

Council of State and Territorial Epidemiologists

Leaders in Applied Public Health Epidemiology

Public Health Practice vs. Research

*A Report for Public Health Practitioners
Including Cases and Guidance for Making Distinctions*

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PREFACE

About this Document

This report has been prepared with funding and personnel support from the Council of State and Territorial Epidemiologists (CSTE) in Atlanta, Georgia. CSTE (<http://www.cste.org/>) is the nation's leading professional association of public health epidemiologists in states and territories. CSTE coordinates relationships among state and other health agencies and provides technical advice and assistance to the Centers for Disease Control and Prevention (CDC) and other public health partners.

The purpose of this report is to provide a practical guide principally for state and local public health officials, their staff, and their partners on the distinctions between public health practice and research for activities carried out by, or under the authority of, state or local health departments. The report may also be helpful to federal government public health officials and public and private sector institutional review board (IRB) members and their staff considering similar issues in reviewing or approving research proposals. Furthermore, law- and policy-makers, covered entities under the HIPAA Privacy Rule (e.g., health care providers, insurers, and data clearinghouses), academics, and others may utilize the report to improve their understanding of the distinctions between public health practice and research.

The report draws heavily from existing legal, public health, and medical scholarship. However, its tone is decidedly practical. Though these issues can be legally complex, the report attempts to explain the issues for the layperson. As such, it does not provide specific legal advice, and should not be relied upon for this purpose.

Many federal and state public health and other governmental entities, notably CDC, have provided input or otherwise contributed to this report. The findings and conclusions of this report, however, do not represent the official policy of CDC or any other governmental entity.

CSTE Advisory Committee

The expert members of an advisory committee provided their guidance, input, and comments as co-authors to this report. Their participation on the advisory committee does not connote their endorsement of the report itself.

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Abbreviations

Throughout this document, the following abbreviations are used to denote the accompanying names, terms, or other items:

| | |
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| ADS | Associate Director for Science |
| CDC | Centers for Disease Control and Prevention |
| CIO | Center/Institute/Office |
| CMS | Centers for Medicare and Medicaid Services |
| Common Rule | Federal Regulations on the Protection of Human Subjects |
| CRP | C-reactive Protein |
| CSTE | Council of State and Territorial Epidemiologists |
| DHHS | Department of Health and Human Services |
| DOE | Department of Energy |
| EPO | Epidemiology Program Office, CDC |
| ESRD | End Stage Renal Disease |
| FACE | Fatality Assessment and Control Evaluation |
| FDA | Food and Drug Administration |
| FOIA | Freedom of Information Act |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 |

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| HSR | Human Subjects Research |
| IHS | Indian Health Service |
| IOM | Institute of Medicine |
| IRB | Institutional Review Boards |
| MSPHPA | Model State Public Health Privacy Act |
| NBAC | National Bioethics Advisory Commission |
| NCCDPHP | National Center for Chronic Disease Prevention & Health Promotion |
| NCHSTP | National Center for HIV, STD, and TB Prevention, CDC |
| NCIPC | National Center for Injury Prevention and Control, CDC |
| NCID | National Center for Infectious Diseases, CDC |
| NIH | National Institutes of Health |
| NIOSH | National Institute for Occupational Safety and Health, CDC |
| NIP | National Immunization Program, CDC |
| OCR | Office for Civil Rights, DHHS |
| OD | Office of the Director, CDC |
| OGC | Office of the General Counsel, CDC |
| OHRP | Office for Human Research Protections |
| OSHA | Occupational Safety and Health Administration |
| PAB | Serum Prealbumin Test |
| PCM | Protein Calorie Malnutrition |
| PHI | Protected Health Information (defined in the HIPAA Privacy Rule) |
| PN | Parenteral Nutrition |
| PRAMS | Pregnancy Risk Assessment Monitoring System |
| Privacy Act | Federal Privacy Act of 1974 |
| Privacy Rule | Privacy and Security Regulations pursuant to HIPAA |
| PHPPPO | Public Health Practice Program Office, CDC |
| PHSA | Public Health Service Act |
| RBP | Retinol-binding Protein |
| RRV-TV | Tetavalent Rhesus-based Rotavirus Vaccine |
| SARS | Severe Acute Respiratory Syndrome |
| TBI | Traumatic Brain Injury |
| VAERS | Vaccine Adverse Event Reporting System |
| YRBSS | Youth Risk Behavior Surveillance System |

EXECUTIVE SUMMARY

What are the distinctions between public health practice and research? This perplexing question constantly arises in the planning and performance of public health activities. It is one of the most important questions in public health practice. Depending on whether a public health activity is classified as practice or research, a variety of federal and state laws may apply. These laws (including the federal Common Rule governing human subjects research and the HIPAA Privacy Act concerning health information privacy) and ethical responsibilities can require practitioners to reshape the nature of the activity, or limit the availability of needed identifiable health data.

In many ways, distinguishing public health practice and research can be easy. Practice is about protecting the public's health. It includes epidemiological investigations, surveillance, programmatic evaluations, and clinical care for the population. These activities are the essence of what public health people do in the United States. Underlying many of these activities is the collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community.

Public health authorities, however, also design and conduct research involving human subjects for the purpose of generating knowledge that often benefits those beyond the participating community who bear the risks of participation. Public health practitioners engage in research activities for reasons similar to any researcher's interests: they seek to explore hypotheses, advance current knowledge, and contribute to the welfare of persons beyond the study itself.

Participants in practice or research activities are protected from potential harms and abuses. In fact, public health authorities are legally and ethically responsible for protecting the interests of individual participants regardless of whether their activity is practice or research. These authorities (and not an IRB) are inherently capable and responsible for determining what activities constitute public health. That a public health authority classifies and performs practice and research activities is not itself a problem; the problem lies in how these distinctions are made.

Most everyone in public health knows how difficult it can be to distinguish between practice and research beyond the easiest of cases. Many approaches to distinguishing public health practice from research have been developed in governmental, private sector, and scholarly settings. Though helpful, these varying approaches collectively fail to clarify distinctions for easy or hard cases effectively. Clearer guidance is needed to help dispel unnecessary IRB review delays and obstacles for public health practice, avoid mistreatment of human subjects or privacy infringements, and eliminate burdens on IRBs and public health practitioners.

This report draws on many existing concepts and criteria, as well as cases where public health practitioners and IRBs have made practice and research distinctions, to develop enhanced guidelines. It reviews and attempts to refine existing conceptions of human subjects research and public health practice (see. Section 2.0). Legal frameworks for these respective activities are discussed in Section 3.0, including discussions of the constitutional and other legal principles

authorizing public health practice, provisions concerning human subjects research under the Common Rule, and key sections of the HIPAA Privacy Rule. A host of cases in which the question of public health practice versus research is prominently featured are presented in Section 4.0. These scenarios, based on real facts involving public health authorities, provide ready examples of the dilemmas and pitfalls of distinguishing between practice and research in the modern era.

Most importantly, this report goes well beyond merely assessing the problem. It proposes a workable, two-stage framework (including a proposed **Checklist** – see Section 5.5) for public health practitioners to use to distinguish their activities as practice or research. The first stage of the framework is built on some key assumptions and foundations of public health practice and research. Essential characteristics of *public health practice* include:

- 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
- Supported by principles of public health ethics that focus on populations while respecting the dignity and rights of individuals.

Some of the essential characteristics of *human subjects research* include:

- 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.

The second stage of the framework challenges 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. Rather, principles of enhanced guidance for distinguishing between practice and research in hard cases should focus on:

- **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. 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.*** Provided a public health authority accurately and honestly assesses its intent concerning its activity, this assessment can help classify the activity. The intent of research is to test a hypothesis and generalize findings or acquired knowledge beyond the activity's participants. Any intent to conduct research, whether primary or secondary, supports a finding that the activity, at least in part, is research. 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 and diseases, or promoting the health of a particular community.
- ***Responsibility.*** In the research context, the focal point of 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 upon government entities. Responsibility for participants' welfare in public health practice activities may arise because of legal and ethical duties assumed by public health practitioners as representatives of government.
- ***Participant Benefits.*** Public health practice should contribute to improving the health of participants and populations. In contrast, while human subjects may benefit from their participation in research, research is designed primarily to benefit the researcher and society through potential gains of scientific knowledge. Thus, if an activity offers no prospect of benefit to the participants, the activity should be classified as research.
- ***Experimentation.*** Research may involve introducing something non-standard or experimental to the research subjects or to the analysis of their identifiable health data. Public health practice is dominated by the use of standard, accepted, and proven interventions to address a known or suspected public health problem. Thus, if an activity involves introduction of non-standard or experimental procedures, the activity is likely to be research rather than public health practice.
- ***Subject Selection.*** Human subjects research is often designed to answer a hypothesis. To reduce the possibility of bias, researchers may select human subjects randomly so that the results can be generalized to a larger group. Practitioners of public health activities rarely choose participants. Participants are self-selected persons with, or at risk of, an affected disease or condition who can 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 randomly selects its subjects to eliminate bias, the activity is likely research rather than public health practice.

No set of principles or checklist may completely distinguish between public health research and practice. There are always difficult examples that do not fit neatly into either category. Some broad activities may involve both public health practice and human subjects research. However, these principles may help resolve a majority of cases, provide consistency in decision-making on a national basis, and help resolve an ongoing question that significantly impacts public health.

1.0 INTRODUCTION

Federal, tribal, state, and local public health agencies engage in a wide array of activities in the interest of protecting the public's health, the majority of which are public health practice activities. Among their many responsibilities are public health functions that involve the collection, use, and analysis of identifiable health data from health care providers, insurers, other agencies, or individuals. These activities include surveillance (e.g., reporting requirements, disease registries, sentinel networks), epidemiological investigations (e.g., disease outbreak investigations), and evaluation and monitoring activities (e.g., public health program development and analysis, oversight functions). The performance of these essential public health activities at the state and local levels is usually legally authorized through statutes or regulations.

As these types of activities involve the acquisition and subsequent analysis of individual health information, they may resemble human subjects research. "Human subjects research" is defined in 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). In some cases, public health agencies are conducting research. For example, in response to a suspected population-based health problem, a public health agency may hypothesize, design, and conduct a double-blinded, placebo-controlled study to assess the efficacy of a new vaccine or medication among a randomly-selected group of persons within the affected population. The study's hypothesis, methods, implementation, and underlying intent may support a conclusion that the activity is research. As a result, the public health agency must adhere to a series of protections and procedures pursuant to the Common Rule. These protections (including individual informed consent absent a waiver) and procedures (including review by an IRB) are designed to protect the health and safety of human subjects.

In other cases, public health practices may share similar qualities, but are not research. For example, a public health agency facing a suspected emerging public health problem may use surveillance to address the problem. With legal authority stemming from existing public health statutes, the agency may establish a surveillance program to gather and monitor various cases of persons with the condition. The assessment of these data over time allows the agency to gauge the extent of the problem and tailor effective responses to protect the public's health. The implementation of this program is justified as public health practice, not research. A range of additional examples of public health activities that constitute practice or research are provided in Section 4.0, **Modern Cases on Public Health Practice and Research**.

Between these examples are a host of public health activities that are not neatly characterized as practice or research.² Classifying these public health activities as practice or research is not easy.³ Some suggest that a lack of clarification as to what constitutes legitimate public health activities contributes to significant confusion.⁴ Others think that the definition and concept of human subjects research are ill-suited for application to public health activities.⁵ Still others suggest (1) the need for national reform to include "some form of explicit, systematic review" for surveillance or other public health practices through ethical bodies external to public health,⁶ and as a result, (2) the exemption of public health agencies from the Common Rule

altogether.⁷ Consideration of each of these divergent proposals may help, but for now the central question remains: *how are public health practice and research distinct?*

For decades, public health agencies and the private sector have debated the distinctions between public health practice and research. The Department of Health and Human Services (DHHS),⁸ Centers for Disease Control and Prevention (CDC),⁹ National Institutes of Health (NIH),¹⁰ Department of Energy (DOE),¹¹ National Bioethics Advisory Committee (NBAC),¹² Institute of Medicine (IOM),¹³ state and local law- and policy-makers, and public health officials, have all noted the importance of drawing these distinctions. The major reasons why clearer distinctions are needed include:

- Public health practice activities specifically authorized under state or local laws cannot be delegated to IRBs for subsequent approval. Existing oversight mechanisms that hold public health officials accountable for their ethical and legal conduct are robust, transparent, and open to the public. They are, however, very different from oversight mechanisms for human subjects research;
- Federal, state, and local laws and ethical principles governing human subjects research (e.g., the federal Common Rule) require sometimes extensive and burdensome approval through IRBs whenever government conducts or funds research. Additional protections of research subjects apply. Misclassification of public health practice activities as research may require public health practitioners to unnecessarily seek approval for practice functions through these processes. This can result in public health activities being delayed, being conducted less efficiently, or costing more;
- The HIPAA Privacy Rule (and other privacy laws) have varying 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 or research in nature. In general, it is more difficult for public health authorities to acquire identifiable health data under the Privacy Rule if their activity is defined as research. Misclassifications can stymie the legitimate flow of health data to public health agencies;
- Legal authorization and funding sources for public health activities are often tied to whether the activity is deemed research or practice. Depending on the designation, some public health activities may be thwarted because of lack of legal authorization or appropriate funds; and
- Widespread variations in the understanding of the legal basis used to distinguish public health practice from research have led to considerable inconsistencies in the ways that some public health programs and functions are carried out. The same functions may be classified as practice and research in different jurisdictions. Incongruities have led to confusion among IRBs and public health agencies, inefficient and duplicative reviews, and infringements on information sharing. When public health agencies seek to contract with non-public health entities (e.g., universities, laboratories) to conduct specific public health functions, collaboration is impeded in some cases.

