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Public Health Practice vs Research: Implications for Preparedness and Disaster Research Review by State Health Department IRBs

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ABSTRACT

Under the current US Department of Health and Human Services regulatory and ethical system for research involving human subjects, research is defined in terms of several key concepts: intent, systematic investigation, and generalizability. If an investigator engages in a systematic investigation designed or intended to contribute to generalizable knowledge, then he or she is engaged in research. If that research involves living individuals and the investigator will either interact or intervene with people or obtain their identifiable personal information, then the research must be prospectively reviewed by an institutional review board (IRB), a federally mandated committee that ensures the ethical and regulatory appropriateness of proposed research. In public health institutions, and especially at state departments of health, this definition of research may prove vexing for determining when particular public health activities must be reviewed by IRBs. This article outlines several reasons for such vexation and 2 key responses from major public health stakeholders. In the current climate of public health preparedness initiatives at state health departments for disasters and bioterrorism, how research is defined vis-à-vis public health interventions may add even more confusion to preparedness initiatives and pose difficulties in determining when IRB review and the added protections it affords are appropriate. This article suggests several practical ways to avoid confusion and attempts to strike a balance between the need for expeditious approvals of research-based responses to public health disasters and to ensure proper protections for human subjects at state health departments. It is hoped that these suggestions can assist not only state health departments but also academically based researchers who either collaborate with those departments or whose research will need to be reviewed by their IRBs. (*Disaster Med Public Health Preparedness.* 2008;2:185–191)

Key Words: institutional review boards, public health preparedness, public health practice

Those who cannot learn from history are doomed to repeat it."

—*George Santayana*

In research ethics, there is general consensus that the system for protection of human subjects consists of 4 "pillars": informed consent; independent review and approval of human research projects by an institutional review board (IRB); the professional integrity of researchers; and minimization of conflicts of interests. Thus, if an activity is research, generally prospective informed consent will be required; research review, approval, and oversight will be required by an IRB; investigator and sponsor conflicts of interests must be minimized; and investigators must safeguard research integrity, the data generated, and the safety and welfare of those who volunteer or whose information is used in the research. In large part, attention to and inclusion of these protections will produce ethical research.[1]

These ethical and regulatory protections apply equally to the approximately 35 departments of health that operate their own IRBs (the following state departments of health have an IRB: Alabama, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, North Carolina, North Dakota, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wyoming).[2] Nevertheless, at these departments, 2 of these protections—review of research and informed consent—take on a decidedly different context than found in other, academically based forms of biomedical or social-behavioral research. Data that a public health agency collects as part of its legally mandated surveillance and prevention activities may be accessed by individuals wishing to conduct generalizable research on many scientific topics. To access such data for research purposes, an IRB must first grant a waiver of informed consent[3] (even if the person who accesses the data is a department employee and will be performing research-related activities using the data to which he or she, outside of a research context, generally does not need permission to access). In addition, during its review, the IRB must determine whether to grant an

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additional waiver of informed consent to use the data for analysis without consent or whether permission should be sought from the subjects or their legally authorized representatives to use the data for research purposes. Guidance exists for IRBs to make these required determinations,[4] and regulations provide specific criteria that must be met in both situations.[5]

These IRB considerations for review and informed consent presume that the project is research. What about projects that blur the line between pure research and pure public health practice? In contrast to IRB review and informed consent determinations, ascertaining the research status of an activity is not as straightforward. Ethical public health practices govern the latter projects.[6] For research projects, there are several ethical and regulatory issues with which IRBs must deal.[7] This article does not concentrate on these settled or debated issues. Rather, this article first examines the implications of making a research determination before IRB review or implementation of a purely public health intervention takes place. The author concludes by describing a specific, and confounding, type of determination and its implications—whether activities at state departments of health during times of emergency or disaster constitute research or public health practice. It is hoped that resolving this vexing determination can assist not only state health departments but also academically based researchers who either collaborate with those departments or whose research requires review by their IRBs.

WHAT IS RESEARCH AND HOW IS IT DIFFERENT FROM PUBLIC HEALTH PRACTICE?

