

INTRODUCTION TO MODULES 3 and 4: Research Ethics in Public Health

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This introduction to research ethics in public health describes types of research, with an emphasis on studies involving humans; the elements of public health that are unique to research; basic ethical considerations in public health research; and standard processes for ensuring the ethical conduct of research.

Types of Public Health Research

Research is an integral component of public health. If there is an obligation to protect the health of the community, then there is also an obligation to learn how best to do that. This entails collecting information to: identify the causes of disease; identify factors affecting the distribution of disease; and evaluate approaches to protect or promote health. Research is defined in the Code of Federal Regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46).

Public health research includes the study of: inanimate substances such as water and air quality; biological processes not involving humans (e.g., the natural history of arthropods that are disease vectors) and questions that involve humans. There are ethical concerns in each of these types of research, but the majority of ethical deliberation is about research involving humans.

In some studies, the research questions pertain to the health, experiences, behaviors, or other aspects of individuals. In these studies, individual people are the unit of analysis. Other units of analysis are: pairs of people (e.g., couples); families; social networks; agencies and institutions; and communities or other populations. Generally, there are two ways to quantify characteristics of a group or population. Measures on individuals in the group (e.g., annual income) can be presented in an aggregate, such as a mean. Other factors more or less affect everyone in a group equally and cannot be measured by obtaining information from each person. Examples include climate, air quality, and whether a town is located on an interstate highway. The ethical concerns in a study will vary according to the population being studied. For example, the process of informed consent will be different in a study with communities than it will be with a study of individuals.

Studies also vary by the degree of participation they offer to those being studied. Some feel the ideal of observational research is to conduct a study as if it weren't really happening; to know what people would be doing in the absence of the study. In many instances, such deception in research is unethical or cannot be achieved. Most typically, the researchers need to interact with participants to pose questions or obtain biological specimens (e.g., a blood sample). In many instances, experiments or intervention studies require that the individual participants agree to follow a regimen, such as a particular diet, dictated by the researchers. In the examples given so far, however, the participants play a small role at best in the collection of data and have little say in how a study is conducted. In some types of participatory action research, the participants are regarded as research collaborators. They can determine what will be studied and how the study will be conducted, collect some or all of the data, and contribute to the data analysis. Advocates of this type of research argue that research that excludes the

participants from active participation can yield irrelevant and inaccurate data, and can disempower those studied (Israel, 1998). The principle of participation is one that is central to public health.¹

The Elements of Public Health that are Unique to Research

Public health often distinguishes itself from medicine by stating that it is concerned principally with populations rather than individuals and with prevention rather than cures. While many in public health agencies work directly with individuals and offer them treatments, claims that the dominant interests in public health are in populations and prevention remain valid. These two emphases bring a number of ethical concerns to the forefront in public health research.

In many instances, the best interests of a population or community as a whole are at odds with the preferences of some members of the community. Less frequently, the good of the community stands in contrast to the recognized rights of individuals. For example, the right to privacy may be abrogated when some people need to know that a person they've been in contact with is infectious with a sexually transmitted disease. More generally, it is often stated that any risk to participants in a study is to be weighed against the benefits that the study will bring to greater society (see, for example, the Belmont Report, part C, section 2). This would apply to many studies in public health, but there are perhaps additional ethical dilemmas in studies where populations are the unit of analysis.

Basic Ethical Considerations in Research on Humans

Philosophers, policy makers and others first turned their attention to the ethical practice of research after the atrocities of medical experiments during World War II were revealed. Since then, much of the agenda in the field of ethics has been driven by the dilemmas presented by advances in medical technology and by research on human subjects. In response, ethics discussions have focused on a number of key issues: informed consent; research in vulnerable populations; and balancing the risks and benefits of research. Contemporary conventions regarding these issues have been guided by three ethical principles.

These three principles, articulated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in their document known as the Belmont Report, are respect for persons, beneficence, and justice.