Despite its critical importance, there is no national consensus on the ways, factors, or bases for making distinctions between public health practice and research. Little guidance is provided in the federal Common Rule, the HIPAA Privacy Rule, or other laws that require public health officials and others to make these distinctions. Numerous scholars and public health practitioners have provided theoretical and practical accounts of the difficulties in making these distinctions.

The Office for Human Research Protections (OHRP), CDC, NBAC,¹⁴ and others offer an array of bases for making distinctions, including an assessment of the intent of the proposed activity, an examination of the risks to or burdens on its participants, and a review of the underlying legal authority. These bases are helpful for guiding some decisions, but lack coherence, coordination, and consensus among the public health practice and research communities and IRBs. “What is urgently needed,” suggest Paul Amoroso and John Middaugh, “is a set of guidelines that clearly differentiates public health practice from research.”¹⁵

This report systematically discusses the distinctions between public health practice and research through an examination of existing laws, scholarly and applied approaches, and realistic case examples. Section 2.0, **Distinguishing Public Health Practice and Research**, begins with modern definitions and conceptions of “human subjects research” and “public health practice.” Similarities between these definitions and their counterparts in the clinical care setting are drawn. Existing processes for making distinctions between public health practice and research through IRBs or public health practitioners are discussed to demonstrate how these choices are made, and illustrate the ways that these processes lead to divergent findings. Existing models and guidance for making distinctions at the governmental (principally CDC), private sector, and academic levels are briefly compared and analyzed. Several reasons justifying the need for clarity in making these distinctions include the (1) presence of differing and divergent standards, (2) limitations of IRBs in public health settings, (3) inconsistent interpretations, and (4) the existence of crossover cases (cases where data are collected for one purpose (e.g., public health surveillance) and subsequently used for another (e.g., health services research)).

Legal bases supporting distinctions between public health practice and research are examined in Section 3.0, **Legal Frameworks Underlying Distinctions**. Public health practice, unlike research, is supported by a constitutional, statutory, and regulatory legal environment that empowers public health officials, authorizes the performance of general and specific public health functions, and provides for oversight and accountability for public health activities. Essential legal and ethical principles for the funding and performance of human subjects research are largely reflected in the Common Rule. Additional state and local laws supplement these requirements. Also relevant are health information privacy protections at the national, state, and local levels. New federal privacy regulations pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provide varying standards for disclosures based on public health practice versus research classifications without attempting to draw clear distinctions.

Modern examples in which the practice versus research distinction was made are presented in Section 4.0, **Modern Cases on Public Health Practice and Research**. These cases provide helpful guidance and some precedence for public health practitioners, IRB members, and

others reviewing specific public health activities. The examples are selected from actual cases involving federal, state, or local public health authorities seeking classification within CDC, other public health agencies, or their IRBs. Analyses following each case provide some specific observations, or key lessons.

Section 5.0, **Guiding Principles**, gleans from the review and analysis of existing approaches, legal frameworks, and cases a series of defining principles to distinguish public health practice and research. Foundational premises of public health practice and research are presented in Figure 1 to help unravel the distinctions, and resolve less complicated cases. Some commonly-used criteria for making distinctions are rejected because they do not actually help separate research and practice. A set of enhanced guidelines follows. These guidelines focus on general legal authority, specific intent, responsibility, , , participant benefits, experimentation, and subject selection. A draft Checklist to help make these decisions is also provided.

2.0 DISTINGUISHING PUBLIC HEALTH PRACTICE AND RESEARCH

Distinguishing public health practice and research can be difficult because, in many ways, they are alike:¹⁶ (1) they may entail the collection and assessment of individually-identifiable health information about living individuals; (2) they may involve actual or potential risks to participants (e.g., privacy violations, discrimination, injuries, coercion, anxiety, or other negative consequences); and (3) they may be justified as laudable, communal activities that further the public good. Society has long accepted the need to acquire identifiable health data (with and without individual consent) for public health purposes like surveillance or epidemiologic investigations. Many individuals also support the acquisition of their own (and others') health data to further health research.

Despite similarities, public health practice is not synonymous with health 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 current understanding within public health sciences. Research involves testing new, unproven treatments or strategies that are not known to be efficacious. As such, research entails the design of a study to enable rigorous monitoring of potential adverse, unexpected consequences to selected human subjects in the application of new, often unproven interventions.

Identifiable health data may be collected for public health practice without informed consent and outside of federal and state human subjects research provisions because (1) traditionally, acquisition of these data has been viewed as a quintessential function of government to achieve public health goals; (2) the public has authorized the activity through laws enacted through the political process (e.g., disease reporting requirements pursuant to state or local laws or regulations); (3) administrative protections of individual interests in public health may be built into authorizing laws and regulations; and (4) public health officials are accountable to the public for their activities.

Identifiable data for research, in contrast, are acquired under a different social construction. Research is not always tied to grants of legislative authority and could operate unchecked absent legal protections. Researchers, unlike public health practitioners, must adhere to regulations including advance written and informed consent of subjects (and sometimes their communities) unless modified or waived in accordance with the Common Rule. These mechanisms are designed to protect the safety, welfare, dignity, and privacy of anyone who volunteers to participate in a research study. Similar protections of individual interests may underlie public health practice, of course, but they stem from different legal requirements.

The sections below (1) provide modern definitions for human subjects research, public health research, and public health practice, (2) summarize prominent practical and scholarly models for distinguishing public health practice from research, and (3) provide reasons for a clarified and unified approach to distinguishing public health practice and research.

2.1 Defining Human Subjects Research

The current, well-accepted definitions of research and human subjects are set forth in the Federal Policy for the Protection of Human Subjects (the “Common Rule”), which is codified under DHHS regulations at 45 C.F.R., part 46, subpart A. Research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”¹⁷ The same definition of research is also featured in the HIPAA Privacy Rule (discussed below in Section 3.4). Human subject is defined as a living individual about whom an investigator [conducting research] obtains (1) data through intervention or interaction with the individual; or (2) individually-identifiable health information.

Human subjects research is not limited to any particular actor within a specific setting. A person engaged in human subjects research may include a public or private sector individual, institution, agency, or corporation, including a public health agency. Accordingly, this definition has also been used by CDC to define public health research.¹⁸ CDC’s conception of public health research focuses on (1) the degree to which information gathering is systematic; (2) the design of the activity; and (3) the generalizable nature of knowledge generated by the activity.

The National Bioethics Advisory Commission (NBAC) and others, however, have questioned whether the common definition of research can or should be applied to public health.¹⁹ Many public health practice activities, such as disease surveillance, are routinely and systematically carried out, but are not considered research. Furthermore, the term “generalizable” is an imprecise conceptual distinction for public health activities that, by their nature, focus on populations rather than individuals. As an alternative, NBAC suggests basing a definition for public health research on the locus of benefits.²⁰ If the benefits from the activity are focused on the members of the participating population through improvements in the public’s health, the activity is public health practice. If the participants in the activity are not the intended primary beneficiaries, then the activity may be classified as research.

A definition of public health research involving human subjects under this view might 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.*

2.2 Defining Public Health Practice

Public health practice is more difficult to define than research, in part, because public health is conceptually broad. Public health, suggests the Institute of Medicine (IOM), is what we do collectively to assure the conditions for people to be healthy.²¹ This conception of public health extends to societal activities well beyond those performed by governmental public health authorities. Protecting the public’s health, however, is a quintessential function of government (see Section 3.1). Accordingly, for the purposes of distinguishing public health practice and research, the focus is on those activities of federal, state, tribal, and local public health agencies, and their authorized partners.

Even when confined to government, public health practice is broad in scope. It can include direct provision of clinical care by licensed health professionals. This care typically

requires informed consent, just as clinical care in any other setting. In fact, most (but not all) public health practices feature the voluntary cooperation of individuals. This includes, for example, performing contact tracing for tuberculosis or other communicable diseases, obtaining food histories in the face of a common source outbreak, or administering testing or screening programs. Just as in the private medical sector, evaluation activities are also conducted by public health practitioners to assure quality of care and program effectiveness.

There are several approaches for refining the definition of public health practice by, or under the authority of state or local health departments. NBAC and CDC view public health practice as those governmental activities performed to “prevent or control disease and improve health or to improve a public health program or service in a specific population.”²² As stated, however, this definition could include research. Others define public health practice categorically, listing various types of traditionally accepted practice activities by government.²³

Another approach examines the statutory or regulatory authorization for a public health agency (or its contracted partners) to conduct an activity. For example, the collection of identifiable data by state or local public health authorities for disease monitoring and reporting is typically based on underlying statutory authority to acquire data for this communal purpose without informed consent (see Section 3.1).²⁴ As Snider and Stroup at CDC suggest, these activities may be viewed as public health practice instead of research largely because law- and policy-makers “recognize that routine surveillance is not research.”²⁵ Arguably, collective individual consent is obtained through the public process of enacting statutes or promulgating regulations that authorize these collections.

However, the existence of statutory authorization is not completely determinative of whether the activity is practice or research. Public health authorities may be legally authorized to conduct research activities in conjunction with or in addition to practice activities. In these cases, the authorities must adhere to research principles and ethics in conducting this activity.

Perhaps a definition for public health practice involving identifiable health data should build on the proposed definition for public health research. Thus, for purposes of data acquisition, use, and disclosure, public health practice may be defined 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.*

2.3 Comparative Analysis of Clinical Care and Health Research

Distinguishing research from practice is also difficult within the context of the clinical health care setting. Typical examples where complications arise include whether evaluation of quality improvement efforts,²⁶ untested pharmaceutical protocols,²⁷ or innovative surgical techniques²⁸ constitute research. What distinguishes research from practice in the clinical setting shares similarities with the public health setting. In either context, the definition of human subjects research is the same. Clinical practice is commonly thought to include “interventions that are designed solely to enhance the well-being of an individual patient or client and that have reasonable expectation of success.”²⁹ Additional distinguishing principles may include: (1)

whether the activity is intended to benefit the individual receiving the care (clinical practice) or the larger public (research);³⁰ (2) whether the methods used to decide the type of care provided are randomized (research) or based on individual needs (clinical care);³¹ and (3) whether additional burdens and risks are placed on participating individuals that are unnecessary for treatment but make the results more generalizable.³²

The analogy to public health practice is that the “patient” in public health is the community.³³ Under this approach, those activities performed to improve the health of the community are deemed public health practice. Though a helpful comparison, the analogy falls short of distinguishing public health practice and research where both activities may be motivated by the need to improve the population's health and may involve the practice of medicine or allied health professions under the standards of professional practice.

2.4 Authority for Making Determinations Through IRBs and Public Health Practitioners

Federal, state, and local laws require IRB review and approval for non-exempt government-funded research involving human subjects. The Common Rule vests authority within IRBs to approve, disapprove, or require modifications of all federally-funded human subjects research (for more information on the Common Rule and other research protections, see Sections 3.2, 3.3 below).³⁴ Many institutions apply the Common Rule principles to all human subjects research regardless of funding sources pursuant to multi-project or federal-wide assurances. A few state and local laws authorize state or local IRBs to review research involving human subjects, including research conducted or funded by state or local public health agencies. In addition, most private institutions that conduct research also require IRB review of human subjects research even if the research does not receive governmental funding.

The legal requirements for IRB review of human subjects research do not address public health practice. If an activity is deemed non-research, IRB review and other human subject protections are not required. This is not to say that persons involved in public health practice are unprotected or at significant risk, nor does it imply that public health investigators are not obliged to act ethically. The responsibility to protect human participants in public health practice is addressed through federal, state, and local administrative and regulatory oversight and protections (see Section 3.3).³⁵

At CDC and within many state and local public health agencies, the initial determination of whether an activity is or is not research is typically made outside of the IRB. CDC's “Human Subjects Activity” program within its Office of Science, Policy, and Technology Transfer (OSPTT) delegates to CDC Centers, Institutes and Offices (CIOs) the primary authority to determine whether a CDC funded activity is public health research or public health practice.³⁶ When questions arise, CIO Associate Directors for Science (ADS) are asked to make a final determination. Although CDC's IRB may question the relevance of any proposal brought before it, it typically only reviews those proposals that are considered research pursuant to this pre-existing assessment. However, in some state or local public health agencies, if there is uncertainty over whether an activity is research or practice, the IRB may be asked to make the determination.

2.5 Existing Models, Processes, and Guidance

An array of existing guidance exists to assist public health practitioners or IRB members at the state, local, and institutional levels decide whether a proposed activity is public health practice or research. This guidance is discussed below in three major categories: governmental, private sector, and scholarship.

