance are of interest to the Model and what biobanking activities contribute to the conformity of the governance to the Model, as well as pinpointing issues that might arise within the governance from the perspective of the Model.

Chapter 6

Extent of Contribution

The contribution of this thesis concerns an authentic research relationship in biobanking ("**an ARR**"), a participant-biobanker relationship that can deal with issues and challenges in biobanking practice. Based on the notion that there may be many types of participant-biobanker relationship that can be deemed an ARR, this thesis proposes one approach to an ARR that looks like a partnership relationship ("**the ARR**"). The proposals relating to the ARR ("**the Proposals**") have been illustrated in the first three chapters of this thesis. In short, Chapter 1 established the fundamental notion of the ARR by proposing its main characteristics. Next, Chapter 2 proposed a conceptual framework for the ARR, which is based on partnership and consists of five key features that are considered to exhibit the main characteristics of the ARR. Then, Chapter 3 proposed a partnership model for biobank governance that is used to foster the ARR in practice ("**the Model**"). A diagram illustrating the overall picture of the Proposals is provided in Box 6.1 below. Ultimately, to demonstrate how the Model is applied in practice, Chapters 4 and 5 tested the Model against biobank initiatives, namely UK Biobank and ALSPAC, respectively.

This chapter draws together all aspects of the contribution and outlines how they add up to – and go beyond – existing knowledge in the area of biobanking, so as to highlight their originality. It is also intended to clarify the Proposals by explaining what types of literature they contribute towards and the extent to which they are applicable, as well as how they handle some issues that commonly arise in biobanking. In so doing, this chapter has four sections. The first section summarises the contribution of this thesis, which essentially involves the Proposals and the lessons learnt from testing the Model against practical biobanking initiatives. The next one pinpoints the scholarly value of the Proposals by reflecting on their academic grounding, i.e. what type of literature they relate to. The third section outlines some limitations of the Proposals when putting them into practice. The last section, from the perspective of the Proposals, discusses some issues that usually arise in a biobanking

context but which are not sufficiently addressed in previous chapters, with the aim to further clarify the Proposals by illustrating how they handle these issues.

6.1 Summary of the Contribution

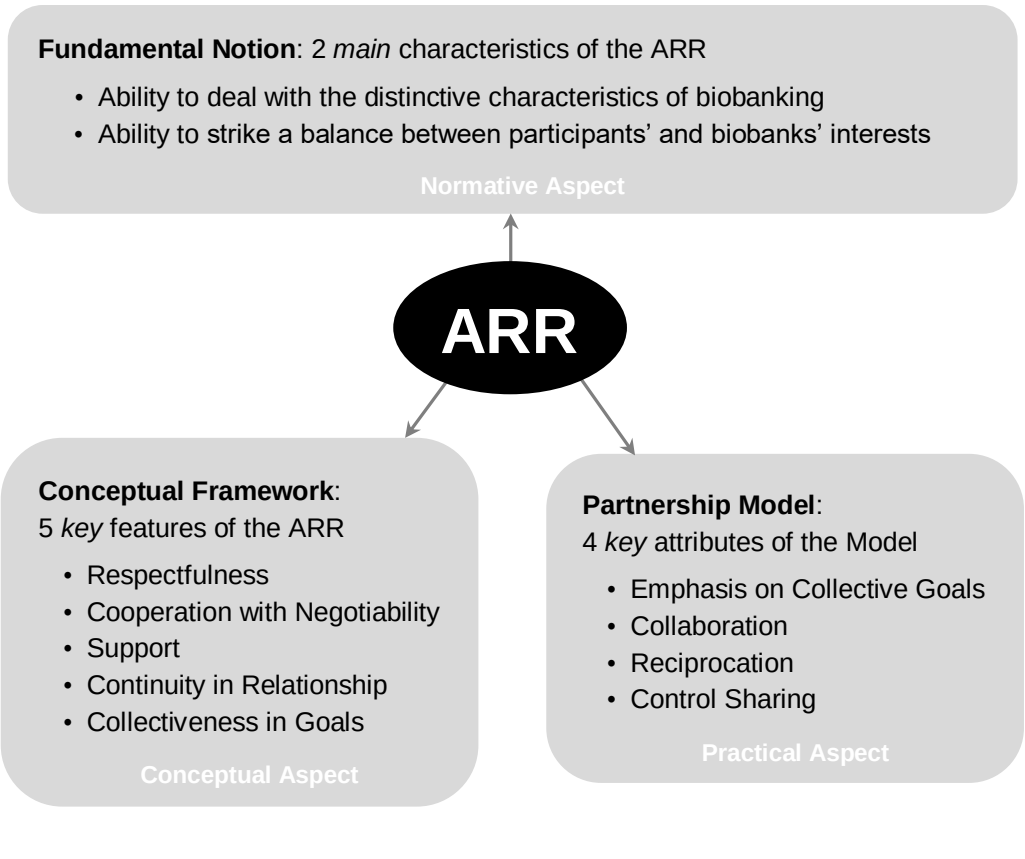
Overall, the contribution of this thesis focuses on a participant-biobanker relationship that can help encourage effective and ethically robust biobanking practices. The reasons behind this focus can be concluded as follows. While biobanking has many distinctive characteristics that are beneficial to research conduct, these characteristics raise many issues and challenges, such as the ineffectiveness of conventional safeguards, the risk of unauthorised identification and the increased need for commercial involvement. These issues and challenges could render biobanking less appealing to participants, thereby inherently undermining biobanking itself. Also, they are so complicated that the implementation of one-off mechanisms or engagement measures may not be able to provide appropriate solutions, thus calling for a relatively holistic solution to those issues and challenges. A focus on a participant-biobanker relationship, which involves an element of continuity and many aspects of interaction, might therefore offer a systemic and coherent solution to those issues and challenges. In addition, it can be said from the above explanation that, to encourage biobanking, this relationship needs to be able to deal with the practical and ethical issues and challenges arising from the distinctive characteristics of biobanking. On the other hand, it is also required to attract participants, who are considered to be crucial contributors to biobanking. Accordingly, this thesis first establishes that, in general, this relationship should be able to enhance the ethical acceptability of biobanking to participants as well as the effectiveness of it in scientific and human health terms.

This premise leads to the principal research question of this thesis: What form of research relationship is appropriate for ethical and effective biobanking practices? To address this top-level question, three sub-questions were dealt with. The first one concerns normative justification for the ARR: Why is the ARR desirable for biobanking? With the aim of establishing a conceptual framework for the ARR, the second sub-question is: What should the ARR look like from a conceptual perspective?

From a practical perspective, the last sub-question concerns how the ARR can be developed in biobanking practice. The answers to these three sub-questions are called the Proposals. They cover the normative, conceptual and practical aspects of the ARR, which were explained in Chapters 1, 2 and 3, respectively. To determine the practicality of the Proposals, they were also tested against biobank initiatives, namely UK Biobank and ALSPAC, in Chapters 4 and 5, respectively. Given this explanation, it can be said that the Proposals and lessons learnt from this testing are considered as the main contribution of this thesis.

To summarise this main contribution, it is briefly outlined in two sub-sections: one deals with the Proposals, and the other explains the results and some notes from testing the Proposals against UK Biobank and ALSPAC.

Box 6.1: The proposals of the thesis



6.1.1 Proposals of the Thesis

As explained above, the Proposals involve the normative, conceptual and practical aspects of the ARR. To give the overall picture of the Proposals, the diagram thereof is provided in Box 6.1 above. In this sub-section, the Proposals are explained in three sub-sub-sections, according to the aspects of the Proposals. In particular, the first sub-sub-section explains the fundamental notion of the ARR, which consists of two main characteristics of the ARR. The second sub-sub-section deals with the conceptual aspect of the ARR by explaining its conceptual framework, which comprises five key features of the ARR. The last sub-sub-section explains the Model, which has four key attributes and can be used to develop the ARR in practice.

a) Fundamental Notion of the ARR

The fundamental notion of the ARR is dealt with in the first chapter of this thesis. It amounts to the main criteria that are used in Chapter 2 to determine the underlying concept of the ARR and develop a conceptual framework for it. This notion stems from an attempt to address two major challenges created by the background problems of this thesis. One major challenge is that the distinctive characteristics of biobanking are beneficial to research conduct, but they can raise many issues and challenges in biobanking practice. For the other one, there are two values that need to be promoted in biobanking, i.e. the ethical acceptability of biobanking to participants and the effectiveness of biobanking. Given these two major challenges, this thesis argues that the ARR should have two main characteristics, each of which can respond to one of these two major challenges. The first is the ability to deal with the distinctive characteristics of biobanking that can raise issues and challenges in biobanking practice, such as the longevity of biobanking and multiple and unexpected uses of biobank resources. The second is the ability to strike a balance between participants' and biobanks' interests. This ability is based on the idea that the ethical acceptability of biobanking to participants and the effectiveness of biobanking can be equated with participants' and biobanks' interests, respectively. Indeed, these two interests might conflict with each other, but they are both crucial for biobanking. To encourage biobanking, these two interests should therefore be balanced with each other.

Given this explanation, it can be said that these two main characteristics can address those two major challenges and thus they can deliver ethical and effective biobanking practices. This thesis therefore argues that they should be considered to be the fundamental notion of the ARR. Indeed, they can also be used to address the first sub-question of this thesis, which concerns normative justification for the ARR. In particular, the reason why the ARR is desirable for biobanking is that, according to its main characteristics, it is intended to address the distinctive characteristics of biobanking that make biobanking unappealing to participants. Also, it requires participants' interests to be balanced with those of biobanks, and thereby it is likely to be able to enhance the ethical acceptability of biobanking to participants as well as the effectiveness of biobanking in an appropriate fashion. In other words, the ARR is designed to solve the background problems of this thesis and to create a situation where the attractiveness of biobanking to participants is in harmony with the benefits of biobanking to health-related research. Based on these explanations, it is therefore arguable that the ARR is desirable for biobanking.

b) Conceptual Framework of the ARR

The conceptual framework of the ARR is proposed in Chapter 2, with the aim of answering the second sub-question of this thesis – concerning the conceptual aspect of the ARR. This chapter performs two tasks. The first is to locate the social-science conceptual basis that is foundational to the ARR by seeking the underlying concept of the ARR. In so doing, it first establishes that such a concept needs to be applicable to biobank governance and able to exhibit the two main characteristics of the ARR. Then, it takes into consideration the concepts of solidarity and partnership. As a reason, these two concepts are applicable to and promising for biobanking: they both involve a strong relationship between individuals and a disposition towards collective interests or goals. Indeed, they have been used in extensive literature that seeks to pursue ethical biobanking practices. To study them, this chapter reviews the literature explaining them and proposes their working notions for this thesis. After studying these two concepts, it argues that solidarity cannot underlie the ARR. The reason is that solidarity cannot be prescribed and it does not sufficiently recognise individuals' interests, thereby making this concept incapable of being applied to biobank governance and

exhibiting one main characteristic of the ARR, respectively. As partnership does not suffer from these issues, Chapter 2 argues that partnership should be the concept underlying the ARR, while solidarity should only be an aspirational concept. This argument suggests that the ARR should look like a partnership relationship.

The second task is to use partnership as a basis for outlining a conceptual framework for the ARR. To do this task, it is proposed that this framework should have five key features, namely: (a) respectfulness, (b) cooperation with negotiability, (c) support, (d) continuity in relationship and (e) collectiveness in goals. These key features can be explained in terms of a participant-biobanker relationship, as follows: from a cognitive perspective, biobankers are required to respect participants as partners; in practice, they need to carry out activities that express respectful gestures towards participants, including collaboration and support; they are required to maintain their relationship with participants; they also need to share the same biobanking goals as participants. Given this explanation, it can be said that these key features echo partnership attributes and, as an added bonus, potentially encourage solidarity. More importantly, they can exhibit the two main characteristics of the ARR. In short, the key feature of continuity in relationship can deal with the longevity of biobanking and unexpected uses of biobank resources, and the other key features can strike a balance between participants' and biobanks' interests. Thus, these key features are considered as the conceptual framework of the ARR, and they are used in Chapter 3 to inform a partnership model proposed for developing the ARR in practice.

c) Partnership Model for Fostering the ARR

With the aim of addressing the last sub-question of this thesis – concerning a practical aspect of the ARR – Chapter 3 proposes the Model, a partnership model for biobank governance that can be used to develop the ARR in practice. The Model consists of four key attributes. They require implementing certain measures and can reflect the aforesaid key features of the ARR, as follows. (1) The key attribute of emphasis on collective goals asks biobankers to clarify biobanking goals and establish mechanisms for encouraging them and participants to share the same biobanking goals. This exhibits the ARR's key feature of collectiveness in goals. (2) The key attribute of

collaboration requires biobankers to give participants opportunities of providing input on biobank governance and ensure the meaningfulness of that input, thereby reflecting the ARR's key features of respectfulness and cooperation with negotiability. (3) The key attribute of reciprocation calls for reciprocating participants' contributions, whether in intangible or tangible form, so as to exhibit the ARR's key features of respectfulness and continuity in relationship. (4) The key attribute of control sharing calls for appropriate sharing of control over biobanking with individual participants. This sharing can reflect the ARR's key feature of respectfulness. Indeed, as most of these key attributes involve providing participants with information about biobanking activities and knowledge about biobanking, they are considered to be empowerment, thereby echoing the ARR's key feature of support. The above explanation suggests that the Model can be used to develop the ARR, since all its key attributes and the measures it requires can reflect all the key features of the ARR.

Three points are noteworthy here. First, the Model also suggests some mechanisms for implementing those measures, such as the establishment of an oversight body and communication about biobanking progress ("**CBP**"). However, these mechanisms are merely suggestions and thus they are not necessary for applying the Model. Second, the Model is not intended to add a more top-down superstructure of detailed rules to follow or mandatory requirements for biobankers to satisfy. Nor does it say that any biobank governance that does not conform to the Model is *always* wrong, unethical or prone to undermine a participant-biobanker relationship. Rather, the Model suggests how to develop the ARR, which is considered desirable for biobanking. Thus, it can be considered to be ethical guidelines for making biobanking attractive to participants and, so, probably more viable. It can also be seen as a form of 'maturity model', whereby biobankers can test their full preparedness on the road to fostering genuine and authentic relationships with their participants. Finally, there are no criteria for when the ARR exists in biobank governance. The Model provides good reasons to believe that the ARR is more likely if the measures it requires are adopted. In this respect, the more certain biobank governance conforms to the Model, the more likely the ARR is developed in that governance.