Under the current regulatory and ethical system for research involving human subjects,[8] research is defined in terms several key concepts: intent, systematic investigation, and generalizability. If an investigator engages in a systematic investigation designed or intended to contribute to generalizable knowledge, then he or she is engaged in research.[9] If that research involves living individuals and the investigator will either interact or intervene with people or obtain their identifiable personal information, then it must be prospectively reviewed by an IRB.[10] For an IRB to approve research, it must either meet specific regulatory and ethical requirements for a waiver of informed consent[3,11] or investigators must obtain prospective informed consent from research subjects.[4,12]

In public health agencies, and particularly at the 35 state departments of health that operate their own IRBs,[2] the current definition of research may prove challenging for determining when particular public health activities must have IRB review.

Authorities in state departments of health obtain identifiable private information about people, living and dead, and use this information to engage in a host of systematic scientific activities. Some activities clearly are research, given that the knowledge gained is generalizable; some, however, are not. In most instances, a public health authority collects identifiable private information (eg, births, deaths, information regarding certain reportable diseases or conditions) under statutory or regulatory authority. Public health professionals at state departments of health and their academic or government colleagues use this information for many activities: surveillance, prevention, outbreak control, or interventions to benefit the public health and welfare.

Whether these activities constitute research and thus require IRB review, approval, and oversight seems to turn on the primary intent of the activity. Is it to generalize conclusions or interventions beyond the population that serve as subjects? Furthermore, the fact that public health officials use systematic, proven scientific methods to collect, manipulate, and use such data frequently blurs the line between public health practice and research. For instance, during disease outbreaks, authorities may quarantine individuals and take blood and/or biological specimens to provide treatment, stem disease spread, or protect others from exposure. Because a quick response is needed, several things may not be clear: Does the activity represent a pure public health response? Does the data point to generalizable scientific information that can assist public health officials in preventing future outbreaks? It may be both, but in such emergencies it is typically only in hindsight or after data analysis that the dual purpose of interventions becomes evident.

The public health community has realized the potential problem that this may cause, especially at state departments of health. The problem, which could potentially impede important public health projects, was so vexing that the US Centers for Disease Control and Prevention[13] (CDC) and Council of State and Territorial Epidemiologists[14] (CSTE) each have issued guidance documents. These separate documents are designed to assist officials at state departments of health in solving this particular determination difficulty. The differences between the documents and how each recommends the research determination be made are important for this topic, and brief consideration of these differences will help elucidate the difficulty and the consequences at stake in making this determination.

The CDC guidance begins with the regulatory definition of research "as a systematic investigation designed to develop or contribute to generalizable knowledge."[15] This definition will be familiar to most of those who work in the area of human subject protections. The author's own anecdotal experience working in a state public health agency suggests that most public health scientists are less familiar with this specific regulatory definition. It is likely the case with other public health agencies. The CDC guidance

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then bases the distinction of whether a public health activity is research or not on the key word "designed" in the regulatory definition. That is, according to the CDC guidance, "the major difference between research and nonresearch lies in the primary intent of the activity." Therefore, the intention of the investigator proposing an activity becomes paramount.

Two difficulties, one philosophical, the other practical, become apparent. The problem of determining one's own, much less another's, intentions remains a controversial and contested problem in philosophical, psychological, and ethical discourse. The CDC guidance assumes that investigators, at the outset of and during the conduct of the activity, will be honest and self-reflective, both with themselves as well as with whomever at the institution is charged with making the research determination. The upshot of this problem is most evident in a hypothetical example. A shrewd and knowledgeable public health scientist wishing to go forward unhindered by the IRB review, approval, continuing review, and oversight process can simply argue that the primary intent of the activity is not research related, even if it is.