2.5.1 Governmental. Virtually every state health department (and some larger local health agencies) has designated their own internal IRB, or has primary access to a state IRB. Some of these agencies and their IRBs have developed or are working toward the creation of guidelines for distinguishing public health practice and research. Others do not have any written policy, preferring to make distinctions on a case-by-case basis. Most defer to CDC's guidelines on the distinctions between public health practice and research.³⁷

In 1999, CDC developed a set of guidelines to distinguish between public health research and non-research (i.e., public health practice activities) for CDC staff as well as local and state health departments that work with CDC on public health programs. These guidelines were reviewed by OHRP. CDC considered and rejected several criteria (e.g., statistical analysis, publication, hypothesis testing, subject selection, methodological design, and statutory authority) as fully capable of distinguishing public health practice and research. These characteristics may support a classification of practice or research, but are not sufficient alone to sustain the classification.

Instead, CDC focuses on the element of "design" within the Common Rule definition of human subjects research. It suggests that the principle distinction between research and practice is best made by examining the *intent* of the project on a case-by-case basis. The intent of public health research is to "generate or contribute to generalizable knowledge."³⁸ "Generalizable knowledge" is defined by CDC as new information that has relevance beyond the study population or program, information that is added to scientific literature, or knowledge that is systematically collected with methods that reduce bias (such as randomization and controls). Additional factors that may contribute to classifying an activity as public health research include (1) whether the intended benefits of the project always extend beyond the study participants; and (2) whether the data collected exceed requirements for care of the study participants.

In contrast, the intent of public health practice according to CDC is to "prevent or control disease or injury and improve health, or improve a public health program or service."³⁹ Additional factors CDC uses to determine whether an activity is public health practice include: (1) if the intended benefits of the project are primarily for participants or their community; (2) if data collected are needed to assess or improve a public health program or service, the health of the participants, or the health of the participants' community; (3) whether the knowledge generated extends beyond the scope of the activity; and (4) whether the project activities are non-experimental. As CDC explains, a practice activity may produce generalizable knowledge provided this was not part of the primary intent from the outset.⁴⁰ If the primary intent changes, what is initially deemed public health practice can become public health research.

According to James Buehler, MD, former ADS, CDC National Center for HIV, STD, and TB Prevention (NCHSTP), some of the more difficult determinations concerning public health practice and research surround instances where CDC identified an unmet public health need for which it was willing to provide funding to a limited number of states to address the need. CDC's primary objective may be to assist participating state health departments to provide more effective prevention or surveillance services. A secondary objective is to gain knowledge that would help inform public health practice in other states. The primary objective typically sustained a "non-research" determination within CDC even though the secondary objective would likely result in the activity being viewed as "research" if proposed as the primary intent. Thus depending on how the intent of the project was characterized and prioritized, the activity would largely be approved as practice, or be forwarded to the IRB for review as research. Under either scenario, the project activities and potential risks to participants, however, were largely the same.

Buehler's analysis reveals one of the weaknesses of CDC's intent-driven criteria: the same program could initially be classified as practice or research depending on the prioritization of its objectives. To avoid more complicated and time-consuming IRB review, public health practitioners have an incentive under CDC's approach to characterize an activity as intended to primarily benefit the public's health. This same incentive, as discussed in Section 3.4, exists in other legal contexts as well. "Ultimately," as Buehler suggests, "this is an unsatisfying way to address the ethical questions inherent in public health research or practice."⁴¹

2.5.2 Private Sector. Institutions that fund or conduct health research have their own IRBs that may be asked to determine whether a proposal involves research or practice. These IRBs utilize different models for distinguishing public health research from practice. Some list conceptual criteria as a basis for making distinctions. Others simply list the types of activities generally considered to be public health or clinical practice.

Many institutional IRBs use criteria similar to CDC's to make these distinctions for clinical and public health activities. For example, the Committee on Human Research at Johns Hopkins University Bloomberg School of Public Health asks the following three questions to facilitate its determination:

- (1) Is the primary intent of the activity to generate new information that will be of benefit to those other than the population served or to improve public health practice?
- (2) Will participants be subjected to additional risks or burdens beyond usual practice to make the results generalizable?
- (3) Will the information that is generated from the activity contribute to peer-reviewed, scientific literature?⁴²

Johns Hopkins' first guideline aligns with CDC's guidance; the second guideline incorporates a scholarly conception of the additional risks or burdens developed out of an analysis of quality improvement initiatives (discussed below).⁴³ The third guideline is

controversial because many, including CDC, explicitly reject the intent to publish the results of an activity as a meaningful criterion for addressing at the outset whether an activity is research or practice.⁴⁴

In contrast to Johns Hopkins' IRB policies, the University of Pennsylvania's IRB Standard Operating Policies do not list criteria to determine whether an activity is research or practice. They merely state that, "activities such as quality assurance or quality control, program and fiscal audits, and certain disease monitoring as prescribed by the Public Health Department generally do not qualify as research."⁴⁵

2.5.3 Scholarship. Significant scholarship has produced varying criteria to distinguish research from practice in the public health and clinical health care settings. John Middaugh proposes several criteria to distinguish public health practice from clinical research. According to Middaugh, public health practice has the following attributes that research lacks: (1) subject (participant) selection in public health practice is usually non-random, (2) public health practice focuses on populations rather than individuals, (3) public health program evaluations are conducted for quality assurance or to develop programs, (4) public health practice is statutorily-authorized, and (5) only state and local agencies are authorized to receive funds to conduct public health practice.

Commentators Casarett, Karlawish, and Sugarman propose two criteria for determining whether a clinical quality improvement initiative constitutes research. A quality-improvement initiative should be considered research if "(1) the majority of patients involved are not expected to benefit directly from the knowledge to be gained or (2) additional risks or burdens imposed make the results generalizable."⁴⁶ Although these criteria refer specifically to quality improvement efforts in clinical settings, they have been applied more broadly by IRBs (such as Johns Hopkins' IRB) to distinguish research from public health practice.

2.6 Assessing the Need for Clarity

With such conflicting views on the distinctions between public health practice and research, there is a strong need to clarify existing standards and definitions. Distinguishing between practice and research, especially in the public health setting, is no mere exercise in semantics. Many reasons strongly support additional clarification:

- The existence of differing standards contributes to varying findings. What is classified as practice in one setting is deemed research in another. Even the very same activity can be simultaneously classified by different persons as practice, research, or both (see Section 4.0). As a result, public health practitioners at every level of government find it difficult to properly assess their own activities;
- Public health practice routinely involves collection of identifiable information without individual consent under state public health powers authorizing disease reporting (e.g., infectious diseases and cancer, injury, immunization, and birth defects registries). Concerning these activities, it is impracticable to assess the conditions by which the

activity will be performed through a research model, or to determine the form of individual consent through IRB-driven processes.

- Public health practice activities that are misclassified as research require public health authorities to engage in time-consuming reviews through governmental or private sector IRBs. In some cases, the mere assessment by an IRB, even when expedited, may thwart an activity to the detriment of the public's health. In other cases, the IRB may require additional protections for persons viewed as human research subjects that defeat public health objectives in principle or design, or for lack of funding;
- Conversely, public health research that is misclassified as practice may allow governmental health authorities to collect and analyze sensitive health data in possible violation of health information privacy interests, or interact with human subjects without complete adherence to research protections to the detriment of the individual participants;
- Existing human subjects research and health information privacy protections support the acquisition and use of identifiable health data for public health practice and research, but impose greater restrictions on researchers in the interests of protecting human subjects. A natural consequence is the creation of incentives for public health practitioners to characterize their activities as practice to avoid potential negative consequences through IRB review;
- Conversely, lacking clearer criteria, a national trend among public health practitioners is to err on the safe side. They submit many activities for IRB review as potentially research (often seeking expedited review to the contrary) to avoid the specter and controversy of engaging in unlawful and unethical human subjects research. These additional inquires further burden IRBs that are already overwhelmed with their responsibilities to protect human research subjects;⁴⁷ and
- Even when a public health activity is clearly and legitimately classified as practice, the activity may change or evolve into research. In these cases where the activity crosses over between practice and research, nearly everyone agrees that IRB review is needed prior to the research activity commencing. Precisely when does practice become research?⁴⁸ Existing criteria do not neatly answer this difficult issue.

3.0 LEGAL FRAMEWORKS UNDERLYING DISTINCTIONS

3.1 Constitutional and Other Legal Principles Concerning Public Health

The provision of public health services in the United States has its basis in the U.S. Constitution.⁴⁹ Though the Constitution does not create an affirmative duty for government to act in the interests of communal health,⁵⁰ federal, tribal, state, and local governments are vested with the ability to regulate, protect, and promote the public's health. The federal government draws upon its enumerated powers under the Constitution, specifically the powers to tax, spend, and regulate interstate commerce, to promote the public's health and safety through national public health laws executed by a host of federal public health and health care agencies.

Primary responsibility for protecting the public's health, however, is held by the states (and local governments via delegated state authority). The Tenth Amendment reserves to the states extensive and broad powers. Commonly known as the police powers,⁵¹ they represent the inherent authority of the state to enact laws and promulgate regulations to protect, preserve, and promote the health, safety, morals, and general welfare of the people.⁵² As these public health powers are reserved to the states, federal public health agencies do not have similarly broad authority to act in the interests of the public's health.

Police powers are exceedingly broad in scope; they justify virtually any exercise of state or local government to preserve, protect, or promote the public's health that does not infringe constitutionally protected individual or community rights.⁵³ The breadth of public health is reflected in state statutory definitions of public health, as well as state and local powers and duties. State legislatures and policymakers define public health (or public health duties or powers) in many ways.⁵⁴ States like New Jersey adopt a traditional view of public health: "Promoting the public health of the community includes preventing disease or controlling the communication of disease within the community."⁵⁵ States like Kentucky conceptualize public health as the sum of multiple responsibilities (e.g., detection, prevention, and control of communicable, chronic and occupational diseases; control of vectors of disease; safe handling of food products; control of narcotics, barbiturates, and other drugs; sanitation of public and semipublic areas; promotion of nutrition in the population).⁵⁶ Other states, like Michigan, statutorily define public health by listing duties for its public health agency: "The department shall continually and diligently endeavor to prevent disease, prolong life, and promote the public health through organized programs," including prevention and control of environmental health hazards, diseases, and health problems of vulnerable populations.⁵⁷

The comprehensive MODEL STATE PUBLIC HEALTH ACT recently completed through the Turning Point Statutory Modernization Collaborative builds a definition of public health around the IOM's conception (see Section 2.2). "Public health" in the Turning Point Act means:

assuring the conditions in which the population can be healthy. This includes population-based or individual efforts primarily aimed at the prevention of injury, disease, or premature mortality, or the promotion of health in the community, such as assessing the health needs and status of the community through public

health surveillance and epidemiological research, developing public health policy, and responding to public health needs and emergencies.

Corresponding to these conceptions of public health are an array of powers and duties authorized under state and local laws. Among other functions, public health laws authorize vaccination,⁵⁸ isolation and quarantine,⁵⁹ inspection of commercial and residential premises,⁶⁰ abatement of public health nuisances,⁶¹ regulation of air and surface water contaminants,⁶² standards for pure food⁶³ and drinking water,⁶⁴ fluoridation of municipal water supplies,⁶⁵ and licensure of health care facilities and workers.⁶⁶ Each of these and other public health functions are supported by state and local efforts to gather identifiable health data for surveillance, investigations, or evaluations through modern scientific methods.⁶⁷

3.2 *The Federal Common Rule on Human Subjects Research*

The Federal Policy for the Protection of Human Subjects (i.e., the Common Rule) is codified in a series of federal regulations that apply to virtually all research involving human subjects and federal funding. For most activities determined to be human subjects research (as defined in Section 2.1 above), the Common Rule requires a prospective review by an IRB or medical ethics board in compliance with various specifications.⁶⁸ IRBs review research proposals to assess the extent to which research subjects are protected during the course and aftermath of the research activities. Among other things, IRBs must assess whether:⁶⁹

- There is appropriate individual or guardian consent for data collection;⁷⁰
- The privacy of identifiable information is protected;⁷¹
- There exists a sound, safe, and effective research design;⁷²
- Research subjects are equitably selected;⁷³
- Appropriate data safety monitoring is provided;⁷⁴ and
- Vulnerable populations (e.g., children, prisoners, mentally-disabled) are protected.⁷⁵

The Common Rule requirements for IRB review are only triggered when an institution seeks federal funding to engage in *human subjects* research or when it decides to use the Common Rule in reviewing all its human subjects research pursuant to a multi-project or federal-wide assurance. Five key questions underlie this determination: (1) is the activity research?;⁷⁶ (2) if so, does the research involve human subjects?; (3) if so, is the research supported in whole or part by federal funds?; (4) if so, is the research subject to exemption?; and (5) if not exempt, is it entitled to expedited review by an IRB?

Is the activity research? Whether an activity is research or not is the basic question for which this report seeks to provide guidance. Though the Common Rule defines research (see Section 2.1), it does not provide much guidance on how to determine if an activity is research or non-research (i.e. a public health activity or clinical practice). Of course, IRB review is unnecessary for non-research activities. As well, an IRB does not have to oversee the determination of whether an activity is or is not research.⁷⁷ The Common Rule states “Department or Agency heads retain final judgment as to whether a particular activity is covered by this policy.”⁷⁸

Specifically, the acquisition of identifiable health data by public health authorities for public health practice is not subject to IRB review. In its guidance documents, OHRP clarifies that identifiable private information or specimens may be acquired and used without IRB review if they are released, “to a State or Local Health Department or its agent for legitimate *public health purposes* within the recognized authority of that Department. However, utilization of such information or specimens by Department investigators for *research purposes* would constitute engagement in research, and would require an Assurance from the Department.”⁷⁹ If the activity is research or possesses significant features of research (described in Section 5.0) the inquiry proceeds to the next question.