6.1.2 Examples of Application

With the main aim to demonstrate how the Model is applied in practice, this thesis eventually tests the Model against actual biobank initiatives, i.e. UK Biobank and ALSPAC, in Chapters 4 and 5, respectively. As the research into the governance of these two biobanks is based on publicly-accessible documents, there are some limitations on the accessibility of information regarding their biobanking activities. This implies that the picture of research relationships in their governance as well as details about their activities are purely based on my interpretation of such documents, and thereby might not be factually accurate. Even so, some lessons can be learnt from this testing: as UK Biobank and ALSPAC have different characteristics and their governance arrangements largely conform to the Model, this testing can help illustrate what aspects of biobank governance are really important for fostering the ARR in practice. This sub-section therefore deals with these lessons by, first, illustrating the similarities and differences between these two biobank initiatives from the perspective of the Model; and then, based on these similarities and differences, it concludes mechanisms that are crucial for developing the ARR in practice.

a) UK Biobank vs ALSPAC

This thesis has argued that the governance of these two biobanks mainly conforms to the Model and thus the ARR is likely to have been developed in them. The reason behind this conformity is that both biobanks have effective communication with participants.[1] In particular, they both give their participants ongoing access to updates about their biobanking activities, including management and uses of their resources, through many communication channels, such as participant newsletters and websites. As a result, participants in both biobanks can properly use their rights of withdrawal to control how their samples and information are used and to reinforce

[1] The term 'communication' in this chapter refers to any mechanisms set up to transfer or exchange information between relevant parties, whether one way or two ways. Thus, this term ranges from the transfer of information through newsletters and websites, to information exchanged through dialogues and discussions. Involvement mechanisms can therefore be considered to be one approach to this communication. The difference is that communication focuses on the transfer of information while involvement mechanisms focus on the act of taking part.

collectiveness in biobanking goals. They can also check whether their goals and interests are respected. Moreover, both biobanks have communication channels that enable participants to provide input about their governance, such as meetings and channels for general enquiries and feedback. Indeed, they also share basic information about themselves and general knowledge about biobanking with participants, thereby empowering participants to engage in biobanking and provide useful input. Thus, it is possible for their participants to collaborate and negotiate with them effectively. To this extent, this is considered as a range of ways in which there is similarity between these two biobanks. Note that, as those communication channels are in line with many measures proposed in the Model, they arguably play an essential role in making the governance of these two biobanks conform to the Model, as emphasised below.

In contrast, there is one major difference between the governance of these two biobanks, i.e. the existence of an oversight body that is assigned to encourage the conformity of biobanking activities to participants' goals, according to the Model's key attributes of emphasis on collective goals and reciprocation. Particularly, UK Biobank has the Ethics and Governance Council ("**EGC**"), which consistently monitors its activities – including the uses and management of its resources – in order to encourage the conformity of its activities to participants' consent. Also, the EGC might resist certain biobanking activities through some latent sanctions imposed by UK Biobank's funders and participants. The EGC is therefore capable of performing such an encouraging task. By contrast, it is unclear whether ALSPAC has an oversight body that is assigned to handle this encouraging task: the ALSPAC Law and Ethics Committee does not routinely oversee its activities to monitor the conformity of its activities to participants' goals; although its co-principal investigators are eligible to perform routine oversight as well as such an encouraging task, it is doubtful from accessible documents whether they actually do so in practice. Given this difference, one can therefore argue that UK Biobank governance better reflects those two key attributes of the Model, thereby making it, overall, more conformable to the Model when compared with ALSPAC governance.

In terms of involvement mechanisms, UK Biobank governance has several public and participant meetings and one public consultation on its access procedures.

It also has channels for general enquiries and feedback, whereby participants can provide their input about it. In ALSPAC governance, similar channels are available and, in addition, participants can engage in some working groups and committees or even become members of participant advisory groups. When compared with UK Biobank, ALSPAC is considered to give its participants more chances of influencing its activities because their input is more likely to be taken into consideration. As a result, its governance has better collaboration between participants and biobankers, and thus its governance conforms better to the Model's key attribute of collaboration. Nonetheless, it is worth noting that such engagement makes its governance prone to the issue of representation, which is undesirable for the ARR:[2] all participants might be represented by those appointed to those groups and committees, and thereby input from those who are not appointed, if any, might be disregarded. While this issue might not and is unlikely to arise in practice, it is difficult either to rule out or to confirm this issue because information about how participants' input has actually been dealt with in ALSPAC governance is not accessible. By contrast, UK Biobank governance does not have such engagement, but it is evident that this governance has mechanisms for preventing participants' input from being disregarded by UK Biobank.

b) Crucial Mechanisms

Given the similarities and differences between the governance of UK Biobank and ALSPAC, it can be concluded that there are two key mechanisms that are crucial for adopting the Model: (1) communication with participants and (2) the establishment of an oversight body that is assigned to monitor biobanking activities and is able to influence biobanking activities. By the term 'crucial', these mechanisms play a substantial role in making certain biobank governance conform to the Model. The reason is that they help exhibit many key attributes of the Model, and thereby they create the likely possibility of the ARR being developed. It is worth emphasising that, as this sub-section concerns lessons learnt from testing the Model against UK Biobank and ALSPAC, these mechanisms basically result from comparing the governance of these two biobanks from the perspective of the Model. In this respect, they are actually

[2] See 6.3.1 (Representation) below.

not important part of the Proposals, which were already summarised in the previous sub-section. That is, they are considered to be merely suggestions about how to adopt the Model in biobanking practice, as opposed to requirements that need to be satisfied in order to comply with the Model.[3] Thus, it can be said that, although certain biobank governance does not have these mechanisms, it still can conform to the Model if it has other mechanisms that can implement the measures required by the Model.[4] As for the structure of this sub-sub-section, it deals with these two crucial mechanisms separately by first explaining reasons why they are deemed crucial and then outlining characteristics that they should have according to the Model.

Communication with Participants

First and foremost is communication with participants, which refers to the transfer of information from and to participants. According to the Proposals, this communication should serve as mechanisms for informing participants of updates on biobanking activities, sharing general knowledge about biobanking with them, and receiving their input about biobank governance. In this respect, it enables participants to understand biobanking and activities, update them on biobanking progress, and receives input from them. In terms of the Model's key attributes, this communication helps emphasise collective goals by clarifying biobanking goals and encouraging participants and biobankers to share the same goals. It can facilitate collaboration in biobanking by receiving input on biobank governance from participants and empowering them to provide useful input. It can also facilitate exercising the right of withdrawal, which is a control-sharing mechanism according to the Model. Moreover, it can be used for reciprocating their contributions: it allows them to know that collective goals are being pursued and their interests are safeguarded; it enables them to negotiate about policies on tangible reciprocation, where it is provided. Notably, in

[3] To make certain biobank governance conform to the Model, biobankers are required to implement the measures that are proposed for applying the key attributes of the Model. This implementation is not necessarily similar to mechanisms that the Model suggests for implementing those measures.

[4] For example, even though it is impractical for certain biobank governance to establish the aforesaid oversight body, it is still possible for that governance to comply with the Model if some parties in that governance, such as biobankers and participants, are tasked with the same role as this body.

practice, it can address the issue regarding an asymmetry of information, which usually arises during negotiation processes: as the Model requires biobankers to clarify those policies as well as deal with the insufficiency of participants' capability to provide input about biobanking, biobankers need to adequately provide participants with the information that is useful for this negotiation.

This explanation suggests that this communication helps biobank governance to comply with all the key attributes of the Model. Furthermore, it can be said that this communication helps exhibit all the key features of the ARR: it empowers participants to deal with many aspects of biobank governance, and thereby it well echoes the ARR's key feature of support; the fact that it can be used to apply all the key attributes of the Model indicates that it can reflect the other key features of the ARR. One can therefore say that this communication is crucial for the development of the ARR. Thus, in practice, biobankers should attach importance to this communication when they adopt the Model. In this respect, any biobank governance that has regular and effective communication with participants is likely to conform well to the Model.

The characteristics of this communication can be concluded as follows. As this communication is used to enable participants to understand certain aspects of biobanking and realise certain biobanking activities, its content generally includes background information about biobanks in which they participate, updates about the activities of these biobanks, and general knowledge about biobanking. Also, its content should be understandable to participants. This is especially the case for information about biobanking goals, which should be sufficiently clear and should emphasise any commercial involvement in biobanking.[5] Its methods are not specific to any form or medium, but it should be effective and accessible to all cohort participants. Indeed, communication about biobank activities should have an element of continuity, thereby reflecting the ARR's key feature of continuity in relationship. In practice, this allows anticipating any changes to the direction of biobanking and, as revealed by some empirical studies, the possibility that participants disregard some information during

[5] See 3.1.1 a) in ch 3.

recruitment.[6] Other than these characteristics, this communication should be open and honest in order to reinforce the ARR's key feature of respectfulness, as well as avoiding causing any scandals.

Note that this communication is in line with extensive academic literature: many authors support communication with participants by citing its benefits, such as trust,[7] transparency,[8] reflexivity and adaptability;[9] some consider it to be a mechanism for developing a partnership relationship with participants;[10] interestingly, some authors say that, due to the identifiability of information in biobanking practice, biobankers have a moral obligation to notify participants of how their information will be used.[11] This communication is also supported by many empirical studies revealing the preference for being informed about biobanking activities,[12] even over the need for consent.[13] It is noteworthy that, to comply with certain key attributes of the Model,

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[6] P Ducournau and R Strand, "Trust, Distrust and Co-production: The Relationship Between Research Biobanks and Donors" in JH Solbakk, S Holm and B Hofmann (eds), *The Ethics of Research Biobanking*, (London: Springer Science, 2009) 115-130; K Hoeyer, "'Science Is Really Needed—That's All I Know': Informed Consent and the Non-verbal Practices of Collecting Blood for Genetic Research in Northern Sweden" (2003) 22 *New Genetics and Society* 3 229-244; H Busby, "Blood Donation for Genetic Research: What Can We Learn from Donors' Narratives?" in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, (London: Routledge, 2004) 39-56.

[7] H Machado and S Silva, "Public Participation in Genetic Databases: Crossing the Boundaries between Biobanks and Forensic DNA Databases through the Principle of Solidarity" (2015) 41 *Journal of Medical Ethics* 10 820-824, at 822.

[8] LM Beskow and E Dean, "Informed Consent for Biorepositories: Assessing Prospective Participants' Understanding and Opinions" (2008) 17 *Cancer Epidemiol Biomarkers Prev* 6 1440-1451.

[9] KC O'Doherty et al, "From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks" (2011) 73 *Social Science & Medicine* 3 367-374, at 372; G Laurie, "Reflexive Governance in Biobanking: on the Value of Policy Led Approaches and the Need to Recognise the Limits of Law" (2011) 130 *Human Genetics* 3 347-356.

[10] AV Campbell, "The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust" (2007) 18 *King's Law Journal* 2 227-245; J Kaye et al, "From Patients to Partners: Participant-Centric Initiatives in Biomedical Research" (2012) 13 *Nature Reviews: Genetics* 5 371-376; K Saha and JB Hurlbut, "Research Ethics: Treat Donors as Partners in Biobank Research" (2011) 478 *Nature* 7369 312-313.

[11] J Kaye, "Abandoning Informed Consent the Case of Genetic Research in Population Collections" in R Tutton and O Corrigan (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, (London: Routledge, 2004) 117-138, at 130-131.

[12] C Grady et al, "Broad Consent for Research with Biological Samples: Workshop Conclusions" (2015) 15 *The American Journal of Bioethics* 9 34-42.

[13] E Vermeulen et al, "Obtaining 'Fresh' Consent for Genetic Research with Biological Samples Archived 10 Years Ago" (2009) 45 *European Journal of Cancer* 7 1168-1174; E Vermeulen et al, "A Trial of Consent Procedures for Future Research with Clinically

additional mechanisms need to be implemented together with this communication. For example, to collaborate with participants, biobank governance is required to have both communication channels for receiving their input and mechanisms for dealing with their input properly. To emphasise collective goals, biobank governance should have communication that keeps participants up-to-date with biobanking progress, aka CBP, and it should also allow them to have the right to withdraw their consent.

Establishment of an Oversight Body

The second mechanism is the establishment of an oversight body that is assigned to monitor and can influence biobanking activities. This body needs to be capable of (1) accessing information about biobanking activities so as to determine biobankers' actual goals and the sufficiency of existing participant safeguards, and (2) influencing biobanking activities in order to either resist activities that do not conform to collective goals or lead biobankers to provide participant with sufficient safeguards, if necessary. According to the Model, this body plays a role in reinforcing the collectiveness in biobanking goals between participants and biobankers, thereby reflecting the Model's key attribute of emphasis on collective goals. It also takes a role in encouraging biobankers to pursue collective goals and to provide sufficient safeguards for participants. This encouraging role is deemed to be a way to provide participants with intangible reciprocation and thus it can fulfil the Model's key attribute of reciprocation. Based on this explanation, the establishment of this oversight body can be considered crucial for the Model because it helps exhibit two key attributes of the Model, i.e. emphasis on collective goals and reciprocation.

It is noteworthy that, as suggested above, the establishment of this oversight body is not necessary to make biobank governance conform to the Model. Thus, biobank governance still can conform to the Model provided that it has other mechanisms that can perform those roles instead of this body. In this respect, the function that this mechanism serves is important, not the form it takes. Nonetheless, it

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Derived Biological Samples" (2009) 101 *British Journal of Cancer* 9 1505-1512;
E Vermeulen et al, "Opt-Out Plus, the Patients' Choice: Preferences of Cancer Patients Concerning Information and Consent Regimen for Future Research with Biological Samples Archived in the Context of Treatment" (2009) 62 *Journal of Clinical Pathology* 3 275-278.

can be said that, in practice, this mechanism is more feasible than assigning those roles to participants. One reason is that participants might not be sufficiently active and/or capable of overseeing biobanking activities. Moreover, they are unlikely to be able to influence biobanking activities or to encourage biobankers to pursue collective goals and provide sufficient safeguards by themselves. Accordingly, in practice, it might be more workable to comply with those two key attributes of the Model by establishing this body to play those roles, rather than giving those roles to participants.