Personal and professional scruples aside, there is also a practical problem with relying solely on the idea of "intention." It is frequently the case that in the course of conducting a scientific investigation, the data gathered can lead the scientist to modify an originally proposed scientific question, idea, data collection method, or other component of the scientific process. So, for example, at the outset of an activity the investigator's intention may have been motivated by purely public health considerations, such as controlling an outbreak. However, after the data have been analyzed, the intention can change to one of preventing the next outbreak or attempting to generalize the conclusions of the outbreak investigation to other outbreaks; other areas of public health science, intervention, education, and prevention; or to other geographical locations or subject populations. This change in intention can change a public health, nonresearch activity into a research activity. An investigator may not know that a line has been crossed, at which point the activity should undergo IRB review and oversight. The consequences of this lack of knowledge are 2-fold. First, the research subjects will not receive the protections to which they are ethically entitled according to the regulations. Second, the public health institution, especially if it receives federal research funding, is conducting human subjects research without IRB oversight. Such institutions may receive formal noncompliance citations and sanctions from the Federal Office for Human Research Protections. Moreover, they may be jeopardizing their Federalwide Assurance, the contract an institution signs with the federal government in which they agree to abide by the ethical[16] and regulatory standards for conducting research. By jeopardizing this contract, the institution is also putting at risk all of its federal research funding from grants, contracts, and agreements. For most state public health agencies, that liability is significant and can represent a large part of the overall research and operational budget. Therefore, it is imperative that if public health agencies are relying on the CDC guidance to determine what constitutes research, safeguards should be built into the agency's procedures to avoid or minimize these 2 problems.

In contrast, the CSTE report provides a more nuanced method to make the research/nonresearch determination. Although it too considers the "intention" of the activity to be important, unlike the CDC guidance, it does not rely solely on this criterion. As such, the CSTE report does not suffer from the same problems that are inherent in the CDC guidance.

In addition to the "specific intention" of both the activity and its progenitors, the following additional criteria are suggested by the CSTE report. First, the legal authority of the public health agency itself should be examined. Does the agency have regulations, laws, or the general legal authority that requires it to conduct the activity? The second criterion is specific intent. Is the specific intent of the activity to answer a particular research question or hypothesis using proven or unproven scientific methods? The third criterion is an attempt to determine who has responsibility for the health and welfare of the individuals who are the subjects of the activity. If this responsibility is vested in 1 individual, such as a principal investigator, then the activity is likely research. A principal investigator conducting research has legal and ethical duties to subjects, whereas in the public health context, it is usually the case that these legal and ethical responsibilities rest with the government or public agency in general, not 1 specific individual. The fourth criterion pertains to whether and to what extent the participants in the activity will benefit. Usually, if the participants will receive direct benefits (eg, improvement of their general health or welfare), the project will likely be considered a public health activity. If the results of the activity and therefore its benefits, if any, will extend beyond the population under scrutiny, a hallmark of a research activity, then the activity is likely to be research. The fifth criterion concerns the methods that are used in the activity. Are they experimental (unproven) or proven methods? Sixth, what procedures will be used to determine who will be the subjects of the activity? If subjects will be randomly selected or sampled, then it is likely that the activity will be research.

These considerations must together be used in the context of the same general definitions and distinctions that the CDC guidance attempts to draw between activities that are research related vs those that lack a research focus. The chart below presents a summary of how the CSTE parses the

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distinctions between public health activities and human subjects research[14]:

Public Health Practice—*Protecting the public's health through epidemiological investigations, surveillance, programmatic evaluations, and clinical care for populations.*

Methods and Purpose

Involves the application of proven methods to monitor health status of the community, investigate unusual occurrences of diseases and other conditions, and implement preventive control measures based on current understanding within public health sciences.

Involves the collection of identifiable private information under appropriate public health legal authority without informed consent and outside of federal and state human subjects research provisions.

Public Health Research—*The design and conduct of studies involving human subjects for the purpose of generating knowledge that often benefits those beyond the participating community bearing the risks of participation.*

Methods and Purpose

Involves testing new, unproven treatments or strategies that are not known to be efficacious.

Involves the collection and use of identifiable private information with the informed consent of the subject, unless modified or waived in accordance with federal regulations.

As in other health and public safety contexts,[17,18] a great deal is at stake in making a proper project determination—time, money, and other important and scarce resources. If a project is wrongly deemed as research, IRB review is required, which takes additional time, money, and other resources, and therefore may adversely affect health and public safety. The CSTE report eloquently articulates both horns of this particular dilemma. The first horn concerns instances when public health activities are misclassified as research. When this occurs, "public health authorities [must] engage in time-consuming reviews through governmental or private sector IRBs. In some cases, the mere assessment by an IRB, even when expedited, may thwart an activity to the detriment of the public's health. In other cases, the IRB may require additional protections for people viewed as human research subjects that defeat public health objectives in principle or design, or for lack of funding."[14] The second horn of the dilemma is the converse of the first: "Public health research that is misclassified as practice may allow governmental health authorities to collect and analyze sensitive health data in possible violation of health information privacy interests, or interact with human subjects without complete adherence to research protections to the detriment of the individual participants."[14]

PUBLIC HEALTH EMERGENCIES AND DISASTERS: RESEARCH OR PRACTICE?

