8 Most Significant Proposed Changes to the Common Rule

Susan L. Rose

Office for the Protection of Research Subjects (OPRS)

Overview

1. Informed Consent
2. Use of Biospecimens
3. Activities Excluded from IRB Review
4. Exempt Research
5. Waiver of Consent
6. Single IRB Review
7. Continuing Review
8. Extend Application of Common Rule

1. Informed Consent

- Final version of every clinical trial consent form must be posted on public federal website.
- Unduly long consent forms not allowed
- Informed Consent required for secondary research with deidentified biospecimens.
  - "Broad" consent for future unspecified research permitted using HHS consent template

2. Use of Biospecimens

- Human Subject definition amended to include all uses of biospecimens by researchers, regardless of identifiability.
- Broad consent for future use must be obtained at point of collection or prior to subsequent use for research with biospeciemens.

3. Exclusions from IRB Review

- Not Research:
  - Program Improvement *(data collection and analysis)
  - Oral history, journalism, biography, and historical scholarship
  - Criminal justice *(data collection and analysis)
- Non-research purposes
  - Quality Assurance and Quality Improvement
  - Public health surveillance
  - Intelligence surveillance

  } Exclusively for activities conducted by federal agencies

- Low-risk and subject to independent controls
  - Educational test, survey procedures, interview procedures, or observation of public behavior
  - Research conducted by government agency using government generated/collected data
  - Activities regulated by HIPAA
  - Study/research of information that has or will be collected

4. Exempt Research

- Feds will develop a tool that determines if a project is exempt– avoids overregulation of low risk studies.
- New and modified exemption categories:
  - *certain research involving benign interventions with adult subjects*
  - *research involving educational tests, surveys, interviews or observations of public behavior when sensitive information may be collected, provided that data security and information privacy protections policies are followed*
  - *secondary research use of identifiable private information originally collected as part of a non-research activity, where notice of such possible use was given*
  - *storing or maintaining biospecimens and identifiable private information for future, unspecified secondary research studies, or conducting such studies, when a broad consent template to be promulgated by the Secretary of HHS is used, information and biospecimen privacy safeguards are followed, and limited IRB approval of the consent process used is obtained*
- Certain secondary research using data/biospecimens, will be reviewed under new "limited IRB review" provisions. IRB will **only** check that broad consent is collected and privacy protection is appropriate.

5. Waiver of Consent

- Limits waiver or alteration of consent for biospecimens research (regardless of identifiability).
- New stringent waiver criteria for biospecimen research:
  - Research must have a “compelling scientific purpose”.
  - Waiver not to be used if consent was obtained or can be obtained.

6. Single IRB Review

- Mandatory single IRB of record for U.S. sites participating in a multi-site study.
  - The funding agency would be responsible for choosing the IRB of record.
  - Excluded: Studies with FDA regulated devices and cooperative group studies
  - For studies with no funding agency, the lead institution conducting the research would be responsible (lead institution not defined).
- The requirement for a single IRB does not apply to:
  1. Cooperative research for which more than single IRB review is required by law
  2. Research for which the Federal department or agency supporting/conducting the research determines and documents that the use of a single IRB is not appropriate.

7. Continuing Review

Continuing Review eliminated for:

- Minimal risk studies that qualify for expedited review (unless a reviewer documents why CR should take place).
- Studies that were reviewed by a convened IRB but have reached a stage of only:
  1. Analyzing data (even identifiable private info)
  2. Observational follow up (accessing follow-up clinical data from standard care procedures)
  3. Doing both
- Certain secondary research using information and biospecimens, under new limited IRB review provisions (IRB will **only** check that broad consent is collected and privacy protection of biospecimens is appropriate).

IRB must receive annual confirmation that such research is ongoing and that no changes have been made that would require CR.

8. Extend Application of Common Rule

- Extend new Common Rule protections to all clinical trials conducted at any institution that receives any federal support for human subject research.
- This change would extend the Common Rule to almost all clinical trials in the United States.

Unknown Impact TBP:

- Exempt determination tool
- HHS Consent Template for broad future use of biospecimens
- List of activities eligible for expedited review/approval
- Data security standards
- Cost of changes
  - IRB Submission system / forms
  - Satisfying new data security standards
  - Updating policies