As regards the characteristics of this oversight body, no precise composition is required by the Model, but there are some notable points in this regard. First, as implied from its roles explained above, it needs to have sufficient knowledge in the areas of research and biobanking, and thereby it should have professionals in these areas as its members. Second, the inclusion of participants and/or external persons in it is neither necessary nor prohibited. Notably, such inclusion is preferable in terms of openness, accountability and collaboration, but the inclusion of participants might inflict the issue of representation, as discussed below.[14] Third, it is possible that some members of this body are biobankers. Indeed, such membership can be advantageous in practice, in that this body can conveniently oversee biobanking activities by simply receiving information thereon from member biobankers. However, it is also possible that this membership allows biobankers to influence or even interfere with this body's activities, thereby hindering this body from properly performing its role. Accordingly, if biobankers are recruited to it, there should be mechanisms for precluding them from causing such hindrance. Finally, this body is not necessarily external to or independent of biobanks because the effectiveness in performing the aforesaid roles is an important consideration. It is therefore possible that biobankers, like principal investigators, will play a role as this body. In this case, it should be evident that they effectively monitor biobanking activities, reliably resist activities that do not conform to collective goals and can encourage providing sufficient safeguards for participants.

[14] See 6.3.1 (Representation) below.

6.1.3 Interim Conclusion

To summarise this section, the contribution of this thesis revolves around the ARR. The first chapter establishes that an authentic relationship in biobanking should enhance both the ethical acceptability and effectiveness of biobanking, and thereby the ARR should be able to handle practical and ethical issues resulting from the distinctive characteristics of biobanking and also to strike a balance between participants' and biobanks' interests. Based on this premise, Chapter 2 explains why the ARR should be based on partnership, and uses this concept to develop the conceptual framework of the ARR by proposing the key features thereof. Then, Chapter 3 proposes the Model, a partnership model for biobank governance that biobankers can use to foster the ARR in practice. The Model has four key attributes, namely emphasis on collective goals, collaboration, reciprocation and control sharing. Eventually, to show how the Model is applied in practice, Chapters 4 and 5 test the Model against two biobanks, i.e. UK Biobank and ALSPAC, respectively. This testing inherently shows how biobank governance can conform to the Model in practice, and it leads to the conclusion that there are two crucial mechanisms that significantly promote this conformity. One is communication with participants, which can exhibit every key attribute of the Model, and the other is the establishment of an oversight body that is able to monitor and influence biobanking activities.

To demonstrate how the practical aspect of the Proposals correspond to the normative aspect thereof, the relation between the Model and the fundamental notion of the ARR, established in Chapter 1, can be summed up, as follows. The Model can be used to make a participant-biobanker relationship exhibit the main characteristics of the ARR because it can respond to issues and challenges in biobanking practice, as well as can balance participants' and biobanks' interests. Particularly, it fundamentally involves ongoing communication with participants, which can deal with multiple and unexpected uses of biobank resources given that broad consent is a mainstream approach to consent in biobanking practice. The need for reciprocation can help maintain a participant-biobanker relationship, thereby addressing the longevity of biobanking. Also, in general, other unprecedented challenges could be solved through collaboration between biobankers and participants. Furthermore, the Model promotes

both biobanks' and participants' interests by emphasising collective goals and allowing participants to be involved in biobank governance or influence biobanking activities, respectively. Thus, it can be used to strike a balance between these two interests. Based on this explanation, it can therefore be argued that the Model can develop a participant-biobanker relationship that can enhance both the ethical acceptability of biobanking to participants and the effectiveness of biobanking.

All aspects of the contribution here have already answered the main research question as well as all three sub-questions of this thesis. Particularly, for the top-level question, the ARR proposed in this thesis is one approach to a research relationship that can deliver ethical and effective biobanking practices. For the three sub-questions, they are addressed, as follows. The ARR is desirable for biobanking, because it is designed to encourage biobanking by dealing with the practical and ethical issues and challenges stemming from the distinctive characteristics of biobanking and by striking a balance between participants' and biobanks' interests, both of which are considered important for the viability of biobanking. From a conceptual perspective, the ARR should look like a partnership relationship, and thereby it should have five key features, i.e. respectfulness, cooperation with negotiability, support, continuity in relationship and collectiveness in goals. To develop the ARR in practice, biobankers can apply the Model to biobank governance. This model has four key attributes, namely emphasis on collective goals, collaboration, reciprocation and control sharing. In the following sections, the contribution of this thesis is further emphasised and clarified by pinpointing its academic grounding and limitations as well as its capability to deal with issues that commonly arise in biobanking practice.

6.2 Academic Grounding of the Proposals

It can be concluded from the previous section that this thesis attempts to make a contribution towards the notion of an ARR, which is assumed to be a participant-biobanker relationship that can promote the ethical acceptability and effectiveness of biobanking. In short, it first proposes the main characteristics of the ARR as a fundamental notion thereof. Next, it argues that the ARR should be based on

partnership, and then translates partnership attributes into five key features of the ARR, which are taken together as the conceptual framework of the ARR. Finally, it uses this framework to develop the Model, which can be used to develop the ARR in biobanking practice. Given this explanation, we might usefully ask what types of literature the Proposals can contribute towards. As the ARR is intended to be a desirable relationship or to deliver appropriate actions between parties in the context of biobanking, two main academic disciplines can be put on the table: ethics and law. Accordingly, this section deals with this question by determining whether or not the Proposals can be used as ethical and legal frameworks for biobank governance.

6.2.1 Ethicality

Chapter 1 has briefly explained about the ethicality of the Proposals and concluded that the Proposals contain an element of ethicality and they use deontological ethics and virtue ethics as their approaches to ethical reasoning.[15] This sub-section engages with this aspect of the Proposals again in order to provide more insight into it and further clarify it by, inter alia, showing how it is reflected in certain part of the Proposals.[16] Thus, this sub-section is to discuss again the question of which moral theories underlie methods that this thesis uses for ethically justifying the Proposals.

As there are three main moral theories of modern philosophy in the field of bioethics – namely consequentialism, deontological ethics and virtue ethics[17] – this discussion is separated into three sub-sub-sections, each of which deal with one of these main moral theories. It is worth emphasising that this sub-section aims to explain the ways in which the content of the Proposals is ethically justified in order to facilitate understanding of the Proposals. It focuses on the methodology of ethical reasoning in

[15] See 1.3.3 in ch 1 above. See also 2.3 (last paragraph) in ch 2 and Conclusion in ch 3 above.
[16] In Chapter 1, the explanation about this aspect of the Proposals is mainly based on the research questions of the thesis.
[17] M Talbot, *Bioethics: An Introduction*, (Cambridge: Cambridge University Press, 2012). Other moral theories are explained in detail elsewhere. See JF Childress, "Methods in Bioethics" in B Steinbock (ed) *The Oxford Handbook of Bioethics*, (Oxford: Oxford University Press, 2007) 15-45;

this respect. For the content of justification, the Proposals have already been justified normatively through the explanation about the fundamental notion of the ARR.[18]

Consequentialism

Consequentialism involves using the results of past actions to determine moral acceptability thereof. From a prospective perspective, actions are morally acceptable if they can yield maximally good consequences and minimally bad ones. Utilitarianism is an exemplar of this theory that considers the happiness of the greatest number as a morally desirable consequence.[19]

This moral theory is the first to be ruled out since the Model generally requires implementing certain measures, not targeting certain consequences. This is evident in many of its requirements. For example, its key attribute of emphasis on collective goals calls for clarifying biobanking goals, not participants' clear understandings of biobanking goals.[20] Also, the key attribute of control sharing does not specify the level of control over biobanking that needs to be shared with participants; rather, it requires biobankers to share control over biobanking with participants in a contextually appropriate fashion. Indeed, although the Proposals aim to foster the ARR, they require neither the existence nor evidence of the ARR. The main characteristics and key features of the ARR are merely used as theoretical bases for proposing its conceptual framework and a model for fostering it, respectively. In this respect, they are merely guidelines for how biobankers should behave towards participants in order to foster the ARR, not criteria for determining the existence of the ARR nor results that biobankers need to achieve. It can therefore be said that the ethicality of the Proposals is not based on certain results and thus the Proposals do arguably not use consequentialism as their approach to ethical reasoning.

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[18] See 1.4 in ch 1 or 6.1.1 a) above.
[19] Consequentialism can be classified into direct and indirect consequentialism, where moral decisions about certain actions are based on the outcomes of those actions and other facts, such as rules or motives underlying them, respectively. See E Carlson, *Consequentialism Reconsidered*, (Dordrecht: Springer Science+Business Media, 1995), at 5. To avoid confusion, the term 'consequentialism' in this sub-section only refers to the former.
[20] See 3.1.1 a) in ch 3.

Deontological Ethics

Deontological ethics bases the rightness of certain actions on duties or rules. That is, the right actions are actions that conform to moral rules. Thus, this moral theory accentuates the features of certain actions when making moral decisions about them. It is agreed that there are a number of moral rules for determining the moral acceptability of certain actions, but explanations of such rules vary according to different deontologists.[21]

Regarding the question of whether or not this ruled-based theory is the approach to ethical justification adopted by the Proposals, it can be said that the answer to this question is positive. Particularly, as suggested above, the Model essentially involves measures that biobankers need to implement in biobank governance, and these measures aim to develop the ARR, which in turn seeks to encourage biobanking by enhancing the ethical acceptability (as well as effectiveness) of biobanking. In this sense, it can be said that those measures could be considered as rules for biobankers who need to make their biobanking activities ethical. That is, biobankers' actions that conform to the Model can be considered ethical in a biobanking context. Accordingly, the Model might be considered to provide criteria or rules for determining whether or not biobanking activities or biobankers' actions can be considered ethical. It can therefore be argued that the Proposals embrace deontological ethics as an approach to their ethical reasoning.

Virtue Ethics

According to virtue ethics, morality is based on the character traits of actors. This moral theory basically deals with the question of what type of persons we should

[21] For example, according to Kant, moral rules need to pass the categorical imperative test, where rules under consideration need to be universally applicable without exception, and moral rules essentially involve forbidding one to treat others as mere means. Scanlon uses the question of whether or not persons can reasonably reject certain rules as a way to test if those rules can be a basis for morality. By contrast, Ross does not call for any tests for determining moral rules. See I Kant, *Ethical Philosophy: Grounding for the Metaphysics of Morals*, (Cambridge: Hackett Publicshing, 1994), Translation by James W. Ellington; TM Scanlon, *What We Owe to Each Other*, (Cambridge, Mass: Harvard University Press, 1998), at 153; D McNaughton and P Rawling, "Deontology" in D Copp (ed) *The Oxford Handbook of Ethical Theory*, (Oxford: Oxford University Press, 2009) 424-458, at 432-433.

become.[22] It focuses on making judgements about persons by considering their overall moral worth.[23] It does not take into consideration only ones' actions but also their virtues, which involve the reasons and emotions required for living in a way that is consistent with their moral commitments.[24] Notably, virtue is also described as a disposition to act in a certain way.[25]

For the Proposals, one can say that they essentially adopt this moral theory as their approach to ethical reasoning, since the ethicality of the Proposals relates to the character trait of virtuous biobankers. Particularly, the Proposals fundamentally stem from the premise that the ARR is considered to be an appropriate participant-biobanker relationship in general[26] and partnership can be used to underlie its conceptual framework.[27] Since, in practice, the ARR involves biobankers' interactions with participants, this premise intrinsically suggests that biobankers should have attitudes and behave towards participants in the same ways that partners do towards each other. Partnership can therefore be considered to underpin the preferred characters that biobankers should have when governing their biobanks. Based on this explanation, it can be said that the Proposals perceive partnership as a virtue that biobankers are required to have in order to develop the ARR. That is, according to the Proposals, this concept can define the virtuous character of biobankers. As a result, biobankers who are disposed to treat participants as partners can be considered as having a virtuous trait. It can therefore be argued from these explanations that the Proposals also adopt virtue ethics as their way to justify their contents ethically.

It can be argued from these discussions that **the ethical reasoning of the Proposals resembles a mixture of virtue ethics and deontological ethics**. In particular, the conceptual framework of the ARR and the Model, both of which

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[22] JF Childress, see note 17 above.
[23] P Montague, "Virtue Ethics: A Qualified Success Story" in D Statman (ed) *Virtue Ethics: A Critical Reader*, (Edinburgh: Edinburgh University Press, 1997) 194-204, at 194-196.
[24] AV Campbell, "The Virtues (and Vices) of the Four Principles" (2003) 29 *Journal of Medical Ethics* 5 292-296.
[25] M Talbot, see note 17 above, at 34-35. However, Statman explains that this explanation is the way in which deontologists define the word 'virtue'. See D Statman, "Introduction to Virtue Ethics" in D Statman (ed) *Virtue Ethics: A Critical Reader*, (Edinburgh: Edinburgh University Press, 1997) 1-41, at 9.
[26] See 1.2 in ch 1 above.
[27] See 2.3 in ch 2 above.

fundamentally stem from partnership attributes, suggest that biobankers should treat participants as partners in order to enhance the ethical acceptability of biobanking, and thereby partnership is considered to be a character trait that is virtuous for biobankers here. Also, as the Model comprises measures that biobankers can use to develop the ARR in practice, it suggests the features of activities that biobankers should conduct for enhancing the ethical acceptability of biobanking, and so it can be considered to formulate rules for biobankers' ethical actions. Accordingly, the Proposals can be considered to suggest both the virtue that biobankers should possess and the rules to which biobankers' actions should conform. Based on these explanations, it can be concluded that the Proposals can be deemed to be an ethical framework for biobank governance, and they use the moral theories of deontological virtues and virtue ethics as methods for ethical justification.