Given the opportunity costs associated with both sides of this dilemma, state departments of health and their IRBs must understand how to make a proper determination. Time, careful analysis, collaboration, and expertise and knowledge from CDC and CSTE guidance documents are required to achieve proper results. New Jersey's influenza preparedness initiatives prompted consideration of what processes would be used to make such a determination when one of the requirements—time—was lacking, as in a disaster or public health emergency. One idea, as the quote that opened this article indicates, is to learn from history, so the literature on recent public health emergencies was consulted.

This literature search revealed several published reports and recommendations for how to handle research conducted after disasters or emergencies, including the ethical issues inherent in such research.[19–26] Little has been published, however, about ethical issues encountered in public health responses during emergencies. This paucity is most likely because, as alluded to earlier, only after the emergency passes does it become clear that such responses may constitute research. It is the author's hypothesis that such was the case with 1 recent public health emergency (the severe acute respiratory syndrome [SARS] epidemic). Analysis of that example shows the need for state departments of health and their federal and local collaborators to understand the importance of making a research determination before public health intervention.

After the SARS epidemic, several articles appeared in the *New England Journal of Medicine* describing interventions that public health scientists engaged in to collect, analyze, and research samples taken from infected individuals. The articles, unlike others in the peer-reviewed scientific literature, did not mention 2 pillars of research protection—IRB review, approval, or oversight and informed consent.[27–29] It is not known whether researchers sought IRB approval and informed consent, whether these facts were simply not reported, or whether the research implications were not evident until afterward. Regardless of IRB review, informed consent and other ethical precepts of public health interventions should have been present[6] and, arguably, included in the articles' methods sections. As Henry Beecher argued in 1966,[30] and the consensus statement of major medical journals indicates,[31] data from research projects involving human subjects that did not receive appropriate review, approval, and oversight should not be published or at least, if published, should denote that investigators did not conduct the activity under IRB review or waiver of informed consent. Projects that lack this information should be viewed as ethically suspect.

SARS is merely 1 anecdotal example from analysis of research activities conducted during a recent public health emergency. It is likely that there are or will be other examples, as awareness grows in the bioethics, public health, and medical communities. Other than the SARS case, evidence of other instances is anecdotal, politically sensitive, and thus far only reported in the lay press.[32] It should be noted that there is an emerging and important literature on ethical issues in conducting research on victims after disasters and after public health emergencies, such as after the terrorist attacks of September 11, 2001, Hurricane Katrina, and the

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2004 Indian Ocean tsunami.[20–26] Moreover, this emerging literature provides ethical and regulatory issues for researchers and IRBs to consider for postdisaster research.[24] This literature represents an excellent starting point for consideration of ethical and regulatory issues in disaster research. What is needed, and what this article attempts to provide, is consideration of what determinations must precede such research at the approximately 35 IRBs at state departments of health, where these determinations (or oversight for them) will likely be made.

POSSIBLE SOLUTIONS

Several extant regulatory precedents point to some potential solutions to the research determination problem during disasters. Food and Drug Administration regulations[33] (echoed in Department of Health and Human Services guidance)[34] allow an exception to obtaining informed consent for certain types of emergency research. These regulations pertain only to drug, biological, or device research procedures conducted without the voluntary, prospective informed consent of subjects in life-threatening emergencies. Such projects, which number only about 25 since the regulations were enacted (as learned in the author's personal communications with the Food and Drug Administration in 2007), require prospective IRB approval and consultation with the community from which subjects will be drawn.

These regulations may serve as a starting point to adapt to the particulars of the public health contexts described in this article. Preemergency public consultation promotes the transparency that good, ethical informed consent requires.[7,35] Although this mechanism will not suffice to solve the problem in all cases, it is reassuring to know that our federal research oversight bodies have provided a mechanism for these controversial types of research. The same is needed for public health activities sponsored and supported by departments of health during times of emergency or disaster.