Does the research involve human subjects? An institution is engaged in human subjects research (as opposed to research that does not involve human subjects) when the researcher obtains (1) data through intervention or interaction with a living individual; or (2) individually-identifiable private information about a living individual. “Individually-identifiable” means the identity of the subject about to whom the private information pertains is or may readily be ascertained by the investigator or associated with the information).⁸⁰ These criteria do not themselves define an activity as research; they merely identify whether it is *human subjects* research.

If the research does not involve human subjects, the Common Rule does not apply. In clear cases, the determination does not need to be made by an IRB. In ambiguous cases, the responsibility for determining whether human subjects are involved may rest with the IRB.⁸¹ A federal agency may assign this responsibility to an IRB. However, federal human subject regulations do not require this assignment. Only if the research involves human subjects does the inquiry proceed.

Is the research funded by a federal source? If human subjects research receives funding or support from any federal agency (that has signed on to the Common Rule – most federal agencies have) or is performed by a federal agency, the Common Rule applies. If human subjects research receives no federal funding or support, the Common Rule does not apply (although an institution may choose to apply its principles (see Section 2.4)). As well, similar human subject protections may still be required by other public or private sector funding organizations.

Is the research subject to exemption? If an activity meets all of the first three criteria, it is covered by the Common Rule, unless specifically exempted. Unlike with the prior questions, a determination of exemption may not be made by those conducting the activity. Rather it should be submitted to the IRB, or some authority other than the investigator. The Common Rule exempts:

1. Research on common educational practices in educational settings;⁸²
2. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, or observations of public behavior that is not recorded in an identifiable format and could not place subjects at risk of criminal or civil liability, or damage the subjects reputation, employability, or financial standing;⁸³

3. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, or observations of public behavior involving elected or appointed public officials or candidates, or if the information is required under Federal statute to be kept confidential throughout the research and thereafter;⁸⁴
4. Research involving existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects;⁸⁵
5. Research conducted by agency/department heads to evaluate public benefit or service programs; procedures for obtaining benefits or services; possible changes or alternatives to the programs or procedures; possible changes in payment levels; and methods for services under these programs. The research must be conducted pursuant to specific federal statutory authority;⁸⁶ and
6. Taste and food quality examinations and consumer acceptance studies.⁸⁷

If the research activity falls clearly into one of the above exemptions, the Common Rule typically does not apply. However, applying these exemption criteria can be problematic. NBAC recommends that an exemption should not be based merely on a review of the research methods, but also on the premise that there are few, if any, risks to participants and that they have a right to refuse to participate.⁸⁸

Is the research entitled to expedited review? Even when it is determined that an activity is non-exempt human subjects research, such research may be entitled to expedited IRB review if it involves minimal risks to participants and only involves activities among a list of categories provided by DHHS.⁸⁹ Expedited review may only be sought through the IRB. Unlike exempted research, the Common Rule still applies. Research categories that may be subject to expedited review as described by OHRP,⁹⁰ include:

1. Clinical studies of new applications of drugs and medical devices when the drug or device is already being marketed;
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture;
3. Prospective collection of biological specimens for research purposes by noninvasive means;
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing;
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis);
6. Collection of data from voice, video, digital, or image recordings made for research purposes;
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research

employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;

8. Continuing review of certain research previously approved by the convened IRB;
9. Continuing review of research (unless conducted under an investigational new drug application or investigational device exemption) where categories two (2) through eight (8) do not apply but the IRB determines and documents that the research involves no greater than minimal risk and no additional risks have been identified.

Several of these categories may be directly relevant to research activities conducted by public health authorities, particularly 1-5, and 7. Each of the categories may enhance the ability of public health practitioners to more efficiently gain IRB approval for a range of research activities that may be commonly performed by public health authorities.

3.3 State/Local Human Subject Protections

State and local public health laws and regulations may supplement the Common Rule, providing additional protections for human subjects in public health activities. Professor Scott Burris has recently analyzed state laws that protect human subjects.⁹¹ Three states, New York, California, and Virginia, have passed laws that specifically govern human subjects research. Other states' protections of human subjects in research are embedded within their public health regulations, authorizing statutes, and case law. Professor Burris summarized his findings⁹² regarding state protections for human subjects in public health practice as follows:

- *Appropriate consent for data collection.* State law explicitly authorizes health data collection for public health purposes through a form of collective consent and provides formal notice of the types of data to be collected and the purposes for their collection. These laws virtually never require individual informed consent.
- *Protection of private information in collected data.* Most states protect the privacy of data collected by public health agencies, though the level of protection and procedures for further use (if any) often vary according to the type of data (e.g., cancer registry data may be treated differently than HIV data).
- *Bona fide, safe, and effective research design.* A few states have provisions that explicitly address research design, but not at the level of specificity of the Common Rule.
- *Equitable Selection of Subjects.* Many states have embodied policies of fair health distribution in special programs designed to promote minorities' or women's health. Federal and state laws broadly prohibit discrimination in the provision of government benefits and services. (These themes are also reflected in the TURNING POINT MODEL STATE PUBLIC HEALTH ACT).
- *Appropriate Data Safety Monitoring.* Depending upon the nature of the risk, harms to subjects of public health practice may be identified through the practice itself or

other methods of government accountability, but state public health laws do not require a specific data-safety monitoring process.

- ***Protection of Vulnerable Populations.*** Federal and state constitutional and statutory laws broadly prohibit discrimination in public health practice (subject to political limitations). State laws provide significant protection of privacy and equal treatment to traditionally vulnerable groups.

In sum, myriad state regulations address the core protections provided by the Common Rule, but the degree of protection and the specific means of protection vary greatly from state to state. Two notable distinctions from the Common Rule are the general absence of a requirement of prior external review for health department research (Florida is the only state with explicit provision of IRB review of health department research⁹³) and the lack of a requirement for individual informed consent.

Different oversight mechanisms are employed by states to hold public health officials accountable for compliance with the relevant state protections of human participants in public health activities. In several states, boards or councils of health maintain a formal supervisory role regarding health department activity.⁹⁴ In a couple of states, the board or council actually conducts oversight activities, including reviewing practice activities.⁹⁵ In New Jersey, the Public Health Council may “consider any matter relating to the preservation and improvement of public health, and may advise the commissioner thereon; study and investigate the public health activities of the State and report its findings thereon to the Governor and the Legislature.”⁹⁶

In addition to explicit oversight provisions, accountability mechanisms inherent in democratic governance hold public health authorities accountable for their research activities. Professor Burriss identifies several of these mechanisms, including: (1) hierarchical management structure, (2) political accountability through the democratic process, (3) legal accountability through the courts for actions that violate state or federal laws or constitutions, and (4) accountability via public opinion through media exposure.⁹⁷

Finally, it is worth noting that public health practice is typically conducted by licensed health care professionals who are accountable for their conduct pursuant to ethical and legal standards related to the practice of medicine, nursing, and other health professions.

3.4 The HIPAA Privacy Rule and Other National Privacy Laws

Individually-identifiable health information has traditionally been used by or disclosed to public and private sector entities (e.g., health care workers, pharmacies, researchers, insurance companies, and employers) for many reasons with or without an individual’s explicit knowledge or consent. Varied policies for sharing health data reflect the fragmented nature of legal protections of health information privacy.⁹⁸ The U.S. Constitution does not explicitly grant individuals a right to health information privacy. Judicial decisions (or case law) do not broadly support individual privacy interests, though the Supreme Court has crafted some basic health information privacy protections from constitutional norms.⁹⁹ Federal and state statutes and

regulations have been the dominant source for health information privacy protections in the United States. As summarized below, these protections vary.¹⁰⁰

Existing Federal Statutory Privacy Laws. Prior to the implementation of the HIPAA Privacy Rule, there was no comprehensive federal health information privacy law. Rather, federal privacy laws applied to certain types of health information collected, maintained, or funded by the federal government through its specific agencies. These laws protect the privacy of an individual's health (and other) information in many ways. The Freedom of Information Act of 1966 (FOIA)¹⁰¹ is designed to give the public broad access to federal government records, although it exempts identifiable health information from public dissemination. The federal Privacy Act of 1974¹⁰² applies fair information practices to many systems of records (e.g., Medicare health records) collected and maintained by federal agencies. Among other things, the Privacy Act protects individual privacy by (1) controlling disclosures of health information by requiring individual consent in most cases, subject to specified exceptions; (2) proscribing governmental maintenance of identifiable health information in a secretive fashion; (3) requiring agencies to publish a notice about each record system describing its purpose, and identifying disclosures outside the agency; (4) requiring agencies to inform individuals of the statutory basis for collecting health information, purposes for which it is used, and consequences for not supplying the information; and (5) allowing individuals to access and amend their own government-held information.

While FOIA and the Privacy Act apply to all federal agencies, other federal privacy laws relate to particular government programs. For example, a federal statute protects the privacy of health information generated in federally-assisted specialized substance abuse facilities.¹⁰³ Additional privacy protections concerning identifiable health data used in health research. Sections 308(d) and 301(d) of the Public Health Service Act (PHSA), respectively, authorize the execution of assurances and certificates of confidentiality to protect statistical and research data. Specifically, these sections allow public health agencies (like CDC) and outside researchers to assure human research subjects and others that recipients of their health data will protect their confidentiality.

Assurances of confidentiality under Section 308(d)¹⁰⁴ apply to statistical data collections conducted by federal public health agencies. Section 308(d) provides that no identifiable information may be used for any purpose other than that for which it was supplied, unless the agency or person has consented. Certificates of confidentiality, available to researchers within and outside government, are authorized under Section 301(d).¹⁰⁵ They may be granted by DHHS to protect research participants from legally-compelled, non-consensual disclosures of any identifiable information (including health data) to persons not connected with the research. This confidentiality protection is generally sought by researchers for sensitive health data (e.g., related to sexual practices or illegal conduct) to encourage subjects to participate or provide accurate or complete data. IRBs reviewing research proposals can recommend that the researcher obtain a certificate of confidentiality as part of the IRB approval for the study.

The HIPAA Privacy Rule. These and other federal privacy laws contribute to a myriad of protections that many viewed as unsatisfactory to fully protect health information privacy as data are increasingly digitized within a national electronic health information infrastructure. In

response, Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), in part to encourage the development of standardized communication systems between various health care entities. Though Congress failed to pass national health information privacy legislation pursuant to HIPAA, DHHS was authorized to promulgate the first systematic national privacy protections in the form of the HIPAA Privacy Rule. Implementation of the Privacy Rule began on April 14, 2003. DHHS' Office for Civil Rights (OCR) is responsible for administering the Rule.

The Privacy Rule concerns "covered entities."¹⁰⁶ Covered entities include *health plans* (e.g., health insurance companies, managed care entities, and specifically-named government health programs), *health-care clearinghouses* (e.g., billing services, repricing companies, or community health information systems that process health data), and *health-care providers* (e.g., doctors, hospitals, clinics) that conduct transactions electronically.¹⁰⁷ *Business associates* (e.g., claims processors, billing managers, data analyzers, and others) of covered entities are also subject to the Rule.¹⁰⁸ Many others who acquire, use, disclose, or store health data (e.g., employers, social welfare agencies, workers compensation systems, and auto, life, and worker compensation insurers) are not directly covered.¹⁰⁹

The Privacy Rule protects most individually-identifiable health information created or received in any form by covered entities. "Protected health information" (PHI) includes individually-identifiable data that relate to the past, present, or future physical or mental health or condition of a person, or the provision or payment of health care to a person.¹¹⁰ PHI does not include non-identifiable health information or "de-identified data" (health statistics or other aggregate health data that do not or cannot identify individuals).¹¹¹ However, the definition of what may constitute PHI is more precise than the Common Rule conception of "private information." PHI is "information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual."¹¹² In other words, more health data may be considered identifiable under the Privacy Rule than the Common Rule based on their respective definitions. For this reason, this report defers to the Privacy Rule definition.

Covered entities are responsible for establishing and adhering to a series of privacy protections related to PHI. This includes: (1) providing notice to individuals regarding their privacy rights and how their PHI is used or disclosed;¹¹³ (2) adopting and implementing internal privacy policies and procedures;¹¹⁴ (3) training employees to understand privacy policies and procedures;¹¹⁵ (4) designating persons who are internally responsible for implementing privacy policies and procedures;¹¹⁶ (5) establishing appropriate administrative, technical, and physical safeguards to protect the privacy of PHI;¹¹⁷ and (6) assisting health consumers exercising their rights under the Privacy Rule to inspect and request corrections or amendments to their PHI.¹¹⁸

The Privacy Rule and Public Health. The impact of the Rule on public health practice and research has been well-documented by CDC, NIH, and many others.¹¹⁹ Most relevant are the Rule's disclosure provisions. In general, a covered entity may not disclose PHI without individual written authorization,¹²⁰ subject to a series of exceptions. Covered entities may, for example, disclose PHI without individual authorization to other entities for treatment, payment, and health care operations purposes (a standard part of most health care transactions).¹²¹ Among

the additional bases for sharing PHI without written individual authorization are disclosures to public health authorities for public health purposes, and disclosures for health research.

