NPRM Overview

Notice of Proposed Rulemaking on Federal Policy for the Protection of Human Research Subjects

September 2015

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Broad Overview

- Background
- Goals of the NPRM
- Summary of major changes

Click here to see the bigger picture

http://www.hhs.gov/ohrp
Why Revise the Common Rule?

- Changes in research
- Attempt to better protect human subjects who are involved in research, while facilitating valuable research
- Attempt to reduce burden, delay, and ambiguity for investigators
Overview of Rulemaking Process

We’re here!

ANPRM
July 2011
Public Comment

NPRM
September 2015
Public Comment

Final Rule
?
18 Common Rule Departments & Agencies

- Department of Agriculture 7 CFR 1c
- National Science Foundation 45 CFR 690
- National Aeronautics & Space Administration 14 CFR 1230
- Agency for International Development 22 CFR 225
- Environmental Protection Agency 40 CFR 26
- Consumer Product Safety Commission 16 CFR 1028
- Department of Veterans Affairs 38 CFR 16
- Department of Transportation 49 CFR 11
- Department of Commerce 15 CFR 27
- Department of Defense 32 CFR 219
- Department of Energy 10 CFR 745
- Department of Education 34 CFR 97
- Department of Health & Human Services 45 CFR 46, subpart A
  Plus subparts B, C, D
- Department of Housing & Urban Development 24 CFR 60
- Department of Justice 28 CFR 46
- Federal Policy for the Protection of Human Subjects (Common Rule 45 CFR 46, Subpart A)

PLUS

- Department of Labor 20 CFR 50
- Food & Drug Administration
- Central Intelligence Agency
- Department of Homeland Security
- Social Security Administration

U.S. Department of Health and Human Services
Office for Human Research Protections
Goals

• Better protect human subjects involved in research

• Simplify the current oversight system
SUMMARY OF MAJOR CHANGES

THERE'S A EARTHQUAKE!
EVERYBODY HOLD STILL
Major Changes

1. Improve informed consent -- content and organization to facilitate understanding
2. Expand definition of “human subject” to include all biospecimens – regardless of identifiability
3. Almost always require informed consent for secondary use of biospecimens
4. Mandate single IRB review of cooperative research conducted at U.S. institutions
Major Changes (2)

5. Eliminate continuing review for certain minimal risk
6. Extend the scope of CR to cover clinical trials – regardless of the source of funding
7. Require privacy safeguards

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8. Exclude categories of activities from coverage
9. Revise the categories of exempt research to better calibrate the level of review to the level of risk
Major Change

1. Improving Informed Consent

Major revision to introduction of §116 does the following:

• Emphasizes need to provide *essential* information a reasonable person would want to know, before providing other supplemental information to the subject.
Improving Informed Consent

Major revision to introduction of §116 does the following:

• Information must be presented in detail, and must be organized and presented in a way that facilitates prospective subject’s understanding of the reasons why one might or might not want to participate.
4 NEW Elements of Informed Consent!

§116(a)(9) and §116(b)(7)-(9)

1. §116(a)(9): Notice to subjects about possible future use of non-identified data
2. §116(b)(7): Notice to subjects about possible commercial profit
3. §116(b)(8): Notice to subjects about research results
4. §116(b)(9): Option to allow re-contact
Posting of Clinical Trial Consent Forms

• Required for clinical trials conducted or supported by Common Rule agencies. Within 60 days of a trial being closed to recruitment, final consent and contact information must be posted on a publicly available website

• One-time requirement
Major Change

2. Definition of Human Subject

- Expand to cover all biospecimens -- regardless of identifiability

BUT

One category of secondary research involving non-identified biospecimens excluded: Research that is only designed to generate information about an individual that is already known
What Does this Mean?

- Many secondary research studies with non-identified biospecimens that are currently being conducted as research not involving human subjects would need to comply with the regulations.
Definition of Human Subject

- Meaning of “identifiable private information” (IPI) is unchanged
3. Almost Always Require Consent for Secondary Research with Biospecimens

“Broad Consent”: what does it mean?

