The Role of State Law in Protecting Human Subjects of Public Health Research and Practice

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"Public health practice" consists of activities and programs managed by public health agencies to promote health and prevent disease, injury, and disability. Some of these activities might be deemed to fit within the broad definition of "research" under federal regulations, known as the Common Rule,[1] designed to protect human research subjects. The Common Rule defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[2] Public health activities that might under some circumstances be considered research include disease reporting, review of medical records, surveys, interviews, focus groups, specimen collection (blood, urine, etc.), and laboratory testing (both identifiable and anonymous).

There are questions about the extent to which the Common Rule applies or was intended to apply to public health practice,[3] and it has been suggested in any case that Common Rule regulation of public health practice may not be socially optimal for both practical and principled reasons.[4] Some commentators have argued that the individualistic, autonomy-centered approach to analysing human subject issues under the Common Rule is unsuited to the population-oriented values and practices of public health, which has a democratically constituted mission to act for the general welfare.[5] The relationship of public health agencies to the people they protect is said to be more like that of a doctor to a patient than a researcher to a research subject.[6] Submitting protocols for institutional review board (IRB) approval, as required under the Common Rule, can take a considerable amount of time,[7] and lead to situations in which IRBs bar or alter studies that public health officials regard as appropriate and necessary under an ethical rubric that places different emphasis on community and individual interests.[8] On the other hand, some commentators have seen a serious problem in the supposed lack of oversight of public health practices that are clearly not within the Common Rule's definition of research.[9] Regardless of their fit with Common Rule definitions or regulatory approaches, public health activities present important ethical issues and risks to human subjects.[10]

The National Bioethics Advisory Commission (NBAC), in its discussion of the application of the Common Rule to public health practice, suggested that state laws constituting and constraining health agencies and their activities offer meaningful guarantees that public health activities will be conducted responsibly and with due concern for the rights and welfare of individuals. The Commission's suggestion is an important one, because it highlights the possibility that society could find new, more efficient means to achieve the universally accepted end of protecting human research subjects. State law and the Common Rule are both "regulatory resources" that can be deployed for human subject protection, and there are other possible resources as well. The usefulness of state public health law, however, rests on an untested premise: that this body of law does indeed provide protection for people subject to public health practice that is comparable to that provided by the Common Rule. This study reviewed state public health law in order to evaluate the accuracy of this important assertion.

Methods

The Common Rule was examined to determine the major safeguards it provides. Six key protections were identified: 1) consent for data collection; 2) protection of private information in collected data; 3) use of a bona fide, safe, and effective research design; 4) equitable selection of subjects; 5)

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appropriate data safety monitoring; and 6) protection of vulnerable populations. All states have sections of their statutes devoted to setting out the powers and duties of health agencies. These were reviewed in order to identify provisions that provided protections analogous to those provided by the Common Rule. These primary protections were analyzed in their broader legal context, including generally applicable principles of constitutional, tort and administrative law. The study did not systematically examine administrative regulations written pursuant to public health statutes, or the actual implementation of these laws.

Results

State law could provide detailed ethical rules for public health practice along the lines of the Common Rule, but does not do so. Only three states (California, New York and Virginia) have regulated human subject research, and all three have chosen to exclude public health practice from coverage.[11] New York's statute, passed in 1975, uses a different definition of research than the Common Rule and excludes epidemiological research generally, as well as many of the sorts of testing involved in surveillance.[12] Similarly, California's 1978 act confines its requirements to "medical experiments."[13] Virginia's 1979 legislation[14] exempts many activities of the Virginia Department of Health, such as surveillance and investigation into preventable diseases and epidemics.[15]

Appropriate Consent for Data Collection

The Common Rule requires, under most circumstances, that prior to any information collection concerning an individual, the individual must be advised of the collection, its purposes, and its risks. The individual must also have an opportunity to consent to or refuse the proposed collection and this consent or refusal must be carefully documented.[16] State public health law does *not* require *individual* informed consent for data collection beyond what would be required to avoid committing a battery — i.e., the normal consent required for a physical touching. State law does, however, clearly provide a collective consent mechanism and a form of public notice of data collection and analysis practices.