DHHS recognized the potential impact the Rule could have on public health, and sought to avoid interfering with public health activities. The Rule leaves intact state and local public health laws requiring covered entities to disclose PHI.¹²² It also permits PHI disclosures to public health authorities for public health purposes without individual written authorization.¹²³ Public health authorities include *federal* (e.g., CDC, NIH, FDA, OSHA); *tribal* (e.g., IHS, tribal health organizations); *state* (e.g. public health departments or divisions, state cancer registries, vital statistics departments); and *local public health agencies* (e.g., county or city health departments, local boards of health).¹²⁴ Also included are those public or private partners that public health authorities work with to carry out their authorized activities through contracts, grants, and agreements.

The Rule allows the disclosure of PHI to public health authorities and their authorized partners for public health purposes without written authorization: (1) when specifically required by federal, tribal, state, or local laws (pursuant to Section 164.512(a)), or (2) as otherwise permitted or authorized by law (pursuant to Section 164.512(b)). Disclosures of PHI pursuant to Section 164.512(a) may be made whenever they are required by law (as typically determined by the public health authority). State public health reporting statutes often mandate the disclosure of PHI to public health authorities for public health purposes. Under Section 164.512(b), public health authorities may acquire PHI from a covered entity provided they are generally authorized to collect or receive information for public health purposes. Thus, public health authorities do not have to rely on specific laws that authorize each collection of information for multiple diseases or conditions to seek disclosure of PHI from covered entities.

Other provisions within Section 164.512 allow covered entities to disclose PHI without individual authorization for specific purposes that have public health relevance, including: (1) in emergency circumstances; (2) to identify the body of a deceased individual, or determine the cause of death; (3) to entities engaged in organ procurement, banking, or transplants; and (4) for activities related to national defense and security. Once PHI is disclosed to a public health authority, the Privacy Rule does not impact the maintenance, use, and disclosure of the data, although other federal, tribal, state, or local privacy laws regulations, or policies may be relevant. Yet, for example, provided that state law permits the sharing of such data by public health authorities across state boundaries, or among agencies within the state, these disclosures may continue unabated by the Privacy Rule.

The Privacy Rule and Research. Provisions within the Privacy Rule concerning the use and disclosure of PHI without written authorization for health research are narrower than the public health provisions. As OCR explains in its guidance on the Rule,¹²⁵ covered entities are permitted to disclose PHI to others for research (the definition of which is identical to that presented in the Common Rule) without individual authorization under certain limited instances. These include:

- IRB or Privacy Board Approval. A covered entity may disclose PHI for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board based on

the following criteria (which are virtually identical to those set forth in the Common Rule):¹²⁶

- (1) The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on the existence of: (a) an adequate plan to protect the identifiers from improper use and disclosure; (b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, absent an additional legal or other justification for retaining the identifiers; and (c) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted;
 - (2) The research could not practicably be conducted without the waiver; and
 - (3) The research could not practicably be conducted without access to and use of PHI.¹²⁷
- Preparatory to Research. The researcher represents that the disclosure of PHI is needed solely to prepare a research protocol or for similar purposes preparatory to research, that PHI will not be removed from the covered entity, and the PHI is necessary for the research.¹²⁸ Under this provision, researchers can initially review PHI to design a research study or assess its feasibility.
 - Research using Decedent's PHI. The researcher represents that the disclosure is solely for research on PHI of decedents, that the PHI being sought is necessary for the research, and, if requested, documentation of the death of the individuals about whom information is being sought.¹²⁹
 - Limited Data Sets with a Data Use Agreement. Some PHI may be disclosed pursuant to a data use agreement between the covered entity and the researcher.¹³⁰ Limited data sets exclude specified individual identifiers from the health data disclosed. The data use agreement establishes permitted uses and disclosures of the limited data set by the recipient consistent with the purposes of the research.

Thus, the Privacy Rule clearly requires differing standards for the disclosure of PHI for public health practice and research purposes. The more difficult procedural requirements for disclosing PHI for research provide an incentive for characterizing a public health activity as practice. Like the Common Rule, however, the Privacy Rule offers no meaningful guidance to distinguish between practice and research. As a result, depending on how a public health activity is classified, various health information privacy protections, including an IRB or Privacy Board review, may be required.

3.5 State/Local Public Health Information Privacy Laws

State and local government health information privacy laws mimic existing federal privacy protections by creating a patchwork of privacy protections. Many states have passed the equivalent of FOIA and Privacy Act laws that govern state and local government data collections. Others have created more comprehensive medical privacy laws that are similar in scope to the HIPAA Privacy Rule. Additional state and local health information privacy laws relate to disease- or condition-specific subjects. For example, many states protect the privacy of genetic tests or information, provide enhanced provisions for super-sensitive health data like HIV/AIDS, or support additional security measures for governmental health data collections.

Though subject to some federal privacy laws, public health practitioners at the federal, tribal, state, and local levels lack comprehensive federal privacy protections for public health data. The HIPAA Privacy Rule does not generally pertain to state and local public health data. As a result, state public health privacy laws continue to be important, but existing legal protections are inconsistent and fragmented.¹³¹ These laws do not always properly balance individual privacy interests with collective public health interests. Some state public health privacy laws may stymie information flows, apply more protections to specific health information with little justification, or significantly discount individual privacy.

A project in 1999 to develop enhanced public health privacy protections under the auspices of the CDC led to the MODEL STATE PUBLIC HEALTH PRIVACY ACT (MSPHPA).¹³² The provisions of MSPHPA, which have also been incorporated into the comprehensive TURNING POINT MODEL STATE PUBLIC HEALTH ACT,¹³³ provide strong and consistent privacy safeguards for public health data while preserving the ability of state and local health agencies to use the data for the common good.¹³⁴ Like most existing public health privacy laws, MSPHPA authorizes uses or disclosures of identifiable health data held by public health agencies for research purposes, but does not attempt to systematically distinguish public health practice from research.

Several states have specific laws to ensure that public health officials preserve the confidentiality of health information. A violation of state privacy regulations is generally categorized as a minor offense under state law.¹³⁵ For example, Montana legislation provides that, "Any department of health and senior services employee, public health authority or coinvestigator of a study who knowingly releases information which violates the provisions of this section shall be guilty of a class A misdemeanor and, upon conviction, shall be punished as provided by law."¹³⁶ Other states provide penalties for privacy violations by public health authorities under broader provisions of state law.¹³⁷ In some states, such as Rhode Island, the law explicitly creates a civil cause of action for violations of state privacy rules.¹³⁸

4.0 MODERN CASES ON PUBLIC HEALTH PRACTICE AND RESEARCH

4.1 *Qualities/Characteristics of Cases*

As discussed Section 2.0, distinctions between public health practice and research are routinely made by public health practitioners, IRB members, researchers, and others based on numerous criteria and legal requirements. The cases below provide some examples of facts that raise the question of what is practice or research. Although individual and some other identifiers have been removed, each of these examples is based on real accounts of proposed or implemented public health activities as reported through federal, state, and local public health practitioners. Following a brief statement of facts, an actual disposition, or finding, is provided. To the extent possible, these findings reflect the actual bases used to distinguish public health practice from research (even if those bases are actually or potentially flawed). In some cases, the bases are scant; in others, they are more developed. Additional analysis about how these cases demonstrate some of the difficulties involved in classifying practice and research is discussed through some key lessons.

Many of these cases stem from reviews of public health activities prior to the implementation of the HIPAA Privacy Rule. They may have originated at CDC or are subject to review through CDC because of proposed CDC funding. Most of the cases also involve state and local public health practitioners who CDC may have requested or funded to participate in the activity. Special thanks to **John Livengood, MD, MPH**, former Deputy Associate Director for Science, CDC, and his staff for their important compilation of and contributions to some of these cases. Many other individuals also provided factual information (see Additional Acknowledgments, above).

4.2 *Specific Cases*

Case 1: Pregnancy Risk Assessment Monitoring System

Brief Facts: CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) is an ongoing, state-specific, population-based surveillance system designed to identify and monitor selected maternal behaviors and experiences among a sample of women who each have recently given birth to a live infant. CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) provides funds to 32 states and one major metropolitan area to implement the system. Thousands of women nationwide are asked via mail (and telephone for non-respondents) to participate in answering a questionnaire that includes a core set of questions, and additional state-specific questions. The core portion of the questionnaire includes questions about attitudes and feelings about the participant's most recent pregnancy; prenatal care; maternal alcohol and tobacco consumption; physical abuse before and during pregnancy; pregnancy-related morbidity; infant health care; maternal living conditions; and knowledge of pregnancy-related health issues. Each state may provide some financial or other small incentive to encourage individual participation.

PRAMS seeks to improve the health of mothers and infants by reducing adverse outcomes such as low birth weight, infant mortality, and maternal illnesses through changes in maternal behaviors during and immediately after pregnancy. It has four primary objectives: (1) to collect high quality, population-based data on pregnancy and early infancy; (2) to conduct comprehensive analyses to understand better behaviors, attitudes, and experiences of mothers during and immediately after pregnancy; (3) to use these analyses to help plan and evaluate pregnancy-related public health programs and policies; and (4) to build state-based capacity. PRAMS data are continually being analyzed, disseminated, and translated into vital information for public health action. For example, one states' PRAMS data were used to support the state's lawsuit against tobacco companies (by showing the level of smoking by pregnant women). Another state's data on unintended pregnancy were used to support a prevention initiative that resulted in federal and state funding being used to set up new family planning services. CDC notes that PRAMS data are available to researchers, and recommends that they contact CDC directly or each state for state-specific data.

Disposition: CDC staff determined that this project constitutes research, and submitted it to its own institutional IRB for review prior to its implementation. CDC also determined that state grantees that undertake PRAMS are not engaged in research and do not have to get approval through their own IRBs. (In spite of CDC's determination, some states chose to submit the activity for review as potential human subjects research). CDC's IRB required that all state grantees (or cooperative agreement recipients) receive "human subjects training" every 3 months. This training (despite its mislabeling) is not equivalent to training related to protecting research subjects under the Common Rule. Rather, it centers on learning quality assurance techniques and information for persons hired to conduct telephone interviewing.

Key Lessons: This case demonstrates the nexus between research and public health practice. The primary tool for gathering sensitive health data in PRAMS is a national survey provided to women specifically chosen because they have recently completed a live birth. Many health researchers routinely use surveys to gather data for their own research purposes. However, unlike a researcher that may use the data to contribute to generalizable data, CDC and its state partners suggest their use of the data is to improve maternal and child health for the population.

The element of intent, as CDC staff and others use it in making determinations between research and practice, seems to distinguish PRAMS as practice rather than research. (It is perhaps interesting to note, however, that PRAMS was initiated well before CDC's 1999 document emphasizing the element of intent as a critical, distinguishing factor. CDC may have traditionally used intent as a basis in prior years). Still, the line of demarcation in PRAMS is not clear. CDC internally viewed the system as research and sought further approval through its IRB, but simultaneously suggested that the administration of the survey by its state and local partners was a public health practice activity.

Case 2: SARS and Airplane Passengers

Brief Facts: In March 2003, during the worldwide SARS outbreak, CDC engaged in a series of surveillance efforts to systematically identify potential SARS cases and those within contact of these persons. As part of these activities, CDC focused efforts on potential cases of

SARS spread through casual contact among airline travelers. CDC asked state and local public health agencies to assist in following up with potential contacts. In particular, during this critical time, if CDC became aware of a person known or suspected to be infected with SARS who had recently flown into or within the United States, it would identify the flight, contact the airline for the flight manifest, and then ask state or local public health agencies to help locate persons who had flown with the individual, and thus may have been exposed to SARS. Sometimes, obtaining flight manifests and locating named individuals would result in a 3-4 weeks administrative delay between the time CDC suspected a potential exposure and when an investigation could be conducted. Nevertheless, CDC requested that state or local agents supervise physicians to draw blood samples and obtain medical histories of healthy, unaffected air travelers who were on the plane with a known or apparent SARS case. When administrative delays mounted, the time period for performing these blood tests on asymptomatic individuals would have surpassed their likely incubation period for SARS, revealing only that they may have been exposed. Thus, the tests would not directly benefit asymptomatic individuals who were not "cases" because they were not ill.

Disposition: CDC's National Center for Infectious Diseases (NCID), in consultation with CDC's Deputy Associate Director of Science, determined that the performance of these blood tests were not research. Rather, they were special investigations sustained by CDC's need for a public health response to this epidemic. CDC suggested that the performance of the study did not require CDC IRB approval. It did recommend, however, that individual written informed consent should be obtained from all potential participants in these investigations (note that because physicians actually performed the blood tests and obtained medical histories, patient informed consent was required pursuant to the practice of medicine). Several state and local public health agencies disagreed with this finding, and subsequently sought state or local IRB approval for an activity they viewed as public health research. In some cases, local IRBs denied public health authorities the right to proceed without additional research protections.