- Would allow storage or maintenance and unspecified secondary research use of biospecimens and identifiable private information
- NPRM proposes the creation of a Secretary's template
Waiver of Consent Requirements More Stringent for Biospecimens

1) Compelling scientific reasons for the use of biospecimens
2) Research could not be conducted with other biospecimens from which informed consent was/could be obtained

- IRBs would not be permitted to waive consent if individuals were asked to provide broad consent and declined

Waiver intended to be rare!
Major Change

4. Single IRB Review of Cooperative Research

- Require single IRB review for cooperative research conducted in U.S. institutions – unless:
  - More than single IRB review required by law; or
  - Federal department or agency determines single IRB review is not appropriate
- Hold independent IRBs directly responsible for compliance with the Common Rule
Major Change
5. Eliminate Continuing Review

- No continuing review required if study undergoes expedited review
- No continuing review required if study has completed interventions and only involves analyzing data, including clinical data
- Annual confirmation that research is ongoing without changes requiring continuing review
- If an IRB overrides this default and requires continuing review – this must be documented
Major Change
6. Extend Common Rule to Cover Clinical Trials

• Scope expanded to cover all clinical trials, regardless of funding source, if:
  • Conducted at a U.S. institution that receives federal funding for non-excluded, non-exempt human subjects research
  • Does not include clinical trials subject to regulation by the FDA
Major Change


- Default position that if privacy safeguards at §105 are met, no need for additional IRB review unless those protections are deemed insufficient

- Required for some exemptions
Major Change

8. Exclusions

- Certain categories of activities are excluded from coverage under the Common Rule
- Activities should be deemed not to be research, are inherently low risk, or where protections are separately mandated
Exclusions – 11 total

• Four involve governmental functions or government-generated information
• Four involve the secondary use of biospecimens or identifiable private information
• One involves interventions
• One involves testing, talking, or watching
• One involves oral history, journalism, biography or historical scholarship
Exclusions
Involves Government Functions or Government-Generated Information (4 Exclusions)

1. Data and biospecimen collection and analysis for criminal justice or criminal investigative purposes

2. Public health surveillance activities -- only if authorized by a public health authority and limited to activities related to public health signals, the onset of a disease outbreak, injuries or conditions of public health importance

3. Certain authorized intelligence, homeland security, defense or other national security activities

4. Federally-conducted research using government-generated or government-collected data
Exclusions
Involves Secondary Use of Biospecimens or Identifiable Private Information (4 Exclusions)

5. Data collection and analysis for an institution’s own internal operational monitoring and program improvement purposes -- if limited to the use of data or biospecimens originally collected for another purpose, or obtained through oral or written communications (e.g., surveys or interviews)
Exclusions
Involves Secondary Use of Biospecimens or Identifiable Private Information

6. Research involving the collection or study of information that has been or will be collected (Revised version of the current Rule’s exemption category 4)
   • Does not include secondary research use of biospecimens
   • Does not require that the data exist as of the time that the study commences

7. Use of protected health information regulated by HIPAA as “health care operations,” “research” or “public health activities”
Exclusions
Involves Secondary Use of Biospecimens or Identifiable Private Information

8. Secondary research use of non-identified biospecimens designed only to generate information about an individual that is already known (e.g., activities such as the development & validation of certain tests and assays)
Exclusions
Involves Interventions (1 Exclusion)

9. Quality assurance or improvement activities involving the implementation of an accepted practice to improve the delivery or quality of care or services
   - Only if limited to altering the utilization of the accepted practice and the effects on the utilization of the practice
   - Does not cover the evaluation of an accepted practice itself
Exclusions
Involves Testing, Talking, Watching (1 Exclusion)

10. Educational tests, survey procedures, interview procedures, or observation of public behaviors if at least one of the following is met:

■ Information recorded by the investigator so that subjects cannot be identified; or

■ Any disclosure of the subjects’ responses would not reasonably place the subjects at risk; or

■ The activity will involve a collection of information subject to the Paperwork Reduction Act, E-Government Act, and Privacy Act

• Similar to current Exemption 2
Exclusions
Involves Oral History, Journalism Biography or Historical Scholarship (1 Exclusion)

11. Oral history, journalism, biography and historical scholarship activities that focus directly on the specific individuals about whom the information is collected
Major Change

9. Revise the Categories of Exempt Research

- To accommodate changes in the scientific landscape
- To better calibrate the level of review to the level of risk involved in the research
- Exemption must be documented in some way
- New categories would allow exemption of research that currently requires IRB review and approval
Exemptions – 8 total

- One involves governmental functions
- Three involve the secondary use of biospecimens or identifiable private information
- Three involve interventions
- One involves testing, talking, or watching
Exemptions
Involves Government Functions (1 Exemption)

1. Research and demonstration projects conducted or supported by a federal department or agency, or subject to their approval
   • Designed to study, evaluate, or otherwise examine a public benefit or service program
   • Published on a publicly available list prior to starting the research
Exemptions
Involves Secondary Use of Biospecimens or Identifiable Private Information (3 Exemptions)

2. Secondary research use of identifiable private information
   • Information has been or will be acquired for non-research purposes and where prior notice has been given to the individuals to whom the identifiable private information pertains that such information may be used in research

❖ Requires adherence to privacy protections
Exemptions
Involves Secondary Use of Biospecimens or Identifiable Private Information

3. Storage or maintenance for secondary research use of biospecimens or identifiable private information that have been or will be acquired for other research studies or for non-research purposes.

4. Research involving the use of biospecimens or identifiable private information that have been stored or maintained for secondary research use, if broad consent was obtained, and other conditions satisfied.
One-time Broad Consent: Two Exemptions

Biospecimens or Identifiable Private information with Broad Consent

Exemption §104(f)(1)
- Privacy Protections
- Limited IRB Review

Biospecimens & Identifiable Private Information Labeled & Tracked

Secondary Research Use

Exemption §104(f)(2)
- Privacy Protections
- No return of results
Exemptions
Involves Interventions (3 Exemptions)

5. Conducted in established or commonly accepted educational settings
   • Involves normal educational practices
   • Includes most research on regular and special education instructional strategies, and research on instructional techniques, curricula, or classroom management methods that are not likely to harm students’ opportunity to learn what is required or harm the assessment of educators who provide instruction
Exemptions
Involves Interventions

6. Research involving **benign interventions**
   - Only involving adult subjects
   - Collection of data through verbal or written responses or video recording if the subject prospectively agrees
   - At least one of the following criteria is met:
     - Information obtained is recorded so that human subjects cannot be identified; or
     - Any disclosure of subjects’ responses outside the research would not reasonably place the subjects at risk.
Benign Interventions

- Brief in duration, harmless, painless, not physically invasive
- Not likely to have a significant adverse lasting impact on the subjects
- The investigator has no reason to think the subjects will find the interventions offensive or embarrassing
- Possible examples: research activities in which a subject is asked to read materials, review pictures or videos, play online games, solve puzzles, or perform cognitive tasks
Deception

- Exemption is not applicable to deception research unless the subject authorizes the deception
- *Authorized deception* is prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research
Exemptions
Involves Interventions

7. Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe

- This exemption is retained unchanged from the current rule
Exemptions
Involves Testing, Talking, Watching (1 Exemption)

8. Research, not including interventions, involving:
   • educational tests (cognitive, diagnostic, aptitude, achievement)
   • survey or interview procedures
   • observation of public behavior (including visual or auditory recording)

   The information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects

   Requires adherence to privacy protections
Submit Comments!

See OHRP Website: http://www.hhs.gov/ohrp
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