Informed consent

The main idea of informed consent is ensuring that each person participating in a study has agreed to do so of their own volition and with full knowledge of the risks and possible benefits to them. The principle was first articulated for studies with individuals as the unit of analysis. There is a need, however, to incorporate respect for and attention to communities in the principles that guide protection of research subjects in public health. Some ethicists have gone as far as recommending that the principle of community ought to be added to the other three identified in the Belmont Report (Weijer, 2000). There are instances, particularly in research conducted by westerners in developing countries,

¹ This and other values that are inherent to a public health perspective are enumerated in a document that accompanies the code of ethics adopted by the American Public Health Association, found on the internet at <http://www.apha.org/codeofethics>.

when it is appropriate to seek the permission of a tribal chief or village elder to conduct a study in their community. But this is generally not understood to be a substitute for also requiring the informed consent of each individual in the study, when individuals are the unit of analysis.

Extravagant benefits offered to a potential study participant are considered to work against voluntary enrollment in a study because the benefits, which may be hard to resist, are seen as tantamount to coercion. This is particularly a concern when conducting research on vulnerable populations, such as children and prisoners. The principle would also apply to those who are extremely poor. For example, a woman living in an undeveloped country, subsisting on an income of a dollar a day, would find it very hard to turn down \$20 paid as reimbursement for a study procedure despite of being informed of the risks.

Extra precautions are taken when the research participants are considered to be vulnerable. Types of vulnerability include: cognitive or communicative (e.g., young children), institutional (e.g., imprisonment); deferential (i.e., cognitively able to consent, but subject to the authority of someone else); medical (e.g., having a serious condition for which there is no satisfactory treatment); economic; and social (i.e., members of undervalued social groups) (National Bioethics Advisory Commission, 2001). Typically, the parents of minors are required to give consent for their child to participate in a study. If the child is old enough to understand the risks and benefits of their participation in the study, it usually required that they give their assent in addition to the consent of their parent(s). Furthermore, there are limits to the level of risk to which a parent can give consent. In the case of prisoners, researchers must take precautions not to give the impression that participation or the refusal to participate in a study will in any way affect the duration of the prisoner's incarceration.

A major concern in every instance of obtaining informed consent is the ability of the potential study participant to truly understand the study and the risks and benefits they may experience; that is, to be truly informed. This concern is heightened when a study is being conducted in a culture where studies are not common or where western scientific thinking is not dominant. In such instances, researchers need to expend an extra effort to understand: the culture of the study participants; what their motivations might be for participating in a study; how best to communicate with them about the study. The researchers also need to enable the potential study participants to understand the culture of the researchers, especially as it pertains to scientific inquiry.

Risks and benefits of research

The risks to a participant of a study vary according to the type of study. Examples include: physical harm from a procedure performed on the participant; illness from a medication; emotional trauma from interactions with the researchers; loss of a relationship or a job because the researchers failed to keep confidential information given to them; and social stigma or embarrassment from loss of privacy. The confidentiality of information, which is one of the most important ethical considerations of research, means that the researchers know who gave the information but they will not tell anyone else. This is contrasted with anonymous data in which even the researchers are unable to identify to which person the information pertains.

In contrast to the obligation to keep some information confidential, researchers have another obligation to share the findings of their research. Research findings, however, are typically presented as aggregated data that do not reveal the identities of the individual participants. There is an obligation to share the findings with the larger society because the information is potentially useful, even if the

results are negative. An increasing number of investigators are also perceiving an obligation to share the study results with the participants because they helped contribute to the study.

Oversight of research

The mechanism that ensures that a researcher adheres to these principles of ethical research is the institutional review board (IRB) for research involving human subjects. The roles of an IRB are to: review study proposals; inform investigators when their study protocols fall short of conventional ethical standards; approve ethically sound protocols; and monitor studies over their duration to ensure that ethical standards are adhered to throughout the course of the study. For an institution, such as a university, to receive funding for research from most funding agencies, it must have an IRB registered with the federal Office for Human Research Protections (OHRP). Many professional journals in which study findings are published also require that a manuscript submitted for publication indicate that an IRB approved the study. An IRB is typically composed of other researchers at the same institution and a number of “community” or lay members from outside the institution.

