ANPRM:
Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators

AKA Lots and Lots of Unanswered Questions

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What is an ANPRM?

- An ANPRM is an **Advance Notice of Proposed Rulemaking**

- Published notice in Federal Register used by agency to solicit ideas before drafting a **Notice of Proposed Rulemaking**
Overview of Rulemaking Process

RFI → ANPRM → NPRM → Final Rule

public comment → public comment → public comment

*All comments will be posted without change to [http://www.regulations.gov](http://www.regulations.gov)*
• Suggestions and comments in the ANPRM are proposals: they will not be implemented without further notice and comment

• Comment period for the ANPRM is open until:

OCTOBER 26th, 2011
Seven Proposed Changes

I. Refinement of Risk-Based Protections
II. Streamlining IRB Review of Multi-Site Studies
III. Improving Consent Forms/Process
IV. Strengthening Data Protections to Minimize Information Risks
V. Improve Data Collection to Enhance System Oversight
VI. Extension of Scope of the Federal Regulations
VII. Clarifying and Harmonizing Regulatory Requirements and Agency Guidance
Current Risk-Based Protections

- **Convened IRB** - default review for greater than min risk & some min risk
- **Expedited review** – eligible categories on “list” & min risk
- **Exempt** -- six categories exempted from IRB review altogether
Greater than Minimal Risk Research

• The requirement that greater than minimal risk research must reviewed by a convened IRB: essentially unchanged

• Should continuing review no be longer required if the research is in the analysis or follow-up phase?
Minimal Risk Research

• Presumption that minimal risk studies will undergo expedited review, which requires review by only one reviewer (the reviewer has the option to send the study for full IRB review)

• Eliminate requirement for continuing review of expedited studies

• Streamline submission requirements: use of standard templates for protocols & consent forms
“Excused” Research

• Currently, research involving the use of educational tests and some surveys may be exempt from the Federal regulations

• The ANPRM proposes to clarify the list of exempt studies, and make all exempt studies subject to new data security and information protection standards

• Given that these studies would no longer be fully exempt, they may be called “Excused”
Tracking Excused Research

- Researchers could begin conducting excused studies immediately after registering them with an institutional office.

- Institutions might prospectively review some submissions to determine if they were, in fact, excused.

- Sample retrospective auditing would be required.
Improving Informed Consent

- Prescribing content
- Restricting content
- Limiting length
- Prescribing how information presented
- Reducing “boilerplate” language
- Templates
Consent Rules

• Use of biospecimens:
  • Consent required, for both prospective and existing biospecimens, even if not identifiable
  • Investigators can ask subjects to give broad consent for future research
  • Applies prospectively (collected after new rule)

• Use of existing data (data that were collected for purposes other than the proposed research):
  • Consent required if collected for research purposes, regardless of identifiability
  • Consent required if collected for non-research purposes, only if identifiable
Multi-Site Studies

• Currently, a domestic multi-site study might be reviewed by tens, or even hundreds of IRBs

• Mandate that all domestic sites in a multi-site study rely upon a single IRB as their IRB of record for that study

• Institutions could still choose to conduct additional internal ethics reviews
Information Risks

• ANPRM proposes to mandate data security & information protection standards for all research with identifiable information, including:
  • biospecimens
  • survey data
  • research with administrative records
  • secondary analysis of data

• These protections would apply to prospective collection after changes to Common Rule
Data Collection

Proposal:

- Web-based, Federal-wide portal that would require investigators to submit electronically certain safety data

- Harmonize safety reporting guidance
Scope of Regulations

• **Current:** HHS regulations apply to non-exempt human subjects research conducted or supported by Common Rule agency, or if institution has “Checked the Box”

• **Proposal:** Require domestic institutions that receive Federal funding from Common Rule agency for research with human subjects to extend protections to all research studies conducted at their institution
Clarifying and Harmonizing Regulatory Requirements and Agency Guidance

• By 1991, 15 Federal agencies adopted the Common Rule
• Each agency may issue its own guidance
• Consequently: variations in the guidances
• Other Federal laws and regulations enacted
  • rules are inconsistent in certain areas
How to Submit Comments

Identify by docket ID number: **HHS-OPHS-2011-0005**

- Mail/hand delivery/courier
- For paper, disk, or CD-ROM submissions:
  Jerry Menikoff, M.D., J.D., OHRP
  1101 Wootton Parkway, Suite 200
  Rockville, MD 20852

*Comments received, including any personal information, will be posted without change*
OHRP Contact Information

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