Public Health Research and Public Health Practice: a CDC Perspective

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- Barbara DeCausey, MPH, MBA
  - Chief, Human Research Protection Office (HRPO), OSI
Overview

- CDC organizational structure
- CDC policy considerations
- CDC locus of responsibility
  - Public health research and public health nonresearch
- Examples
CDC
ORGANIZATIONAL STRUCTURE
Office of Scientific Integrity,
Office of the Associate Director for Science

Director – Ron A. Otten, PhD
Deputy Director – Kimberly S. Lane, MBA

Animal Care and Use Program Office

Human Research Protection Office

Information Collection Review Office

Privacy & Confidentiality Unit

Public Health Ethics Unit

Training Unit

Chief, Tim J. Barrett, PhD

Chief, Barbara DeCausey, MPH, MBA

Chief, Tony Richardson, MS, MPH, MSCJ, CPHA

Lead, Drue H. Barrett, PhD

Lead, Julie Orta, MPH, MCHES
CDC
POLICY CONSIDERATIONS
Ethical and legal obligation to ensure individuals are protected in all public health activities

All CDC activities must be reviewed for whether research involving human subjects is being conducted.

CDC and collaborators comply with 45CFR part 46 (Common Rule) and/or 21CFR parts 50, 56 to ensure human research protections.
CDC Policies for Research involving Human Subjects (continued)

- Human Research Protections Policy (July 2010)

- Distinguishing public health research and public health nonresearch (July 2010)
### A CDC Perspective

<table>
<thead>
<tr>
<th>Public Health Research</th>
<th>Public Health Practice</th>
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<tbody>
<tr>
<td>Purpose is to develop or contribute to knowledge which will be used beyond the immediate activity</td>
<td>Purpose is to identify and control a health problem or improve a public health program or service</td>
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<tr>
<td>Benefits may or may not include study participants, always extend beyond the study participants</td>
<td>Benefits of the project are primarily or exclusively for the participants or their community</td>
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<tr>
<td>Data collected exceed requirements for care of study participants or extend beyond scope of activity</td>
<td>Data collected are needed to assess or improve the program or service, the health of the participants, or their community</td>
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Distinguishing Public Health Research from Nonresearch

- Surveillance projects, emergency responses, and evaluations
  - Some activities can be research
  - Consideration on a case-by-case basis

- Prevention or control of disease or injury or to improve public health program, clearly without a research component, is deemed nonresearch
  - Changeover to incorporating a research component remains a possibility during emergency situations

- Determinations require careful consideration

CDC's Research and Nonresearch Determinations

N = 1,215*

*From July 2010 to June 2011
CDC's Research Portfolio involving Human Subjects: Active Protocols

N = 1,090*

64% Domestic
36% International

*As of April 2012; not including NIOSH or NCHS
CDC
LOCUS OF RESPONSIBILITY
Team Effort by All Stakeholders

- CDC Investigators
- CDC ADSs, Human Subjects Contacts
- Institutional Official
- IRBs
- IRB Administrative Staff

Responsible for ensuring human research protections
Determination for Review

- All projects undergo a formal review by the Associate Director for Science (ADS) in each Center, Institute, Office.
- Projects determined to be research involving human subjects where CDC is engaged are routed to the Human Research Protection Office (HRPO).
  - Nonexempt research is reviewed by an IRB.
  - Exempt research is reviewed by the Chief of HRPO.
- All determinations are submitted to HRPO on a monthly basis for quarterly review to ensure accuracy.
Research Determination Process

CIO

Investigator
Branch Chief/Country Director
Division ADS
ADS/HSC

OD

Research Determination

HRPO, OSI, OADS

CDC IRB

Research requiring IRB review or exemption

ADS – Associate Director for Science
OD – Office of the Director CDC
HSC – Human Subjects Contact
HRPO – Human Research Protection Office
OSI – Office of Scientific Integrity, OADS, CDC OD

With input from Aun Lor, CDC
**HRPO, OSI, OADS**

- Supports CDC’s IRBs and performs IRB-related oversight functions
- Initial review of submission for completeness
- Protocols are assigned to an IRB based on subject matter, experience, and conflicts of interest
  - 5 Atlanta-based IRBs: A, B, C, G, and S
  - 2 off-site IRBs: NCHS (Hyattsville) and NIOSH (Cincinnati)
HRPO Chief

- Grants exemptions
- Approves reliance on a non-CDC IRB
- Serves as a resource to Human Subjects Contacts and ADSs
- Corresponds with the Office for Human Research Protections (OHRP) and the FDA
CDC Options for IRB Review

- **CDC IRB: Convened Board (Quorum)**
  - Expedited review not permitted
  - Project may meet the expedited review criteria, but the research is controversial or includes sensitive topics or issues

- **CDC IRB: Expedited Review (45 CFR 46.110)**
  - Permissible categories
  - Experienced reviewer outside convened meeting

- **Non-CDC IRB: Reliance Request**
  - Reliance on an outside IRB
  - Limited criteria primarily based on CDC’s role
EXAMPLES
Surveillance: Example 1*

- **Description:** a diabetes surveillance system is used to regularly describe the burden of diabetes and its complications

- **Purpose:** to provide information for the development and improvement of services for the prevention and control of diabetes

Surveillance: Example 1 (continued)

- Determination:  nonresearch

- Intended benefit: those who have diabetes or are at risk for diabetes
Surveillance: Example 2*

- Description: a sentinel surveillance system is used to identify and describe cases of Lassa fever

- Purpose: to generate baseline information on the Lassa virus and human clinical Lassa fever

Surveillance: Example 2 (continued)

- Determination: research

- Intended benefit: none for study participants since no interventions are planned and thus the results will contribute to knowledge of Lassa fever
Emergency Response*

- **Response activities tend to be nonresearch**
  - Goals are to identify, characterize, and solve an immediate health problem
  - Direct benefit for participants and communities involved
  - Consideration of project intent is done on a case-by-case basis

- **Emergency response may contain research components**
  - Specimens collected and stored for future research use where analysis is not needed to solve the immediate health crisis
  - Systematic study of non-standard interventions or a comparison of standard interventions

- **Examples available within CDC policy document**

Program Evaluation: Example 1*

- **Description:** as part of the evaluation of a school-based HIV prevention program, the status of students receiving HIV prevention education was assessed.

- **Purpose:** to provide information to a public school system within a state that will be used to improve their own school-based HIV prevention program.

Program Evaluation: Example 1 (continued)

- Determination: **nonresearch**

- Intended benefit: those school students within a specific state population
Program Evaluation: Example 2*

- **Description:** a three-tiered project addresses diabetes care, community screening for persons at high risk for developing diabetes, and population-based approaches to increase physical activity to reduce preventable complications via a health systems approach.

- **Purpose:** to evaluate new and innovative interventions to prevent diabetes and its complications.

Program Evaluation: Example 2 (continued)

- **Determination:** research

- **Intended benefit:** knowledge gained from this project will be used to develop intervention projects in other communities
Summary

- Research determinations require careful consideration
- CDC uses a team-based approach
- Examples and case studies are helpful
For more information please contact Centers for Disease Control and Prevention

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.