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Robert Plant

University of Miami, rplant@miami.edu

Alexander P. Pons

University of Miami

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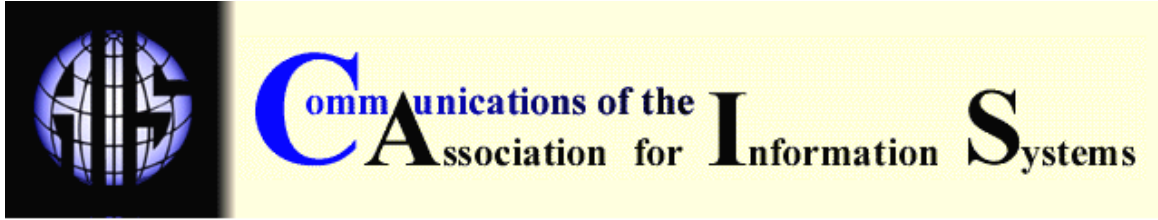
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MIS RESEARCH INVOLVING HUMAN SUBJECTS: PROCESSES AND IRB REQUIREMENTS

Robert Plant
Alexander P. Pons
Dept of Computer Information Systems
University of Miami
rplant@miami.edu

ABSTRACT

This paper discusses major issues and institutional requirements for human subjects' research. In particular, it considers the responsibilities of principal investigators or individual researchers conducting human subjects research in management information systems. The paper introduces the issues related to human subjects' research and presents the background and responsibilities of institutional review boards. An overview is presented of institutional review boards as they relate to management information systems within the broader context of social and behavioral science research. The data collection instruments commonly used in management information systems studies are considered in relation to human subject involvement. New developments such as the Internet as a mechanism for data collection are also considered.

Keywords: research ethics, institutional review boards, code of conduct

I. INTRODUCTION

Management Information Systems (MIS) scholarship covers a wide array of topics, including the issues facing CIO's, the impact of technology, customer-vendor technology relationships, and the role that IT plays in the larger organizational context. Common to the research undertaken by members of the MIS community, in these and other areas, is the use of research methods involving an interaction with human subjects. These methods include techniques such as the use of focus groups, surveys, interviews, experimentation with observation, and tests for cognition, each of which involves one or more human subjects. It is important for researchers to be aware of their obligations to subjects, their institutions, and any funding source that sponsors the research either directly or indirectly. Failure to recognize these obligations and adhere to the correct processes, policies, and procedures can result in harsh outcomes. MIS researchers should understand clearly that they can be held culpably liable, sent to jail, and their institutions punished. For example, in the United States the Federal government can remove all federal funding from an institution not adhering to human subjects research guidelines. All MIS researchers are obligated to adhere to government regulations and their institutions' research policies and practices. Senior researchers are further obligated to ensure that their students and junior colleagues also learn the proper techniques and adhere to these policies as they develop their studies. The MIS research community is also bound by professional codes of conduct or ethics, such as the AIS Code of Research Conduct

“Respect the rights of research subjects, particularly their rights to information privacy, to being informed about the nature of the research and the types of activities in which they will be asked to engage. AIS Research Conduct Committee [2004]:

Scholars are expected to maintain, uphold and promote the rights of research subjects, especially rights associated with their information privacy. Subjects in academic research routinely volunteer information about their behavior, attitudes, intellect, abilities, experience, health, education, emotions, aspirations, and so on. If you are collecting such data, you have an obligation to respect the confidentiality of your subjects by storing data in a secure place, destroying it after a specified period of time, and never using it for any purpose other than that to which the subjects agreed prior to their participation. In addition, unless an institutionally-approved research protocol allows otherwise, research subjects should be informed in advance of the purpose of any research procedure or activities in which they may be asked to participate. They also have the right to withdraw from the research at any stage. Researchers must respect these rights and not coerce or otherwise force research subjects to participate against their will, or in a manner that is not conducive with their best interests.” AIS Research Conduct Committee [2004]:

Since the importance of researchers understanding their obligations to their human subjects is paramount, this paper aims to be a primer for MIS researchers and students who propose to undertake human-subjects-based research studies. Section II presents the background to human subjects research oversight. Section III discusses the principal investigator's¹ responsibilities in cases where their research involves human subjects. Section IV describes the processes surrounding the preparation of protocols for submission to Institutional Review Boards (IRBs) and the process itself. The paper concludes with commentary and conclusions.

II. A BACKGROUND OF HUMAN SUBJECTS RESEARCH OVERSIGHT

Research in the post Second World War era has been framed by the experimentation performed on human subjects by the Nazi party. The subsequent examination of these actions at the second war trials tribunal in Nuremberg led to The Nuremberg Code [1947] and the development of the concept of 'required informed consent' by individuals participating in research studies. The code took the form of ten standards of which future researchers (physicians) were to abide in their studies involving human subjects [Mitscherlich and Mielke, 1949] [Anonymous, 1996].

