Evaluating Ethics in the Conduct of Public Health Surveillance

by

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Abstract

The practice of public health can require the collection of individual-level data and information in order to benefit health at the population level. Public health surveillance is one such activity. The methods and processes through which surveillance data and information is obtained can be very similar to those used in human subjects research. Public health and research data collection activities can also be similar in that ethical issues are raised when data and information are collected at the individual level. In the research paradigm, these ethical issues are managed in a systematic way through the process of ethical review and approval by institutional review boards (IRBs). There is not a parallel system for the systematic ethical review and approval for public health activities such as surveillance. In order to address these issues in the surveillance context, some sponsors and implementers of surveillance have elected to send the activities through the IRB review system. However, the IRB system is an imperfect fit for public health practice. The ethical framework employed by IRBs is based on the protection of individual-level rights, whereas public health activities are designed to provide benefit at the population level, even if that requires a compromise of individual rights in some circumstances. In addition, the boundaries of what is allowable in research ethics are set by a system of regulations to which IRBs must adhere. A new framework and structure for the review of public health ethics is needed that builds on the strengths of the regulations-based IRB model and preserving the authority of public health agents to achieve their mandate while ensuring that ethical issues are addressed.
Public health surveillance is the systematic collection and analysis of health related data in order to assess health status, determine public health priorities, inform public health programs, and answer research questions. (Thacker, 2000) Public health surveillance requires the collection of sensitive information from individuals. This raises a host of ethical issues related to privacy, confidentiality, informed consent, and the responsible use of the data including the obligations of public health authorities to those from whom data was collected. These issues are compounded when the purpose of the surveillance is to collect data on HIV in a population.

In order to prospectively address these ethical issues, many surveillance activities are submitted to institutional review boards (IRB) or research ethics boards (RECs) for review and approval prior to implementation. IRBs and RECs are committees constituted to evaluate the ethics of research activities involving human subjects by applying research ethics standards for the protection of human research subjects. This paper describes the tensions that are created when the ethics of public health surveillance activities are evaluated using a framework designed for the evaluation of human subjects research ethics, and considers what alternative framework might look like.

**Public health surveillance as a public health function**

Surveillance is an essential public health function that is used to support multiple activities that are conducted by public health authorities. The public has authorized surveillance activities because societal benefits derived from surveillance data outweigh the risks it imposes on individuals. (Snider, 2000) However, surveillance does require the collection of information about individuals. Depending on the nature of the condition
under surveillance, the data collected may be behavioral, biological, or both. In HIV surveillance activities, people are asked to provide sensitive personal information about risk-taking behaviors including sexual partners and practices, drug and alcohol use, and participation in social networks. (MacQueen & Buehler, 2004) The information can be very sensitive, linking individuals to activities that are highly stigmatizing and, in some cases, illegal. This effectively raises ethical issues that are also common to research involving human subjects. Maintaining the confidentiality of respondents is a paramount concern. HIV surveillance activities also require the collection of biological samples to test for HIV infection, and frequently will test for common sexually transmitted infections as well. Ethical issues include the need to provide effective pre- and post-test counseling, partner notification, and local requirements for the disclosure of communicable disease infections to public health authorities. These ethics issues, as well as those related to obtaining proper informed consent prior to data collection, must be considered before implementing a surveillance protocol. However, neither the mere presence of these ethical issues or their similarity to research ethics issues means that surveillance must be considered research.

**Research versus non-research**

To determine if surveillance is research involving human subjects, we must first consider how the relevant regulations define both “research” and “human subjects.” The U.S. Code of Federal Regulations for the protection of human subjects defines research as:

- a systematic investigation, including research development, testing and
evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

The regulations go on to define human subjects as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR §46,)

In applying the definition of research to surveillance, there is no question that surveillance is a systematic investigation. Surveillance protocols employ accepted methodological standards for sampling, data management, statistical analysis, and informed consent. In addition, participants in the data collection activity are living individuals from whom the data collector is obtaining either behavioral information or biological specimens for testing, or both. What is less clear when applying the research definition to surveillance is whether or not surveillance is “designed to develop or contribute to scientific knowledge” or what the regulations refer to as generalizable. Snider suggests that some surveillance activities are research and others are not, noting that the Behavioral Risk Factor Surveillance System (BRFSS) is a research project that is also a surveillance activity. (Snider, 2000)

