

IRB Considerations for Disaster Epidemiology

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Disclaimer

“The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.”

Mission

CDC [works 24/7](#) to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.



CDC's Role



- Detecting and responding to new and emerging health threats
- Tackling the biggest health problems causing death and disability for Americans
- Putting science and advanced technology into action to prevent disease
- Promoting healthy and safe behaviors, communities and environment
- Developing leaders and training the public health workforce, including disease detectives
- Taking the health pulse of our nation

CDC's Mission

Public Health Practice Defined...

- Belmont Report – “Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another...or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others...”
- CIOMS – “Many studies using the tools of epidemiology which are performed on a regular basis by public health agencies, such as routine surveillance for disease outbreaks, are correctly viewed as “practice” even though the information produced may contribute to generalizable knowledge.”
- Coughlin (2006) - ...surveillance, emergency response, program evaluation
- OHRP (2007 draft) - Public health practice includes a wide range of activities whose objectives include the prevention and control of diseases and injuries and the delivery and improvement of public health programs and services. Common types of public health practice activities include surveillance, evaluation, and emergency response.
- CDC - ...identify and control a health problem; implement evidence-based practices; data collected needed to access or improve implementation of evidence-based programs or services; activities focused on health of participants or the participants' community
- CSTE (2004) – “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.

Research

Several Regulatory Definitions

- 42 CFR 52
- 45 CFR 75
- 21 CFR 56
- 45 CFR 46

Definitions CDC Uses

Research

Technically several regulatory definitions

- 42 CFR 52
- 45 CFR 75
- 21 CFR 56

For purposes of IRB,
45 CFR 46.102 - Research Involving Human Subjects

Public Health Practice

General Attributes

- identify and control a health problem or improve a public health program or service
- Implementing evidence-based practices
- data collected are needed to assess or improve the program or service, the health of the participants or the participants' community

Specifically,

- 45 CFR 46.102(l)(2) – Public Health Surveillance

CDC's Portfolio



CDC's IRB

- Perform Review Required by Regulation
 - 45 CFR 46
 - 21 CFR 56
 - PHS HIV Notification
 - HIPAA Board