The period following the Second World War also saw a large growth in public medicine in the United States. The role of ethical medical practices was at the forefront of the efforts. In the United States the National Institute of Health (NIH) was tasked to build on the provisions of the Nuremberg code. With the construction of the Warren Grant Magnuson Clinical Center at Bethesda, Maryland in the 1950s a 'medical advisory board' was created to review and oversee the protocols administered by the clinicians associated with the center [Office of NIH History, 2006]. The NIH used the Bethesda advisory board as the gold standard. Institutions receiving grants from the NIH were required to 'state the ethical principles guiding their research involving humans [Office of NIH History, 2006]. In 1966 the United States Public Health Service put forth a policy framework that required every institution receiving Federal research funds to put in place a

¹ The term Principal Investigator (PI) is normally associated with funded research. IRB protocols tend to use the term to characterize the person who leads the research as the PI whether the research project is funded or not. We use the term PI and researcher interchangeably in this document. However it should be noted that the lead researcher is the person the IRB identifies as being responsible for the experiment and for the work performed by the researchers involved in the experiment/research.

committee to review the protocols and policies associated with every study involving human subjects [Stuart 1966].

The common working regulatory framework used by American research institutions was further strengthened in the 1970's following the revelations of the Tuskegee syphilis experiments which came to light in 1972, together with incidents such as the 1971 Stanford University Prison Experiment [Zimbardo 1973]. These issues led to the state of human subjects experimentation being extensively re-examined by the Federal Government. In 1974 the U.S Government enacted a more thorough set of legislation that became known as the "Federal policy for the Protection of Human Subjects" also known as the 'Common Rule [United States department of Health and Human Services, 2005a]. The Common Rule is a part of the Code of Federal Regulations (CFR) that define a set of the protocols and procedures which are required to be in place to protect the individual human subject involved in experimentation that is either conducted, funded or overseen with support from the Federal Government or one of its agencies. The Rule also covers any studies performed at an institution that is receiving Federal Funding regardless of whether a particular study is directly receiving funding or not. The Common Rule however is not applicable to private institutions that are not receiving any Federal funding. Clearly however the subjects and institutions involved in and performing studies, are still subject to the applicability of normal Federal and State laws.

These review committees eventually became the Institutional Review Boards when the Public Health Services Act was amended in 1975 and were tasked with implementing the findings of the 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, in the form of the National Research Act [NRA 1974]. The findings laid out in the 1979 Belmont Report [Belmont 1979] detailed the principles through which oversight processes for research on human subjects would be developed [Ryan, 1979].

The Belmont report itself aimed to summarize the 'basic ethical principles' [Ryan 1979] as identified by the 1974 commission and was 'stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects' [Ryan, 1979].

Three basic principles are defined in the Belmont report: Respect for the person; Beneficence; and Justice.

Respect for the Person: Respect for the person is based on two major ethical convictions: "first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection' [Ryan, 1979]. Thus the Belmont Report offered protection to individuals in need of protection from potential exploitation and provided autonomy to individuals such that they enter into agreements with agents performing research of their own free will. This development of the 'informed consent' is a vital aspect of all human subjects research and is based upon the principle that the subject was properly and clearly informed of the research procedure and that all information was disclosed to them about the purpose, risks, anticipated benefits, and alternatives available. Further, the individual must be informed that they are volunteers and that they can withdraw from the study at any time being under no obligation or inducement to participate.

In some situations revealing all pertinent data to the subject potentially negates certain aspects of the research. The Belmont report notes three instances where full disclosure may be unnecessary:

"In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them" [Ryan, 1979].

Building upon these concepts the Belmont report stresses the necessity to present information to subjects in a clear and accessible manner and that special provision be made in the case of subjects who may have underdeveloped, limited or an impaired ability to understand such as children, or disabled subjects [Belmont 1979].

Benificence: Beneficence ensures that 'persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well being' [Ryan 1979]. Beneficence builds on the medical Hippocratic creed of 'do not harm' and 'maximize the benefits while minimizing potential harm'.

Justice: Justice ensures that consideration is given to 'who ought to receive the benefits of research and who bears the burden?' [Belmont 1979]. It promotes the ethical considerations about the selection of research subjects and the fair distribution of the gains from the research. This principle is seen today in NIH funded research where the technology or drug developed must be made available to the public at a reasonable charge.

The Belmont report was a landmark report and subsequently acted as the cornerstone of institutional research policies. While most of the early emphasis on research policies and procedures originated with consideration of medical research, significant growth occurred in social and behavioral research since the 1960s. This growth necessitated the creation of specialized IRB panels that focus on the issues of social and behavioral research and on cross-discipline research such as medical informatics or bio-medical engineering. The 1970's saw a significant number of ethically troubling studies which led to a re-examination of the policies associated with social science research. In 1981 the DHSS released revised regulations relating to sponsored research [NRC, 2003]. Several areas were modified by DHSS:

1. IRBs could expedite the review process for a class of research protocols defined in 15 U.S.C. §46.110² in which '(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk', or '(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized [United States department of Health and Human Services, 2005b].
2. IRBs can exempt certain protocols from a full IRB examination and subsequent monitoring if certain criteria were found to exist in the research proposal (Appendix I).
3. The DHSS also emphasized the importance of ensuring that any data generated during the course of a research study be secure and that security be maintained for the life of the data.