The question of whether or not surveillance is research has been discussed in both bioethics and public health fora. The Council of State and Territorial Epidemiologists (CSTE) agreed that the distinction between public health research and practice can be blurry. Among the concerns expressed by the CSTE is the concern that public health
activities that are authorized by law cannot be subject to IRB review and approval. Moreover, ancillary research requirements such as the Health Insurance Privacy and Portability Act requirements would make the collection of surveillance data extremely difficult. The CSTE contends that the application of research regulations is unnecessary because of the existence of State and local laws authorizing the activity which include ethical standards and requirements and, importantly, are not transparent to the public. (Hodge & Gostin, 2004) The National Bioethics Advisory Commission (NBAC) agreed, noting that State and local laws address informed consent, privacy and confidentiality, procedures for collecting and handling information, and penalties for public health professionals who do not comply with the legal requirements. The NBAC also suggested the existing regulatory system be replaced with one to be developed by a group that includes representatives from the public health and other professional domains that would therefore be applicable to a wider range of research activities. (National Bioethics Advisory Commission, 2001)

The World Bank has taken the view that surveillance is not research. Rather, it views surveillance as an activity designed to document diseases and their causes, resulting in public health action. Research, on the other hand, is used to test hypotheses using experimental designs, and by its nature collects large amounts of additional data that are not only unnecessary, but are also overly costly for the needs of public health surveillance. (Garcia-Abreu, Halperin, & Danel, 2002)

The Centers for Disease Control and Prevention (CDC) has developed Guidelines for Defining Public Health Research and Public Health Non-Research that focuses on the intent of the activity with respect to the development of generalizable information. The
CDC deems data to be generalizable when it may be applied to other populations that the ones from which the data were collected. The guidelines also caution that activities may include both generalizable- and non-generalizable-data collection activities; therefore the intent of each component must be assessed. (Centers for Disease Control and Prevention, 1999) It should be noted that these guidelines were developed following a review by the U.S. Office for Protection from Research Risks (now the U.S. Office for Human Research Protections) of the CDC’s practices for determining which activities required IRB review and approval. Prior to that time all surveillance activities developed by the CDC were considered non-research. (Burris, Buehler, & Lazzarini, 2003)

**The research ethics framework**

Once an activity is considered human subjects research, the protocol is subject to review by an institutional review board (IRB). Amdur and Bankert define an IRB as a committee that protects the rights and welfare of research subjects. (Amdur & Bankert, 2006) IRBs in the United States operate according to accepted ethical standards as well as operational standards for applying the ethical framework. The three ethical principles that US IRBs must follow are respect for persons, beneficence, and justice. These principles are described in The Belmont Report, a product of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that was convened following public disclosure of the U.S. Public Health Service study *Untreated Syphilis in the Male Negro*, more commonly known as the *Tuskegee Syphilis Study*. The focus of the principles is on the individual first, rather than the community of participants or the public in general. (The National Commission for the Protection of Human Subjects
The ethical principle of respect for persons is focused on the ability of a person to act as an autonomous agent. In research, this means that the individual may decide for himself whether or not he wishes to participate in research. The primary mechanism through which this is achieved is the process of informed consent. Through the informed consent process the individual is informed of the demands being placed on him, and affirms his role as willing participant in the activity. This principle also acknowledges that some there are circumstances in which individual autonomy may be limited, such as children or the mentally incapacitated. (Levine, 1988)

The ethical principle of beneficence requires that the risks of research-related harms are minimized as much as possible. At the same time, the researcher is expected to provide the highest possible level of benefit to participants, resulting in a favorable balance of benefits to risks. Again, the focus is on the individual, and ancillary benefits to the subject’s community or society more generally, while acknowledged, are of lesser importance. In addition, the regulations instruct IRBs to avoid consideration of the “long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those ... within the purview of its responsibility.” (45 CFR §46, ) The irony here is that public health surveillance is an activity that is intended to inform policy. Ultimately, beneficence insists that the welfare of the individual outweighs the benefits to science and society. (Levine, 1988)

Justice as an ethical principle is based on distributive justice framework. In the distributive justice framework the benefits and burdens of participation in research are distributed equally. The principle of justice is intended to prevent the exploitation of one
group of individuals for the sole benefit of a separate population. Individuals who
participate in research must also be the intended recipients of benefits, if any, that result
from the study. The focus of the justice principle remains firmly on the individual, with
the larger community being considered secondarily. (Levine, 1988)

