Public Health Practice and Human Subjects Research: Boundaries and Distinctions

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Protecting Patients and Participants: Does It Matter Whether It's Research or Public Health Practice?

YES, IT DOES

- Key differences in the legal authority and oversight for public health practice and for human subjects research
- Misclassification of activities leads to multiple complications
- Both systems working together provide robust oversight, protection, and accountability

Similarities

- Both public health practice and human subjects research may entail the collection and use of identifiable health information
- Both are conducted in a manner that seeks to protect individuals
- Both may be justified as laudable, communal activities that further the public good

- Public health practice is not human subjects research

- Issue: So, if public health practice does not fall under IRB review, then how can we be certain that those public health people are protecting individuals?

Research

- "An activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective."

The Belmont Report

45 CFR 46 Definition of Research

"a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

Specific Intent

The intent of research is *to test a new hypothesis and seek to generalize the findings or acquired knowledge beyond the activity's participants.*

Practice

- "Interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success."
- "The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals."

The Belmont Report

45 CFR 46 Definition of Practice

NONE

- Specific Intent -
  - The intent of public health practice is *to assure the conditions in which people can be healthy through public health programs primarily aimed at preventing known or suspected injuries, diseases, or other conditions, or promoting the health the community that are authorized by and accountable to the public*.

Legal Authority

- Foundations of Public Health Practice
  - **Specific legal authorization 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**

Legal Authority

- Public Health Practice – grounded in constitutionally-approved authority of government to protect the public's health, safety, and general welfare
- Human Subjects Research – grounded in the principles of the federal Common Rule that focus on protecting individuals in the pursuit of knowledge

Legal Authority
Public Health Practice

- US Supreme Court
  Whalen v. Roe, 429 U.S. 589 (1977)
  Mandatory disease reporting
- 3 Standards that must be met:
  - Valid public heatlh purpose
  - Limited to public health departments
  - Adequate statutory confidentiality provisions

Legal Authority
Public Health Practice

- Cancer Registries Amendment Act of 1993
- US Congress explicitly acknowledged distinctions between public health practice and human subjects research

Legal Authority
Public Health Practice

- OHRP specifically acknowledges that acquisition of identifiable health data or specimens by public health authorities for "...legitimate public health purposes..." is not research.

Legal Authority Public Health Practice

- HIPAA Privacy Rule – provides different rules for the disclosure of PHI for public health and research purposes.
- Expressly permits PHI to be shared with public health authorities

HIPAA Privacy Rule and Public Health
MMWR 2003; 52 (Suppl): 1-20.

Stubbed Toes

- Exempt research
- Principal investigator
- Subject selection
- Consent
- Differing status at federal vs. state level
- HIPAA – “may report”
- FERPA - “don’t report”
- “practice” not defined in 45 CFR 46

Exempt Research

- If the activity is public health practice, then it is not research and it does not fall under 45 CFR 46.
- It is the State that makes the determination if the activity is practice or reseach, not an IRB

Principal Investigator

- Responsibility for the health, safety, and well-being of individual participants in research typically falls on a specific individual, i.e.. the principal investigator (PI)
- Responsibility for individuals' welfare concerning public health practice generally falls on governmental public health entities.

Subject Selection

- Research - subjects are selected by the researcher (both cases and controls) and may be randomized to reduce bias so that results can be generalized to a larger group
- Public health practice - self-selected individuals with a disease or condition participate to seek benefits for themselves or their community from participating in the activity

Consent

- **May legitimately involve persons who did not specifically volunteer to participate (i.e., they did not provide informed consent)**
- **Disease reporting laws**
  - **Authority rests with States**

Federal vs State

- Authority for public health is reserved to the states under the US Constitution
- Federal agencies do not have authority for public health practice
- Therefore, an activity that is conducted by a state public health authority can be public health practice, but that same activity when conducted by a federal agency falls under 45 CFR 46

HIPAA

- HIPAA provides language to permit ongoing public health practice, including disease reporting
- Because authority for disease reporting resides with States, federal regulations cannot mandate disease reporting
- Therefore, HIPAA regulations enable sharing of public health information through language that practitioners "may" share PHI with public health authorites

FERPA

Family Education Rights Privacy Act 1974

- **No provision for public health purposes**
- **No definition of an emergency**
- **Recent restrictive guidance by DOE**
  - **Instruct health care providers not to report under state reporting laws**
  - **Instruct schools not to share immunization records with public health authorities**
  - **Interrupted birth defects surveillance by CDC**

Rejected Criteria

- Whether the findings will be published
- Urgency underlying the activity
- Source of funding
- Data collection methods
- Statistical approaches

Synergism

- Research and Practice have powerful systems to protect individual autonomy and rights
- These systems draw their legitimacy from different legal authority
- Together, they offer robust protection and accountability for both practice and research

Public Health Practice vs. Research. A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions

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- The CSTE report available at: http://www.cste.org/pdffiles/newpdffiles/CSTEPHResRptHodgeFinal.5.24.04.pdf

- CSTE website, http://www.CSTE.org scroll under “publications”