Thus, an Institutional Review Board is charged with acting in accordance with the 'pertinent requirements' of the Policy for Protection of Human Research Subjects as defined in CFR Part 46³ (Appendix I). The IRB for an organization thus:

1. Sets policies and establish the processes for an organization through which individual studies are reviewed
2. Once authorized, monitors those studies through established procedures and policies.
3. Ensures that the institution maintains privacy and protection policies that ensure any information pertaining to individuals involved in the study is (a) securely stored and (2) accessed only by authorized individuals whose use of the data falls within the mandate of the original study as authorized by the IRB.

² "15 U.S.C. §46.110" Refers to Volume 15 of the United States Code Section 46 subsection 110

³ Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46)

The U.S. Federal Government in Fiscal Year 2003 allocated \$21,833,953,000 [NSF, 2003a] in research and development expenditures for Universities and Colleges (Science and Engineering). In addition, it supported, through its agencies, 36 Research and Development Centers [NSF, 2003b]. While all public or private institutions have an ethical mandate to perform according to the Common Rule, it is also exceptional for academic institutions based in the United States not to use any Federal funding source. In 2005, there were 2956 individual IRBs [United States department of Health and Human Services, 2005c] in the United States and her territories, and 1536 International IRBs in 132 countries [United States department of Health and Human Services, 2005c].

Institutional IRB structures vary. It is not unusual for a single institution to operate several IRBs registered with the DHSS. Large research hospitals may, for example, use three or four IRBs to share the protocol submission load and simplify the internal administrative burden. General research institutions such as universities frequently split the IRB function under the umbrella of an 'Office of Research' into two primary categories, one covering the medical sciences and a second to cover research in the social and behavioral sciences. This separation also simplifies the internal structures, staffing requirements, and processes involved in IRB administration. Principal investigators then submit their protocols to the most appropriate board for review. For some disciplines the choice is clear: research in medical schools or pharmaceutical laboratories is subject to medical IRBs. However multi-disciplinary research projects such as medical informatics within the auspice of management information systems (MIS) may require the researcher to select an IRB based upon the scope and impact of the project, its data, and the expertise required to judge its protocol.

Human subject's research based upon approval of protocols by IRBs within both the contexts of medical research and social behavioral research continues to evolve and be subject to both Federal and state legislation. As human subjects research continues to evolve, requirements on researchers and IRBs will also change. Expected dimensions of growth include:

1. Technical developments such as the Internet,
2. Changes in research fields themselves as they evolve and morph. For example, telemedicine, a sub-discipline of medical informatics, itself a sub-discipline of both medical and systems research;
3. Development of the regulatory frameworks that surround the research fields themselves. For example, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 which covers medical records and patient information security;

Management information systems research is frequently at the confluence of these factors because MIS subject matter becomes ever more multi-disciplined and wider in scope. Thus the area of human subjects' research requires constant monitoring and observance by MIS researchers. The remainder of the paper considers some of these issues in greater depth.

III. HUMAN SUBJECTS AND MIS RESEARCH

The adherence to the Federal guidelines for human subjects research is applicable regardless of the discipline or the vehicle by which the participant interacts with the researcher, be it a face-to-face interview, a telephone conversation, a paper survey document or an Internet e-mail survey. The convenience and speed at which Internet-based surveys are developed and sent out can be alluring to researchers desiring data. However, the safeguards of traditional human subjects research practices need to be implemented and the instruments cleared by the institution's IRB unless the survey is clearly exempt⁴ and the institution does not require a 'formal exemption'

⁴ The 'exemption' process is discussed later in the paper.

certified by an IRB. The obligation for IRB certification always falls to the principal investigator in any research project involving human subjects. The obligations, process, and implications for human subjects' research are discussed in this Section.

MIS RESEARCH INSTRUMENTS

MIS research can be described as research "concerning both the management of information technology and the use of information technology for managerial and organizational purposes" [Lee 2000]. It covers many topic areas and approaches involving human subjects in collecting data.

Protocol

Research teams need to incorporate a protocol into their research design and submit it to the IRB. The first step is for researcher is to ensure that their team are "certified" in human subjects' research This step needs to be done before any study is undertaken due to the time lag involved in becoming certified. In developing the experimental design for a research study the question of data is the primary factor leading to the need for involving an IRB. Research studies that are purely theoretical in nature, use only public available data or do not involve human subjects do not require IRB certification. For study designs involving human subjects the protocol must be considered and approved by their IRB. Three major types of research project and data collection instruments are considered here: survey instruments, case studies and interviews.

Survey Instruments

Traditional non-Internet based survey instruments involving human subjects require consideration by IRBs when exemption is not clear or if the policies of the institution require all protocols to be submitted for formal exemption by the IRB. Internet-based survey instruments are popular and extensively used by MIS researchers. The literature in the area of Internet-based survey research grew considerably since the Internet was deregulated in 1994. Academic researchers in many disciplines realized the Internet presented them with the opportunity for a wider access to potential survey respondents and offered the potential for faster response rates coupled with a higher degree of accuracy. While the realities of using the medium as a data collection channel are mixed, the principles of ethical human subjects research are still applicable.