Key Lessons: Like Case 1 on PRAMS, this case includes an element in its design (i.e., the collection of identifiable health data from participants) that is commonly featured in research. Unlike the PRAMS case, these data are collected through the administration of blood tests to a group of persons who may or may not benefit from the results, especially when the tests are implemented well after the incubation period for SARS. The use of actual blood tests as contrasted with a written survey may have led some state and local public health authorities to view these efforts as research, and thus seek IRB approval.

Yet, it is standard public health practice to investigate disease outbreaks. This requires effective surveillance, medical diagnosis, confirming the existence of the outbreak, characterizing those at risk, implementing disease control measures, and evaluating their efficacy. These activities involve the practice of public health and medicine. Informed consent for the medical activities is always required.

This case reveals how federal and state/local public health practitioners and their IRBs can disagree about the classification of a particular public health activity as research versus practice. That disagreements may occur is inevitable under existing criteria; that the consequences of these disagreements in some instances may be the non-performance of an

important public health objective (i.e., determining existing cases of a serious, communicable disease like SARS) is unacceptable. Though CDC viewed these activities as epidemiological investigations to control the spread of SARS, it further recommended that each contact of a known or suspected infected person provide their informed consent for the administration of a blood test (pursuant to the performance of medical services by physicians). Individual informed consent is essential in conducting non-exempted human subjects research and one of the more burdensome requirements that may stymie the performance of some public health practice activities. Yet, by classifying the investigation as practice, CDC could avoid any additional delays through IRB review as it sought to respond to exigent circumstances.

The presumed exigencies underlying the collection of the data cannot be discounted. Snider and Stroup provide justification for moving forward without IRB review under similar circumstances: “[r]equiring emergency responses to include the traditional development of a written protocol and IRB review is not practical nor would it be in the best interests of either the individuals or the community . . . because resulting delays . . . would frequently result in excess disease and death.”¹³⁹ In retrospect, however, CDC and state and local public health authorities might not significantly benefit from information provided through the administration of blood tests for SARS among persons who would have already shown symptoms for the condition at the time the tests were performed in some cases.

Case 3: Investigating Infant Intussusceptions Concerning Rotavirus Vaccine

Brief Facts: On August 31, 1998, a new vaccine was introduced into the national childhood immunization schedule, a tetravalent rhesus-based rotavirus vaccine (RRV-TV). CDC and FDA were monitoring health conditions that occurred in recipients of the rotavirus vaccine through the Vaccine Adverse Events Reporting System (VAERS), a passive surveillance system that relied on health providers case reporting. By May 27, 1999, VAERS had received nine reports of intussusception among infants given RRV-TV. The number of actual cases was probably higher. Intussusception is a serious, potentially life-threatening health condition. Use of RRV-TV was temporarily suspended pending further investigation. CDC urgently needed to determine the incidence of infant intussusception and explore whether there was an association between receipt of the rotavirus vaccine and intussusception. CDC’s National Immunization Program (NIP) initiated a case control study in 19 states where 80% of RRV-TV had been distributed.

Disposition: CDC staff did not consider the proposed study research for the following reasons: (1) the investigation was triggered by the report of a serious adverse event; (2) the investigation was designed to answer important questions that would direct further public health action; (3) the collection of data did not allow the investigators to address issues beyond what was intended by the investigation; and (4) the intent of the investigation was to address an urgent public health problem and to respond in a way that would directly benefit the community affected. Although CDC noted that the study would likely yield knowledge useful to others, the primary intent of this study was to determine the cause and extent of an identified public health problem.

Key Lessons: As with Cases 1 and 2, the proposal for the performance of a study activity resulted in the need to distinguish the activity as practice or research. CDC's conclusion that the activity is public health practice may be supported by the sole criteria of intent. CDC's intent was not to investigate a proposed hypothesis and contribute to generalizable knowledge (as perhaps a researcher would propose). Rather, CDC wanted to quickly learn more about an identified public health problem that it deemed was urgent. CDC and FDA both have public health responsibility for addressing potential negative consequences of vaccines that are recommended for the national childhood immunization schedule.

Case 4: Linking Services and People on the Traumatic Brain Injury Registry

Brief Facts: CDC's National Center for Injury Prevention and Control (NCIPC) has supported traumatic brain injury (TBI) registries in multiple states for some time. State departments of health often collaborate with university hospitals to create and maintain the registries. Follow up research using registry data is often conducted to assess service needs of affected persons. CDC staff help develop the registries and conduct research. CDC views the surveillance activities as public health practice, and thus not subject to IRB review. However, research studies are subject to review by university, state, and CDC IRBs. In all cases, they were approved.

One state and its university partner conducted a follow up study to determine the feasibility of linking persons identified in the state registry with TBI information. Persons with TBI and representatives from service agencies were interviewed about the feasibility and logistics of linking this information. State agency staff drafted a report recommending a model program based on this research. CDC provided additional funds for the state to pilot one part of this model. This part would attempt to link persons identified through the registry with a 1-800 phone line established as part of a statewide system of services for people with TBI. The state health agency would mail letters announcing the availability of this 1-800 service to a sample of 600 persons reported to the TBI registry. The state agency and its contractual partner, a non-profit TBI organization answering calls to the line, would collect intake information (through a series of questions on how callers heard about the phone resource) and provide information on TBI services. All intake data would be rendered anonymous by the contractor, then analyzed by the university partner. CDC investigators would not be actively involved in the work or receive any data, but would provide technical assistance as requested.

Disposition: CDC staff determined that this part of the model program was human subjects research subject to IRB approval because it was an intervention study. However, when the protocol was submitted to the respective IRBs at the state health agency and university, they determined that these planned activities were not research.

Key Lessons: The complete bases for the differing determinations of research versus public health practice by the CDC, state agency, and university IRBs are not provided. Regardless, the case further supports a key lesson from Case 2 on SARS surveillance that the same activities may be classified differently by various IRBs. Also, how and under what circumstances can existing surveillance data (gathered via public health practice) be used for research? CDC acknowledges in its 1999 guidance that an accepted practice activity may lead

to, become, or support research, and thus be subjected to IRB approval. This case provides an example where CDC determined that practice data were to be used for research purposes. However, the reasons for this finding are unclear.

Case 5: Evaluating a Non-name Based HIV Reporting System

Brief Facts: A local department of public health within a major metropolitan area sought cooperative agreement funds from CDC to conduct a pilot study of HIV reporting systems using a non-name (soundex) code. Non-named reporting of HIV status has been used in other states as an alternative to named reporting. Named HIV reporting raises significant privacy concerns, particularly among the HIV/AIDS community. Non-named reporting, however, may not be as accurate or complete as named HIV reporting.

The pilot study proposed to establish an HIV reporting system at two hospitals in the metro area that routinely treated a large number of AIDS patients. These hospitals would provide the local health department with coded HIV case reports for identified HIV+ individuals based on lab testing. Hospital labs retained a list of reported names and corresponding codes that were used by the local health department to match against its own registry, and thus evaluate the efficacy of the system. All of this was to be accomplished without specific patient consent, consistent with other disease reporting practices in the state. At the time, there was no specific statutory authorization for HIV reporting within the state although reporting of AIDS cases was authorized.

Disposition: In considering whether to fund the proposal, CDC regarded it as an evaluation of surveillance, and thus public health practice. CDC did not submit the proposal to its own internal IRB for approval. However, the local department of health viewed the pilot study as research, based largely on the absence of a state reporting requirement for HIV at the time. The department submitted the proposal through an IRB of one of its university partners. The IRB found that the proposal met its criteria for a waiver of individual informed consent, and allowed the study to proceed.

Key Lessons: The essential lesson of this case is the effect of statutory support for reporting practices on the determination of whether an activity is practice or research. From its national perspective, CDC viewed the system proposed for non-name reporting of HIV as practice. From its state-based perspective, however, the local department of health viewed the system as research, principally because the state did not specifically authorize HIV reporting (whether by name or otherwise). Lacking specific statutory authority, the local department of health perceived the study as outside its approved public health practice activities. It could have sought legal clarification or amendment of its potential public health reporting powers under state or local laws. Perhaps broader state or local public health laws may support HIV reporting even if it is not specifically listed in statute or regulation. Instead, the department simply chose to submit the proposal for IRB approval, perhaps to seek an exemption from the Common Rule requirements. Ultimately, the IRB allowed the study to proceed without individual informed consent, consistent with most other reporting practices.

Case 6: Fatality Assessment and Control Evaluation Program

Brief Facts: CDC's National Institute for Occupational Safety and Health (NIOSH) funds state-based Fatality Assessment and Control Evaluation Programs (FACE) through cooperative agreements. The objectives of the FACE program are to (1) identify work environments that place workers at high risk for fatal injury, (2) identify risk factors for these fatal injuries, and (3) develop and disseminate information on prevention strategies. Several state health and labor departments receive CDC funds to:

1. Develop a surveillance system to identify all traumatic occupational fatalities in a timely fashion to allow investigations of targeted types of fatalities. Much of the information included in the surveillance database is from existing records (e.g., death certificates, newspaper stories, OSHA or workers' compensation reports);
2. Conduct on-site investigations of targeted types of fatalities. Without assigning blame, the purpose of the investigations is to identify steps that can be taken to prevent future deaths and injuries. Investigations include review of existing records, examination of the fatality site, and non-standardized interviews with employers and some witnesses;
3. Develop written reports for each investigation. Identifying information is used during the investigation, but is not retained when the investigation is completed or included in the surveillance database. The reports are provided to the employer, disseminated to a network of interested persons within each state, and posted on state and CDC/NIOSH Internet sites; and
4. Develop health communication documents and undertake other efforts to prevent future deaths. For example, states and NIOSH often conduct epidemiologic analyses of information from the investigations. These include coupling data from fatality investigations with surveillance data, and analyzing information from multiple similar fatality investigations to develop comprehensive and broad-based prevention recommendations.

Disposition: CDC considers the collection of surveillance data on occupational injury fatalities and through FACE to be public health practice. The primary purpose of the surveillance components is to identify high-risk situations and investigate fatalities in a timely fashion. Any state health or labor department that publishes information from the surveillance component of the project is also engaged in public health practice because although the surveillance data are generalizable at the state level, the primary intent is to focus and encourage efforts to prevent worker injury deaths in the state.

The investigation of targeted occupational injury fatalities is also public health practice because, as CDC suggests, the findings from a single investigation are not generalizable and the intent is to identify steps that can be taken by that employer and others to prevent future deaths and injuries under similar circumstances. The dissemination of summary reports of individual fatality investigations is a practice activity as well. Reports of individual investigations are not generalizable. The intent of disseminating these reports to relevant parties and posting on state

and the CDC/NIOSH websites is to provide information that may be useful in protecting workers.

CDC considers the analysis of information from multiple similar fatality investigations and coupling of this information with surveillance data as public health practice (when resulting publications are in the form of state health communication materials) and research (when they are published in peer-reviewed journals or CDC/NIOSH publications).

Key Lessons: Like Case 1 on PRAMS, this case shows how identifiable health data are collected, used, and analyzed by public health authorities for a variety of purposes within a unified objective of protecting the public's health. CDC and other public health authorities may legitimately take an expansive view of these data uses, linking each back to the original purpose or intent of the project. Here, for example, CDC determines that the development of the surveillance system, the performance of investigations, and the analysis of resulting information are each public health practice because they are intended to reduce workers' injuries. CDC's reference to the production of generalizable data at each stage is not particularly helpful to distinguish these activities from research, since research activities produce similar data.

Curiously, CDC suggests that only if the results of data analyses are published in peer-reviewed journals or CDC/NIOSH publications might the underlying activity be considered research. This demonstrates how publication decisions are an imperfect standard for distinguishing research from practice. Public health authorities and researchers may both seek to publish to share the knowledge gained through the results and analysis of their work. Whether shared through health communication materials within state public health agencies (viewed as public health practice) or articles in peer-reviewed journals (associated with research), publication is inconsequential because (1) data in both settings are (or could be) publicly available; (2) the privacy risks to participants are equivalent (though hopefully negated or minimized through the use of truly non-identifiable data); and (3) the intent of the data collector to share knowledge is similar. As Marjorie Speers, former Deputy Associate Director for Science, CDC, and her colleagues note: "[R]esults from both research and nonresearch activities may be worthy of publication in a medical journal or presentation at a national meeting; such discussion of a project in a public forum does not define a project as research."¹⁴⁰

Case 7: Laboratory Markers To Assess and Treat Protein-Calorie Malnutrition

Brief Facts: Protein calorie malnutrition (PCM) increases patient morbidity and mortality, slows wound healing, and impairs immune response. These effects can increase incidence and duration of hospitalization, readmission, and disease-related complications. The most frequently used laboratory test to detect PCM has been serum albumin levels. The usefulness of serum albumin is limited, however, by its long half-life (changes cannot be detected quickly) and the effects of inflammation and chronic disease (e.g., kidney, liver disease) on albumin levels. Other, more sensitive lab tests include serum prealbumin (PAB), retinol-binding protein (RBP), and C-reactive protein (CRP). Use of these tests allows quicker assessment of the patient's condition.