State law provides a form of collective consent for data collection through public health laws that authorize the collection of individual information through surveillance and epidemiological investigation. For example, legislation creating cancer registries may be found in every state,[17] many states have legislation establishing registries for conditions such as metabolic diseases[18] and birth defects,[19] and all states have laws requiring the reporting and maintenance of vital statistics, as well as certain communicable diseases.[20] Information collection is authorized by specific enabling legislation, and often exercised through detailed regulations.[21] These statutes have been promulgated by democratic institutions through deliberative processes that have theoretically weighed the value of the information to the community against the risks posed to individuals by the data collection and as such can be seen to provide a type of public consent to the collection of such data.

State laws also provide a form of notice to the public. State public health codes uniformly identify the kinds of information that may be collected and the allowable uses for the collected information, including research, disease control and prevention, criminal prosecution, and child welfare.[22] (See Table 1.) But while all codes generally make clear that personal medical and behavioral data may be collected for purposes of disease prevention and control, the laws vary considerably in their specificity.

North Dakota, for example, has adopted the Model Public Health Privacy Act, which allows the release of private health data to the health department only when explicitly required by law or if the individual's identity is necessary to prevent or reduce serious harm to any individual or the public health.[23] The statute also stipulates that recipients of such data must use or disclose the information solely to achieve these purposes and that the disclosure be limited to the minimum amount of information necessary.[24] Detailed specifications on the collection and use of health data by health departments can also be found in the laws of Utah, Colorado, Connecticut, Delaware, Illinois, Louisiana, Michigan, Minnesota, Montana, Nebraska, North Carolina, and California. Most states' laws are less detailed.

Protection of Private Information in Collected Data

The Common Rule places strong emphasis on ensuring that information collected about human research subjects will be used only for the purposes for which it was collected and will be protected from improper disclosure. Privacy protections for public health data are not governed by a single consistent rule; rather, privacy law is a complex aggregation of rules that differ across jurisdictions.[25] State laws generally protect the privacy of public health data. Several states only confer privacy protection to reports of particular conditions, such as sexually transmitted diseases (STDs)[26] or communicable diseases, or to particular sources, such as laboratory disease reports. Other states apply general privacy protections to most or all public health data, limiting disclosure of these data to persons inside[27] or outside[28] the public health agency. State laws classify violations of privacy provisions as misdemeanor offenses or civil infractions. Massachusetts will, for example, levy a fine of $50-100 for a privacy violation,[29] while the District of Columbia will fine a willful violator $5000.[30]

State public health privacy laws typically allow for the release of identifying information for core public health purposes, such as surveillance and epidemiology, with

limited authorization for research use. Most states recognize an explicit or implicit duty to use data for health promotion purposes.[31] Moreover, modern and comprehensive health information provisions may specifically enumerate the allowable uses of data.[32] State law imposes a general duty on the public health agency to respect and protect data confidentiality that is similar to the duty placed on researchers under the Common Rule. Unlike the Common Rule, however, state law rarely imposes specific data security requirements, and in many states, specifies a wide range of allowable disclosures.

State laws vary considerably regarding circumstances under which data may be disclosed by the public health agency to other researchers, for commercial or other private purposes, or for law enforcement or child welfare purposes. (See Table 2) Nearly all states allow use or disclosure of deidentified information for extramural research or practice without informed consent. Many states do not require informed consent for the release of identifiable information for public health purposes, including research. Eight states have detailed provisions that include qualifying criteria, conditions for approval, or monitoring provisions (Illinois, Maryland, Nebraska, Missouri, Montana, New York, North Dakota and Utah). Thirty-five states restrict the release of identifiable data for civil and/or criminal cases in some instances, and case law has demonstrated that general concepts of privacy may suffice to prevent a disclosure where explicit statutory or regulatory prohibitions are not in place.[33] Finally, states may authorize disclosures for other purposes such as informing a third party of their exposure to a reported condition. Larry Gostin and his colleagues reported, for example, that 35 states had some provision allowing release of information to a person at risk of contracting disease.[25]

Bona Fide, Safe, and Effective Research

A primary function of the Institutional Review Board under the Common Rule is to assess risk and judge whether proposed research has sufficient scientific validity to justify the risks it creates. Proposed research will only receive IRB approval when the potential benefits of the research exceed any risks to human research subjects.

