

Distinguishing Public Health Practice and Human Subjects Research¹

*A White Paper for the University of Virginia
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Introduction

Public health agencies collect and analyze significant identifiable health data from multiple sources to perform an array of public health activities including surveillance, epidemiological investigations, and evaluation and monitoring. Few debate that these essential public health activities, often specifically authorized by law, are classifiable as public health practice. Other public health activities involving identifiable health data may constitute human subjects research, defined by the federal Common Rule as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”¹ that involves living human subjects (or their identifiable, private data). For example, a public health agency may conduct a double-blinded, controlled study to assess the efficacy of a new vaccine among a randomly-selected group of persons. The study’s hypothesis, methods, and underlying intent support classification of the activity as research, requiring the public health agency to adhere to a series of research protections (e.g., individual informed consent absent a waiver) and procedures (e.g., review by an institutional review board [IRB]) designed to protect the health and safety of human subjects.

Beyond these examples is an array of public health activities that are not neatly characterized as either practice or research.² Classification of these activities can be complicated.³ Many public agencies and practitioners acknowledge the importance of drawing

distinctions between public health practice and research⁴⁻⁹ because (1) federal, state, and local laws and ethical principles governing human subjects research can require extensive and burdensome procedures. Misclassification of public health practice activities as research can result in these activities being delayed or conducted less efficiently or at higher costs due to the need to adhere to these procedures; (2) the HIPAA Privacy Rule (and other privacy laws) employ different standards for the disclosure of identifiable health information to public health practitioners (or others) without individual written authorization depending on whether the underlying activity is public health practice or research. In general, it is more difficult to acquire identifiable health data under the Privacy Rule for research purposes; and (3) widespread methodological variations in distinctions between public health practice from research have led to inefficient and duplicative reviews among IRBs and public health agencies.

Despite its critical importance, there is no national consensus on the ways, factors, or bases for making distinctions between public health practice and research. The federal Common Rule (governing human subjects research), the HIPAA Privacy Rule, and other laws require public health officials and others to make these distinctions, but provide little guidance on how to do so. The Office for Human Research Protections (OHRP), CDC, NBAC and others offer varied approaches for making distinctions that include factors like assessing the intent of the proposed activity, examining the risks to or burdens on its participants, and reviewing underlying legal authority. While helpful, these guides lack coherence, coordination, and consensus among the public health practice and research communities and IRBs.¹⁰

This White Paper discusses a comprehensive approach for distinguishing public health practice and research developed by the Council of State and Territorial Epidemiologists [“CSTE Report”].¹¹ This methodology proposes enhanced criteria to distinguish public health practice

and research developed through analysis of existing laws, scholarship, and applied approaches. Modern definitions of “human subjects research” and “public health practice” are presented together with meaningful principles to classify public health practice and research activities. Rejecting some existing, commonly-used criteria, these guidelines focus on foundational principles (for easy cases) and enhanced guidance (for hard cases) that include assessments of (1) general legal authority, (2) specific intent, (3) responsibility, (4) participant benefits, (5) experimentation, and (6) subject selection.

Key Concepts of Public Health Practice and Human Subjects Research

Distinguishing public health practice and human subjects research is difficult because, in some ways, they are alike. Both may (1) involve the collection and use of individually-identifiable health information; (2) present actual or potential risks to participants (e.g., privacy violations, discrimination, injuries, coercion); and (3) be justified as laudable activities to further the public good. Of course, public health practice is not synonymous with human subjects research. Public health practice involves the application of proven methods to monitor the health status of the community, investigate unusual occurrences of diseases or other conditions, and implement preventive control measures based on prevalent public health sciences. The CSTE Report defines public health practice as: *the collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community.*

Alternatively, research involves testing new, unproven treatments or strategies that are not known to be efficacious. As such, research entails rigorous monitoring of potential adverse, unexpected consequences to selected individuals through new, often unproven interventions. A definition of *public health research* involving human subjects may be stated as follows: *the*

collection and analysis of identifiable health data by a public health authority for the purpose of generating knowledge that will primarily benefit those beyond the participating community who bear the risks of participation.