The process framework that IRBs use to apply the ethical principles to research
activities is the U.S. regulations for the protection of human research, which U.S. IRBs
are required to follow. Like the ethical principles of the Belmont Report, the regulations
were developed in response to public revelations of scandalous research. (Levine, 1988)
In regulatory framework, IRBs evaluate research to determine if seven criteria have been
met. (See Table 1) The seven criteria, viewed in isolation from the rest of the
regulations, should not inappropriately prohibit the conduct of surveillance activities.
Those who design surveillance activities should indeed seek ensure that their
methodology is sound and to minimize risks and maximize benefits. Likewise, selection
of participants should be equitable, the project should ensure that consent is obtained
whenever possible, and when personal information is obtained that individual
confidentiality should be strictly maintained. However, there are other requirements
imposed by the regulations that can limit the ability to conduct surveillance.

Table 1. Criteria for IRB approval of research (45 CFR 46.111(a))

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<td>1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.</td>
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<td>2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.</td>
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evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The regulations promote the application of the principle of respect for persons through the requirements for obtaining and documenting individual informed consent. The requirements for informed consent, when applied to a public health activity, put several important limitations on the activity. The regulations require that potential participants are informed through the provision of eight essential elements of informed consent. (see Table 2) Among these elements is the statement that participation is voluntary. This may be problematic if data is being collected for the improvement of
public health and there is a legal mandate to collect the information. This is analogous to giving individuals with a highly infectious disease the option of whether or not to go into quarantine. In addition, seemingly innocuous elements such as the requirement that the informed consent document identify the activity as research become problematic if an activity is not clearly research, or if the local public health authority that is implementing the activity does not consider it to be research. There are also requirements related to how informed consent is documented, which can be problematic when collecting data on stigmatized activities and risk-taking behaviors that may be illegal or otherwise threaten one’s social or economic standing.

### Table 2. Basic elements of informed consent for research (45 CFR 46.116)

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<th>(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;</th>
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<td>(2) A description of any reasonably foreseeable risks or discomforts to the subject;</td>
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<td>(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;</td>
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<td>(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;</td>
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<td>(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;</td>
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<td>(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;</td>
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<td>(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</td>
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Finally, there are additional requirements that protect groups with potentially diminished autonomy. The three categories of persons with additional research protections are pregnant women and fetuses, prisoners, and children. In pregnant women the additional regulatory protections are primarily directed at the fetus. The ability to conduct research on pregnant women requires a justification that the research is for the benefit of the fetus or the woman. In addition, the father of the unborn child may be required to give permission to conduct the research, which can impede the ability to collect information.

Extra protections for prisoners were developed in response to decades of exploitative over-use of prisoners as research subjects. (Amdur & Bankert, 2006) Prisoners were seen as an ideal population because they were easy to track, and participation was considered a privilege. Additional protections for prisoners require that the research offer the potential for direct benefit of prisoners, and the inclusion of a prisoner representative on the IRB when prison-based research is reviewed.

When children are to be enrolled in research, the level of extra protection afforded by the regulations is commensurate with the level of risk in the research. Low-risk research requires little additional documentation on the part of researchers. Research with moderate risk requires parental permission from at least one parent. High-risk research may require the permission of both parents, and at the highest level of risk, a special ruling from the department or agency funding the research. The parental
permission requirements can be difficult to manage in a clinical research context. In surveillance, these regulatory expectations can derail data collection. For example, in targeted surveillance of HIV in most at-risk groups, members of the target groups will include adolescents who meet the regulatory definition of children. Obtaining parental permission for members of this group may be possible, but the participants will not want the data collection activity to identify them to their parents as being involved in high-risk activities.

While restricting access to these vulnerable populations in a research setting is consistent with the three ethical principles, one can conceive of public health scenarios in which these regulations could impede the ability of public health authorities to do their work effectively, thereby denying them the product of the surveillance – interventions designed to improve the health of the public. As Kass notes, the emphasis in public health is not focused on the individual; instead the emphasis is on protecting and promoting the well being of communities. (Kass, 2001) This major shift in focus means that tensions will surface when an IRB assesses the ethical merits of a public health activity, such as surveillance, using a research ethics-based framework.