Two points should be noted from this conclusion. First, as the Proposals have ethical grounds and provide an ethical framework for dealing with practical issues and challenges in biobanking, they can be categorised in the area of **applied ethics**.[28] Second, for Statman, this ethical reasoning is called **the reductionist radical approach to virtue ethics**, where judgements of rightness are reducible to those of character and thus judgements of character are considered prior to those of action.[29] Particularly, the Model is considered ethical fundamentally because it can exhibit the key features of the ARR: the measures it requires, which involve biobankers doing something, are designed to incorporate the key features of the ARR, which are based on partnership, into a participant-biobanker relationship; also, as explained above, partnership is considered to be the character trait of biobankers that is deemed virtuous here; one can therefore say that the Model is desirable since it can introduce a partnership relationship into biobank governance. This can be explained by some of the measures required in it which, by themselves, are not always preferable and are even prone to criticism. As an example, sharing control over biobanking with

[28] E Winkler, "Applied Ethics: Overview" in R Chadwick, D Callahan and P Singer (eds), *Encyclopedia of Applied Ethics*, (San Diego, CA: Academic Press, 1998) 191-196.
[29] D Statman, see note 25 above, at 8-9. Note that this literature usefully explains how the relationship between deontological ethics and virtue ethics is perceived diversely by different authors. See also P Montague, see note 23 above.

participants is disapproved of by some authors,[30] but it is deemed acceptable since it is used to show that participants are respected as partners in biobank governance. Thus, this sharing is considered an acceptable action in this thesis because it can reflect a partnership attribute of respectfulness.[31] On the other hand, it can also be said that, although the measures required by the Model might be preferable in biobanking practice, they – according to the Proposals – are per se not considered ethically justifiable unless they can manifest a partnership relationship between participants and biobankers. In this respect, they are not intended to be a source of ethicality. This is why the explanation of the Model, in Chapter 3, constantly shows how they can reflect the key features of the ARR. Given all these explanations, one can therefore say that the ethicality of the Model basically stems from judgements of character traits, not those of action, and thereby the Proposals perceive trait appraisals to be prior to act appraisals. From a philosophical perspective, it can also be said that the Model is ethically explicable in terms of its capability to reflect partnership, a virtuous trait of biobankers. Notably, the fact that the Proposals consider virtue ethics to be prior to deontological ethics is additionally echoed in their focus on relationship, as opposed to certain measures or mechanisms – that is, they are based on the notion that developing certain measures is unlikely to provide a solution to the issues and challenges existing in biobanking practice, and so they instead focus on proposing a form of a participant-biobanker relationship, which goes beyond actions or duties.

6.2.2 Legality

The question arises as to whether law plays a role in the Proposals. To address this question, this sub-section considers the nature and content of the Model, and then determines whether it is suitable to use legal mechanisms to put the Model into practice. Before addressing this question, some points should be noted here. First, the discussion in this sub-section concentrates on the Model, since it deals with the question regarding the practical aspect of the Proposals. In this respect, it does not involve the fundamental notion and conceptual framework of the ARR. Second, this

[30] See 6.4.1 below.
[31] See 3.4.2 in ch 3 above.

sub-section only has the aim of clarifying the contribution of this thesis. In this respect, it does not involve a discussion about whether the Model theoretically deserves legal protection, since this discussion involves lengthy scrutiny in the area of legal theory – which is outside the scope of this thesis. Nonetheless, it is worth briefly mentioning that, in terms of regulatory rationales, it is justifiable for the Model to be used as legal regulation, because the ARR, which the Model aims to develop, seeks to promote the interests of individuals (participants) and collectives (biobanking) and both of these interests can be rationales for regulation.[32] It can therefore be said that it is possible to use the Model as a basis for legal mechanisms.

Third, an issue on the role of law in governing biobanks has been raised in the context of the UK. This is because there are as yet no legal mechanisms for directly governing biobanks in the UK, unlike some jurisdictions such as Estonia and Sweden, and this has provoked criticism about the effectiveness of governance mechanisms in this area.[33] The discussion in this sub-section, however, does not engage with such an issue since it only concerns application of the Model, not the governance of all biobanks in the UK. Finally, the discussion here involves any legal mechanisms that might be used to enforce the Model. In this respect, it is not limited to legal partnership, which basically refers to business associations established for generating profits.[34] It is, however, arguable that legal partnership is not applicable here. My research suggests that there are two main reasons behind this argument. One is that, while both the Model and legal partnership similarly involve cooperation and collectiveness in goals, the themes of their goals are different: partnership in the Model mainly involves medical advances, although commercialisation might also be embraced to some extent, but legal partnership fundamentally aims to deliver profit; that is, the former primarily concerns collective health benefits, but the latter is basically based on the commercial

[32] Individuals' rights and social solidarity can be rationales for regulation. See T Prosser, "Regulation and Social Solidarity" (2006) 33 *Journal of Law & Society* 3 364-387; R Baldwin et al, *Understanding Regulation: Theory, Strategy, and Practice*, 2nd ed (Oxford: Oxford University Press, 2012), at 22-23.
[33] M Cutter Anthony et al, "Balancing Powers: Examining Models of Biobank Governance" (2004) 1 *Journal of International Biotechnology Law* 5 187-192, at 189-190; SMC Gibbons, "Are UK Genetic Databases Governed Adequately? A Comparative Legal Analysis" (2007) 27 *Legal Studies* 2 312-342.
[34] *Partnership Act 1890*, s 1(1).

interests of certain individuals. Moreover, the content of the former chiefly involves positive interactions and dispositions towards other partners (i.e. participants), but that of the latter is essentially about responsibilities and liabilities among partners, as well as protection against fraudulent actions between them.

Regarding a legal role for the Model, this thesis does not recommend directly translating the Model into legal provisions, mainly because the Model is only intended to offer guidelines for biobankers who want to foster the ARR in their biobanking. This reason is echoed in the content of the Model. Particularly, first, biobanking activities that do not conform to the Model are not always considered unethical, let alone illegal. Indeed, as explained above, some measures proposed in the Model are prone to criticism. It can therefore be said that the Model is not seen to set minimal standards for biobanking practices, and thereby it might not be suitable to enforce it legally. Second, its content is broad, with the aim to make it flexible and generally applicable. Thus, one can ask whether or not its content is clear and specific enough for such translation. That is, such translation might result in practical problems with regard to, inter alia, enforcement and interpretation of translated provisions. An example is the requirement for appropriate sharing of control: as the Model does not provide details about when control sharing is considered appropriate,[35] one might question what criteria a court will use to determine the appropriateness of this sharing and how a court legally enforces this requirement in different circumstances.

Other than the content of the Model, this recommendation can also be justified from a practical perspective. In particular, some biobanks have practical limitations that prevent their governance from complying with the Model. An example of these limitations is limited resources, from which small-scale biobanks usually suffer. This limitation can hinder some biobanks from establishing, inter alia, ongoing communication with participants or a body that can oversee and influence biobanking activities in their governance, both of which are deemed crucial to application of the Model.[36] In the light of this limitation, such translation might undermine the sanctity of law by making translated provisions unable to be applied to some biobanks in

[35] See 3.4.1 b) in ch 3 above.
[36] See 6.1.2 b) above.

practice. Given all these reasons, it can therefore be argued that **legal mechanisms are not preferable for directly reinforcing the whole of the Model**.

However, **this argument does not mean that legal mechanisms are neither possible nor acceptable for applying the Model at all**. Rather, the Model might be used to inform legal provisions about biobanking. As an example in the context of the UK, the Health Research Authority might adopt the Model's measures for collaboration and reciprocation, which mainly aim to promote participants' interests, for underlying its guidance on how biobankers should manage and conduct biobanking activities, which is published under the Care Act 2014.[37] Alternatively, the Model might be wholly translated into legal provisions which can only be applied in certain circumstances. Indeed, some measures proposed in the Model can benefit from the enforceability of legal mechanisms. One example is the measure for reinforcing collectiveness in biobanking goals within the Model's key attribute of emphasis on collective goals: this measure requires resisting biobanking activities that do not conform to collective goals, if any;[38] the ability to resist such non-conformity can be consolidated by legal mechanisms, thereby enhancing the effectiveness of this measure. It can therefore be said that, by being facilitative as well as prescriptive and sanction-driven, law could be beneficial to application of the Model by playing a supportive role.

Despite the aforesaid possibility and benefit, it needs to be emphasised again that the Model is not designed to rely on legal mechanisms, as already explained above, and thus to enforce the whole of the Model by law is not suggested here.

6.3 Limitations of the Proposals

As outlined in the first chapter of this thesis, the discussion in this thesis focuses on a relationship between *participants and biobankers at a micro level*, by

[37] *Care Act 2014*, s 111(6), (7).
[38] For this aspect of the Model, the effectiveness of mechanisms for resisting this non-conformity is an important consideration. See 3.1.1 b) (Changes to Biobankers' Goals) in ch 3 above.

dealing with both the micro- and meso-levels of a management approach to biobank governance.[39] This scope can be explained separately into two aspects. On the one hand, the expression 'micro level' means that this thesis focuses on biobankers' relationships with individual participants, not with participant collectives. On the other hand, this scope suggests that the parties in biobanking, other than participants and biobankers, are not involved in the contribution of this thesis. These two aspects impose some limitations when putting the Proposals into practice.

To clarify the contribution of this thesis, these limitations are explained in this section. The explanations of these limitations can be separated into two sub-sections, each of which deals with one of those two aspects: one deals with the fact that the ARR involves the micro level of a participant-biobanker relationship, and the other describes the roles of other parties, i.e. communities and members of the public, in the Proposals.

6.3.1 Micro Level of Relationship

As explained in Chapter 1, the contribution of this thesis focuses on the micro level of a participants-biobanker relationship because the interests of every participant are an important consideration.[40] This focus is echoed in many measures proposed in the Model. For example, the Model's key attribute of collaboration calls for giving *all* participants opportunities to provide input,[41] not appointing some participants to provide input on behalf of others or a whole participant cohort. The Model's key attribute of control sharing requires giving participants control over biobanking at an individual level, and so it mainly deals with control-sharing mechanisms that allow individual participants to make decisions about biobanking, such as the consent procedure and the right of withdrawal.[42] Thus, one can say that the Model is basically directed at biobankers' interactions with each participant individually, as opposed to participant collectives. As, according to the Model, individual participants engage in biobanking separately, it is difficult in practice for them to influence biobanking

[39] See 1.3 (last paragraph) in ch 1 above.
[40] See 1.3.2 in ch 1 above.
[41] See 3.2.1 a) in ch 3 above.
[42] See 3.4.1 a) in ch 3 above.

activities, particularly activities that cannot be personalised. It can therefore be said that their ability to initiate any changes in the direction of biobanking is very limited in practice. Only exceptional cases involving a mass withdrawal, which normally results from some scandals,[43] and categorical/tiered consent can be imagined to make such changes possible. Accordingly, **one limitation of the Model is that participants do not have much control over the direction of biobanking as a whole.**

Representation

Moreover, the focus on a micro-level of participant-biobanker relationship can be related to the issue of representation, where certain participants represent the interests of other participants. This issue is highlighted and criticised by some authors,[44] while others seem not to consider it problematic.[45] As the ARR is based on the notion that the interests of every participant are important, it can be argued that, basically, the Proposals do not consider this issue desirable. The reason is that, when suffering from this issue, the interests of some participants are disregarded and such disregard undermines the ARR.

From a procedural perspective, mechanisms that suffer from this issue are involvement mechanisms where some participants are appointed to voice their thoughts on behalf of others or a whole participant cohort.[46] Thus, these mechanisms do per se not accord with the Proposals. However, they do not always undermine the conformity of biobank governance to the Proposals: as long as biobankers allow all participants to provide input and give that input serious consideration, the Proposals are complied with, regardless of whether these mechanisms are adopted in biobank governance or not. Notably, in practice, this scenario needs strong evidence of such consideration for confirming that the input of non-appointed participants is not

[43] H Widdows, *The Connected Self: The Ethics and Governance of the Genetic Individual*, (Cambridge, UK: Cambridge University Press, 2013), at 140.
[44] KG Hunter and GT Laurie, "Involving Publics in Biobank Governance: Moving beyond Existing Approaches" in H Widdows and C Mullen (eds), *The Governance of Genetic Information*, (Cambridge: Cambridge University Press, 2009) 151-200. See also DE Winickoff, "Partnership in U.K. Biobank: A Third Way for Genomic Property?" (2007) 35 *The Journal of Law, Medicine & Ethics* 3 440-456.
[45] J Kaye, see note 11 above, at 133; KC O'Doherty et al, see note 9 above, at 371.
[46] See 6.1.2 a) (last paragraph) above.

disregarded.[47] This implies that these mechanisms will undermine such conformity if it is evident that biobankers do not allow non-appointed participants to provide input, or that they only take into account the input of appointed participants.

In reality, however, it can also be said that the issue of representation is in practice inevitable, even after applying the Model, since participants are not always active.[48] In particular, the Model's key attribute of collaboration merely requires biobankers to give all participants opportunities to provide input, not to receive input from all of them. Thus, it is possible that, despite giving such opportunities, biobankers can only receive and take into account input from participants who actively engage in biobanking, thereby inherently causing that input to represent the voices and attitudes of non-active participants. That is, although biobank governance complies with the Model, which attempts to address the issue of representation, it might still suffer from this issue. It can therefore be said that this issue might be unavoidable when putting the Model into practice. Since the Model does not have measures for dealing with this scenario, **one might consider this form of representation to be another limitation on the contribution of this thesis**.

Given the explanations about the issue of representation, it can be concluded, as follows: The Proposals do not conceptually advocate any representation for participants in biobank governance, because it is likely to undermine the ARR. Involvement mechanisms where some participants are appointed to voice their thoughts on behalf of others do per se raise the issue of representation, but these mechanisms do not necessarily undermine the conformity of biobank governance to the Proposals. In practice, because participants are not always active, this issue inevitably arises even when adopting the Proposals, making this scenario become another limitation on the contribution of this thesis. Note that this issue may arise

[47] As an example, ALSPAC adopts these involvement mechanisms, but there is not enough evidence for completely ruling out the issue of representation within its governance. See 5.2.2 c) (last paragraph) in ch 5 above.
[48] This non-activeness can be inferred from some empirical studies revealing that people relatively prefer broad consent partly because this consent approach imposes less burdens on them. See CM Simon et al, "Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models" (2011) 13 *Genetic Medicine* 9 821-831, at 826.

within the governance of ALSPAC due to many involvement mechanisms in the governance that only involve some participants.[49]

6.3.2 Communities and the Public

As suggested above, the Proposals are merely applied to participants and biobankers. The reason behind this was already explained in the first chapter: the Proposals stem from an attempt to enhance the ethical acceptability and effectiveness of biobanking by promoting and balancing the interests of participants and biobanks.[50] This implies that the Proposals fundamentally exclude communities and members of the public, parties who might be positively and/or negatively affected by biobanking, although it is acknowledged that there is extensive literature arguing for involving these two parties in biobanking.[51] Accordingly, basically, these parties do not have any roles in the measures or mechanisms proposed in the Model. The Model is not applied to them in this respect.

