

US EPA ARCHIVE DOCUMENT

## Didactic Session C12

# *Distinguishing Health Care Practice from Health Care Research: When Is IRB Review Required?*

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# Disclosure/Disclaimer

- Drs. Bierer, Botkin, and Lux have all participated in the activities of the Secretary's Advisory Committee on Human Research Protections (SACHRP) of the U.S. Department of Health and Human Services (DHHS) during periods when SACHRP may have considered matters related to the topic of this session.
- Their views as expressed here, however, do not represent the official position of SACHRP or of DHHS.
- The views of Dr. Bierer and Dr. Botkin are their own.
- The views of Dr. Lux represent the official position of the U.S. Environmental Protection Agency on the matters under discussion.

# Framing the Issues

- Inappropriate application of human research regulations to clinical practice activities diverts resources required for regulatory oversight of research, thereby increasing the potential risks inherent in the research enterprise while simultaneously impeding practice.
- Failure to apply human research regulations when they are required risks violating the interests of human research subjects
- Distinguishing *research* from *practice* is therefore critical to the effective and efficient functioning of IRBs.

# *Practice vs. Research* in the Belmont Report

- Key features of *practice*:
  - Designed solely to enhance the well-being of individuals
  - Interventions have a reasonable expectation of success
  - Purpose is to provide diagnosis or treatment
- Key features of *research*:
  - Designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge
  - Usually described in a formal protocol
- Caveats:
  - The distinction is “blurred”
  - Departures from standard or accepted practice do not in and of themselves constitute research
  - Research and practice may be carried on together

# *Research* in the Common Rule

- A systematic investigation
- Designed to develop or contribute to generalizable knowledge
- Includes research development, testing and evaluation
- May be conducted under a program which is not considered research for other purposes (e.g., a demonstration or service program)

# Are Belmont and the Common Rule Dispositive?

- For the easy cases, certainly
- But what about the hard cases:
  - The systematic collection of identifiable personal information about health outcomes from people receiving the swine flu vaccine to assess efficacy and possible side effects – is that research or public health practice?
  - A systematic intervention in the care of immunosuppressed patients to introduce a newly released antibacterial soap with monitoring of the ongoing infection rate – is that research or health care quality improvement?
  - A physician's use of an approved drug for an unapproved indication because she believes it may have a therapeutic effect in a particular patient – is that research or innovative care?

# Outline of the Session

- Research vs. practice in activities that fall within the domain of *public health* (Dr. Lux).
- Research vs. practice in activities that fall within the domain of *health care quality improvement* (Dr. Botkin).
- Research vs. practice in activities that fall within the domain of *innovative clinical care* (Dr. Bierer).

# Distinguishing Public Health Practice from Public Health Research

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# Acknowledgement

- My thinking about these matters has drawn heavily on the document *Public Health Practice vs. Public Health Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions* prepared for the Council of State and Territorial Epidemiologists (CSTE) in 2004 by James Hodge and Lawrence Gostin with the CSTE Advisory Committee and published on the CSTE website ([www.cste.org](http://www.cste.org)).
- Responsibility for the views expressed here, however, remains solely with me.

# Case Study: Air Sampling at the Libby, MT BMX Track

- Stationary air samplers are placed at intervals around the track and in the stands each time the track is used
- Human exposures to asbestos are measured for both the riders and the spectators throughout the period of use
- The purpose of the project is to guide decision-making about the need for further clean-up of the track

# Case Study: Air Sampling at the Libby, MT BMX Track

- This is an easy one – as described, it's a surveillance activity that is clearly public health practice
- But what if riders are asked if they will volunteer to have personal air samplers attached to their vehicles?
- And what if they are asked if they will volunteer to wear the personal air samplers while they ride?

# Key Distinguishing Characteristics of Public Health Practice Activities

- Conducted under appropriate legal authority for engaging in public health practice
- Participants are either legally required to participate or are self-selected, not randomly chosen
- The intent of the activity is to provide a specific health benefit to a defined community or group of individuals
- The activity uses standard, accepted, or proven interventions

# Key Distinguishing Characteristics of Public Health Practice Activities

- The nature of the knowledge generated is specific to the participants or to the target community
- There is no intent to generate knowledge that is generalizable beyond the participants
- The benefits accrue to the participants themselves
- Participants do not take on additional risks to make the benefits more widely available

# Distinguishing Public Health Practice from Public Health Research

- Except for legal authority, no single feature is dispositive
  - Specific legal authority may place the activity into the domain practice
  - The absence of general or specific legal authority removes the activity from the domain of practice
- The more key characteristics of practice that are present, the more likely the activity is to be public health practice
- The fewer key characteristics of practice that are present, the more likely it is to be public health research

# Commonly Shared Features of Public Health Practice and Research

- Use of rigorous (and systematic) scientific methods for data collection and analysis
- Involvement of individuals trained in research methodology
- Publication of findings
- Funding by government agencies

# Case Study: Air Sampling at the Libby, MT BMX Track

- Legal authority – yes
- Participation mandatory or by self-selection – yes
- Intended to provide health benefit to defined group – yes
- Uses standard interventions – yes
- Knowledge specific to the participants or target community - yes
- Not intended to generate knowledge generalizable beyond the participants – yes initially, then no
- Participants receive the benefit – yes
- Participants do not take on additional risk – yes initially, then no to an increasing degree
  
- Conclusion – clearly public health practice initially but approaching the border of research with the first modification and crossing it with the second

# The Swine Flu Vaccine Surveillance Example

- Legal authority – it depends on the particulars of the surveillance
- Participation mandatory or by self-selection – it depends on the methodology
- Intended to provide health benefit to defined group – yes
- Uses standard interventions – yes
- Knowledge specific to the participants or target community - no
- Not intended to generate knowledge generalizable beyond the participants – it depends on the methodology
- Participants receive the benefit – yes
- Participants do not take on additional risk – it depends on the methodology
  
- Conclusion – would likely be done as public health practice but could also be done as a public health research project depending upon the legal authority governing the activity and the participant selection methodology

# 101(c) of the Common Rule

- Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.
- Principal factors that I consider when making this judgment in ambiguous cases:
  - Do the interests of the agent diverge from the interests of those with whom the agent is interacting or intervening?
  - Are participants being asked to take on any burden or risk under circumstances in which the benefits accrue to a broader group, even when the participants share fully in the benefits as well?
- Rationale:
  - Ensuring that the interests of potential participants are protected
  - Ensuring that justice is served