Enhanced Guidance to Distinguish Public Health Practice and Research

Existing definitions, theories, approaches, and legal foundations underlie the distinctions between public health practice and research, but do not sufficiently guide public health practitioners, IRB members, and others to make clear classifications. Presently DHHS, through its Secretary's Advisory Committee on Human Subjects Research Protections (SACHRP) and OHRP, is currently examining these issues in an attempt to provide national clarification. OHRP's draft "Guidance on Research" has not to date been released for public review, but federal agencies within DHHS report that it addresses the need for clear distinctions.

Classifying a public health activity as practice or research can be relatively simple in easy cases. The challenge is to develop improved criteria for making distinctions in hard cases, including activities that have practice and research components. The CSTE Report presents a two-stage process utilizing guidelines and a corresponding checklist (see Appendix A) to make distinctions between public health practice and research for easy and hard cases. The first stage neatly separates public health practice and research based on some of their essential characteristics. A second stage introduces enhanced guidelines that provide justifiable, additional factors for making distinctions in hard cases.

In either case, public health authorities must describe their intent, motivation, and objectives for their activities by answering some basic questions: (1) what prompted the performance of the activity; (2) on what (or whose) authority is the activity conducted; (3) what is the activity designed to achieve; (4) how will information from the activity be used; and (5)

who will benefit from the activity? Incomplete facts, inaccurate observations, misstatements, or manipulations of stated objectives can lead to improper classifications or erroneous findings.

Stage 1 - Essential Characteristics of Public Health Practice and Research. The initial step to distinguish public health practice from research is to review those parameters that are exclusive to each activity. What is it about public health practice that is unique? What must be shown for an activity involving identifiable health data to be characterized as human subjects research under the Common Rule? These essential characteristics, or foundations, of public health practice and research help separate the easy and hard cases, and eliminate some cases altogether from further need for classification. Essential characteristics of *public health practice* include that it:

- Involves specific legal authorization for conducting the activity as public health practice at the federal, state or local levels;
- Includes a corresponding governmental duty to perform the activity to protect the public's health;
- Involves direct performance or oversight by a governmental public health authority (or its authorized partner) and accountability to the public for its performance;
- May legitimately involve persons who did not specifically volunteer to participate (i.e. they did not provide informed consent); and
- Is supported by principles of public health ethics that focus on populations while respecting the dignity and rights of individuals.

Essential characteristics of *public health research* include that it:

- Involves living individuals;
- Involves, in part, identifiable private health information;
- Involves research subjects who are selected and voluntarily participate (or participate with the consent of their guardians), absent a waiver of informed consent; and
- Supported by principles of bioethics that focus on the interests of individuals while balancing the communal value of research.

These characteristics distinguish practice from research in many of the easy cases. For example, a public health reporting requirement may be specifically authorized via legislation or

administrative regulation that obligate the public health agency to perform the activity to protect the public's health. Some states, like New York, statutorily clarify that epidemiological investigations or other common public health practices are not human subjects research.¹² These activities are public health practice so long as their design and implementation do not cross over to the realm of research. As well, if an activity may lawfully require the non-voluntary compliance of autonomous individuals, it is likely not classifiable as research because voluntary consent is a foundation of research.

Stage 2 – Enhanced Guidelines. The essential characteristics of public health practice and research suggested in Stage 1 may help resolve the simpler cases, but more complicated scenarios remain. The second stage of the framework first rejects some of the existing criteria often used by public health practitioners, IRBs, and others to draw distinctions, including examining (1) who is performing the activity, (2) whether the findings of the activity are to be published (and where), (3) the urgency underlying the activity, (4) the source of funding, and (5) the methods for collecting and analyzing health data. These criteria are not particularly helpful in making meaningful distinctions because their answers may be the same for either activity.