As a result of this exclusion, the Proposals are widely applicable since they can be applied to both private and public biobanks – the former of which do normally not call for public involvement in biobank governance. On the other hand, this exclusion arguably places another limitation on the application of the Proposals. Particularly, **the Model might per se not be able to properly handle some issues that require either communities or members of the public to deal with**, such as the maintenance of public trust, improvement in the accountability to the public, the involvement of communities' interests, social/community priorities and, as explained further below, commercial involvement.[52]

This is, however, saying neither that the Proposals inhibit members of the public and communities from being involved in biobanking at all, nor that such involvement undermines conformity to the Proposals. Rather, it is merely emphasised

[49] See note 47 above.
[50] See 1.2 (first paragraph) and 1.4.2 in ch 1 above.
[51] KC O'Doherty et al, see note 9 above, at 371-372; J Kaye, see note 11 above, at 132-133; AV Campbell, see note 10 above, at 244; D Chalmers, "Genetic Research and Biobanks" in J Dillner (ed) *Methods in Biobanking*, (London: Humana Press, 2011) 1-38, at 4-6.
[52] See also 6.4.3 (last paragraph) below.

that the Proposals do not directly deal with the roles of these parties in biobank governance. Indeed, such involvement may even enhance conformity to the Proposals. For example, since participants and these parties may share the same interests (e.g. genetic information privacy), such involvement might help promote participants' interests by allowing members of the public or communities to help improve the safeguards for participants, thereby complying with the Model's key attribute of reciprocation and enforcing the ARR's key features of respectfulness and continuity in relationship. Moreover, such involvement might also help improve recruitment procedures, thus promoting biobanks' interests by increasing participation. Other than benefits to the Proposals, such involvement is also arguably beneficial to biobanking in general by, inter alia, addressing the aforesaid issues and avoiding criticism of participants representing communities and the public.

It can therefore be concluded from this sub-section that, although the Proposals exclude communities and members of the public, they do not prohibit the involvement of these two parties. Indeed, this involvement might even help foster the ARR by promoting participants' and/or biobanks' interests.

To summarise this section, given that the contribution of this thesis basically deals with a research relationship between biobankers and individual participants, this section has pinpointed three limitations on the application of the Proposals. First, while participants have control over biobanking at an individual level, they do not have much control over the direction of biobanking activities. Second, the Proposals cannot address the issue of representation that results from non-active participants being represented by active ones. Finally, the Proposals themselves do not involve members of the public and communities, and so they might not properly address issues that should be settled by these two parties. Some points are noteworthy here. First, as explained in the following section, there are other issues with which the Proposals do not deal, i.e. participants' competence in making decisions to engage in biobanking and property rights over tissue samples. The second point concerns a situation where input from certain participants conflicts with input from other participants or parties. This situation is likely to occur when adopting the Proposals, since the Model requires giving all participants opportunities to provide input about biobanking. To foster the

ARR in this situation, the Model requires biobankers to show participants whose input is not acted on that their input is taken into consideration by, inter alia, providing them with justifications for putting their input aside.[53]

6.4 The Proposals and Some Biobanking Issues

In a biobanking context, there are some controversial issues that have been usually discussed in extensive literature on biobanking and which might either undermine the ARR or conflict with the Proposals. Indeed, while these issues have occasionally been mentioned in previous chapters, they have not been dealt with yet. Accordingly, it is necessary to discuss these issues in this section in order to address them properly. This discussion serves not only to further clarify the Proposals by demonstrating their true extent and capability for securing the ARR despite the existence of those issues, but also to explain how their application can move beyond UK Biobank and ALSPAC towards other biobanking contexts. Indeed, as this discussion engages with extensive literature on biobanking, it inherently delineates how the Proposals contribute towards existing knowledge in this area. There are five issues that are to be addressed in this section:

(i) participants' control;
(ii) individual feedback;
(iii) commercial involvement;
(iv) financial incentives;
(v) property rights.

These issues will be dealt with separately in five different sub-sections. For the general structure, each sub-section first pinpoints the nature and content of these issues by taking into consideration academic discussions about them, and then explains how the Proposals are related to or respond to them. Note that this section focuses on explaining how these issues can be handled from the perspective of the Proposals. In

[53] See 3.2.1 b) (Disregard for Participants' Input) in ch 3 above.

this respect, it is not intended to provide in-depth discussions or arguments directly concerning these issues.

6.4.1 Participants' Control

The issue of sharing control over biobanking with participants has been discussed in extensive literature in the area of biobanking. As some argue against this sharing, a question arises as to why they disagree with the Proposals, which allow this sharing.[54] To address this question, literature that makes arguments on this matter was reviewed and the reasons behind those arguments were also examined. My review suggests that there seems to be two authors whose arguments clearly provide the reasons for supporting and opposing this sharing, namely Kaye and Campbell, respectively. In this sub-section, their arguments are explained and then the reasons behind their arguments are compared with those provided in this aspect of the Proposals, with the aim of finding justification for the similarities or differences between these three arguments.

a) Three Arguments

To recall this aspect of the Proposals, the Model requires biobankers to share control over biobanking appropriately with individual participants, not participants as a collective. From a conceptual perspective, this requirement enforces the ARR's key feature of respectfulness, which allows participants' interests to be balanced with those of biobanks. In practice, this sharing is mainly performed through control-sharing mechanisms that allow participants to make decisions about biobanking at an individual level, such as the consent procedure, the right of withdrawal and meaningful involvement in making decisions about biobanking activities that can be personalised. The level of control is determined by the consent approaches employed, the amount of information about biobanking activities provided for participants, and the extent to which participants are allowed to make decisions, respectively. It is also notable that the Model mainly involves communication with participants that allows biobankers to

[54] See 3.4 in ch 3 above.

share information about biobanking activities and knowledge about biobanking with participants, as well as to receive input about biobank governance from them.[55]

For the other two arguments, Kaye's argument supports participants' ongoing control over uses of biobank resources, aka a dynamic consent model. She first establishes that, due to the risk of identifiability in population collections, participants have a moral right to control the uses of their information and this right increases over time.[56] Thus, she argues for broad consent at recruitment, re-consenting every five years and the right of withdrawal. Participants can also opt out of any secondary uses. To legitimise this opt-out, biobankers need to provide them with ongoing updates about biobanking activities and allow participant representation on committees that are assigned to oversee biobanking activities and approve access to biobank resources.[57] Campbell's argument opposes sharing control over biobanking with participants. He argues for safeguarding participants' altruism and trust in the context of population genetic databases, since he considers these values to be a primary motivation for participating in these databases when no financial incentives are involved.[58] As regards the sharing of control in biobanking, Campbell counters Kaye's argument for this sharing by citing a donation or 'gift', which reflects a willingness to surrender control, and the aim of biobanks to benefit the health of the collective, as opposed to participant individuals. Instead, he suggests, inter alia, establishing ongoing communication with participants in order to build a partnership by keeping them aware of biobanking progress and receiving input from them.[59]

b) Comparison between Three Arguments

By comparing Kaye's and Campbell's arguments with the Proposals, one similarity is that all three arguments advocate communication with participants that enables them to be kept updated on biobanking progress and to provide input about biobanking.[60] They are, however, different in terms of participants' control over

[55] See 6.1.2 b) (Communication with Participants) above.
[56] J Kaye, see note 11 above, at 130-131.
[57] *Ibid*, at 131-133.
[58] AV Campbell, see note 10 above, at 240-241.
[59] *Ibid*, at 241-242.
[60] See 6.1.2 b) (Communication with Participants) above.

biobanking: Campbell explicitly argues against the provision of this control; but Kaye and the Proposals embrace it, although the Proposals do not specifically argue for dynamic consent. This difference might be justified by the basic notions behind these three arguments. Particularly, Campbell's argument mainly stems from participants' altruistic giving and benefits for the collective, while Kaye and the Proposals tend to accentuate participants' interests.

Based on this analysis, it might therefore be said that the answer to the question of whether to give participants control over biobanking depends on what is considered paramount. The answer seems to be positive for those who incline towards the protection of participants' interests, but negative for those who perceive the interests of the collective or biobanks to be overriding. Regarding the Proposals, because the ARR is based on the notion that the interests of participants need to be balanced with those of biobanks,[61] the Model calls for sharing control over biobanking with participants (at an individual level). It is, however, worth emphasising that, with the expression 'paramount', none of these arguments neglects other interests: other aspects of Campbell's and Kaye's arguments also promote participants' and biobanks' interests, respectively; the Proposals seek to strike a balance between participants' and biobanks' interests. In this respect, this analysis merely highlights that these arguments might attach more importance to certain interests over the others.

Two points should be noted here. First, this difference is in line with the general trend in desire for control over biobanking that has been reflected in many empirical studies, especially studies on participants' preferences vis-à-vis consent approaches. Particularly, participants normally need to have some degree of control over biobanking activities.[62] One reason why they decline to have this control, or too much of it, is that it could be counterproductive for biobanking by, inter alia, imposing financial and logistic burdens on biobankers as well as hindering biobanking and research from having sufficient cohorts.[63] Note that there are also other circumstantial

[61] See 1.4.2 in ch 1 above.
[62] AL McGuire et al, "DNA Data Sharing: Research Participants' Perspectives" (2008) 10 *Genetics in Medicine* 1 46-53; J Murphy et al, "Public Perspectives on Informed Consent for Biobanking" (2009) 99 *American Journal of Public Health* 12 2128-2134.
[63] CM Simon et al, see note 48 above.

factors that might affect participants' desire for this control, such as their trust in a research institution,[64] the complexity of information they need to deal with, and their feelings of being unqualified to have this control.[65] On the second point, Winickoff also implicitly makes an argument for participants' control over biobanking: he suggests using a shareholder model used in corporate governance for involving participants in UK Biobank governance; this suggestion indirectly gives control over biobanking to the participant collective in UK Biobank.[66] Nonetheless, this argument is not discussed above because it involves participants' control at a collective level, not an individual level. Indeed, it also raises the issue of representation, which has already been discussed in 6.3.1 above.

6.4.2 Individual Feedback

The second issue relates to the provision of individual feedback in a biobanking context. The term 'individual feedback' here refers to any information about individual participants resulting from their participation in biobanking, i.e. individual research results, incidental findings and analysed health information. For the Proposals, this provision is one way to reciprocate participants' contributions according to the Model, and it can reflect the ARR's key features of continuity in relationship and respectfulness. However, there is vast literature that argues against it, as illustrated below. The question therefore arises as to whether this provision is really desirable in a biobanking context. To address this question, this sub-section first briefly reviews the literature on this matter so as to explore the controversy surrounding this provision, and then justify this aspect of the Proposals by explaining how the Proposals deal with this controversy. It is noteworthy that different types of individual feedback have different content. In the academic literature, some authors well appreciate this difference,[67] while many do not clearly do so. In practice, this difference might not be

[64] KB Brothers et al, "Two Large-Scale Surveys on Community Attitudes toward an Opt-Out Biobank" (2011) 155 *American Journal of Medical Genetics Part A* 12 2982-2990.
[65] AL McGuire et al, see note 62; CM Simon et al, see note 48 above.
[66] DE Winickoff, see note 44 above, at 449.
[67] SM Wolf et al, "Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets" (2012) 14 *Genetics in Medicine* 4 361-384.

distinct in some circumstances, such as genomic research.[68] However, the discussion in this sub-section does not distinguish different types of individual feedback. This is because they all are used to serve the same function, i.e. reciprocation, in the Model and they can similarly affect participants in both positive and negative ways. This difference is therefore considered insignificant here.

a) Extensive Controversy

The provision of individual feedback is one of the most controversial issues in biobanking. Various perspectives have been taken into consideration and many compelling reasons have been set out by both proponents and opponents of this provision to argue for and against it, respectively.

For proponents, as concluded by Haga and Beskow, three principles – namely respect for participants, beneficence and reciprocity – are commonly used to argue for this provision,[69] especially the first one. Some even use this first principle to override any costs and burdens resulting from this provision.[70] Similarly to the Proposals, some deem the provision of individual research results to be a reflection of partnership, since participants are treated respectfully as partners in biobanking – not simply a means to an end.[71] Indeed, in the context of UK Biobank, Johnston and Kaye consider this provision to be a legal duty, which might inflict a negligence liability.[72] From a practical perspective, Fernandez et al use the potential benefits of individual feedback,

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[68] LM Beskow and W Burke, "Offering Individual Genetic Research Results: Context Matters" (2010) 2 *Science Translational Medicine* 38 available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3136874/ (accessed on 10 June 2016); MK Cho, "Understanding Incidental Findings in the Context of Genetics and Genomics" (2008) 36 *The Journal of Law, Medicine & Ethics* 2 280-285.

[69] SB Haga and LM Beskow, "Ethical, Legal, and Social Implications of Biobanks for Genetics Research" in DC Rao and CC Gu (eds), *Advances in Genetics*, Academic Press, 2008) 505-544, at 528-529.

[70] DI Shalowitz and FG Miller, "Disclosing Individual Results of Clinical Research: Implications of Respect for Participants" (2005) 294 *JAMA* 6 737-740; CV Fernandez and C Weijer, "Obligations in Offering to Disclose Genetic Research Results" (2006) 6 *The American Journal of Bioethics* 6 44-46.

[71] CV Fernandez et al, "The Return of Research Results to Participants: Pilot Questionnaire of Adolescents and Parents of Children with Cancer" (2007) 48 *Pediatric Blood & Cancer* 4 441-446.