Only one state, Florida, has an explicit provision calling for the prior review of research activities conducted under the auspices of the department of health.[34] State public health law and the U.S. Constitution require, however, that public health practice be reasonably necessary to achieve legitimate health goals. The Constitution has been interpreted as limiting governmental power, including public health practice, by requiring that activities that infringe upon individual rights be necessary, reasonable, proportional, and harm-minimizing.[35] State laws grant public health departments the power and the duty to undertake practices necessary to protect and promote the public's health, while constraining activities not meaningfully related to the accomplishment of valid public health ends.

Equitable Selection of Subjects

The Common Rule requires the fair and equitable selection of research subjects who can benefit or face risk from the research. IRB review complements the introspection of the researcher in the selection process. To some extent, this requirement addresses a problem more commonly found in experimental designs than in the sort of population-based data collection or observational research conducted by public health agencies. For surveillance, for example, the qualification for inclusion is having the specified condition, and "subjects" are not excluded based on demographic characteristics.

The Common Rule requirement can be seen as addressing the broader problem of conscious or unconscious bias, from which public health agencies enjoy no special immunity. State laws governing public health practice address biased treatment in three ways. First, many states have embodied policies of fairness in special programs designed to promote minority or women's health. Second, federal and state law broadly prohibits discrimination in the provision of government benefits and services. Finally, the political process and media scrutiny may provide a means of promoting fairness in access to the benefits of public health practice.

Appropriate Data Safety Monitoring

The Common Rule requires that research that poses a risk to subjects be monitored. State public health codes do not specifically require that agencies incorporate safety monitoring into data collection activities.

Protection of Vulnerable Populations

The Common Rule seeks to protect the vulnerable from exploitation. Like the Common Rule, state law provides substantial protection to vulnerable populations subject to government data collection and other public health practices. Federal and state law broadly prohibits discrimination in public health practice, which is also limited by political factors.[36] Furthermore, state law provides significant protection of privacy and equal treatment to traditionally vulnerable groups, including persons with disabilities,[37] persons with HIV,[38] and prisoners.[39]

Accountability

Researchers, IRBs, and institutions are accountable to the federal government under the Common Rule. Public health practice occurs within a similar hierarchy of accountability. Individual public health workers operate within a hierarchical

management structure; local health officers are normally accountable to state-level department heads; state department heads are accountable to boards of health, governors, and the legislature; officials at all levels may be held accountable by the courts, the media, and the electorate. Public health codes, particularly privacy provisions, also commonly include penalties for prohibited behavior that can be and sometimes are applied to public health workers.[25]

Discussion

This study's findings validate NBAC's supposition that state public health and other statutes confer significant and meaningful protection upon individuals who become subjects of public health practice. Data cannot be gathered without the collective consent of the citizenry, expressed through democratic processes of legislation and rule-making. Although there is often little public interest in the practices of health departments, there are numerous instances of extensive public involvement in matters such as HIV reporting,[40] the ethics of blinded seroprevalence testing,[41] and the collection and use of genetic information.[42]

State law protects the privacy of information collected by public health agencies. This protection varies in its strength on paper, and in many instances contains problematic provisions for non-health use.[40] Common Rule requirements of fair selection of subjects and protection of vulnerable populations against exploitation can be seen in state law as elements of a constitutional and statutory framework prohibiting discrimination and in the proper administration of a public health department, though only a few states have explicitly addressed these issues. Likewise, overall accountability in public health practice is largely a function of the regular administration of government in a democratic state. Data safety monitoring is not specifically required by state public health law (Table 3).

The protection provided to the subjects of public health practice by state law is comparable to the protection provided to research subjects under the Common Rule, but clearly not identical. There is no state law requirement for individualized consent for many kinds of data collection; consent may not be revoked; notice for most people will be formal rather than actual. Data collection plans are not required under state law to be formally reviewed for either scientific or ethical quality. Ethical performance, including protection or inclusion of vulnerable populations, is not an explicit performance measure in the accountability/management framework of public health.

Comparing state law protections to those provided by the Common Rule requires a series of more or less strained analogies between regulatory systems of quite different natures and origins, but is nevertheless a useful exercise. It highlights a crucial point for the future evolution of human subject protection: that the Common Rule represents only one of many current or conceivable ways of regulating data collection involving human beings. Traditionally, decisions about how to allocate the risks, burdens and benefits of public health practice were made collectively (and primarily at the state level) through legislation, regulation and the decisions of executive officers and judges, applying specific statutory language and broad principles of individual rights and government powers. Accountability was generally retrospective, and as in other areas of government, depended to a considerable degree on the mobilization of non-governmental actors, like the news media and professional organizations. The gradual inclusion of public health activities within the Common Rule offers another model: the prospective application of a specific set of federal rules, by IRBs, using standards rooted in bioethics, under the ultimate supervision of federal administrators.