Surveillance and Research

Research was defined at the beginning of this paper as “a systematic investigation . . . designed to develop or contribute to generalizable knowledge.” In some instances, public health surveillance activities can fit this definition. Yet, most researchers and public health agencies have not regarded surveillance as research; thus it has not been subject to the scrutiny of an IRB. To better understand the distinctions and similarities between surveillance and research, we will describe in this section how surveillance works and the criteria used by the Centers for Disease Control and Prevention (CDC) for distinguishing between surveillance and research.

Perhaps the best known public health surveillance system is the National Notifiable Disease Surveillance System (NNDSS). This system requires physicians to report certain diseases, such as tuberculosis and some sexually transmitted diseases when they are diagnosed. When a physician diagnoses gonorrhea, for example, he or she is to fill out a brief report form with information on the patient, including: name, age, sex, race and ethnicity, residential address, the diagnosed disease, the date of diagnosis, and the reporting physician. The form (often a card) is then usually mailed to the local health department. They may use the information to follow-up with an interview to learn the names and addresses of sexual partners and then visit them to notify them of their potential exposure to infection. In some instances, the sexual contacts will be taken to the health department for treatment of an infection.

The local health department will send a copy of the reported infections to the state health department. They will use them to monitor the rates of infection throughout the state and to allocate resources for disease control. In a similar fashion and for similar purposes, the state health department will send its reports to the CDC. The data forwarded to the CDC often does not include personal identifiers for each case. Instead, the state will report the numbers of cases of a particular disease by age group, sex, race/ethnicity, and county.

The system described is “passive” in that the local health department relies on physicians to report without prompting from the health department. In some instances, the health department will proactively call physicians’ offices to ask if they have identified any cases of a particular condition. Because this “active” surveillance is more expensive than passive surveillance, it is typically reserved for relatively infrequent but important infections or events. The diseases of importance vary regionally. In

California one such disease is Kawasaki syndrome, a rare and fatal disease of unknown cause that most often affects children. Also, the information sought on cases for which there is active surveillance is usually more detailed than the cursory information required for passive surveillance. Active surveillance is used in some instances because the disease is not well understood and the surveillance system provides a means to collect information that may help identify the causes or risk factors for the disease. Sentinel surveillance is a type of active surveillance in which a sample of physicians are contacted regularly to learn about any diagnosed cases.

Other situations in which data are collected systematically in a public health system include disease registries, program evaluations, and emergency responses. As with active surveillance, a disease registry collects thorough information on individuals with a particular condition (for example a cancer registry would include information on the primary site and morphology of the cancer). A registry usually aims to collect information on every case occurring within some geographical area. Diagnosing physicians are not required by law to report diagnoses to registries; instead, registry personnel identify cases through hospital record reviews. The purpose of a registry is to gather information that may advance the scientific understanding of a disease.

When a public health program has been implemented, such as seat belt laws or an anti-smoking campaign, data are often collected to evaluate the efficacy (whether the program can work in a single instance), effectiveness (whether the program works more generally in many settings), efficiency (e.g., whether the program is economical), and other characteristics of the program. Public health programs are typically implemented in non-emergency situations. In an emergency, such as an acute disease outbreak, data may be collected on each case in order to guide the emergency response.

Each of the data collection processes named—surveillance, registries, evaluation, and emergency responses—entails the systematic collection of data and may, in some situations, meet the criteria for research. When those criteria are met, and when the data are collected on human subjects, the data collection needs to be reviewed by an IRB. The key consideration for distinguishing routine data collection inherent to the daily functioning of public health systems from research is the intent of the data collection. The primary intent of research is to generate generalizable knowledge. The CDC does not consider as research data collection in which the primary intent is the prevention or control of a disease, or the improvement of a particular program (Snider, 1999). To generalize means to infer the findings from the analysis of one data set to other settings or populations where the data were not collected. In contrast, non-research is typically concerned with one specific situation.