Instead, the enhanced guidelines below provide meaningful bases to distinguish research and public health practice involving identifiable health data. It is important to note that none of these guidelines are sufficient alone to fully classify an activity. For more complex, multi-stage, or multi-dimensional activities, the activities themselves must first be unbundled and examined separately using these criteria. Public health practitioners, for example, should not conclude that a multi-faceted activity that includes research components is public health practice just because the majority of the work is practice. Rather, they must separate and examine each of the various

components to make proper distinctions, and apply appropriate regulatory frameworks depending on each components' classification. These guidelines include:

General Legal Authority. In cases where specific legal authority for a public health practice activity is missing, public health authorities may conduct activities pursuant to general legal authorization (e.g., to “acquire health data to monitor health conditions in the population”). Absent other criteria favoring a research classification, general legal authorization to conduct a public health activity supports a conclusion that the activity is practice, although analysis of the meaning, scope, and limits of the legal authorization is necessary.

Specific Intent. CDC and others have historically focused on intent as a primary factor to distinguish practice and research. CDC has previously suggested that the intent of public health practice is to “prevent or control disease or injury and improve health, or improve a public health program or service” and the intent of research is “to generate or contribute to generalizable knowledge.” The weakness of these statements is their generality; they might easily apply to either practice or research. Greater specification of underlying intent is needed. The CSTE Report restates the intent of **research** “*to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity’s participants.*” If any intent underlying the activity relates to research, OHRP advises that the activity must be viewed as research, at least under this element of the enhanced guidelines. The intent of **public health practice** is “*to assure the conditions in which people can be healthy through public health efforts that are primarily aimed at preventing known or suspected injuries, diseases, or other conditions, or promoting the health of a particular community.*”

Responsibility. In the research context, responsibility for the health, safety, and welfare of individual participants falls upon a specific individual, typically the principal investigator (PI),

as well as those working under the supervision of the PI. Public health practice does not always feature direct individual responsibility for the welfare of participants. In many practice activities, the responsibility for individuals' well being falls generally on government entities which arises because of legal and ethical duties assumed by public health practitioners as representatives of government.

Participant Benefits. Assessing the potential (or expectation) of benefits to participants concerning practice and research provides an opportunity for drawing better distinctions. Research is designed primarily to help researchers and society make potential gains through advancements in scientific knowledge. Participants in human subjects research may not receive (or expect) any direct benefit from the activity. They may even be harmed by it. Whenever risks are imposed on participants to make the results generalizable beyond the participants themselves, the activity should be classified as research.

Unlike research, public health practice activities are premised on providing some known or expected benefit to participants or the population of which they are members. Though failures in design or implementation of public health practice activities may limit or defeat these benefits, the objective remains the same: public health practice should contribute to improving the health of participants. Research, however, may not. Correspondingly, if the activity offers no expectation or prospect of benefit to the participants, then the activity should be classified as research.

Experimentation. There is an experimental quality to research that public health practice does not always share. Research may involve introducing something non-standard to research subjects or to the analysis of their identifiable health data. What is introduced may be experimental (e.g., the application of a new and unproven medical procedure). In other cases,

existing methods of analysis are used to produce new knowledge (e.g., exploration of a subject's health data to assemble knowledge previously unknown).

Although innovations are part of public health practice, it is dominated by the use of standard, accepted, and proven interventions to address a known or suspected public health problem. Through the use of standard practices, public health practitioners can properly assess the nature of the problem and apply proven techniques to limit its impact on the population's health. Applying non-standard approaches in public health practice activities may not provide meaningful data to guide additional public health responses. Thus, if any activity involves introduction of non-standard or experimental procedures, the activity is more likely research than public health practice.

Subject Selection. Human subjects research is largely (though not exclusively) driven by the desire of a researcher to test an underlying hypothesis. To reduce the possibility of bias, the researcher may select human subjects randomly so that the results can be generalized to a larger group. Practitioners of public health activities rarely choose participants in this sense. Participants are selected because they have, or are at risk of, a particular disease or condition and can likely benefit from the activity. Public health practice activities are not designed to test hypotheses but to benefit the participants or their communities. Thus, if an activity utilizes control groups or randomly selects its participants to eliminate bias, the activity is likely research rather than public health practice.