It is essentially impossible today to compare the two approaches by a standard of efficacy. Data on harms to human subjects of public health practice today, and data on the effects of IRB review on public health activities, are both sparse.[43] In any event, the impetus for protective regulation may come more from the unacceptability of insufficiently careful conduct, or the fear of a repetition of Tuskegee,[44] than from the belief that there is a high rate of incident harm to subjects. Some commentators have suggested that the Common Rule's underlying ethical orientation is unsuited to the governance of public health practice,[45] but there can be no challenge to the fundamental value of respecting the dignity of human subjects as an essential element of excellence in public health practice.[46]

The comparison of state law and the Common Rule is most useful in raising a question of governance. From a standpoint within bioethics and the human subject protection regime, collective consent and formal notice look like distinctly second-best options. If one steps outside that framework, however, and asks how decisions about the risks, benefits and burdens of public health practice should be made in a democratic society, it is not unreasonable to question the desirability of placing so much control in the hands of unelected IRBs whose decisions are effectively private and unreviewable, and which, more importantly, are not responsible for addressing larger issues of social good and distributive justice.[47]

It is beyond the scope of this study to enter the debate about the efficacy or desirability of Common Rule regulation of public health practice. But if there are reasonable concerns about the costs or benefits of the current approach, the findings of this study suggest a useful path towards reform. The issue presented is, in the end, a generic one of regulation: how can society's resources of governance best be deployed to ensure that public health research and practice are conducted with a high regard for the rights and dignity of subjects? Seeing the matter in these terms can helpfully turn the attention of ethicists, researchers, advocates and policy makers towards a largely untapped

body of theory and data on effective regulation.

The limitations of rule systems have been well identified by contemporary regulatory scholars.[48] The sorts of problems reported at least anecdotally about the Common Rule — the difficulty of achieving satisfactory implementation, the gradual increase in the number of rules, the spasmodic cycle of violation and increased regulatory pressure, the tendency of those governed to become alienated — are actually quite common to regulatory systems.[49] Because regulation, although imperfect, is usually a better alternative than inaction, governments and scholars have struggled to develop approaches to regulation that address the common problems associated with top-down rules.[50] Any regulatory system can be said to have three generic components: a standard against which conduct is to be measured, a means of monitoring performance, and a mechanism for bringing the non-compliant into compliance.[51] Significantly, however, it is not necessary for all three elements to operate under the same auspices: different entities (various levels or branches of government, firms, professional organizations) may take on the tasks of standard setting, monitoring or enforcement. Likewise, there are tools other than hierarchically imposed rules, agency oversight and government enforcement to implement the three elements.[52] Ethics themselves are a prime example of standards that emerge outside of government that can be monitored through forms of peer review and enforced through peer pressure. Regulatory scholars are increasingly interested in how system design can be used to regulate activities "automatically," by, for example, designing buildings to discourage crime.[53] Together, this range of possible regulators and regulatory tools represent a rich supply of regulatory resources that may be deployed to accomplish desirable social ends while reducing the negative effects of control.

This study has shown that state public health law remains an important regulatory resource for the protection of human subjects. Other regulatory resources include codes of professional ethics, performance standards within agencies, the tort system,[54] publication practices of journals, social norms – and the Common Rule. Effective public health practice is important enough to our well-being as a people to justify investment in a careful, creative and sustained effort to craft a regulatory approach that can promote public health practice that is excellent in all aspects, including but not limited to respect for human subjects.

Conclusion

Our review of state law indicates that respect for human research subjects is reflected in and served by the state public health infrastructure. A review of the law and ethics in public health suggests the need for further collective work to examine different approaches to achieving ethical public health practice, whether through an exception to the Common Rule, through an enhanced system of state law and regulation, or through other mechanisms that take advantage of available regulatory resources in public health. At the very least, the existence of a set of protections for human subjects in state law should be considered by IRB chairs in determining whether a study conducted by a regulated public health agency should be subject to exemption or expedited review. The development of these tools and ideas will allow for a framework that protects human subjects.

