Proposed Revisions to the “Common Rule” for Protection of Human Subjects

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“Common Rule”

  “Protection of Human Subjects”
  - Regulations for the Department of Health and Human Services
  - 1981: Regulations revised and expanded
  - 1991: Adopted by 14 other federal departments and agencies
  - No significant changes since 1981
- Created “Institutional Review Boards” (IRBs)
Revision Procedure
Advanced Notice of Proposed Rule Making (ANPRM)
“Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators” (July 26, 2011)
Concerns of the ANRPM

- IRBs spend too much time reviewing research with minimal risk of harm.
- Multi-site studies are reviewed by multiple IRBs, which is inefficient and inconsistent.
- Informed consent documents are often long, confusing, and designed to protect the research institution not the subject.
- Use of genetic information, biospecimens, medical records, etc. has changed risks and benefits of research.
- IRBs do not have the expertise to evaluate “informational risk”.
Proposed changes

• Replace category of “exempt” with “excused”
• Eliminate annual reviews of minimal risk research and data analysis
• Improve the informed consent process
• Limit secondary analysis of existing biospecimens and data to purposes in the informed consent
• Use HIPAA to evaluate informational risks
• Require institutions to assure data security
Proposed changes (continued)

- Extend Federal IRB regulation to all research, regardless of funding source
- Improve collection of data on unanticipated problems and adverse events
Current Levels of IRB Review

- Not human subjects (not regulated)
- Exempt
  - Listed types of research activities, such as educational tests, public settings, or existing documents or specimens
- Expedited review
  - Certain minimal risk types of research
  - Review by one member of the IRB
- Full committee review
The IRB Catch 22

Question: How does a researcher know if a research project is “exempt” from IRB regulation?

Answer: The researcher must ask an IRB.

“OPRR advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research.”

Welcome changes:

• “Excused” Research
  – primary risk is informational; must meet standards to protect privacy/confidentiality
  – register research using a simple form
    • PIs decide themselves
    • Records are audited periodically
  – includes social/behavioral methods, such as interviews, focus groups, and surveys of competent adults
Welcome changes

- Changes to informed consent
  - Guidance on required content
  - Restricting inappropriate content
  - Limiting length
  - Reducing institutional “boilerplate” language
  - Providing standardized consent form templates
  - Allowing more oral consent
Problematic proposals

Changes to the Re-use of Pre-existing Data

- Data collected for research can only be used for a purpose covered in the informed consent, even if the data are de-identified.
- A standard broad consent would be accepted.
- Biospecimens would always require written consent.
Re-use of existing specimens and data

- Uses of biospecimens are changing rapidly
- Concern over biospecimens was extended to existing data

The tribe understood that specimens were collected to study diabetes, and they were offended when other research was conducted.
Problematic proposals

Mandatory Data Security and Information Protection Standards

- IRBs would not review “informational risk”
- Institutions would provide data security for all research
- HIPAA standards would extend to Common Rule research
HIPAA is inappropriate for most research

*Health Insurance Portability and Accountability Act of 1996 (HIPAA)*

- Designed to protect medical records
- De-identification based on removal of 18 identifiers
- No standard for deductive disclosure
Data sharing in the social sciences

The ANPRM ignores two decades of National Research Council reports on data sharing in the social sciences. The social sciences have a working system for sharing restricted-use data.
Now there are two more reports:

**PROPOSED REVISIONS TO THE COMMON RULE**
Perspectives of Social and Behavioral Scientists

**PROPOSED REVISIONS TO THE COMMON RULE**
for the Protection of Human Subjects in the Behavioral and Social Sciences
Thank you!

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