Early research showed that e-mail surveys produced higher response rates than traditional surface mail methods [Tse et al, 1995]. However, Couper et al. [1999], who compared the response rates for e-mail and traditional mail requests, found a higher response rate from the recipients of traditional mail than e-mail. Couper also found a variance in the responses (more positive in the e-mails than the mail). This finding has been reproduced by other researchers [Kwak and Radler, 2000; Guterbock et al., 2000; Medlin and Ham Chai, 1999]. Reasons for this variance include the difficulty of crossing over techniques for obtaining high response rates from the physical to the virtual environment, the decreasing tolerance for e-mail surveys by potential participants as well as the ability of filters and technologies that block surveys as spam [Crawford et al, 2001]. The studies, however, did not consider the impact of human subjects' requirements and no research was found on the impact of IRB qualified instruments in MIS studies.

If it is found that the research is not exempt and that no waiver of informed consent is given by the IRB, a solicitation document and informed consent document must be created. While these documents are extremely valuable in the subject's education and knowledge, they can be off-putting and intimidating to the human subjects and act to lower the response rate.

Selection of subjects in self administered surveys is an active area of research. Traditional random sampling techniques used in mail surveys are non-transferable for the Internet where there is no central store of e-mail addresses from which a random sample can be created. Several researchers created sampling frameworks for 'subject pools' that reside on list serves, newsgroups, and other forums [Swoboda et al., 1997; James et al. 1995; Anderson and Gansneder, 1995]. However the issue of human subjects recruitment was not studied. It is not

uncommon for inducements to be used that include financial and other prizes offered as rewards to lure potential subjects. While this approach is not unethical if no personal identifiable data is given when responding to the survey, the lack of IRB oversight coupled with an incentive program for attracting subjects is of concern.

Babbie [1990] showed that the 'more burdensome the task the lower the response rate' [Kaye and Johnson, 1999]. To make the researcher-subject interaction as pleasant and easy as possible (thus raising the participation rate), a variety of approaches to conducting web surveys are being studied for effectiveness, these include:

- A direct e-mail including an attachment of a survey instrument to a subject group. The subjects then are requested to return the survey via regular anonymous mail.
- The use of an e-mail request mechanism, where the human subject then e-mails back a request to perform the survey. This mechanism that was found to be more effective than direct e-mail [Smith, 1997].
- The use of an e-mail web hyperlink mechanism, where the hyperlink connects through the Internet directly to a database and the human subject responses are input directly to the database.

Each of these approaches needs to be considered by the researcher in developing their protocol for submission to their IRB. The first method needs to ensure that the sample reflects the study design submitted by the researchers to the IRB, that issues such as minority, child, or prisoner involvement are actively understood, and that the use of the relevant informed consent documents are developed and issued. The second method, while still subject to population sample concerns, would be considered a positive method of achieving satisfaction in determining whether the survey response was voluntary or not. The third method is subject to the same issues as the first in terms of population selection. In addition, the software used must delete all data that could lead to participant identification from the e-mail or database interaction. The human subject needs to be made aware that this is being done in the recruitment letter.

Internet-based surveys are still in their infancy as an instrument. Schleyer and Forrest goes as far as to suggest that the sampling used in many studies through online mechanisms reflect 'unknown samples' and that when subjects are targeted through newsgroups or similar that 'it is nearly impossible to determine the distribution of the sample population' [Schleyer and Forrest, 2000]. These findings are confirmed by Zhang who discusses the inability of e-mail survey findings to be generalised across populations [Zhang, 2000]. Other sampling problems such as non response errors, measurement error, and non observation led researchers such as Couper to propose more robust mechanisms for probability based surveys built around pre-recruited populations [Couper, 2001]. Again, pre-recruited populations needs to be protected by applying the same values applicable to all human subjects research. An example of a pre-selected population would be an academic researcher who uses a university class of students as a population. Assuming that the study is not exempt, if it asks for personal data, a student in such a class must be allowed the option not to participate and no coercive measures or rewards should be offered such as a grade for participation.

A survey instrument that collects corporate data and records no personal data requires no IRB protocol submission. However, surveys that examine behavioral issues and request personal data require IRB protocol submissions before the study can be executed. An example would be the use of a survey to investigate hiring and promotion of MIS personnel at an organization and requiring that the person send their resume the researcher together with a survey response. A survey request that does not provide correct warnings to the individuals about the risks associated with responding to the survey, together with information on how the data will be used, stored, shared with others and ultimately disposed of would be a violation of human subjects IRB practices. Authors of surveys that are authorized by IRBs will generally be provided with an authorization code for their study that must accompany all communication with subjects.

Case Study Research, Interviews and Data Acquisition

Much applied MIS research and data involves case studies. Some case studies involve corporate data that is in the public domain. These do not need to be cleared by the IRB. Case studies that involve extracting data or quotes from personal interviews with members of organization require careful examination of the types of information to be extracted. Primarily, if the interviewee is covered by the definition of a human subject 15 U.S.C. §(46.102(f)(2)) then interviewers need to be cognizant of the "identifiable private information" concept as it pertains to their research methodology. In 15 U.S.C. §46.102(f)(2) "private information" is defined as "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place." As such, any information extracted in an interview that allows a subject to be identified or "place the subjects at risk of criminal or civil liability or that could be damaging to the subjects' financial standing, employability, or reputation" (15 U.S.C. §46.101(b)(2)) needs to be extracted through a protocol cleared by an IRB.