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Table 1. Specified Uses for Data Reported to or Otherwise Collected by Health Agencies

State	Uses Related to Disease Prevention and Control	Criminal prosecution	Child protection/ placement	Other
AL	AL ST § 22-11A-2			
AK	AK ST § 18.05.042			
AZ	AZ ST §§0 36-662, 36-664	x		Significant exposure; as required by law
AR	AR ST § 20-46-103			
CA	17 CA ADC § 2500 et seq.; CA CIVIL §§ 1798 et seq	x	x	Numerous
CO	CO ST § 25-1-122		x	
CT	CT ST § 19a-25			
DE	DE ST Ti 16 §§ 1230 et seq			
DC	DC Code § 7-131	x	x	
FL	FL ST §§ 381.0031 - .0032			
GA	GA ST 31-2-1, 31-12-2			
HI	HI ST § 324-32			
ID	ID ST §§ 39-606, -610 (VD, HIV,HBV only)			Significant exposure; as required by law

Table 1. (continued) Specified Uses for Data Reported to or Otherwise Collected by Health Agencies

State	Uses Related to Disease Prevention and Control	Criminal prosecution	Child protection/ placement	Other
IL	410 ILCS §§ 520/1 et seq			
IN	IN ST § 16-41-8-1			Child lead poisoning program
IA	IA ST §§135.11, 135.40			
KS	KS ST § 65-118		x	
KY	KY ST §214.220 (STD and HIV only)			
LA	LA ST § 40:3.1			
ME	22 M.R.S.A. § 824	x		
MD	MD Health Gen §§ 18-101 to- 103			
MA	MA ST 111D § 6 (clinical lab disease reports), 111 § 24A (dept research), MA ST 111 § 119 (VD)			By court order or to any whose official duties require (VD)
MI	MI ST §§ 333.2601 et seq			
MN	MN ST § 144.053			
MS	MS ST § 41-3-15			§ 41-23-1 (notification of third parties or health care providers at risk)
MO	MO ST 192.67			
MT	MT ST 50-16-603	x (child abuse only)	x	
NE	NE ST §§81-663 et seq			
NV	NV ST 441A.220	x		Notification of third parties or health care providers at risk
NH	NH ST § 141-C:10			
NJ	§26:1A-37.2	x (VD only)		
NM	NM ST §§ 24-1-20, 24-14A-1 et seq			
NY	NY PUB OFF § 96, NY PUB Health § 201			
NC	NC ST §§ 130A-143, 130A-371 et seq			Court order, or in bioterror investigation
ND	ND ST 23-07-02.2, 23-01.3-01 et seq	x[1]		Emergencies
OH	OH ST § 3701.24	x		
OK	OK ST Ti 63 § 1-502.2			Court order, notification of people suffering a defined "risk exposure"
OR	OR ST § 433.008			
PA	35 P.S. § 521.15			
RI	RI ST § 23-11-9 (STDs) § 23-6-17 (HIV)			Numerous (HIV)
SC	SC ST 44-29-135 (STD)		x	School authorities (HIV)
SD	SD ST § 34-22-12.1			To protect life/health of a named person
TN	TN ST §68-10-113 (STD)	x	x	Medical emergency
TX	TX HEALTH & SAFETY § 81.046		x	Medical emergency
UT	UT ST § 26-6-27 (disease reports), 26-3-1 et seq (health data system)	x (disease reports re. child abuse only)	x (disease reports)	Numerous (disease reports)
VT	18 VT ST. § 1001			
VA	VA ST §§ 32.1-36, 32.1-41	x (disease used as weapon)	x	Employers if subject is a threat in workplace
WA	WA ST § 70.24.105 (STDs and HIV)			Numerous
WV	WV ST § 16-4-6 &WV ADC § 64-7-14 (STDs)		x	Employer in a licensed facility when needed to protect public health
WI	WI ST 146.82 et seq., (health records), 252.11 (STDs), 252.12 (HIV)		x	Numerous
WY	WY ST §§35-4-132 (STDs), 35-4-107 (investigation records)			As needed to protect life and health, or as req by law (STDs)

1. For purposes of law enforcement release, 23-01.3-06 appears to supersede the reporting statute, 23-07-02.2, which would not allow use in criminal prosecution.