Some of the obstacles that are erected by the regulatory structure can be mitigated through built-in mechanisms that were developed to allow flexibility. For example, the regulations establish criteria to allow for a waiver of selected elements of informed consent and documentation, provided that the criteria are met and accepted by the IRB. However, this requires that IRBs are willing to be flexible in their interpretation of the regulations. Obstacles may also be overcome by placing the right people on the IRB. The regulations require that the IRB “shall be sufficiently qualified through the experience
and expertise of its members . . . possessing the professional competence necessary to review specific research activities.” An IRB would be in non-compliance with the regulations if it were to review public health activities without also having public health professionals serving as members of the IRB. (45 CFR §46, )

Ultimately the problem does not lie with the regulations themselves. The primary flaw of using the IRB system is two-fold. First, it is inappropriate to evaluate the ethics of selected public health activities with a framework that is focused on the protection of the individual and their personal rights. There will be circumstances when the good of the public requires that limitations be imposed on personal rights, and surveillance by its nature is meant to produce benefit at the community level. Second, it is inappropriate for public health activities to be contingent on the approval of a research ethics committee. If the government has a mandate to implement certain activities for the good of the people, then the government’s ability to conduct public health work should not be subject to a veto from an IRB that is applying individual-based ethical principles. Clearly, a different ethical framework and review mechanism is needed to effectively manage the ethical issues that arise in the conduct of public health data collection activities. (Burris et al., 2003)

A public health ethics framework

One candidate for an appropriate public health-based ethics framework is the 2002 publication of Principles of the Ethical Practice of Public Health by the Public Health Leadership Society. (Public Health Leadership Society, 2002) The developers of the code note that public health ethics were traditionally implied due to the nature of
public health, but by the end of the 20th century, the complexity of modern public health compelled the development of a code of ethics specifically for public health. The modern challenges to public health include the ethical challenges of emerging technologies; health challenges such as HIV; the potential for abuses of power including the still-recent abuses by public health authorities in the Tuskegee study; and the challenge of working across cultural boundaries. While the field of medicine has a long history of attempting to manage ethical challenges, its focus on treatment of disease and conditions at the individual level is incoherent with the public health focus on prevention of disease at the population level.

The Principles of the Ethical Practice of Public Health provide an appropriate ethical framework to guide public health practice. (See Table 2) The first element acknowledges that the goal of public health, and therefore surveillance, is to address the cause of disease and prevent negative health outcomes.

Elements 2, 3, 8, 10, and 12 address the competing interests of community health in individual rights. The code addresses this issue by recommending that public health activities maintain respect for individual rights through proactive engagement with communities. This engagement is meant to ensure that activities are culturally competent and that with community input the risks of harm to individuals are minimized. In addition, individual confidentiality is emphasized, with justification required before private information is disclosed. Unlike research ethics principles, the public health code ultimately emphasizes the supremacy of community health.

The code emphasizes in elements 9 and 11 that, in order to be ethical, public health activities must be implemented by qualified professionals who have been properly
trained and are technically competent to do the work. While this issue is implied in research ethics requirements, it is explicit in the public health code. When public health activities are implemented by unqualified people, it presents the opportunity for improper activities that could lead to harm at both the individual and community level.

The public health code is not divergent from research ethics with respect to the ethical use of data. In research ethics, since the focus of the protection is at the individual level, ethical oversight and mechanisms such as IRB review generally conclude when interactions with individuals end. In the public health code, elements 4, 5, 6, 7, and 9 emphasize that data collected through public health practice must be used responsibly. Information collected for public health purposes is used responsibly when it is used to act in a timely manner to meet their public health mandate; to inform policies and programs to maximize effectiveness and impact; to inform and empower all members of the community, including the disenfranchised; and to ensure that the physical and social environment is enhanced.

Table 2. Principles of the Ethical Practice of Public Health

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<td>1. Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.</td>
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<td>2. Public health should achieve community health in a way that respects the rights of individuals in the community.</td>
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<td>3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.</td>
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<td>4. Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.</td>
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<td>5. Public health should seek the information needed to implement effective policies and programs that protect and promote health.</td>
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6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.

7. Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.

8. Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.

9. Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.

10. Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.