The use of human subjects in interviews or focus groups in MIS research studies are subject to the same procedures and policies as survey based instruments. Care must be taken about how interviews of this type are undertaken. For example, does the population involve a vulnerable group such as children, prisoners, or the visually impaired? A study that incorporates interviews of retirees or members of a minority group such as a Native Americans on their aptitude for Internet use, would for example, need IRB approval. In the case of a non exempt study, the IRB would require the protocol submitted by the researchers to provide the questions that would be asked during a structured or semi-structured interview. Open-ended unstructured interviews require particular care and consideration.

In case studies where there are no personal identifiers, the data will not be attributable to any individual and therefore no IRB submission is required. Case studies where the interviewee is identifiable, but who only talks about corporate data (sanctioned and cleared by the organization) does not require IRB submission. However case studies that involve the extraction of personal information (such as in a case studying 'workplace technology performance,' an impact study involving medical information e.g., carpal tunnel syndrome) would require an IRB protocol submission.

While each of the policies discussed in this Section and the next one are generic to all human subjects research, each institution and IRB will follow its own policies and procedures that need to be considered and adhered to.

IV. IRBS AND THE ACADEMIC RESEARCHER

In this section we consider the processes surrounding the preparation of protocols for submission to an IRB and the process itself upon submission.

INSTITUTIONAL QUALIFICATION

Typically researchers perform under the umbrella of an institution such as a University, Institute, or Research Laboratory. While it is not mandatory that the institution's IRB to be formally registered with the government agency for which it is undertaking formal research, the Institution will be required to sign off on a "Statement of Investigator" or "assurance," for any study conducted for a government agency. The name and address of the IRB responsible for review of the study is provided to the agency (through the DHSS) [United States department of Health and Human Services, 2005d]. IRBs tasked to approve studies must be established and operated in compliance with 21 CFR part 56 [United States department of Health and Human Services, 2005d]. The DHSS does provide compliance audits to ensure that institutions are adhering to all Federal and state regulations and acting according to all guidelines, policies, and procedures. Failure to comply can result in a major penalty for the institution. For researchers not working under an umbrella organization it is permissible for independent researchers to use remote IRBs

and, through a formal agreement between the two parties, undertake a study with oversight of the remote IRB.

THE COMPOSITION OF IRBS

As described in Section II, it is the function of an IRB to ensure adherence to all Federal, state, local, and institutional regulations about protecting human subjects involved in research studies undertaken by members of that institution (Appendix II). The composition requirements are defined by DHHS as:

“Federal Policy Requirements. *The Federal Policy [§46.107] provides that IRBs must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.*

In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas. No IRB, however, may consist entirely of members of one profession.

If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB must consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. Department of Education (ED) regulations require, in addition, that when an IRB reviews research for one of its programs that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these subjects [34 CFR 350.3(d)2]; 34 CFR 356.3(c)(2)].

The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The IRB must make every nondiscriminatory effort to ensure that it does not consist entirely of men or entirely of women. Selections must not, however, be made on the basis of gender.

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.

No IRB member may participate in the review of any project in which the member has a conflicting interest, except to provide information requested by the IRB” [United States department of Health and Human Services, 2005e].

The composition of IRBs that examine protocols for medical studies are thus usually different from those that assess social and behavioral science research, however an institution can always

exercise its prerogative to create specialist IRBs for studies that require unique skills sets for adequate consideration.

THE PRE-SUBMISSION PROCESS

The first step that researchers are required to undertake prior to submitting their initial protocol for consideration by an IRB is to become “certified” in human subjects protections. The Federal government guidelines for human subjects research ‘require that all personnel involved in the design or conduct of human subjects’ research receive training and education in human subjects protections [Human Subjects Research Office, 2004b]. Institutions are thus required to provide a mechanism to provide this training. Many institutions use web services such as the Collaborative IRB Training Initiative (CITI). The CITI initiative was co-founded by Karen Hansen and Paul Braunschweiger in March 2000 as a collaborative venture between the University of Miami and the Fred Hutchinson Cancer Research Center (now a part of the University of Washington). The content for the first 12 bio-medical modules was provided by experts at ten institutions around the United States. CITI currently provide courses for over 400 participant institutions and provides basic, refresher and special courses in the Protection of Human Research Subjects for Biomedical and for Social / Behavioral Research.

THE PROTOCOL SUBMISSION PROCESS

Every institution creates a research protocol application template through which formal submissions are made to the IRBs. This detailed and extensive document provides the IRB with a comprehensive description of all aspects of the proposed project and the steps taken by the research team to ensure that the IRB guidelines are adhered to. The IRB uses the documents not only to act as their resource to assess the study but as a mechanism to record the IRB decision trail to ensure DHSS audit compliance (Appendix II). The research protocols are tailored to the institutional research parameters of specific colleges in order to streamline the administrative overhead to exempted and expedited paths through their IRBs and flag full reviews for special consideration. Many universities automate the process of protocol submission by using a web-based protocol management system for submission, tracking, and reporting.