[72] C Johnston and J Kaye, "Does the UK Biobank Have a Legal Obligation to Feedback Individual Findings to Participants?" (2004) 12 *Medical Law Review* 3 239-267.

i.e. the possibility of improving participants' quality of life and preventing harms, to defend this position. This provision is also claimed to benefit health-related research itself by underlining its importance,[73] recruiting participants and retaining support for it.[74] This position is also supported by many empirical studies revealing that the provision of individual feedback is desirable[75] even though the content of such feedback is likely to be negative.[76]

On the other hand, many reasons have been used to counter the aforesaid position. Ossorio refutes the argument that the provision of individual feedback is a way to respect participants by citing alternative measures for expressing such respect, the possibility of participants having little interest in this feedback, and an untenable burden on research infrastructure.[77] Therapeutic misconceptions and possible harm to participants,[78] as well as the right not to know,[79] are frequently used to reject this provision. Some even consider this provision to be an undue inducement for participants.[80] As discussed in 6.4.4 below, this provision can raise the issue of

[73] CV Fernandez et al, "Considerations and Costs of Disclosing Study Findings to Research Participants" (2004) 170 *Canadian Medical Association Journal* 9 1417-1419.
[74] J Murphy et al, "Public Expectations for Return of Results from Large-cohort Genetic Research" (2008) 8 *The American Journal of Bioethics* 11 36-43.
[75] J Murphy et al, *ibid*; AA Lemke et al, "Biobank Participation and Returning Research Results: Perspectives from a Deliberative Engagement in South Side Chicago" (2012) 158A *American Journal of Medical Genetics Part A* 5 1029-1037; NL Allen et al, "Biobank Participants' Preferences for Disclosure of Genetic Research Results: Perspectives from the OurGenes, OurHealth, OurCommunity Project" (2014) 89 *Mayo Clinic Proceedings* 6 738-746.
[76] AH Partridge et al, "Offering Participants Results of a Clinical Trial: Sharing Results of a Negative Study" (2005) 365 *The Lancet* 9463 963-964; CV Fernandez et al, "Disclosure of Research Results to Research Participants: A Pilot Study of the Needs and Attitudes of Adolescents and Parents" (2005) 10 *Paediatrics & Child Health* 6 332-334.
[77] PN Ossorio, "Letting the Gene Out of the Bottle: A Comment on Returning Individual Research Results to Participants" (2006) 6 *The American Journal of Bioethics* 6 24-25.
[78] E Clayton and L Ross, "Implications of Disclosing Individual Results of Clinical Research" (2006) 295 *JAMA* 1 37-38; JF Merz et al, "Use of Human Tissues in Research: Clarifying Clinician and Researcher Roles and Information Flows" (1997) 45 *Journal of Investigative Medicine* 5 252-257.
[79] G Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms*, (Cambridge: CUP, 2002); JV McHale, "Regulating Genetic Databases: Some Legal and Ethical Issues" (2004) 12 *Medical Law Review* 1 70-96.
[80] FA Miller et al, "When Research Seems like Clinical Care: A Qualitative Study of the Communication of Individual Cancer Genetic Research Results" (2008) 9 *BMC Medical Ethics* 4 available at http://www.biomedcentral.com/1472-6939/9/4 (accessed on 16 June 2015).

financial incentives. From a practical perspective, McHale argues that this provision can place participants and researchers at risk of stigmatisation and litigation, respectively.[81] Many practical limitations and challenges have also been highlighted, such as the validity of individual feedback,[82] the design of research and biobanks, the characteristics of participants, and intensive consumption of resources that are created by relocating, re-contacting participants and validating individual feedback.[83]

b) The Proposals' Approach

After considering the arguments from both sides, it is arguably difficult to conclude a position that is, in general, most desirable for both participants and biobanking: in the academic literature, the arguments presented to support either of these positions are compelling but can still be countered in some ways; the results of empirical studies incline towards the provision of individual feedback, but they are not unanimous. Thus, it is not pragmatic for the Proposals to strongly advocate either position for many reasons. First, the ARR aims to strike a balance between participants' and biobanks' interests, and it is unclear which position can be considered to definitely promote each of these interests. Second, participants' individual preferences need to be honoured and satisfied, due to the ARR's key features of respectfulness and continuity in relationship. Indeed, the Proposals are based on the notion that the interests of every participant are important.[84] This implies that the results of those empirical studies should not be generalised; otherwise, the interests of some participants would inherently be disregarded. Finally, some biobanks have a limited capability of providing individual feedback, due to some contextual factors such as types of biobank resources and the availability of management resources. It

[81] JV McHale, see note 79 above, at 91.
[82] JF Merz et al, see note 78 above, at 255; JN Hirschhorn et al, "A Comprehensive Review of Genetic Association Studies" (2002) 4 *Genetics in Medicine* 2 45-61.
[83] SM Wolf et al, see note 67 above; V Ravitsky and BS Wilfond, "Disclosing Individual Genetic Results to Research Participants" (2006) 6 *The American Journal of Bioethics* 6 8-17.
[84] See 1.3.2 in ch 1 above.

can therefore be argued that the question of whether to provide participants with individual feedback should be decided on a case-by-case basis.[85]

This argument justifies why the Model does not necessitate the provision of individual feedback. Particularly, the Model's key attribute of reciprocation neither requires nor recommends this provision. Rather, it asks biobankers to, first, clarify policies on this matter so as to enable participants to realise the actual extent of biobanks' capability to provide individual feedback and other factors that potentially affect their preferences regarding this provision, including the possible content and implications of individual feedback; then, the Model requires biobankers to allow participants to negotiate about these policies through, inter alia, the collaborative measures proposed in the key attribute of collaboration.[86] Given this explanation, it can be concluded that the Proposals deal with the controversy over the provision of individual feedback by using (i) mutual learning, which allows participants' and biobanks' interests in certain circumstances to be put on the table and taken into consideration, and (ii) negotiation, which can be assumed to be the most promising way to balance these two interests in a contextually appropriate fashion. One can therefore say that, despite the storm of controversy over the provision of individual feedback, it is still possible for the Proposals to use this provision to develop the ARR, which seeks to strike a balance between participants' and biobanks' interests.

6.4.3 Commercial Involvement

The meaning of commercial involvement in biobanking might range from the possibility of biobank resources being accessed by for-profit entities, to biobanks being established and organised by these entities. Particularly, the low end of this spectrum refers to a situation where for-profit entities are not involved in biobank governance but might access biobank resources. At the other end, these entities establish, organise and fund biobanks, and thus they are influential in biobank governance. One example

[85] This is supported by Hoeyer, who argues for acknowledging the diversity of participants' perceptions and expectations about the provision of research results. See K Hoeyer, "Donors Perceptions of Consent to and Feedback from Biobank Research: Time to Acknowledge Diversity?" (2010) 13 *Public Health Genomics* 6 345-352.
[86] See 3.3.1 b) (Negotiation over Policies) above.

on this spectrum is a situation where for-profit entities do not directly run biobanks but they are funders who can influence biobanking activities through their funding. Based on this meaning, the questions in this sub-section are whether commercial involvement hinders the Proposals' ability to develop the ARR and, if so, how the Proposals tackle this hindrance. These questions are dealt with in two sub-sub-sections. The first one briefly reviews the literature on commercial involvement in biobanking and explains how this involvement might undermine the ARR. The second sub-sub-section then demonstrates how the Proposals handle this involvement. Note that, despite the aforesaid gradations of this involvement, the discussion in this sub-section does not distinguish them because, as suggested below, they all undermine the ARR in the same way.

a) Issues Arising

In general, it has been said that the involvement of the private sector is necessary for medical advances.[87] However, because this involvement usually relates to the commercialisation of biobanking, it has attracted many criticisms in the academic arena. These criticisms encompass various issues, such as exploitation,[88] the

[87] G Haddow et al, "Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal" (2007) 64 *Social Science & Medicine* 2 272-282; B Zycher et al, "Private Sector Contributions to Pharmaceutical Science: Thirty-Five Summary Case Histories" (2010) 17 *American Journal of Therapeutics* 101-120; T Sullivan, "NEJM The Private Sector Discoveries Account for 79--90% of Pharmaceutical Products" (15 February 2011) available at http://www.policymed.com/2011/02/nejm-the-private-sector-discoveries-account-for-79-90-of-pharmaceutical-products.html (accessed 24 February 2016). In terms of biobanking, there is a survey revealing that funding shortage is a main concern for in a biobanking context. See RJ Cadigan et al, "Neglected Ethical Issues in Biobank Management: Results from a U.S. Study" (2013) 9 *Springer-Verlag* available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228790/ (accessed on 14 July 2016).

[88] G Williams and D Schroeder, "Human Genetic Banking: Altruism, Benefit and Consent" (2004) 23 *New Genetics and Society* 1 89-103.

commodification of biomaterials,[89] patenting,[90] the unfair distribution of benefits,[91] and distrust among participants and the public.[92] This involvement was even partly responsible for the well-known scandal of Icelandic biobank project.[93] This creates a dilemma lying in a biobanking context. This dilemma is evident in many empirical studies that reveal ambivalent attitudes towards commercial involvement in biobanking:[94] some people deem this involvement acceptable or inevitable, in spite of some concerns; but others oppose it or even express distrust in it.[95] Furthermore, it can be suggested from these studies that, in practice, there are many circumstantial factors affecting participants' attitudes towards this involvement, such as the degree of this involvement, participants' characteristics and their experiences. One can therefore

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[89] S Holland, "Contested Commodities at Both Ends of Life: Buying and Selling Gametes, Embryos, and Body Tissues" (2001) 11 *Kennedy Institute of Ethics Journal* 3 263-284; RM Green, "What Does it Mean to Use Someone as "A Means Only": Rereading Kant" (2001) 11 *Kennedy Institute of Ethics Journal* 3 247-261.

[90] LB Andrews, "Harnessing the Benefits of Biobanks" (2005) 33 *The Journal of Law, Medicine & Ethics* 1 22-30; Y-H Huang, "Gene Patents: A Broken Incentives System" (2013) 52 *Journal of Religion and Health* 4 available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3819421/ (accessed on 26 February 2016). See also JA Goldstein, "Human Gene Patents" (2002) 77 *Academic Medicine* 12(2) 1315-1328.

[91] A Boggio, "Public Domain Sharing, Patents, and Fees Resulting from Research Involving Genetic Databases" in B Elger, N Biller-Andorno, A Mauron and AM Capron (eds), *Ethical Issues in Governing Biobanks: Global Perspectives*, (Hampshire: Ashgate Publishing, 2008) 207-216.

[92] M Anderlik, "Commercial Biobanks and Genetic Research: Ethical and Legal Issues" (2003) 3 *American Journal of Pharmacogenomics* 3 203-215; CR Critchley, "Public Opinion and Trust in Scientists: The Role of the Research Context, and the Perceived Motivation of Stem Cell Researchers" (2008) 17 *Public Understanding of Science* 3 309-327; CR Critchley and D Nicol, "Understanding the Impact of Commercialization on Public Support for Scientific Research: Is It about the Funding Source or the Organization Conducting the Research?" (2011) 20 *Public Understanding of Science* 3 347-366; T Caulfield et al, "A Review of the Key Issues Associated with the Commercialization of Biobanks" (2014) 1 *Journal of Law and the Biosciences* 1 94-110, at 97-102.

[93] JF Merz et al, "'"Iceland Inc."?: On the Ethics of Commercial Population Genomics" (2004) 58 *Social Science & Medicine* 6 1201-1209; Gs Pálsson and P Rabinow, "The Icelandic Genome Debate" (2001) 19 *Trends in Biotechnology* 5 166-171.

[94] A Boggio, see note 91 above.

[95] E Vermeulen et al, "Obtaining 'Fresh' Consent for Genetic Research with Biological Samples Archived 10 Years Ago", see note 13 above; G Haddow et al, see note 87 above; T Porter, *Public Perceptions of the Collection of Human Biological Samples*, (October 2000) 130, at 63-64; A Webster et al, *Public Attitudes to Third Party Access and Benefit Sharing: their Application to UK Biobank*, (30 June 2008) 91; SB Trinidad et al, "Genomic Research and Wide Data Sharing: Views of Prospective Participants" (2010) 12 *Genetics in Medicine* 8 486-495; Ipsos MORI, *The One-Way Mirror: Public Attitudes to Commercial Access to Health Data*, (March 2016) 154.

argue that it is difficult to provide a definite answer to the question of whether commercial involvement in biobanking should be accepted or refused, and thus it seems sensible to leave this question to be decided by participants in certain biobanks.

In terms of the Proposals, it is possible for commercial involvement in biobanking to undermine the ARR. On the one hand, this involvement might entice or lead biobankers to incline towards the commercialisation of biobanking, thereby making profitability become more central to biobankers' actual goals beyond what were originally agreed with participants. On the other hand, in practice, participants might not be sufficiently or clearly informed about this involvement when being recruited. These two scenarios might hinder development of the ARR by weakening two key features of it. One is collectiveness in goals: an inclination towards the commercialisation of biobanking causes biobankers' actual goals to deviate from participants' goals, and thereby collectiveness in biobanking goals is no more; the insufficiency of information about this involvement might lead participants to mistake biobankers' goals, and thus there are no collective goals to begin with. Another ARR's key feature that might be weakened is respectfulness. In particular, informing participants insufficiently about this involvement might be considered to express disrespect, or even make dishonest gestures, towards them. One can therefore argue that commercial involvement in biobanking might hinder development of the ARR. Notably, given the nature of this hindrance explained above, it can be said that this hindrance is possible no matter what the degree of this involvement is.

b) Solution in the Model

The explanation above suggests that there are two measures for dealing with the possible hindrance to development of the ARR. The first measure is effective communication that informs prospective participants of any commercial involvement, especially when recruiting them, thus allowing them to realise and understand this involvement properly and to decide whether to accept it as part of their biobanking goals. As a result of using this measure, their decisions to participate can amount to acceptance of this involvement, and thereby all participants and biobankers can be assumed to share the same goals, which contain certain degrees of this involvement.