References

1. 45 C.F.R. § 46.101 *et seq* (2003).
2. 45 C.F.R. § 46.102(d) (2003).
3. Centers for Disease Control and Prevention, "Guidelines for defining public health research and public health non-research," *available at*: <http://www.cdc.gov/od/ads/opspoll1.htm> (last visited November 4, 2003).
4. S. Burris, J. Buehler and Z. Lazarrini "Applying the Common Rule to public health agencies: questions and tentative answers about a public health exemption," *Journal of Law, Medicine & Ethics* 31 (2003): 633–648.
5. H.G. Rubinstein, "If I am Only for Myself, What am I? A Communitarian Look at the Privacy Stalemate," *American Journal of Law and Medicine*, 25 (1999): 203-31; N.E. Kass, "An Ethics Framework for Public Health," *American Journal of Public Health*, 91 (2001): 1776-1782; J.F.

Table 2. Confidentiality Provisions in State Public Health Laws

State	Confidentiality	Conditions/procedures specified for extramural research or practice				Protected against use in civil or criminal cases other than public health enforcement
		Use or release w/o identifiers allowed w/o informed consent	Use w/ identifiers allowed w/o informed consent	Subsequent recipients bound	Informed consent or other authorization explicitly described	
AL	AL ST § 22-11A-2	x				
AK	AK ST § 18.05.042		x	x		
AZ	AZ ST § 36-664	x	x	x	x	
AR	AR ST § 20-46-103	x	x			x
CA	17 CA ADC § 2500 et seq; CA HLTH & S § 100330 ; CA CIVIL §§ 1798 et seq	x	x		x	
CO	CO ST § 25-1-122	x				x
CT	CT ST § 19a-25		x[2]			x
DE	DE ST Ti. 16 § 1232	x		x	x	x
DC	DC Code § 7-131	x				
FL	Fl. Stat. § 381.0031	x[3]	x[2]			x
GA	GA ST § 31-12-2	x	x			x
HI	HI ST §§ 324-31 to -33	x				x
ID	ID ST §§ 39-606, -610 (VD, HIV, HBV only)	x				x[4]
IL	410 ILCS §520/5	x	x	x	x	x
IN	IN ST § 16-41-8-1	x			x	
IA	IA ST § 135.42	x	x	x		x
KS	KS ST § 65-118	x			x	x (except child abuse)
KY	KY ST §214.220 (STD and HIV only)	x			x	x
LA	LA ST § 40:3.1	x	x	x		x
ME	22 M.R.S.A. § 824	x		x		x
MD	MD Health Gen § 18-201 (reporting data)[5] MD Health Gen § 4-101 et seq (govt research)	x	x			x
MA	MA ST 111D § 6 (clinical lab disease reports), 111 § 24A (dept research), MA ST 111 § 119 (VD)	x	x			x (except VD)
MI	MI ST §§ 333.2601 et seq	x	x			x
MN	MN ST § 13.3805, § 144.053	x				x
MS	MS ST § 41-41-11	x			x	x
MO	MO ST 192.67	x	x	x		x
MT	MT ST 50-16-601 et seq	x	x[6]	x		x (except child abuse)
NE	NE ST §§81-663 et seq	x	x	x		x
NV	NV ST 441A.20, .30	x			x	x (except child or elder abuse)
NH	NH ST § 141-C:10	x	x		x	
NJ	§26:1A-37.2	x	x			x (except venereal disease, § 26:4-41)
NM	NM ST §§ 24-1-20, 24-14A-1 et seq	x	x[7]			
NY	NY PUB OFF § 96, NY PUB Health § 201	x	x		x	
NC	NC ST §§ 130A-143, 130A-371 et seq	x	x		x	
ND	ND ST 23-01.3-01 et seq., 23-07-02.2, 23-01-15	x	x[8]			[9]
OH	OH ST § 3701.24	x			x	
OK	OK ST Ti 63 § 1-502.2	x			x	
OR	OR ST § 433.008	x			x	x
PA	35 P.S. § 521.15	x	x			x
RI	RI ST § 23-11-9 (STDs), § 23-6-17 (HIV)				x (HIV)	x (HIV & STD)
SC	SC ST 44-29-135 (STD)	x			x	x
SD	SD ST § 34-22-12.1	x			x	x
TN	TN ST §68-10-113 (STD)	x			x	
TX	TX HEALTH & SAFETY § 81.046§ 81.046	x			x	x
UT	§§ 26-6-27, -28 (disease reports), 26-3-1 et seq (health data system)[10]	x	x (health data system)	x (health data system)	x	x (except child abuse)

