

NIH CLINICAL CENTER ETHICS GRAND ROUNDS
October 5th, 2011



ANPRM:

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

AKA Lots and Lots of Unanswered Questions

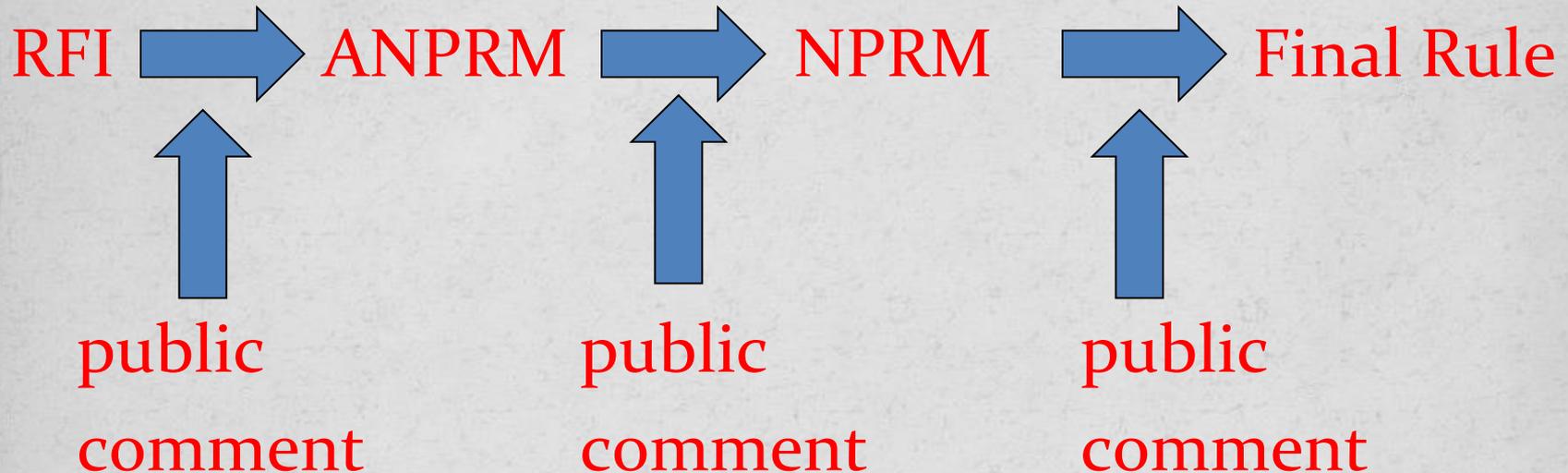
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Office for Human Research Protections (OHRP)**

What is an ANPRM?

- An ANPRM is an **A**dvan**N**ce **N**otice of **P**roposed **R**ule**m**aking
- Published notice in Federal Register used by agency to solicit ideas before drafting a **N**otice of **P**roposed **R**ule**m**aking

Overview of Rulemaking Process



*All comments will be posted without change to <http://www.regulations.gov>

ANPRM?

- 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**

- Federal eRulemaking Portal:
<http://www.regulations.gov/>
- Mail/hand delivery/courier
- For paper, disk, or CD-ROM submissions:
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Rockville, MD 20852

Comments received, including any personal information, will be posted without change

OHRP Contact Information

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<http://www.hhs.gov/ohrp/news/index.html>