This also intrinsically establishes open and honest communication with participants. One can therefore say that this measure can exhibit the ARR's key features of collectiveness in goals and respectfulness. For the Proposals, this measure is similarly required in the Model's key attribute of emphasis on collective goals: during recruitment, this key attribute requires biobankers to clarify biobanking goals as well as inform prospective participants of commercial involvement, if any.[96] Indeed, after recruitment, it also requires establishing CBP, which enables participants to realise and monitor this involvement through updates on biobanking activities. Given these requirements, it can be said that the Model has measures for allowing both prospective and actual participants to know about commercial involvement in biobanking.

The second measure is to prevent biobanking activities, which assumedly reflect biobankers' actual goals, from being excessively commercially-oriented beyond participants' expectations. In practice, this measure involves a mechanism for resisting or impeding biobanking activities that incline towards profitability beyond the extent that was originally agreed with or is acceptable to participants. As a result of this measure, it can be perceived that biobankers' goals are not excessively influenced by commercial involvement and are the same as participants' goals throughout biobanking endeavours. For the Proposals, this measure is in line with the measure for reinforcing collectiveness in biobanking goals, required by the Model's key attribute of emphasis on collective goals. In short, this reinforcement measure requires encouraging the conformity of biobanking activities to collective goals, i.e. the goals shared with participants, by implementing mechanisms that can be used to consistently monitor biobanking activities and resist biobanking activities that deviate from collective goals.[97] From a conceptual perspective, this measure helps maintain and reinforce the ARR's key feature of collectiveness in goals. One can therefore say that the Model has a measure for hindering biobankers' goals from being changed by commercial involvement.

Given the explanations in these last two paragraphs, it can be concluded that the Proposals have measures for preventing the development of the ARR from being

[96] See 3.1.1 a) in ch 3 above.
[97] See 3.1.1 b) (Changes to Biobankers' Goals) in ch 3 above.

hindered by commercial involvement in biobanking. Indeed, it can be inferred from those explanations that, to maintain a participant-biobanker relationship, commercial involvement in biobanking should not be unlimited; rather, it should be in a respectful way as partners treat each other, by informing participants clearly and regularly of it, and should conform to the stated objects and purposes of certain biobanks.

It is worth mentioning some measures in the Model that could also be used to deal with commercial involvement in biobanking because they can respond to the literature on this matter. Particularly, one empirical study reveals that, provided that commercialisation is involved, participants tend to have a preference for more control over the uses of their samples and information.[98] In the Model, this preference can be satisfied by its key attribute of control sharing, which calls for appropriate sharing of control over biobanking with participants.[99] Indeed, its key attribute of collaboration also requires biobankers to allow participants to provide input about biobank governance and give their input serious consideration,[100] thereby allowing them to express such a preference and leading biobankers to respond to their preference. In addition to a preference for control, reciprocation is also suggested when biobanking involves commercialisation.[101] This suggestion might be followed by the Model's key attribute of reciprocation, which requires biobankers to reciprocate participants' contributions. Indeed, this key attribute also requires biobankers to allow participants to negotiate about policies on tangible reciprocation, and thereby participants can express their thoughts on this matter. It can therefore be said from this explanation that the Proposals can deal properly with commercial involvement in biobanking.

As the conclusion of this sub-section, commercial involvement in biobanking might hinder development of the ARR, which the Proposals are intended to foster, by undermining the collectiveness in biobanking goals between participants and biobankers as well as by making disrespectful gestures towards participants. However, the Proposals can arguably deal with this hindrance and even respond to some

[98] JI Valle-Mansilla et al, "Patients' Attitudes to Informed Consent for Genomic Research with Donated Samples" (2010) 28 *Cancer Investigation* 7 726-734.
[99] See 3.4.1 b) in ch 3 above.
[100] See 3.2.1 in ch 3 above.
[101] D Nicol and C Critchley, "Benefit Sharing and Biobanking in Australia" (2012) 21 *Public Understanding of Science* 5 534-555.

preferences that participants might have as a result of commercial involvement, through some measures proposed in the Model. Thus, this involvement is arguably not problematic for the Proposals – that is, it is unlikely to hamper the Proposals' ability to develop the ARR. Notably, as some authors suggest that members of the public should also be involved in dealing with commercial involvement in biobanking,[102] the fact that the Proposals do not cover a role for the public in biobanking[103] might limit their capability to tackle this involvement. As a result of this limitation, the ways in which the Proposals handle this involvement might not be in accordance with the public interests, thereby indirectly undermining the viability of the biobanks that rely on public support. Because the Proposals do not prohibit members of the public from being involved in biobanking, the suggestion here is that biobankers should engage members of the public in dealing with commercial involvement in biobanking.

6.4.4 Financial Incentives

In a biobanking context, financial incentives generally refer to benefits that have a financial value, including monetary offers, analysed health information, and the provision of individual feedback. In practice, these incentives have usually been used to encourage participants to participate or engage in biobanking activities, especially measurement and data-collecting sessions. As a real-world example, ALSPAC has offered monetary benefits to participants in return for their visits at its assessment centres, as mentioned in Chapter 5.[104] According to the Proposals, these incentives are conceptually considered to be an instrument for valuing participants' contributions and compensating them for the burdens imposed upon them by their participation, thereby promoting the ARR's key features of continuity in relationship and respectfulness.[105] For the Model, it is possible for biobankers to offer participants financial incentives since it is one way to reciprocate participants' contributions with tangible benefits, as explained in the Model's key attribute of reciprocation.[106] A question, however, arises

[102] KC O'Doherty et al, see note 9 above.
[103] See 6.3.2 above.
[104] See 5.3.2 in ch 5 above.
[105] See 3.3.2 in ch 3 above.
[106] See 3.3.1 b) in ch 3 above.

as to whether these incentives hinder development of the ARR and, if so, how the Proposals handle this hindrance. These two questions are dealt with separately in two sub-sub-sections, as follows.

a) Possible Hindrance

Although the Proposals use financial incentives to develop the ARR, it is ironically arguable that these incentives might hinder this development. This is particularly the case when their value is additional to necessary expenses incurred by participation in biobanking, because they can be perceived as profit resulting from participation. On the one hand, these incentives might entice participants to base their decisions to participate primarily on financial benefits. While this form of enticement is acceptable to some, it is not always so according to the Proposals since these incentives might inhibit the ARR's key feature of collectiveness in goals: they make profitability become influential in participants' goals rather than medical advances, thereby preventing participants from sharing the same goals with biobankers. On the other hand, in some circumstances, these incentives may also expose participants to undue influence, which is likely to impair their capability to make rational decisions, according to many authors.[107] In terms of the ARR, this potential can detract from the ARR's key feature of respectfulness by disrespecting participants or their autonomy.

Given these implications, a question arises as to whether or not financial incentives can actually help foster to the ARR. It is even questionable whether the provision of these incentives can amount to reciprocation or not, considering that this provision might hinder or prevent participants from properly assessing the risks and benefits of their participation or safeguarding their interests. For Titmuss, in his now classic research, the answer to this question seems to be negative, as he argues for

[107] R Macklin, "'Due' and 'Undue' Inducements: On Paying Money to Research Subjects" (1981) 3 *IRB: Ethics & Human Research* 5 1-6; D Evancs and M Evans, *A Decent Proposal: Ethical Review of Clinical Research*, (West Sussex: John Wiley & Sons, 1996), at 84-85; P McNeill, "Paying People to Participate in Research: Why not?" (1997) 11 *Bioethics* 5 390-396; RE Ashcroft, "Money, Consent, and Exploitation in Research" (2001) 1 *The American Journal of Bioethics* 2 62-63; T Phillips, "Exploitation in Payments to Research Subjects" (2011) 25 *Bioethics* 4 209-219.

voluntary blood donation and explains that an incentive scheme for blood giving can erode social bonds and a sense of community.[108]

b) Solution in the Model

The Model does not propose any measures for dealing directly with the aforesaid implications, since it does not require biobankers to determine participants' actual motivation or to investigate their capacity for making rational decisions. To reinforce collectiveness in biobanking goals from the perspective of participants, the Model's key attribute of emphasis on collective goals merely calls for providing them with the right of withdrawal and CBP, both of which enable them to reinforce such collectiveness by withdrawing their consent when they feel that they no longer share the same biobanking goals with biobankers.[109] This reinforcement mechanism is, however, unlikely to be effective in addressing those implications since it relies upon participants' cognition, which might be impaired as a result of those implications.

Even so, the Proposals still allow biobankers to offer financial incentives to participants because this offer does not always have those implications. This is supported by many authors who – despite acknowledging the possibility of undue influence, exploitation or coercion – argue for paying research participants.[110] It can therefore be concluded from these discussions that the Proposals do not strictly prohibit offers of financial incentives, but these offers need to be made cautiously so as not to hinder development of the ARR. For example, before making any offers of financial incentives, biobankers might take into account circumstantial factors that possibly influence participants' cognition, such as the characteristics of participants, the purpose of those offers and the value of those incentives. Note that this aspect of

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[108] RM Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, (London: LSE, 1997).
[109] See 3.1.1 b) (Changes to Participants' Goals) in ch 3 above.
[110] N Dickert and C Grady, "What's the Price of a Research Subject? Approaches to Payment for Research Participation" (1999) 341 *New England Journal of Medicine* 3 198-203; C Grady, "Payment of Clinical Research Subjects" (2005) 115 *Journal of Clinical Investigation* 7 1681-1687; A VanderWalde and S Kurzban, "Paying Human Subjects in Research: Where are We, How Did We Get Here, and Now What?" (2011) 39 *Journal of Law, Medicine and Ethics* 3 543-558; TB Phillips, "A Living Wage for Research Subjects" (2011) 39 *The Journal of Law, Medicine & Ethics* 2 243-253.

the Model might be considered another limitation of the Proposals – that is, the Model is unable to deal properly with a situation where participants' decisions to participate are adversely influenced by financial incentives.

6.4.5 Property Rights

Property rights refer to claims or entitlements that the law allows ones to have to, or over, certain property. These rights can be broadly categorised – in terms of the nature of property – into rights over intangible property, such as intellectual property, and tangible property, e.g. goods, chattels and real estate. In terms of biobanking – or the use of human tissues in particular – the former particularly concern patents, i.e. the rights over inventions, which exclusively enable inventors to legally commercialise their inventions and forbid others from doing so, in exchange for publicly disclosing details of their inventions. In this respect, human tissues do not themselves establish patents, unless they are part of inventions that meet the legal requirements of patentability (e.g. novelty, inventiveness and industrial applicability)[111] and are patented, such as patented cell lines from human tissues. By contrast, the latter refer to rights over human tissues as physical matter. In general, owners of certain tangible property normally have the rights to, inter alia, possess, use, transfer and destroy their property.[112] This is, however, not the case for human tissues in their natural state since, as explained below, the recognition of property rights over human tissues is limited. Based on these explanations, questions arise as to the extent to which property rights affect application of the Proposals, and how the Proposals deal with property rights that might arise in a biobanking context. This sub-section addresses these two questions by discussing them separately according to the nature of property.

[111] Nuffield, *Human Tissue: Ethical and Legal Issues*, (April 1995) 153, at para 11.2-11.9.
[112] These various types of rights are all together called 'the bundle of rights.' As listed by Honoré, this bundle of rights comprises eleven standard incidents of ownership, including the right to manage, the right to income and the incident of transmissibility. See AM Honoré, "Ownership" in AG Guest (ed) *Oxford Essays in Jurisprudence: A Collaborative Work*, (London: Oxford University Press, 1961) 107-147.

a) Patenting

For intangible property, there are two main issues that might arise from patenting in biobanking.[113] First, patenting inherently relates to the commercialisation of biobanking. Thus, the ways in which this aspect of patenting undermines the ARR and is handled by the Proposals are the same as those already illustrated in 6.4.3 above. The second issue concerns the possibility that participants might benefit financially from patents. In general, researchers normally hold patents in a biobanking context as they are, factually, inventors – i.e. they use biobank resources to invent something. It is, however, legally possible to reach an agreement that allows participants to benefit from, or even hold, patents. Regardless of possible controversy over such an agreement,[114] the Proposals neither require nor prohibit this form of agreement. Indeed, this can be considered as one way to tangibly reciprocate participants' contributions, although this form of reciprocation is not necessary according to the Model.[115] Nonetheless, as this agreement basically provides participants with financial incentives to participate in biobanking, the ways in which the Proposals respond to this issue are similar to those explained in Sub-section 6.4.4. Given these explanations, it can therefore be said that the implications of patenting for development of the ARR have already been illustrated in previous sub-sections.

b) Rights over Human Tissues

As regards tangible property, the recognition of property rights over human tissues from the living has been the subject of ongoing debate, due to the notion that a human body cannot be an object of rights.[116] While such recognition was traditionally inadmissible, this has been changing in recent years and in a number of key respects:

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[113] In theory, there are also other issues, such as the legitimacy of gene patenting. See JF Merz and MK Cho, "What Are Gene Patents and Why Are People Worried about Them?" (2005) 8 *Community Genetics* 4 203-208; G Watts, "The Locked Code" (2007) 334 *BMJ* 7602 1032-1033.

[114] A Ganguli-Mitra, "Benefit-sharing and Remuneration" in B Elger, N Biller-Andorno, A Mauron and AM Capron (eds), *Ethical Issues in Governing Biobanks: Global Perspectives*, (Hampshire: Ashgate Publishing, 2008) 217-229, at 224-225.

[115] See 3.3.1 b) in ch 3 above.