2. Reporting data may only be used for public health purposes, but other data collected by the health department may be used for research.
3. Department may release information when necessary for public health and has discretion to work with extramural researchers.
4. Exemption for civil and administrative matters only.
5. A 1999 court of appeals case concluded that the government research confidentiality provisions of § 4-102 do not apply to case investigations . Haigley v. Department of Health and Mental Hygiene, 736 A2d 1184 (Md App. 1999) . A statute passed in 2001 extends the protection of the research confidentiality section to HIV but not reportable diseases generally. MD Health Gen § 18-201.1. It may therefore be prudently assumed that epidemiological investigation and reporting data are to be treated separately from other health department data.
6. Section 50-16-606 provides that data originally obtained from a health care encounter is subject to a different privacy law governing health care data, which allows release of identifiable information for research under specified conditions, including IRB approval. See MT ST 50-16-529.
7. Section 24-1-20, governing disease reporting data, does not explicitly authorize research using identifiable data; the health data law, §§ 24-14-1 et seq., would cover reporting data collected in the central health database, and does not explicitly allow such research.
8. Sections 23-01.3-01 et seq, based on the Model Public Health Privacy Act, govern all information collected and maintained by the department. The provision allows release with identifiers for biomedical research approved by an institutional review board, but specifies that such release is subject to more strict limits on release set in other sections of the code, including 27-07-02.2. See also ND ST § 23-01-15 (confidentiality rules for health department research).
9. For purposes of law enforcement release, 23-01.3-06 appears to supersede the reporting statute, 23-07-02.2, which would not allow use in criminal prosecution.
10. The disease reporting confidentiality provision conflicts with the health data system statute with respect to the legality of release of identifying information for research and other purposes. It is not clear which rule would apply to health department activities using data generated in the health care system.

Table 2. (continued) Confidentiality Provisions in State Public Health Laws

State	Confidentiality	Conditions/procedures specified for extramural research or practice				Protected against use in civil or criminal cases other than public health enforcement
		Use or release w/o identifiers allowed w/o informed consent	Use w/ identifiers allowed w/o informed consent	Subsequent recipients bound	Informed consent or other authorization explicitly described	
VT	18 VT ST. § 1001	x	x	x	x	x
VA	VA ST §§ 32.1-36, -41	x	x[11]		x	
WA	§ 70.24.105 (STDs and HIV)[12]	x				
WV	W VA ST 16-4-6, WV ADC § 64-7-14	x	x	x		
WI	WI ST 146.82 et seq., (health records), 252.11 (STDs), 252.12 (HIV)[13]	x	x		x	x (STDs) (HIV except for exposure victim)
WY	WY ST § 35-4-132 (STDs),	x	x	x	x	x
	35-4-107 (investigation records)					

11. Data obtained from medical records during investigations are authorized under to be used for research under § 32.1-41; confidentiality provisions for reported data do not mention research, § 32.1-36.
12. Washington does not have a general confidentiality statute explicitly focussed on health department records generally. However, health department records obtained from health care records covered by the Uniform Health Care Information Act and must be protected by rules comparable to those required by the Act. See WA ST § 70.02.050(3).
13. Under WI ST 252.05, reports to the health department are to be treated as records under this general health care confidentiality statute. This creates some ambiguity with respect to STD and HIV records, both of which are subject to detailed statutes on confidentiality and use that are not entirely consistent with the broader statute. See, e.g., WI ST 252.11 (STDs), 252.12 (HIV).

Table 3. Comparison of State Law and Common Rule Protections

The Federal Common Rule's Six Principle Safeguards	Analogous Safeguards Under State Law
Informed consent from individual for data collection and actual notice given to individuals	Collective consent through democratic processes and formal notice through statutes and regulations
Protection of private information in collected data	State privacy law protections for collected data
Bona fide, safe, and effective research design	Limited state public health powers may only be applied to accomplish valid public health ends under state law and the U.S. Constitution; political constraints
Equitable selection of subjects	Discrimination protections in state law and the U.S. Constitution, programs designed to reduce health disparities
Appropriate data safety monitoring	None
Protection of vulnerable populations	Discrimination protections, programs designed to protect the rights of vulnerable populations

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