Checklist for Making Distinctions Between Public Health Practice and Research. The CSTE checklist (see Appendix A) presents a working model to help guide public health practitioners through a process to determine whether an activity is public health practice (practice) or human subjects research (research) consistent with the Common Rule and the

HIPAA Privacy Rule. This checklist is designed to help resolve a majority of cases to provide consistency in decision-making on a national basis, although it may need to be tailored to specific requirements within various jurisdictions or agencies.

Conclusion

Distinguishing between public health practice and research activities conducted by public health authorities is not always hard, nor is it always easy. The similarities of these activities and underlying intents, coupled with a lack of clarification among key legal and ethical policies, complicate classification. Existing proposals for how to distinguish between practice and research have led to disagreements and incongruous results among public health authorities, IRB members, and others. Nearly everyone seeks a better way to clarify these concepts, which perhaps underlies existing activity at the federal level to provide additional guidance.

The CSTE Report presents a two-stage process for distinguishing public health practice from research activities. This process may improve uniformity of analysis for difficult cases when they are based on the full assessment of facts and applied across various levels of governmental public health authorities and by IRBs in the public and private sectors. Ultimately, better distinctions support the overriding objective to perform public health activities that respect and protect the legal rights and ethical interests of individual participants while improving or promoting the public's health.

Appendix A. Checklist for Making Distinctions Between Public Health Practice and Research²

Steps and Related Assumptions and Questions	Yes	No	Next Action	
			If Yes, then	If No, then
Step 1: Check Key Assumptions				
Assumption 1.A: Are you a governmental public health official, agent, agency, or entity at the federal, tribal, state, or local level (or an authorized partner conducting public health activities via contract or other agreement)?			Go to A 1.B.	Stop. This Checklist does not apply.
Assumption 1.B: Does your activity involve the acquisition, use, or disclosure of identifiable health data (i.e., individually-identifiable data that relate to a person's past, present, or future physical or mental health or condition or provision or payment of health care, or identifiable bodily tissues or biological samples)?			Go to Step 2.	Stop. This Checklist does not apply.
Step 2: Assess the Foundations of Public Health Practice				
Assumption 2.A: In general, does your activity involve the collection and analysis of identifiable health data for the purpose of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community?			Go to Q 2.A.	Go to Step 3.
Question 2.A: Is there a <i>specific</i> legal authorization (via statute, administrative regulation, or other law) and corresponding governmental duty to use identifiable health data for a public health purpose that underlie the activity?			Stop. This activity is practice.	Go to Q 2.B.
Question 2.B: Does your activity involve direct performance or oversight by a governmental public health authority (or its authorized partner) and accountability to the public for its performance?			Go to Q 2.C.	Go to Step 3.
Question 2.C: Does your activity legitimately involve persons who must participate in the activity or did not specifically volunteer to participate (i.e., they did not provide informed consent absent a waiver under the Common Rule?)			Stop. This activity is practice.	Go to Step 3.
Step 3: Assess the Foundations of Human Subjects Research				
Assumption 3.A: In general, does your activity involve the collection and analysis of identifiable health data for the purpose of generating knowledge that will benefit those beyond the community of persons who bear the risks of participation?			Go to Q 3.A.	The activity is likely practice. Go to Step 4.
Question 3.A: Does your activity involve living individuals?			Go to Q 3.B.	Stop. This is not human subjects research.
Question 3.B: Does your activity involve, in part, private information as defined in the Common Rule?			Go to Q 3.C.	Stop. This is not human subjects research.
Question 3.C: Does your activity involve persons who voluntarily participate via informed consent or the consent of their guardian, absent a waiver of informed consent under the Common Rule?			Go to Step 4.	Stop. This activity is practice.
Step 4: Consider Enhanced Guidance				
Question 4.A: General Legal Authority: Is there <i>general</i> legal authorization (via statute, administrative regulation, or other law) and a corresponding governmental duty supporting the use of identifiable health data for a legitimate public health purpose?			The activity is likely practice. Go to Q 4.B. 1-2	Go to Q 4.B. 1-2
Question 4.B.1: Specific Intent: Is there any intent underlying the activity to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity's participants?			The activity is likely research. Go to Q 4.C.	Go to Q 4.B.2.