THE PROTOCOL DOCUMENT

A full examination of protocol application documentation that includes the data collection requirements for medical studies is beyond the scope of this paper. Instead, we focus upon the issues that pertain to social and behavioral research with special emphasis on aspects relevant to the management information systems researcher.

Protocol Identification Information

As stated in Section III, the project leader at most institutions is required to be “certified” in human subjects’ protections and to list the members of the research team including co-investigators, key personnel and collaborators including their credentials and human subjects “certification” levels.

Types of IRB review

The applications are typically filtered by administrative support staff through the response the researcher gives to the review type requested. The least stringent review type is that of “Exempt”. To be exempt the protocol must fall into one of six categories as defined by Title 45 in the Code of Federal Regulations Part §46.101 (Effective August 19, 1991):

“Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:¹

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular

and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture." [United States department of Health and Human Services, 2005f]

A second review type is "Expedited", described in Appendix III. To be expedited the protocol must "present no more than minimal risk to human subjects," and fall into one of seven categories as defined by Title 45 in the Code of Federal Regulations Part §46.110 (Effective December 13, 2001) covering 'Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

In the most stringent review, a study must undergo a "Full Review". This type of review is associated with studies where, for example, the risk to human subjects is more than minimal such as would be associated with the use of invasive observation of an individual, or where the study involves minors, minorities, or members of a vulnerable group. In such a case the protocol goes before the full IRB panel and processes.

Conflict of Interest

IRBs require full disclosure. The application protocol requires that members of the team disclose any conflict of interest that may potentially be seen as interfering with the neutrality of the research study. Potential conflicts of interest range from team members receiving salaries or compensation from sponsors of the research, family members affiliated with the sponsoring entity such as a Director of the company, equity interest by team members or family members in sponsoring entities, to team members or their family members whose intellectual property interests involve the study.

Performance Site Information

Research that is performed with co-investigators at multi-site locations such as in collaborative research at multiple universities needs to be considered in light of IRB approval requirements. Within the United States the coverage of IRBs is universal among major research universities. It is the IRBs obligation to ensure the collaborators on projects outside their institution are similarly qualified and will work according to the same policies and processes as would be adhered to at the sponsoring institution; alternatively they can take action to reject the project or make arrangements to ensure compliance.

Research Objectives and Background

IRBs require that the specific objectives of study, the specific question(s) that the study is intended to answer, how the research study may contribute to the advancement of knowledge, and the context of the study be explained to them in lay terms. The composition of an IRB in the social and behavioral sciences is, as in the medical sciences, built around the Federal Policy Requirements [§46.107]. IRB members come from the faculty. The non technical lay aspect of the study description is used by the IRB to raise 'red flags' to outstanding or extraordinary issues such as the use of alcohol in a study on a college campus.

Risk/benefit Assessment

The IRB must determine the risk/benefit ratio associated with a project. To assess risk, the IRB must know 'the nature, degree and expected frequency of all potential economic/financial, legal, physical, psychological, social or other risks to which human subjects may be exposed as a result of participating in the research study [Human Subjects Research Office, 2004a]. To balance this risk assessment, they also require both details of the protections put in place by the researchers to prevent placing the human subjects at risk and the details of intervention policies 'in the event of adverse events or adverse effects [Human Subjects Research Office, 2004a] result from the study. It is important that the 'potential benefits pertaining to the subjects as a result of participating in the research studies [Human Subjects Research Office, 2004a] are presented together with a description of 'the potential benefits to society as a result of the research [Human Subjects Research Office, 2004a].

Human Subjects Information

The subject population of the study also requires careful examination by the research team and the IRB. The parameters of the population census typically include: number of subjects, sex ratios (M/F), health profile (healthy volunteers/inpatients/outpatients/descendants), age range, classification based upon vulnerability taxonomy. Inclusion/exclusion criteria also need to be examined. Is the study, for example, targeting a population based on a special criterion such as being able to speak a certain language? Exclusion criteria include: age e.g., minors, seniors; sex (e.g., exclusion of females); and minority status (e.g., Native Americans).

Recruitment

The mechanism by which subjects are recruited is important to the IRB in relation to the voluntary informed consent requirement of human subjects' research. Researchers typically use a variety of mechanisms to recruit including: advertisements, letters, telephone campaigns, flyers, posters,

notices, and more recently mechanisms through Internet technologies. To ensure the voluntary nature of the subjects' involvement, the recruitment mechanism must not include excessive inducements or put undue expense upon the subject. An assessment of liability and compensation issues also needs to be made should unforeseen problems occur as a resultant of the study.

Record Keeping and Data Identification

The IRB is tasked to ensure that the lifetime data security of a research project meets the institutions policy regulations. One mechanism to do so is to use the Code of Federal Regulations 28 CFR §22.23 on 'Privacy Certificates' as the basis for developing an institutions policy. These regulations include:

- Procedures to ensure data confidentiality;
- Procedures to ensure the physical and administrative security of data;
- Procedures for subject notification if data were to be transferred to another institution; and
- Procedures for final disposition of data [National Institute of Justice, 2005].