CDC's Public Health Practice Program Office (PHPPO) proposed to fund a study to determine the value added to hospital screening protocols and to patient monitoring by testing for these proteins. All non-maternity, non-palliative, non-parenteral nutrition inpatients who are at a certain nutrition risk would be eligible and asked to enroll in the study. Patients who decline participation would be asked why they chose not to participate. Responses would be recorded anonymously and used to devise strategies to increase patient participation in future studies. Enrolled patients would receive nutrition care according to the current standard of care at the hospital. If enrolled patients require parenteral nutrition (PN) or transition to palliative care, they will receive enhanced care but would not be withdrawn from the study.

All patients would have an initial testing for protein levels using each of the four available tests (i.e., albumin, PAB, RBP and CRP), bedside nutrition assessment, and a treatment plan. They would be scheduled for follow-up testing three times a week during their admission. The patients would be divided into two groups. The control group would receive standard care with additional laboratory testing for the proposed markers, but these results would not be shared with the patients or their caregivers. In the experimental group, the results for prealbumin, RBP, and CRP testing would be shared with the patients and their caregivers. Clinical outcomes (including length of stay in the hospital, days spent on the ventilator, infection rate) would be compared between the two groups to determine if knowing the lab results affects clinical outcomes. Data collection would include patients' protein results, cost and demographic information, risk factors, and functionality.

Disposition: CDC staff determined that these activities clearly constitute research because the information produced by the study is intended to contribute to generalizable knowledge, human research subjects are involved, and personally identifiable health data are being collected.

Key Lessons: These facts suggest a series of activities that most would collectively classify as research, and thus would require IRB review. Besides the factors specifically used by CDC to classify the activity as research (e.g., the contribution to generalizable knowledge, the participation of living humans, and the collection and use of identifiable health data), a finding of research may also be supported by additional relevant factors (e.g., patients are randomized, patients are asked to voluntarily participate, control and experimental groups are designated, and the primary benefit does not necessarily accrue to the participants themselves).

Yet, the identified intent of the activity is to determine the value added to hospital screening protocols and to patient monitoring by testing for these proteins. This may be seen as a public health objective as well as a research hypothesis. What is interesting about this case is that after CDC determined its intent, it decided to pursue this objective through what most would identify is a research study. Public health practice alternatives may have also existed to achieve this public health goal. As discussed in cases above, what is the value of the identified intent in making this distinction where the same intent to improve the public's health may support research or practice activities?

Case 8: Improvement Studies of End Stage Renal Disease Networks

Brief Facts: End Stage Renal Disease (ESRD) Networks are congressionally mandated, peer-reviewed organizations under contract with CMS to collect data on the US ESRD population and conduct quality improvement projects. One of the 18 ESRD Networks proposed a quality improvement project that would aim to increase utilization of stenosis monitoring and vascular access surveillance processes in dialysis facilities. Increases in this monitoring activity could decrease the incidence of clotted arterio-venous grafts (AVG) among patients, thus raising patient life expectancies.

The project proposed to collect baseline information from participating dialysis facilities on numerous process indicators, such as the percent of facilities with a vascular stenosis surveillance program. An educational, informational intervention would be disseminated to all facilities. A follow-up survey identical to the baseline survey would be conducted. The pre- and post-intervention survey results would be analyzed and compared for improvements and changes. All facilities would be invited to participate, and no controls would be used. Three data sources would be utilized: (1) the CMS Standardized Information System database; (2) facility-specific data from surveys; and (3) a voluntary survey on treatment team opinions. Only aggregate, facility-level data would be collected. No identifiable health information for individual patients would be acquired. If the project is successful, the intervention could be replicated at other Networks' facilities.

Disposition: ESRD Network Regional Office policies required all quality improvement projects to be reviewed as research. The question before the IRB was whether the project was required to follow Common Rule procedures including obtaining individual informed consent. The IRB waived the consent requirement under the Common Rule. The project was deemed not to require individual informed consent under 45 C.F.R. 46.116(d) (concerning research to study, evaluate, or examine public benefit or service programs) as it would involve no more than minimal risk, and would not adversely affect the rights and welfare of the subjects.

Key Lessons: Distinctions between research and public health practice can be even more complicated when considering quality improvement studies. Strong public health objectives underlie these studies, but their implementation often has the look and feel of research. In this case, CMS' ESRD Network Regional Office internally decided that all quality improvement projects should be reviewed as research. This, however, does not mean that all quality improvement projects have to meet the requirements of the Common Rule. The Common Rule exempts from human subjects research protections those studies that are subject to approval by the heads of an agency and which are designed to study, evaluate, or examine public benefit or service programs. Research concerning these objectives does not require IRB approval or adherence to other Common Rule requirements.

Case 9: Youth Risk Behavior Survey

Brief Facts: The national Youth Risk Behavior Surveillance System (YRBSS) involves the administration of anonymous survey questionnaires to middle and high school students

across the United States through state and local public health agencies. These surveys, funded in part by CDC, inquire about risky behaviors related to some of the major causes of morbidity and mortality (e.g., smoking, alcohol consumption) in the nation. The survey is entirely anonymous, standardized, and routinely administered. The survey design selects classrooms of students to participate, not individual students who remain anonymous. Each local school district approves the survey, the decision to participate in it, and the mechanism for active or passive parental consent. Some persons challenged the survey as human subjects research because it is administered to a vulnerable population of young children.

CDC NCCDPHP developed the YRBSS in 1990 to monitor health risk behaviors that contribute to the leading causes of death, disability, and social problems among youth and adults in the United States. These behaviors include tobacco, alcohol, or drug use, unhealthy dietary behaviors, inadequate physical activity, sexual behaviors that lead to unintended pregnancy or STD transmission, and activities that lead to unintentional injuries and violence. The YRBSS was designed to determine and assess the prevalence of health risk behaviors and provide comparable national, state, and local data among subpopulations of youth. The system includes national, state, and local school-based surveys of representative samples of 9th through 12th grade students. These voluntary surveys are conducted every two years, usually during the spring semester. A national survey, conducted by CDC, provides data representative of high school students in public and private schools in the United States. The state and local surveys are conducted by departments of health and education. They provide data representative of the state or local school district. Selective, additional surveys are also conducted. For example, the Youth Risk Behavior Survey involved the administration of anonymous survey questionnaires to nearly 11,000 students between 12–21 years of age across the United States through state and local public health agencies.

Participating students are informed within the surveys about the nature and purposes of the information requested and other facts. For example, students taking the 2003 State and Local Standard High School Questionnaire are advised as follows:

This survey is about health behavior. It has been developed so you can tell us what you do that may affect your health. The information you give will be used to develop better health education for young people like yourself. DO NOT write your name on this survey. The answers you give will be kept private. No one will know what you write. Answer the questions based on what you really do. Completing the survey is voluntary. Whether or not you answer the questions will not affect your grade in this class. If you are not comfortable answering a question, just leave it blank. The questions that ask about your background will be used only to describe the types of students completing this survey. The information will not be used to find out your name. No names will ever be reported.

Multiple, methodological studies are also conducted to improve the quality and interpretation of the YRBSS data.

Disposition: The CDC IRB determined that the Youth Risk Behavior Survey is not

research. Correspondingly, IRB review and approval is unnecessary, as is individual or guardian informed consent under the Common Rule.

Key Lessons: The basis for classifying this activity as public health practice (and not research), as with other cases, is not entirely clear. The underlying objective of the activity is to accomplish a strong public health goal. However, this intent is present in other cases where the activity is classified as research. Despite what is suggested to students that the information provided is non-identifiable (i.e., no names requested or to be used), the requested data in the survey (including individual age, sex, height, weight, ethnic background) could possibly be used to identify individual respondents under the Privacy Rule. That the survey is administered to minors suggests that different rules for conducting the activity (if classified as research) would follow under the Common Rule. Research protections for children are stronger than for autonomous individuals. Characterizing these survey practices as research would require parental/guardian and subject consent, absent an exemption.

Despite the classification of this survey activity as public health practice, the informed consent of the subjects is still likely. Some state and local health departments adhere to informed consent procedures in the administration of public health surveys in accordance with state or local laws.

Case 10: Evaluating Lab Coagulation Practices

Brief Facts: Although variations in lab coagulation testing practices between hospital laboratories have been documented, little is known about the extent or nature of these variations. CDC proposed to fund a study to assess the variability for coagulation laboratory testing practices across the United States. To accomplish this, a self-administered laboratory practice survey would be provided to a representative, random sample of 800 hospitals across the nation. The objectives of the survey were to assess (1) the availability of specific tests, (2) various pre-analytical, analytical, and post-analytical issues that affect test results, and (3) the use of selected laboratory practices for each test. The survey would be conducted by an outside contractor. They would include an identifying number for tracking purposes only that would be kept separate from responses through a secure process that allows for re-linking. This may allow for follow-up activities (a reminder letter and a phone call) concerning laboratories that have not returned their surveys. Once these follow-up activities were complete, links would be destroyed. The information sent to the CDC would thus become completely anonymous.

Disposition: The evaluation of laboratory practices is public health practice, not research because CDC is not seeking to produce generalizable data. Furthermore, no personally-identifiable health information is being collected, and accordingly no human subjects research is being conducted.

Key Lessons: As with the similar finding of Case 9, CDC staff deemed this survey activity as practice, not research. Unlike the prior case, however, a stated basis for this determination is that no personally-identifiable health information is to be collected. If true, the Privacy Rule would not impede the flow of this data because they are non-identifiable. However,

it is questionable whether there is an exchange of personally-identifiable health data involved. CDC's private contractor seeks data on lab testing procedures. This may or may not involve the transmission of identifiable health data to the contractor, depending on how the labs respond to the questions. If identifiable health data are provided to the contractor, the subjects of the research may be seen as those whom the data concern. This sharing of health data may trigger different disclosure rules for the sharing of data under the HIPAA Privacy Rule.

While CDC and its partner/contractor are defined as public health authorities under the Privacy Rule, their ability to freely seek disclosure of identifiable data from a covered health provider (like the labs) is contingent upon them acquiring the data for a public health purpose. If a public health authority (or anyone for that matter) seeks data from covered entities for research purposes, a very different set of standards in the Privacy Rule applies (see Section 3.4). If public health authorities collect data for purposes that are research-related, but do not involve human subjects research, by default these activities should be labeled as public health practice.

5.0 GUIDING PRINCIPLES

Existing definitions, theories, approaches, legal issues, and cases provide a significant amount of information and some helpful criteria and analysis on the distinctions between public health practice and research. Utilizing this existing knowledge, however, will not completely allow public health practitioners, IRB members, and others to make distinctions in every case. While classifying a public health activity as practice or research is relatively simple in easy cases, the challenge is to develop improved criteria for making distinctions in harder cases, including activities that have both practice and research components.

This section provides a two-stage process utilizing guidelines and a corresponding Checklist to distinguish practice and research. The first stage addresses the easy cases. It neatly separates public health practice and research based on some of their essential characteristics. For harder cases, enhanced guidelines provide justifiable, additional factors for clarification through a second stage of review.

These guidelines and Checklist are grounded in honesty and simplicity. Public health authorities must honestly 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 do the performers of the activity hope to achieve; (4) how will information from the activity be used; and (5) who will benefit from the activity? Furthermore, some persons seeking to make distinctions may simply misunderstand the core elements of the case or some basics of public health practice and research. Incomplete facts, inaccurate observations, misinterpretations, and manipulations of stated objectives can lead to improper classifications or erroneous findings.

No set of criteria will completely resolve these quandaries. The objective is, however, to provide enhanced guidance that leads to a clear resolution in a wider majority of cases. Additional, agency-specific analyses may also be required. For example, additional regulations applying to the CDC, FDA, CMS, or other potential funders or performers of practice or research activities may be applicable and require further analyses.

5.1 Primary Assumption Underlying the Guiding Principles

A primary assumption underlying any case on the distinctions between public health practice and research in which the Common Rule and HIPAA Privacy Rule are implicated is that a public health agent or entity (or an authorized partner) seeks to collect, use, or disclose identifiable health information, bodily tissues, or biological samples for a specified activity. The collection of data will likely come through persons within and outside of public health (e.g., private sector health care providers). If the data are non-identifiable from the outset, the Common Rule provisions and the HIPAA Privacy Rule requirements for disclosure are largely not implicated. If the data are not health-related, the Privacy Rule is unimportant, though the Common Rule may still apply because it also covers non-health data used for research purposes.

Although this primary assumption addresses prominent data collection practices for public health or research purposes, other data uses may fall outside of this assumption and yet

still require distinction. For example, public health authorities may acquire identifiable health data from non-covered entities. These data acquisitions would not implicate the Privacy Rule, but may still require an assessment of whether the collection supports public health practice or research. Furthermore, public health authorities may engage in research activities under the Common Rule without acquiring identifiable health data. Human subjects research, for example, can include the collection of non-identifiable data through intervention or interaction with a living individual (see Section 3.2). Such collections do not implicate the Privacy Rule, but Common Rule protections may still apply. Although these examples are not directly addressed, many of the enhanced guidelines may still be helpful to distinguish public health practice and research.

Unraveling and separating the essential features of public health practice and research is the first stage (addressed in Section 5.2 below). Many of the easy cases may be resolved on these foundational bases alone. A second stage (involving additional steps) applies to the hard cases. The sections below set forth some key principles of guidance (and reject others) to help analyze and classify difficult cases consistently, with greater confidence, and without significant, additional review of IRBs (if the activity constitutes public health practice). A Checklist summarizing these analyses follows.