Standard disease reporting, such as in the NNDSS, is not considered research; it is used to guide the management of public health programs and the allocation of resources for disease control and prevention. Standard data collection in such a system is limited to information on the specific health condition or disease, demographic information, and accepted, known risk factors. When the data collected extend significantly beyond these standard data, it is usually for the purpose of studying the etiology of the disease or injury in which case it is research. Thus, disease registries are often regarded as research and are subject to review by an IRB. Their purposes may be dual in nature, to guide public health responses and to elucidate the etiology. Regardless of other intents, where research on human subjects is involved, the data collection must be approved by an IRB.

On occasion, surveillance data are subsequently used for research purposes. The use of surveillance in this way must be preceded by the review of an IRB. The publication of findings based on surveillance

data, however, is not necessarily an indication that the data have been used for research purposes. For example, with the publication of disease trends by state in the United States, the intent of the article may be to inform public health practitioners of disease trends in the country and how their state figures into the bigger picture. This is an intent that is consistent with the management of public health programs rather than elucidation of the causes of the disease patterns. Similarly, data collected for an emergency response, such as an outbreak investigation, are used to inform that one response, thus the process is not considered research. A disease outbreak may be published and even used as a teaching tool, but it would not be considered research unless extra data were collected in order to further elucidate the etiology of the infection or identify new mechanisms of transmission.

Program evaluation is also typically concerned with management of a particular program. This is especially so when it is a program shown by prior research to be efficacious. Evaluation data are then used to adjust the program components to achieve the maximum benefit for a given cost. If a program is new, however, and has not been tested before, then the purpose of the evaluation is to establish whether the program is efficacious. By the CDC standards, this is considered research (Snider, 1999).

Data Confidentiality

Information about a person can be used for their benefit or can harm them either intentionally or unintentionally. Some information carries a particularly strong possibility of resulting in harm. For example, in a study of sexually transmitted diseases, researchers may ask a study participant the number of people with whom he or she had sex in the last month. If the number is greater than zero, that piece of information could lead to retribution, such as physical abuse or the termination of a relationship, if it were to be made known inadvertently to a parent or a sexual partner. Other types of information can lead to unemployment or loss of health insurance if it falls into the hands of a person who can make such decisions, and social stigmatization or psychological distress.

The first step in avoiding deliberate or inadvertent breeches of confidentiality is to inform the study participant of the potential risk to him or her if information is not properly guarded by the researcher. The complementary step, of course, is to actually guard the information properly. The precautions to be taken depend on the type of study and the potential benefits to study participants from the information they provide. For example, some epidemiologic studies require information on each study participant at two points in time (i.e., longitudinal or follow-up studies). If the information collected initially lacks identifiers, there will be no way to associate it with information collected on the same person at a later date. Without the ability to link initial and follow-up data, there is no means to calculate risk (i.e., the proportion of study participants who experienced a particular outcome by the end of the study). This formal calculation of risk is a basic measure in epidemiology; losing this tool would greatly limit the benefits to be gained by epidemiologic research. One should not assume that the risk of participating in a study can or must be completely eliminated, particularly when the value of otherwise beneficial research may be significantly compromised. It is important not only to assess the likelihood that identifiable, private information obtained or generated in the course of research could be inappropriately disclosed, but also the probability and magnitude of the harms that could realistically result if such disclosure were to occur.

There are several levels of identification or anonymity of samples or data. A data set that includes for each participant a personal identifier, such as the name or patient number, along with other information on the person is called *directly identified* data. The utility of the identifiers for linking information to

other datasets or information collected on the same person at other times can be maintained while decreasing the risk of revealing the identity of study participants by replacing the identifiers with a code. This is done by creating another data set that lists the code and identifiers for each study participant. Access to this *coded* data set is restricted to the minimum number of people (perhaps just the lead investigator) and it is further protected by a password or by keeping it locked in a file cabinet or safe.