The research team is required to document such issues as where the records will be physically stored (paper:, onsite, offsite storage,; electronic: computer or server location), how they will be stored (e.g., paper in file cabinets, safes or fire safes, electronic storage in encrypted form, stored on CDs in a fire safe), who has access to the data, and if the data contains personal identifiable data. Disclosure of the mechanisms through which electronic transmission of data between team members is also required (e.g., encoded XML).

HIPAA: Data Collection Methods in Medical-Informatics/MIS

Research involving human subjects requiring medical data is subject to an evaluation by IRBs and requires that the research be constrained by the data protection requirements associated with HIPAA. The prospective or retrospective use of personal records (e.g., medical, school, criminal) require the researcher to develop a comprehensive protocol and a full IRB review may be required. Studies using human subjects, such as the assessment of expert systems in relation to decision making performance levels in the context of medical decision making, comparing medical professionals versus the system, would require a full protocol to be developed and submitted to an IRB.

Any MIS research involving human subjects and the administration of drugs needs to be considered by the IRB. For example, a study to determine human negotiation skills through a computer mediated system, while the subjects are under the influence of a drug such as alcohol, testing negotiation skill levels and inhibition during negotiation would need to be submitted to an IRB [Schweitzer and Kerr, 2000].

Data collection and storage of data pertaining to personal medical information is covered by the Health Insurance Portability and Accountability Act (HIPAA) which became law in 1996. HIPAA is an extensive piece of legislation that aims at simplifying the administrative processes surrounding health care. Central to HIPAA is the transition to uniform standards for the electronic patient record and the transmission of health data between entities. A consequence of the move to electronic medical data systems is that health care entities can easily share data. HIPAA combats the threat of unauthorized data access and the unauthorized data sharing.

HIPAA thus requires IRBs to be assertive in protecting the health information of patients (generally known as PHI) and human subjects within their institution. PHI covers any form or data:

'a) created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

b) relates to the past, present or future physical or mental health or condition of a patient, the provision of health care to a patient, or the past, present, or future payment for the provision of health care to a patient; and

c) identifies the patient or with respect to which there is a reasonable basis to believe the information can be used to identify patient [Human Subjects Research Office, 2004a]

The IRB must be shown that PHI in the form of 'individually identifiable' information is protected this includes data items such as Social security numbers, account numbers, names, address, and prescription numbers etc. (A more exhaustive list is provided in Appendix IV).

Four major categories of data access by researchers are generally considered by IRBs.

1. When an 'investigating team obtains HIPAA authorization signed by the research participant. This release gives the team permission to use or disclose protected health information collected or created during the research for the defined purposes [Human Subjects Research Office, 2004a] of that research.
2. Where the team has access to a limited data set and limited use of the data, in this category 'the investigative team does not need access to information that directly identifies the research participant; and the team will not maintain a link which would enable re-identification of the research participant or their records [Human Subjects Research Office, 2004a]. A limited data set is one stripped of individually identifiable information.
3. Research with a deceased person's protected health information where the authorization for any use is signed by a decedent's legal representative.
4. Where 'the investigative team requests a waiver of HIPAA authorization because the use and/or disclosure of PHI involves minimal risk to the subject's privacy, and the research cannot be practicably carried out without access to or use of PHI [Human Subjects Research Office, 2004a].

Researchers involving PHI, such as medical informatics, are required to submit protocols that adhere to one of these major categories and satisfy the IRBs that adequate data capture, storage and disposal are in place for the length of the study and life of the data.

Informed Consent

Central to all human subjects' research is the concept of informed consent and that the three basic principles are adhered to: respect for persons, voluntarily, and autonomy. Federal regulations [§45.116] pertaining to informed consent are based upon providing information to the subjects in eight areas:

'The Regulations. *The federal regulations require that certain information must be provided to each subject [Federal Policy §46.116(a)]:*

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled [United States department of Health and Human Services, 2005g].

Researchers can request one of three consent options in their protocol: written signed consent, waiver of informed consent, and waiver of signed consent. Written signed consent is the strongest of the three categories and provides complete and comprehensive information on the study to participants. To obtain a waiver of informed or signed consent, where the consent document is amended by 'omitting one or more elements of information or to provide no information at all [CITI, 2000] the IRB is guided by the Federal requirements [§46.116] which state that four conditions must be present in the protocol for a waiver to be given: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The protocols details the mechanism through which the informed consent process is executed, the settings and conditions used are also considered and the mechanisms to provide a voluntary response by the subjects. Personnel involved in obtaining informed consent from subjects are also examined by the IRB to ensure that they are 'certified' in the nature of human subjects' research and are proficient in the ability to judge and assess issues such as the capacity to consent on the part of potential subjects.