[116] TH Murray, "On the Human Body as Property: The Meaning of Embodiment, Markets, and the Meaning of Strangers" (1987) 20 *University of Michigan Journal of Law Reform* 1055-1088.

for example, the courts recently started recognising some aspects of property rights over human tissues. A notable example is the Yearworth case, where the court held that persons who had provided sperm for a reproductive purpose had ownership over those sperm since, legally, they had absolute control over those sperm, at least for the purposes of a successful negligence action.[117] This ruling was later followed by the Canadian Court of Appeal in the Lam case, which identically involved damage to human sperm deposited for a reproductive purpose.[118] In a research context, the US court in Missouri held that researchers had ownership over tissue samples donated for research, since this ownership had been transferred from participants to them through an *inter vivo* gift.[119]

However, despite these court decisions, it remains unanswered as to whether, in general, persons have property rights over tissues excised from them, as well as the extent to which such rights are legally recognised. More importantly, it is also questionable whether or not the answers to these questions and the aforementioned court decisions will be applied to the context of research biobanking. It can therefore be said that, at present, it is unclear as to who has property rights over tissues that participants provide for biobankers when participating in biobanking, and the extent to which such rights are legally recognised. Undoubtedly, there are many controversies over this matter in the academic arena, including the area of biobanking.[120]

As regards the relation between the recognition of property rights and the Proposals, it can be said that these two matters have different aims. In particular, the former has the aims of resolving conflicts between two parties and providing certain parties with remedies and protection. In contrast, the aims of the Proposals are to

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[117] *Yearworth and others v North Bristol NHS Trust*, [2009] 3 WLR 118 (CA).
[118] *Lam v University of British Columbia*, [2015] 2 BCCA (CA).
[119] *The Washington University v Catalona*, [2006] 437 F.Supp.2d 985 (E.D. Mo.).
[120] RA Charo, "Body of Research - Ownership and Use of Human Tissue" (2006) 355 *New England Journal of Medicine* 15 1517-1519; A Boggio, "Ownership of Samples and Data and Territorial Restrictions Concerning Data and Samples beyond National Boundaries" in B Elger, N Biller-Andorno, A Mauron and A Capron (eds), *Ethical Issues in Governing Biobanks: Global Perspectives*, (Farnham Surrey: Ashgate Publishing Limited, 2008) 197-205; K Gatter, "Biobanks as a Tissue and Information Semicommons: Balancing Interests for Personalized Medicine, Tissue Donors and the Public Health" (2012) 15 *Journal of Health Care Law and Policy* 303-347, at 318; I Goold et al, "The Human Body as Property? Possession, Control and Commodification" (2014) 40 *Journal of Medical Ethics* 1 1-2.

prevent conflicts between participants and biobankers and to encourage biobanking, by suggesting how to develop a relationship that is desirable for both of them. Thus, one can say that they focus on different aspects of a participant-biobanker relationship, and thereby the recognition of property rights does not affect how the Proposals work in terms of developing the ARR. For example, according to the conceptual framework of the ARR, the ARR is based on, inter alia, respectfulness, collectiveness of goals and collaboration,[121] all of which can prevail regardless of the extent to which property rights over participants' samples are recognised and who holds such rights. From a practical perspective, the Model requires reinforcing collectiveness in biobanking goals by resisting biobanking activities that deviate from collective goals,[122] and thus any misuses of biobank resources can be hindered or even inhibited, no matter whether participants have property rights over biobank resources or not. It can therefore be argued that these two matters are basically not related to each other. One might also say that the Proposals do not deal with this recognition, nor are they affected by it.

Conclusion

To conclude the contribution of this thesis, this thesis' original contribution concerns one approach to an ARR, a participant-biobanker relationship that can deliver ethical and effective biobanking practices. This thesis first establishes that, as a fundamental notion, the ARR proposed should be able to deal with the distinctive characteristics of biobanking and to strike a balance between participants' and biobanks' interests. Based on this premise, it then argues that, conceptually, the ARR should look like a partnership relationship, and thus it should have five key features – i.e. respectfulness, cooperation with negotiability, support, continuity in relationship and collectiveness in goals – as its conceptual framework. To suggest how to foster it in practice, this thesis proposes the Model, the model for biobank governance that can incorporate those key features into biobanking activities. The Model comprises four key attributes, namely emphasis on collective goals, collaboration, reciprocation and

[121] See 2.3 in ch 2 above.
[122] See 3.1.1 b) (Changes to Biobankers' Goals) in ch 3 above.

control sharing. To show how to apply the Model, it is tested against the governance of UK Biobank and ALSPAC. The results of this testing suggest that mechanisms that are crucial for fostering the ARR in practice are ongoing communication with participants and the establishment of an oversight body that can encourage the pursuit of collective goals and the provision of participant safeguards. It is worth emphasising again that these two mechanisms are merely suggestions resulting from this testing, not requirements that need to be satisfied in order to comply with the Model.

In this chapter, the nature and full extent of this contribution are emphasised and clarified. In so doing, this chapter explains the academic grounding of the Proposals: it first delineates the ethicality of the Proposals (further from Chapter 1) by explaining that the Proposals adopt deontological ethics and virtue ethics, not consequentialism, as their approaches to ethical reasoning and this adoption can be called the reductionist radical approach to virtue ethics; it then deals with the legality of the Proposals by arguing that it is not suitable to use the Model directly as a legal framework for biobank governance due to the nature and content of the Model, although it is possible to do so in certain limited circumstances or to use the Model to inform legal mechanisms. Moreover, this chapter pinpoints the limitations on the application of the Proposals, namely the inability to (i) give participants control over the direction of biobanking activities, (ii) prevent non-active participants from being represented by active ones and (iii) address issues that should be settled by the public and communities. Ultimately, this chapter demonstrates how the Proposals respond to some controversial issues that usually arise in a biobanking context, i.e. participants' control, individual feedback, commercial involvement, financial incentives and property rights.

Some key points about the contribution of this thesis should be noted here. First, from a philosophical perspective, this thesis provides an ethical framework for biobank governance that perceives partnership as a virtuous trait for biobankers and provides rules for acquiring this trait through biobanking practices. Second, the ARR is essentially fostered through communication between biobankers and participants. This communication is intended to inform participants about biobanks in which they participate, to provide them with general knowledge about biobanking, and to receive

their input about biobanking. In practice, it helps them to deal with and negotiate about biobanking activities as well as to cooperate with biobankers properly. Third, the Proposals do not advocate participants' full control over biobanking activities. Rather, they call for sharing control over biobanking with participants at an individual level and the extent of this sharing should be contextual. Fourth, for the Proposals, it is generally acceptable to provide participants with individual feedback and/or financial incentives, because this provision is considered to help maintain a research relationship with them by reciprocating their contributions towards biobanking. Fifth, commercial involvement in biobanking is unlikely to undermine development of the ARR as long as biobanking activities are managed in line with the Proposals properly. Finally, while the ARR cannot hope to meet all expectations, it can nevertheless help participants and biobankers to work towards a common understanding of what is at stake and to support them in all decisions on whether to proceed together in the research enterprise.

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Appendix 1

Materials Used for Analysing UK Biobank Governance

This appendix lists materials that were accessed and reviewed to set up the discussions and develop the arguments in this thesis, especially Chapter 4, in addition to those listed in Bibliography. It also demonstrates how the titles of those materials are simplified, as appearing in bold, when being used as references in the discussions and footnotes in Chapter 4. It is notable that this simplification has the aim of avoiding confusion arising from the use of common referencing styles.

The EGC's Materials

- EGC Annual Reports
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- UK Biobank Ethics and Governance Council, *Report on the EGC 42nd Meeting*, (9 March 2015) 8. ("**Report on 42nd EGC Meeting**")
- UK Biobank Ethics and Governance Council, *Report on the EGC 43rd Meeting*, (1 June 2015) 8. ("**Report on 43rd EGC Meeting**")
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  - UK Biobank Ethics and Governance Council, *Report on Public Meeting*, (2010) 12. ("**Report on EGC Public Meeting 2010**")

- Other Materials
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- UK Biobank Ethics and Governance Council, *Feedback of Health Related Findings: Foreground Principles and Background Perspectives*, (June 2015) 41.
- UK Biobank Ethics and Governance Council, *Workshop Report: Involving Publics in Biobank Research and Governance*, (8 December 2009) 24. ("**Report on EGC Workshop on Public Involvement**")

UK Biobank's Materials

- Ethics and Governance Framework
  - UK Biobank, *UK Biobank Ethics and Governance Framework Version 1.0 (for Comment)*, (September 2003) 34. ("**UK Biobank EGF v1**")
  - UK Biobank, *UK Biobank Ethics and Governance Framework Version 3.0*, (October 2007) 20. ("**UK Biobank EGF v3**")
- Policy Documents
  - Trehearne, A, *UK Biobank Communication Plans*, (June 2011) 4. ("**Communication Plans**")
  - UK Biobank, *Re-contact Procedure*, (16 April 2013) 12. ("**Policy on Re-contacting**")
  - UK Biobank, *UK Biobank Access Procedures v1.0*, (November 2011) 36. ("**Policy on Access**")
- Recruitment Documents
  - UK Biobank, *Consent Form*, (24 November 2006) 1. ("**Consent Form**")
  - UK Biobank, *Further Information Leaflet*, (2009) 11. ("**Further Information Leaflet**")
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- UK Biobank Coordinating Centre, *Public Consultation on Draft Access Procedures: Summary of Responses and Modifications*, (21 September 2011) 11. ("**Report on Public Consultation on Draft Access Procedures**")

Others' Materials

- House of Commons (Science and Technology Committee), *Third Report on the Work of the Medical Research Council*, (2003) 35.
- Review of the EGC:
  - Medical Research Council and Wellcome Trust, *Review of the UK Biobank Ethics and Governance Council*, (July 2010) 13. ("**Review of the EGC 2010**")
  - Medical Research Council and Wellcome Trust, *Review of the UK Biobank Ethics and Governance Council*, (June 2015) 16. ("**Review of the EGC 2015**")

Appendix 2

Materials Used for Analysing ALSPAC Governance

This appendix lists materials that were accessed and reviewed to set up the discussions and develop the arguments in this thesis, especially Chapter 5, in addition to those listed in Bibliography. It also demonstrates how the titles of those materials are simplified, as appearing in bold, when being used as references in the discussions and footnotes in Chapter 5. It is notable that this simplification has the aim of avoiding confusion arising from the use of common referencing styles.

- Annual Reports (ascending by time)
    - ALSPAC, *Report on ALSPAC Milestones 1st Jan 2006 - Oct 2006*, (2007) 19. ("**Annual Report 2006**")
    - ALSPAC, *Report on ALSPAC Milestones Year 2 1st Jan 2007 - Dec 2007*, (March 2008) 14. ("**Annual Report 2007**")
    - ALSPAC, *Report on ALSPAC Milestones Jan - Dec 2008*, (March 2009) 20. ("**Annual Report 2008**")
    - ALSPAC, *Report on Annual Milestones January - December 2009*, (February 2010) 18. ("**Annual Report 2009**")
    - ALSPAC, Strategic Award Milestones Year 1*: April* 2011 *to March* 2012, (2012) 6; ALSPAC, *Strategic Award Milestones Year 1, Appendix 5: Yr1 Milestones for ALSPAC G2 (COCO90s) Study*, (11 May 2012) 4. ("**Annual Report 2011-12**")
- Participant Newsletters (ascending by time)
    - Newsletters for all participants
        - ALSPAC, *Participant Newsletter Issue 25*, (200?) 8. ("**Participant Newsletters Issue 25**")
        - ALSPAC, *Participant Newsletter Issue 26*, (2003) 8. ("**Participant Newsletters Issue 26**")
        - ALSPAC, *Participant Newsletter Issue 27*, (2004) 8. ("**Participant Newsletters Issue 27**")

- Parents Newsletters
    - ALSPAC, *Parents Newsletter Issue 33*, (August 2008) 8. ("**Parents Newsletters Issue 33**")
    - ALSPAC, *Parents Newsletter Issue 34*, (2010) 8. ("**Parents Newsletters Issue 34**")
    - ALSPAC, *Parents Newsletters*, (September 2011) 6. ("**Parents Newsletters 2011**")
- Young Participant Newsletters
    - ALSPAC, *Young Participant Newsletter*, (April 2008) 3. ("**Young Participant Newsletters 2008**")
    - ALSPAC, *Young Participant Newsletter*, (November 2009) 6. ("**Young Participant Newsletters 2009**")
    - ALSPAC, *Young Participant Newsletter*, (March 2012) 4. ("**Young Participant Newsletters 2012**")
- Family Newsletters
    - ALSPAC, *Family Newsletter*, (July 2013) 8. ("**Family Newsletters 2013**")
    - ALSPAC, *Family Newsletter* 2014-2015, (July 2014) 8. ("**Family Newsletters 2014-15**")
    - ALSPAC, *Family Newsletter* 2015-2016, (2015) 8. ("**Family Newsletters 2015-16**")

- Policy Documents
    - ALSPAC Ethic & Law Committee, *Policy regarding Disclosure of Biomedical Information to Participants*, (March 2011) 2. ("**Policy on Feedback**")
    - ALSPAC, *Access Policy v.5.40*, (December 2014) 24. ("**Policy on Access**")
    - ALSPAC, *Complaints Policy v3*, (June 2014) 4. ("**Policy on Complaints**")
    - ALSPAC, *Withdrawal of Consent Policy*, (February 2011) 5. ("**Policy on Withdrawal**")
- Recruitment Documents
    - ALSPAC, *Consent Form*, (14 March 2014) 2. ("**Consent Form**")

- ALSPAC, *Summary Booklet*, (2011) 4. ("**Summary Information Booklet**")
- ALSPAC, *The Detail: Detailed Booklet v.7*, (14 March 2014) 36. ("**Detailed Information Booklet**")

- Terms of Reference
  - ALSPAC, *Executive Committee: Terms of Reference*, (November 2014) 4. ("**Terms of Reference - AEC**")
  - ALSPAC, *ALSPAC Steering Group: Terms of Reference*, (April 2014) 4. ("**Terms of Reference - ASG**")
  - ALSPAC, *Independent Scientific Advisory Board: Terms of Reference*, (June 2014) 2. ("**Terms of Reference - ISAB**")
  - ALSPAC, *ALSPAC Ethics & Law Committee (ALEC): Terms of Reference*, (December 2014) 14. ("**Terms of Reference - ALEC**")

- Other Materials
  - ALSPAC, *ALSPAC Progress Report 2006-2010*, (2011) 69.
  - ALSPAC, *New Data Collection Review Dates*, (2016) 1.
  - ALSPAC, "The Avon Longitudinal Study of Parents and Children (ALSPAC) Access Policy" (October 2012) available at (accessed 12 January 2016).
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  - Centre for Ethics in Medicine (University of Bristol), "EPEG Project" (October 2000 - September 2003) available at http://www.bris.ac.uk/Depts//Ethics/CEM/epeg.htm (accessed 5 January 2015).
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  - Young Health Participation, "Involving Children and Young People in Research - PRWE Forum" (11 December 2013) available at https://younghealthparticipation.com/page/2/ (accessed 20 June 2016).