Steps and Related Assumptions and Questions	Yes	No	Next Action	
			If Yes, then	If No, then
Question 4.B.2: <i>Specific Intent</i>: Is the primary intent underlying the activity to assure the conditions in which people can be healthy through public health efforts that are primarily aimed at preventing known or suspected injuries, diseases, or other conditions, or promoting the health of a particular community?			The activity is likely practice. Go to Q 4.C.	Go to Q 4.C.
Question 4.C: <i>Responsibility</i>: Is responsibility for the health, safety, or welfare of the participants vested or assigned to an identified person, like a principal investigator?			The activity is likely research. Go to Q 4.D 1-2	Go to Q 4.D.1.
Question 4.D.1: <i>Participant Benefits</i>: Is the activity designed to provide some benefit to the participants or their population?			The activity is likely practice. Go to Q 4.E.	Go to Q 4.D.2.
Question 4.D.2: <i>Participant Benefits</i>: Does the activity impose risks on participants to make the results generalizable beyond the participants themselves?			The activity is likely research. Go to Q 4.E.	Go to Q 4.E.
Question 4.E: <i>Experimentation</i>: Is the activity designed to introduce non-standard or experimental elements or methods to the research subjects or the analysis of their identifiable health data?			The activity is likely research. Go to Q 4.F.	Go to Q 4.F.
Question 4.F: <i>Subject Selection</i>: Are the participants in the activity selected randomly so that the results of the activity can be generalized to a larger population?			Stop. The activity is likely research.	Stop. The activity is likely practice.
Step 5: Conclusions				
<p>Conclusion 5.A: <i>Public Health Practice.</i> If your responses affirm that your activity (or some part thereof) is or is likely public health practice, the activity is not subject to the Common Rule. However, it must still be conducted consistent with principles of law and ethics designed to protect individuals and their privacy while furthering the public’s health. In addition, while the HIPAA Privacy Rule allows sharing of identifiable health data without written authorization for public health purposes, note that the Rule does not require data sharing. Authorization for disclosures from covered entities under the Rule derive from other public health laws or policies. For helpful guidance on the impact of the HIPAA Privacy Rule on public health practice, please see HIPAA Privacy Rule and Public Health: Guidance from CDC and DHHS, available at: http://www.cdc.gov/privacyrule/Guidance/Content.htm.</p>				
<p>Conclusion 5.B: <i>Human Subject Research.</i> If your responses affirm that your activity (or some part thereof) is or is likely human subjects research, follow the disclosure provisions related to human subjects research in the Privacy Rule. The Common Rule may also apply, subject to an exemption. Note, however, that the activity may be entitled to expedited review under the Common Rule. For additional guidance and a helpful flowchart, please see the Guidelines for the Conduct of Research published by the Office for Human Subjects Research at NIH, available at: http://www.nihtraining.com/ohrsite/guidelines/graybook.html.</p>				

References and Notes

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¹ This White Paper is based on the following sources: (1) Hodge, JG, et al., *Public Health Practice v. Research: A Report for Public Health Practitioners including Cases and Guidance for Making Distinctions*. Council of State and Territorial Epidemiologists 2004: Atlanta, GA: 1-61; (2) Hodge, JG, An enhanced approach to distinguishing public health practice and human subjects research. *Journal of Law, Medicine, and Ethics* 2005; 33:1: 125-141; and (3) Presentation by James G. Hodge, Jr., *Distinguishing Public Health Practice and Research*. Ethical Public Health Research: Developing a Practical Framework for Applying the Principles of Ethical Public Health Practice to Research Strategies, APHA Annual Meeting, Boston, MA (November 6, 2006).

² Reprinted from Hodge, JG, An enhanced approach to distinguishing public health practice and human subjects research. *Journal of Law, Medicine, and Ethics* 2005; 33:1: 125-141.