V. COMMENTARY AND CONCLUSIONS

The paper was driven by a desire to clarify some of the major issues and institutional requirements for human subjects' research as they pertain to the academic MIS researcher. While the paper can not claim to be exhaustive and cover every situation a researcher may encounter, we aimed at providing a comprehensive introduction to the IRB process. The future of MIS research involving human subjects must be closely related to the 'Common Rule'. Adherence to IRB human subjects' policies and procedures must be universal. All studies will require approval by IRBs and no study can be assumed exempt if it involves a human subject or personal data. Researchers will need to become certified, learn the policies and procedures of their own institution, and become active in the development of IRB activities as they pertain to MIS. It is clear that the role of IRB accredited research in MIS is vital one to creating stability and authority to the studies that researchers perform. Researchers must understand their obligations to their human subjects. MIS researchers are at the forefront of technology and lead in the development of technology-based research instruments. Being amongst the earliest of adopters of technologies such as e-mail and the Internet, they can formulate and create instruments,

frameworks, and methods that will be later followed by others in other disciplines. They also can understand the technology and give advice on the limitations of technology in human subjects research, again providing a valuable service to other researchers. Technology-based instruments and mechanisms should be created with the very best of intentions. Human subject should always be treated with the highest degree of respect and integrity and that these qualities are thus built into the systems when are created not as an afterthought. MIS researchers should not only act with integrity and with the highest ideals in their interaction with human subjects but should also be seen to act with integrity, developing the highest levels of confidence in the ethics of the studies performed.

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1. these links existed as of the date of publication but are not guaranteed to be working thereafter.
2. the contents of Web pages may change over time. Where version information is provided in the References, different versions may not contain the information or the conclusions referenced.
3. the authors of the Web pages, not CAIS, are responsible for the accuracy of their content.
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APPENDIX I. TITLE 45 CODE OF FEDERAL REGULATIONS AND PART 46 PROTECTION OF HUMAN SUBJECTS⁵

Subpart A	Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)
	Source: 56 FR 28003, June 18, 1991.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal Department or Agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal Department or Agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an Institutional Review Board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:¹

Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:¹

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt

⁵ Revised June 18, 1991; Effective August 19, 1991

under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

APPENDIX II. INSTITUTIONAL REVIEW BOARD GUIDEBOOK

CHAPTER I. INSTITUTIONAL ADMINISTRATION

Administration of the Institutional Review Board⁶

Record keeping

The institution, or when appropriate the IRB, must prepare and maintain adequate documentation of IRB activities [Federal Policy § 46.115]. In addition to the written IRB procedures and membership lists required by the Assurance process [Federal Policy § 46.103], such documentation must include copies of all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects (as required by Federal Policy § 46.116(b)(5)).

Minutes of IRB meetings must be kept in sufficient detail to record the following information: attendance at each meeting; actions taken by the IRB; the vote on actions taken (including the number of members voting for, against, and abstaining); the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution [Federal Policy § 46.115(a)(2)].

IRB records must be retained for at least three years; records pertaining to research that is conducted must be retained for three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner [Federal Policy § 46.115(b)].

⁶ Code of Federal Regulations, Title 45, Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects, Revised June 23, 2005, Effective June 23, 2005

APPENDIX III. CATEGORIES OF RESEARCH THAT MAY BE REVIEWED BY THE INSTITUTIONAL REVIEW BOARD (IRB) THROUGH AN EXPEDITED REVIEW⁷

PROCEDURE⁸

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

⁷ [Source: 63 FR 60364-60367, November 9, 1998.](#)

⁸ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR § 46.110](#).

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children⁹², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

⁹ Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR § 46.402\(a\)](#).

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101](#)(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

APPENDIX IV. PROTECTED HEALTH INFORMATION

- Social Security Numbers
- Account numbers
- Biometric Identifiers (e.g., finger or voice prints)
- Certificate or license numbers (e.g., driver's license numbers)
- E-mail addresses
- Fax numbers
- Full face photographic images or comparable images
- Geographic subdivisions smaller than State (e.g., street address, city, five-digit zip code, county)
- Health Plan Beneficiary numbers
- Internet Protocol (IP) address numbers
- Linkage codes (to permit re-identification or longitudinal tracking derived from or related to any of the above)
- Medical device identifiers or serial numbers
- Medical record or prescription numbers
- Months or specific dates (date of birth, admission date, month of discharge, date of death)
- Names
- References to age 90 or older, or references to dates or years indicative of age 90 or older
- Telephone numbers
- Vehicle identifiers or serial numbers (e.g., license plate numbers, VINs)
- Web Universal Resource Locators

- Any unique identifying number, characteristic or code

ABOUT THE AUTHORS

Robert Plant is Associate professor at the School of Business Administration, University of Miami, Coral Gables, Florida. He obtained his Ph.D. in Computer Science at The University of Liverpool, England, previously having previously studied computation at Wadham College, Oxford University. He holds visiting teaching and research positions at: Templeton College, Oxford University, England; Universidad Gabriela Mistral, Santiago, Chile; and is a visiting Professor at Wuhan University, P.R. China. His current research interests are in the area of information systems in strategic management. His publications appear in such journals as *Sloan Management Review*, *Communications of the ACM*, *JMIS* and *Information & Management*.

Alexander P. Pons is Associate Professor of Computer Information Systems in the School of Business at the University of Miami. Dr. Pons is a Ph.D. in Computer Engineering with extensive industry experience. His research interests include database design, object-oriented modeling, real-time systems and Internet technologies. His publications appear in such journals as *IEEE Transactions*, *ACM Transactions*, *Communications of the ACM*, and *DATA BASE*.

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