The next step towards enhancing confidentiality is removing the link between a code and personal identifiers. These data are then referred to as *unlinked* or "*anonymized*." Data or samples for which identifiable information was either never collected or was not maintained and cannot be retrieved are termed *unidentified* or *anonymous*. By using anonymous data or rendering it anonymous, it is difficult, though not necessarily impossible, to identify the person associated with the information. Genetic data are difficult to anonymize because, at least in theory, they can be linked to another biological sample with genetic information and identifiers. Also, although identifying information such as names and patient numbers can be removed from data or samples, the remaining data needed for the analysis may point to one or a small number of individuals. This is referred to as deductive identification. For example, in the case of a dataset pertaining to people in a particular town or city section, information on the gender, age, race, occupation, and street block of residence of a study participant, could be used to deduce who the person is.

Some studies cannot be done with anonymous data, however, particularly when a researcher needs identifiers to link one record to another. This can be the case when merging datasets from two different sources or in a longitudinal study with measurements taken from the same person at several points in time. The data can often be anonymized once the study is over, but the risks of failed confidentiality persist for the duration of the study.

We have mentioned that the benefits of research often accrue to society as a whole. Likewise, the harms from research can be experienced by a group of people; they need not be only to individuals. Thus, even with anonymous data, and short of deductive identification, the way in which study findings are reported can have the effect of stigmatizing either a particular subset of study participants or the people they are intended to represent in the community. This can occur, for example, when a particular group is singled out and only negative study findings are used to characterize them. Alternatively, when a community is the unit of study, particular communities can be damaged by the study findings when the community is identified. For example, new industries may choose not to locate in a town based on information from a study that paints the town in a negative light.

Definitions and Concepts

Anonymous data	Data or samples for which identifying information, such as name, social security number, or address was either never collected or was not maintained and cannot be retrieved. Such data are referred to as “unidentified” by the National Bioethics Advisory Commission (NBAC, 2000). When a data set has been made anonymous by the removal of identifiers and any hope of making a connection back to identifying information it is called an “anonymized” data set (or “unlinked” by NBAC).
Coded data	A data set that lacks explicit identifiers of study participants, such as name, social security number, or address, but contains a code that links each observation to another data set with identifiers. Access to the code that links the data sets is limited to the smallest number of people feasible to aid in the protection of confidentiality.
Community advisory board	A group of people from a community under study who advise researchers on the design, conduct, or other aspects of the study, especially as it pertains to interactions with the community.
Confidential data	A data set containing information identifying study participants; information which the researchers are to conceal from others.
Deductive identification	The use of information other than a direct identifier, such as a name or social security number, to deduce the identity of a study participant; for example, the age, gender, race, and street block of residence may point to just one or two people who fit all the criteria.
Evaluation	The systematic application of scientific and statistical procedures for measuring program conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes (Rossi and Freeman, 1993; Fink, 1993).
Informed consent	A potential study participant’s voluntary consent to participate in research after having been adequately informed of the relevant risks and benefits of the research in a way that is understandable to the potential participant.
Institutional review board (IRB)	A group of people, often affiliated with a research institution, who review scientific protocols for research involving humans and who decide whether the proposed study design is ethical. Also known as a human subjects review committee. More detail on IRB purposes and procedures can be found in the Code of Federal Regulations (CFR), Title 45, Part 46.
Program evaluation	An essential organizational practice in public health using a systematic approach, including data collection and analysis, to improve and account for public health actions (Snider, 1999).

Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Code of Federal Regulations, Title 45, Part 46).
Risks and benefits	Risks in a study are the harms that may be experienced by a participant because of their participation. Examples are physical trauma and social embarrassment. Examples of benefits from participating in a study are improved health and contributing to the betterment of society through the accrual of useful information.
Surveillance	The ongoing, systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury (Thacker and Berkelman, 1988).

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