Other commentators—most notably National Institutes of Health physician, philosopher, and bioethicist Ezekiel Emanuel and colleagues—have suggested reconfiguring the IRB system into regional networks to avoid redundancy of review.[36] This recommendation is broader than the suggestion of Collogan et al[24] that IRBs should collaborate within specific regions to ensure that research activities postdisaster are not redundant and therefore do not pose additional risks to study populations. Emanuel and colleagues's recommendation has more in common with the phenomenon reported in North et al[25] that IRB review and oversight of research on the Oklahoma City bombing was, via executive order of the governor of Oklahoma and with the support of the Oklahoma Department of Health, centralized at the University of Oklahoma Health Sciences Center IRB. It has been the experience at the New Jersey Department of Health and Senior Services that academic health centers may be able to review biomedical research, but given the context and uniqueness of public health activities, such research may be better reviewed at IRBs operated by state departments of health. State public health agencies, unlike their academic counterparts, must have experts who understand the differences between public health practice and research and who have familiarity with the ethical and regulatory requirements of waiver of informed consent, secondary use of public health data for research purposes, and other considerations unique to public health. To extend Emanuel's argument, perhaps state departments of health should regionalize their own review and determination of public health activities into an overarching IRB for states within a region or at the federal level for all states. This type of reconfiguration should be explored by groups such as CSTE, CDC, and the various state departments of health.

Another recommendation concerns greater awareness. Based on the paucity of literature on research versus practice during public health disasters or emergencies, it is likely that officials at state departments of health require greater awareness, given that the scientific interventions designed for emergencies or disasters will need to be proposed in some form of protocol and made available for IRB review. It is hoped that this article will prompt more discussion, investigation, and education on the topic by the bioethics, public health, and medical communities.

In addition to increasing awareness, 2 additional recommendations can be implemented now and would work within the current system of research oversight. We should ensure that, first, each state public health agency has its own IRB (only 35 states seem to have their own IRB) and, second, that each IRB has policy and procedures to ensure an expedited review mechanism to approve public health projects during times of disaster or emergency. Most state public health agencies have preparedness initiatives in place. Such initiatives should take into account the need to have activities quickly triaged to determine whether any intervention has a research component. Those that do require IRB approval can be quickly reviewed and approved by an IRB member on the emergency preparedness team. (A separate question, and a matter for further investigation and debate, is whether the same regulatory and ethical standards should prevail for IRB reviews conducted during emergencies or disasters.) A well-trained IRB member on the preparedness planning team in a state department of health can conduct such a review in a relatively short time frame (in hours rather than the usual time it takes to approve a project through traditional IRB submission procedures).

CONCLUSIONS

Making a determination of whether public health interventions constitute research or not can prove difficult and vexing for officials at state departments of health. Moreover, the stakes are even higher during times of emergency or disaster. Time is essential, and the utilitarian ethics of public health may serve to unwittingly steamroll attempts to provide ethical oversight of such activities as currently practiced. Cur-

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rent regulations and guidance documents issued by federal agencies do not articulate a mechanism to address how state departments of health should handle research determinations during emergencies or disasters. Time and a host of other public health considerations (including lack of attention to this particular issue in the public health, bioethics, and medical literature) may limit the ability of officials in departments of health to seek approval of research during emergencies or after disasters. Two concomitant issues must be considered in these situations. First, the public must be assured that public health officials will safeguard their individual rights of protection under the federal regulations governing research involving human subjects. Second, the need for protections must be balanced against the greater public good—ensuring quick, efficient, and scientific-based intervention during public health emergencies or disasters. The current system is too bureaucratic to be effective for making a quick but correct decision about whether activities are practice or research during emergencies or disasters.

In summary, state departments of health require a mechanism to balance the 2 horns of the dilemma presented in the CSTE report—to balance the need for quick, scientific-based intervention to prevent or control public health disasters or emergencies versus the need for ethical and regulatory oversight over activities that are truly research driven. The current system of protection of human subjects is not equipped to tackle this particular problem at this point. Moreover, given the dearth of literature devoted to making the determination during public health emergencies, it is possible that few officials at state departments of health are aware of the problem and its potential consequences. This situation must change. It is in this spirit that this article has been prepared.

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