11. Public health institutions should ensure the professional competence of their employees.

12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

The human subjects research regulatory system

While the Principles of the Ethical Practice of Public Health provide an ethical framework for evaluating public health practices, it stops short of describing a mechanism or processes through which the principles can be applied consistently. In the research ethics realm the principles of research ethics were made operational through the creation of a regulated system of human research protections featuring the IRB review and approval process. In this model IRBs are guided by a comprehensive set of regulations that are reflective of the ethical principles.

In addition to establishing the criteria for review and approval of research, the regulations include standards for the composition of IRBs to ensure that appropriately qualified individuals are part of the process. In addition, regulations describe a minimum package of processes and procedures to control the committees’ functions. It should also
be noted that the regulations have built-in flexibility, allowing institutions to triage protocols to different levels of review that are commensurate with the anticipated risk of harm to participants. In addition, there are several instances where the IRB has the authority to determine whether or not a project meets regulatory requirements, as in the case of informed consent requirements.

In addition to having a common regulatory structure, IRBs are also subject to compliance oversight by regulatory agencies, most notably the U.S. Office for Human Research Protections (OHRP). OHRP and similar agencies not only monitor and audit IRBs, but also have the authority to suspend federally-funded research at non-compliant institutions. (Office for Human Research Protections, 2005) The desire to remain in compliance has driven institutions to formalize the IRB within the organization, and provide resources for its operations. It has also led to the professionalism of IRB employees and voluntary accreditation of human research protection programs. All of these factors have a positive impact on both the process and substance of research ethics review.

There are also concerns about the current system of IRBs and ethics review of research. In its report the NBAC recommends that the existing research oversight system needs to be replaced with one that is comprehensive, effective and streamlined. (National Bioethics Advisory Commission, 2001) Other critics point to a system that is out of control, with IRBs and regulatory agencies attempting to expand the definition and scope of what is subject to IRB review to beyond what the framers of the regulations intended. (Post & Levine, 2007) This is of particular concern to behavioral and social science members, who contend that the regulations where written to address the needs of
biomedical clinical trials, and that non-biomedical research has suffered as a result. The research community, including IRBs themselves, is further concerned that the regulations are both overly prescriptive and proscriptive, and that changing the regulations is all but impossible. Finally, there are concerns that the regulatory oversight structure is insufficiently supported to meet its mandate, increasing the likelihood that problems will fall through the cracks and lead to unethical actions on the part of researchers.

*Lessons from the research model and implications for public health*

So what are the lessons of the research ethics review system that could be applied to a system for reviewing public health ethics? First, it is important to have the right people engaged in the activity, both as reviewers and as staff to manage the process. Second, the effective implementation of a code of ethics requires an operational support structure. Without a structure, there will be little consistency across committees. Committees will be inconsistent in both their make-up and their application of the principles, creating tensions when divergent outcomes are reached for identical projects. Third, regulations may be more harmful then helpful. While regulations can convey authority upon the process, the accompanying inflexibility and bureaucracy can be severely limiting, and even when the need for change is agreed upon it may be difficult to realize.

With these lessons in mind we can imagine what a model for the review of public health activities such as surveillance would look like. In this model institutions that routinely sponsor public health data collection, such as the CDC and national ministries of health, would create standing permanent committee comprised of a limited number of
public health experts. These members will have received additional training in public health ethics and the application of the Principles of the Ethical Practice of Public Health, including guidance on areas such as informed consent and data collection in vulnerable populations. This committee would evaluate the ethics of proposed activities according to both the principles as well as the additional guidance. Consultation from the committee will be sought should ethical issues arise either during the conduct of data collection or concerning the use of the data afterwards. Parallel review by IRBs would not be required.

Conclusion

Public health agencies have a mandate to prevent illness and promote health within the community. In order to meet this mandate, public health practitioners must engage in activities such as surveillance in order to collect data on the health of the community. However, the mere collection of data does not make the activity research in the academic or regulatory sense. Therefore, subjecting such activities to review and approval by a research ethics committee is inappropriate. Moreover, it is inappropriate for a research-based body to have the authority to prevent public health activities. Instead, a new model is needed that uses the best qualities of the research review system and couples them to an appropriate public health ethics framework. Achieving this will ensure that public health is advanced while providing the most appropriate degree of protection to individuals.
Reference List


4. 45 CFR §46.


