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 statutorally 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))

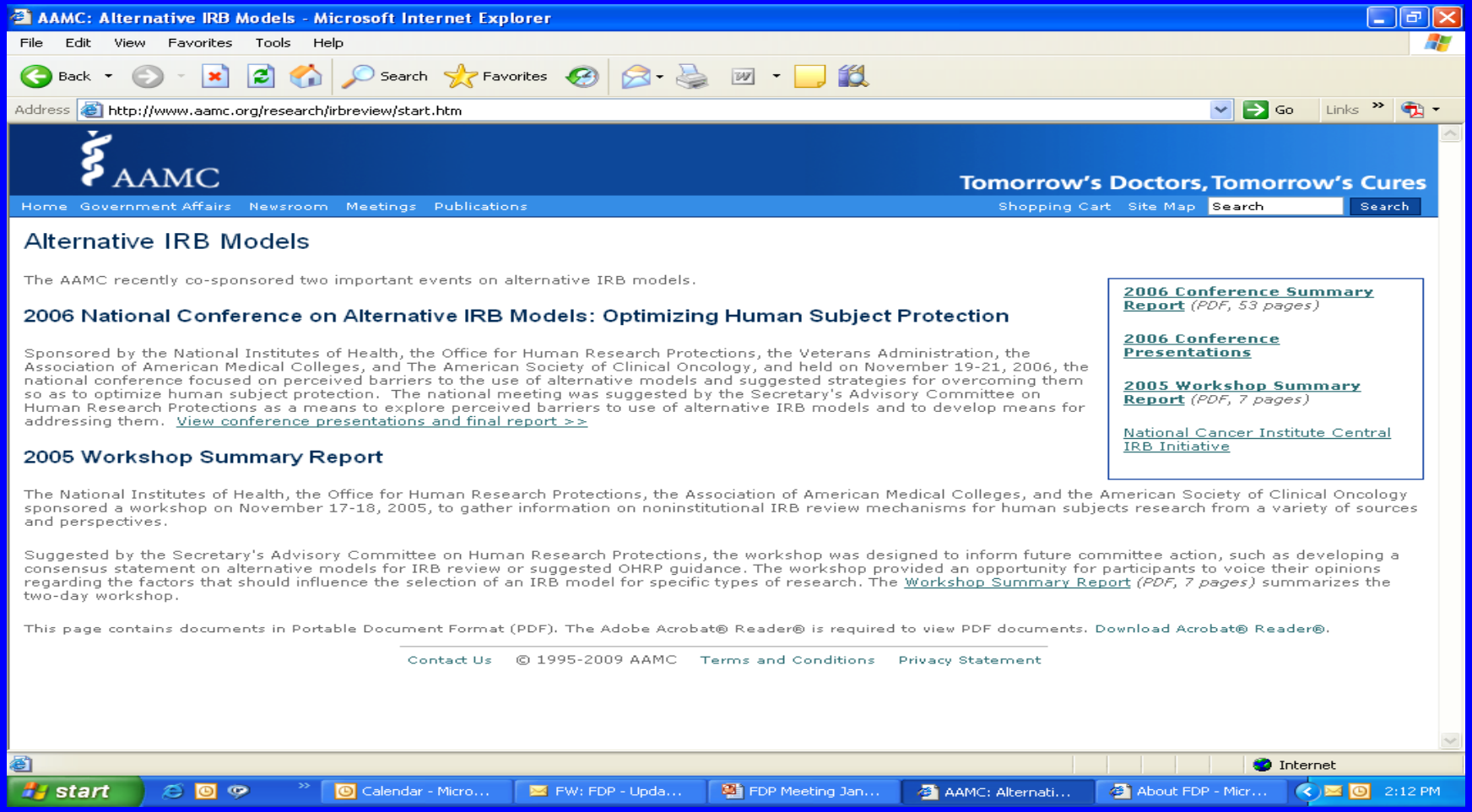
“Exemption Determination”

“*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



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