5.2 Essential Features of Public Health Practice and Research

An initial step toward distinguishing public health practice activities from human subjects research activities 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.

Figure 1. Foundations of Public Health Practice and Human Subjects Research

Public Health Practice: *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.* Essential characteristics of public health practice include:

- 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
- Supported by principles of public health ethics that focus on populations while still respecting the dignity and rights of individuals..

Human Subjects Research: *the collection and analysis of identifiable health data by a public health authority for the purpose of generating knowledge that will benefit those beyond the participating community who bear the risks of participation.* Essential characteristics of human subjects research include:

- Involves living individuals;
- Involves, in part, identifiable private health information;
- Involves research subjects who voluntarily participate (or participate with the consent of their guardian) 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 foundations 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. The laws may require the public health agency to perform the activity to protect the public's health. Some states, like New York, clarify in statute that epidemiological investigations or other common public health practices are not human subjects research.¹⁴¹ These activities are public health practice, so long as their design and implementation do not cross over to the realm of research (see additional discussion below).

As well, if the 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. Only through the approval of a waiver of the consent requirement pursuant to regulatory reviews may persons participate in human subject research without providing specific informed consent. Furthermore, if an activity is designed as research, but does not involve identifiable health data about living individuals, it should not be classified as research for the purposes of this analysis (because it does not implicate the HIPAA Privacy Rule). If a human subjects research study is specifically exempted from the Common Rule, the activity can be performed without adhering to the requirements of the Common Rule. Some institutions may voluntarily elect to require that an IRB or other body or institutional office determine whether the activity is human subjects research, and if it is, whether the research meets the requirements for exemption.

5.3 Rejected Criteria

The foundations of public health practice and research may help resolve the simpler cases, but more complicated scenarios remain. A state public health authority may, for example be specifically authorized to investigate a public health problem, and choose to engage in a series of activities, part of which include asking participants to voluntarily complete a written survey that indirectly references health data. An assessment of the essential characteristics of public health practice or research may not fully allow the practitioner to properly classify the project. Additional guidance is needed.

Many criteria have been proposed to facilitate these distinctions. These include an examination of (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. For the reasons discussed below, none of these criteria are particularly helpful in making meaningful distinctions.

- **Performance.** Consideration of who is performing the activity has been proposed as an important factor for distinguishing practice from research. Authorized, governmental public health officials or their agents or private sector contractors are deemed as the only persons who can conduct public health practice activities. Similar activities, like disease surveillance, performed by academic figures may be classified as research because an academician lacks the imprimatur of governmental authority. In other words, if a governmental public health agency is doing the activity, it must be practice. Conversely, if a private sector actor is performing the activity, it is probably research. This criteria is dissatisfying for two primary reasons: (1) remember the primary assumption that a public health authority is either conducting, funding, or overseeing the activity, thus implicating the Common Rule or other research protections regardless of who actually performs the activity; (2) the HIPAA Privacy Rule and other laws allow governmental public health agencies to authorize private sector actors (via contract or other agreements) to conduct public health functions. Thus, under the Privacy Rule, a private hospital that lawfully contracts with a local public health agency to establish a cancer registry within the hospital is considered a “public health authority” for that purpose. While this criterion may not be helpful for making distinctions between practice and research, it may be important for deciding what regulatory approach or systems apply.
- **Publication.** Some may suggest that intention to publish the results of their analyses of identifiable health data in a peer-reviewed journal or other source supports a finding of research. However, whether persons performing the activity intend to publish is not particularly helpful for distinguishing practice versus research (see Section 4.0, Case 6, Key Lessons). Public health practitioners and researchers routinely publish their findings (without identifiable health data) whether engaged in practice or research.
- **Urgency.** The exigencies of a set of circumstances may justify a quick classification of an activity as public health practice, or even immediate action without prior classification (see Section 4.0, Case 2, Key Lessons). However, urgency alone is insufficient to distinguish between practice and research. Public health dilemmas may require quick actions through activities that are practice-oriented and activities that are research. Public health agencies and IRBs have processes designed to expedite a review and decision as to a proper distinction.
- **Funding.** The Common Rule is only implicated when federal funds are used to conduct or support human subjects research, or if an institution has voluntarily extended its assurance of compliance with the Common Rule beyond federally-conducted or supported human subjects research. States may apply similar funding criteria to state funding support for research. The absence of governmental funding or support for an activity may lawfully remove it from application via the Common Rule. (Note again, however, that a primary assumption is that such funding or support is proposed). Even if governmental funding is not present, Common Rule standards are nearly universally

applied by private sector IRBs. As well, the HIPAA Privacy Rule applies waiver requirements that are similar to the Common Rule for uses and disclosures of protected health information without written authorization on a national basis regardless of funding sources. In short, the source of funding or support for the performance of a public health activity is an insufficient basis to classify the activity as research or practice.

- **Data Collection Methods.** Some may suggest that the methods for collecting and analyzing health data help distinguish practice from research. Thus, if a proposed activity is supported by health data acquired from private sector health care workers through a public health reporting requirement, this may be viewed as practice. If the data are systematically acquired through a formal survey of randomly-selected persons, it may be viewed as research. In reality, the methods for collecting the data are irrelevant. Public health authorities routinely gather data via surveys for public health practice activities. Researchers routinely access data reported to public health authorities for specific research studies.

5.4 Enhanced Guidelines

Enhanced guidelines (below) provide meaningful bases to distinguish between research and public health practice when applied to any proposed or actual activity that fits the parameters of the primary assumption. None of these guidelines alone are sufficient to fully classify an activity. For more complex, multi-stage, or multi-dimensional activities, the activities themselves may need to be unbundled and examined separately using these criteria. Public health practitioners, for example, cannot conclude that a multi-faceted activity that includes research components is public health practice just because the majority of the work conducted is practice. Rather, they must separate the various components, examining each to make proper distinctions, and applying appropriate regulatory frameworks to each activity depending on its classification. Thus, if the application of any one of these guidelines leads to a classification that the activity is research, the aspect of the activity that gives rise to this classification should be treated as research. These guidelines include:

5.4.1 General Legal Authority

One of the foundations of public health practice (see Figure 1) is that there may be specific legal authority to engage in public health practice and a corresponding duty of public health agencies to fulfill that duty. In most of the cases, a specific legal duty supports finding a corresponding activity as practice. In some cases, however, public health authorities may act pursuant to general legal authorization. For example, a public health agency may seek to collect data on the prevalence of an emerging condition within a subset of the population, but not have precise legal authority to begin data collection for the specific condition. It may instead rely upon a general authorization from the legislature to “acquire any health data needed to monitor health conditions in the population.”

The existence of general legal authorization supports a finding of public health practice, but does not conclusively lead to this end. General legal authority may also allow the public health authority to use research methods to improve the public’s health. The brief statement of authority above, for example, may authorize a public health authority to use practice or research

techniques to fulfill its objective. Analysis of the meaning of the scope and limits of the general legal authorization within a set of facts is necessary to draw firm conclusions, but is a potential factor to consider.

5.4.2 Specific Intent

CDC and others have focused on the role of intent as a primary factor to distinguish practice and research. As discussed in Section 2.5.1, this focus on intent is problematic because the very same activity may be justified as research or practice depending on how the actor expresses intent. This criterion is still useful, however, within a larger framework for making distinctions that restructures the role of assessing intent. Any intent to conduct research, whether primary or secondary, supports a finding that the activity is research. CDC suggests 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.” The intent of research is “to generate or contribute to generalizable knowledge.” The weakness of both of these statements is their generality; they might easily apply to either practice or research. Greater specification of the expression of intent is needed.

The intent of research may be restated as “*to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity’s participants.*” The intent of public health practice may be restated as “*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.*” If the intent clearly and irreversibly changes during the administration of the activity (e.g., a surveillance activity crosses over to a research study), renewed analysis of the activity is needed. If the intent underlying the activity is sustainable as research and practice (e.g., a hybrid case), the activity must by default be viewed as research (at least under the intent criteria). If any intent underlying the activity relates to research, OHRP advises that the activity must be viewed as research, at least concerning this element of the enhanced guidelines.

5.4.3 Responsibility

In the research context, the focal point of responsibility for the health, safety, and well being of individual participants falls upon a specific individual, typically the principal investigator (PI), as well as those working under the supervision of the PI. The PI must adhere to the conditions of the Common Rule in conducting the research and can be held personally accountable for the health and safety of research subjects. Research subjects are entitled to expect that the PI and the PI’s staff will conduct the research within the limits of the subjects’ informed consent and other ethical duties consistent with the Common Rule.

Public health practice does not always feature direct individual responsibility for the welfare of participants. In many practice activities, the responsibility for individuals’ welfare falls generally upon government entities. Public health practitioners are still responsible for their actions that may impact the health, safety, or welfare of participants in a practice activity. However, their responsibility does not arise because of a relationship with participants like that of a PI and her subjects. It arises because legal and ethical duties assumed by public health

practitioners as representatives of government requires them to promote these interests in the performance of their activities.

5.4.4 Participant Benefits

Participants in human subjects research frequently receive no direct benefit from (and may even be harmed by) the activity. While human subjects may benefit from their participation, research is designed primarily to benefit the researcher and society through potential gains of scientific knowledge. Whenever additional risks are imposed on participants in order to make the results generalizable beyond the participants themselves, the activity should be classified as research.

Public health practice activities, however, are premised on providing some 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 supporting objective remains the same: public health practice should contribute to improving the health of participants. Research, however, may not. If the activity offers no prospect of benefit to the participants, then the activity should be classified as research.

5.4.5 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. Sometimes, what is introduced is 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., the 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.¹⁴² 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 likely research rather than public health practice.

5.4.6 Subject Selection

Human subjects research is largely (though not exclusively) driven by the desire of a researcher to test an underlying hypothesis. The research study is designed to answer the question. 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. Participants are self-selected persons with, or at risk of, an affected disease or condition who can benefit from the activity. They are more like clinical patients who need treatment, not human subjects selected by a researcher. 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.

5.5 Checklist for Making Distinctions Between Public Health Practice and Research

This Checklist presents a working draft 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. Additional questions related to the subject matter of the Checklist may require additional review of relevant sections of this report.

Please note that the principles within this Checklist have not been “field tested,” and may not completely distinguish public health research from practice in each case. There are always difficult examples that do not neatly fit into either category. However, this Checklist is designed to help resolve a majority of cases to provide consistency in decision-making on a national basis. Furthermore, the Checklist may need to be tailored to specific requirements within various jurisdictions or agencies.

To use this Checklist, please answer the key **Assumptions [As]** and **Questions [Qs]** in Steps 1-4 below, proceeding in accordance with your responses, to reach the Conclusions in Step 5. In some cases, this process will not require addressing all of the steps; in other cases, each of the steps may contribute to clarifying the distinction.

| 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. |

| Steps and Related Assumptions and Questions | Yes | No | Next Action | |
|---|-----|----|---|--|
| | | | If Yes, then | If No, then |
| 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. |
| Question 4.B.2: Specific Intent: 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: Responsibility: 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: Participant Benefits: Is the activity designed to provide some benefit to the participants or their population as a whole? | | | The activity is likely practice. Go to Q 4.E. | Go to Q 4.D.2. |
| Question 4.D.2: Participant Benefits: Does the activity involve additional risks imposed on participants in order 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: Experimentation: 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: Subject Selection: 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 | | | | |

| Steps and Related Assumptions and Questions | Yes | No | Next Action | |
|---|-----|----|--------------|-------------|
| | | | If Yes, then | If No, then |
| <p>Conclusion 5.A: Public Health Practice. 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 Act 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 <u>HIPAA Privacy Rule and Public Health: Guidance from CDC and DHHS</u>, available at: http://www.cdc.gov/privacyrule/Guidance/Content.htm.</p> | | | | |
| <p>Conclusion 5.B: Human Subject Research. If your responses affirm that your activity (or some part thereof) is or is likely human subjects research, the Common Rule may apply, subject to an exemption. In addition, the activity may be entitled to expedited review under the Common Rule. For additional guidance and a helpful flowchart, please see the <u>Guidelines for the Conduct of Research</u> published by the Office for Human Subjects Research at NIH, available at: http://www.nihtraining.com/ohsrsite/guidelines/graybook.html</p> | | | | |

CONCLUSION

Distinguishing between public health practice and research activities conducted or funded by governmental public health authorities is not always easy. The similarities of these activities and their underlying intent, coupled with a lack of clarification among key legal and ethical policies, makes classification even more difficult. 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.

This report provides a two-stage process for distinguishing public health practice from research activities. A template that neatly separates these activities based on some of their essential characteristics may help resolve the simpler cases. For more complicated cases, enhanced guidelines provide justifiable, additional factors for clarification. These include analysis of the general legal authority concerning the activity, underlying relationships, specific intent of the activity (or its unbundled parts), participant benefits, and planned interventions. These criteria may improve analysis for difficult cases more uniformly if applied across various levels of governmental public health authorities and through IRBs in the public and private sectors.

Though drawing distinctions is critical, in many ways the objective of public health practice and public health research is the same: *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.* Researchers understand this objective and adhere to the Common Rule and other requirements in pursuit of their ethical research activities. Public health practitioners strive to act in ways that promote the public's health while respecting individuals under other legal and ethical norms. This objective should underlie all public health practice activities in the United States.

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