

The Federal Demonstration Partnership Mission

“....The goal of improving the productivity of research without compromising its stewardship has benefits for the entire nation...

....At its regular meetings, faculty and administrators talk face-to-face with decision-makers from agencies that sponsor and regulate research. They hold spirited, frank discussions, identify problems, and develop action plans for change. Then – again working jointly – they test the new ways of doing things in the real world before putting them into effect.”

Against Meetings: Education, Exemptions, and External IRBs

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Federal Demonstration Partnership 1/12/09

Education

- HHS Officer of the Inspector General Report “Institutional Review Boards: A Time for Reform” (1998)
- NIH key personnel training requirement (2000)
- National Bioethics Advisory Commission “Ethical and Policy Issues in Research Involving Human Subjects” (2001)
- Institute of Medicine :Responsible Research: A Systems Approach to Protecting Research Participants” (2002)
- Secretary’s Advisory Committee on Human Research Protections Recommendation (2007)
- OHRP Compliance Evaluation Experience

Education: Issues

- Data or Arguments?
- Guidance or Regulation?
- Education for Who: IOs? IRB members?
IRB administrators? Investigators?
- Content?
- Proficiency?
- Timing?
- Procedures, Documentation, Costs?

Learning from the Standards-based Education Reform Model

Using standards specifying what students should and be able to do to align:

- Teacher preparation

- Curriculum

- High Stakes Tests

The Human Subjects Protections High Stakes Test: IRB Approval

- Minimized risks
- Risks reasonable relative to anticipated benefits
- Equitable selection of subjects
- Informed consent or waiver
- Documentation of consent or waiver
- Safety data monitoring
- Privacy/confidentiality provisions
- Additional safeguards for vulnerable populations

Demonstration Project #1

Using the Standards-Based
Reform Model to Reduce the
Number of Re-Tests/Review
Meetings

Exemptions

- Is the activity HHS supported or conducted?
- Is the activity “research”?
- Does the research involve “human subjects”?
- Is the human subjects research “exempt”?

“Research”

- “*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

(46.102(d))

“Human Subject”

“*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.”

(46.102.(f))

“Exempt”

- ...normal educational practices
- Nonsensitive or anonymous education tests, survey or interview procedures, or observation of public behavior
- Education tests, survey or interview procedures, or observation of public behavior involving public officials or statutorily confidential data
- Studies of anonymous existing data, documents, records, or specimens
- Studies of federal public benefit programs
- Food quality/consumer acceptance studies

(46.101(b))

“Exemption Determination”

“*HHS Decision*: The final regulations will not require that an investigator file a separate justification for exemption, although the appropriateness of a claimed exemption will be evaluated in the case of HHS-funded research on the basis of information contained in the research application. Institutions remain free to adopt any administrative procedures relative to exempt categories of research, if they deem them appropriate.” (Federal Register, 1/26/81)

Demonstration Project #2

Reducing IRB Member/Meeting
Time Dedicated to Exemption
Decisions

External IRBs

The screenshot shows a Microsoft Internet Explorer browser window displaying the AAMC website. The address bar shows the URL <http://www.aamc.org/research/irbreview/start.htm>. The page title is "AAMC: Alternative IRB Models". The website header includes the AAMC logo and the tagline "Tomorrow's Doctors, Tomorrow's Cures". The navigation menu includes links for Home, Government Affairs, Newsroom, Meetings, Publications, Shopping Cart, Site Map, and a Search box. The main content area is titled "Alternative IRB Models" and contains the following text:

The AAMC recently co-sponsored two important events on alternative IRB models.

2006 National Conference on Alternative IRB Models: Optimizing Human Subject Protection

Sponsored by the National Institutes of Health, the Office for Human Research Protections, the Veterans Administration, the Association of American Medical Colleges, and The American Society of Clinical Oncology, and held on November 19-21, 2006, the national conference focused on perceived barriers to the use of alternative models and suggested strategies for overcoming them so as to optimize human subject protection. The national meeting was suggested by the Secretary's Advisory Committee on Human Research Protections as a means to explore perceived barriers to use of alternative IRB models and to develop means for addressing them. [View conference presentations and final report >>](#)

2005 Workshop Summary Report

The National Institutes of Health, the Office for Human Research Protections, the Association of American Medical Colleges, and the American Society of Clinical Oncology sponsored a workshop on November 17-18, 2005, to gather information on noninstitutional IRB review mechanisms for human subjects research from a variety of sources and perspectives.

Suggested by the Secretary's Advisory Committee on Human Research Protections, the workshop was designed to inform future committee action, such as developing a consensus statement on alternative models for IRB review or suggested OHRP guidance. The workshop provided an opportunity for participants to voice their opinions regarding the factors that should influence the selection of an IRB model for specific types of research. The [Workshop Summary Report \(PDF, 7 pages\)](#) summarizes the two-day workshop.

This page contains documents in Portable Document Format (PDF). The Adobe Acrobat® Reader® is required to view PDF documents. [Download Acrobat® Reader®.](#)

On the right side of the page, there is a sidebar with the following links:

- [2006 Conference Summary Report \(PDF, 53 pages\)](#)
- [2006 Conference Presentations](#)
- [2005 Workshop Summary Report \(PDF, 7 pages\)](#)
- [National Cancer Institute Central IRB Initiative](#)

The footer of the page includes the following text:

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The taskbar at the bottom of the screen shows the Windows Start button and several open applications: Calendar - Micro..., FW: FDP - Upda..., FDP Meeting Jan..., AAMC: Alternati..., and About FDP - Mic... The system clock shows 2:12 PM.

Cooperative Research

“In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. ...[A]n institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.”
(45 CFR 46.114)

...And External IRBs

An Anticipated *Request for
Information* about Direct
Accountability for External
IRBs

Demonstration Project #3

Reducing Duplication of Meeting Review Efforts