Overview of Proposed Revisions to the Common Rule

February 11, 2016

Taunton Paine, MA
Policy Analyst, Office of Science Policy, National Institutes of Health
Overview of the Presentation

• Background on the Common Rule and NPRM

• Overview of Major Proposals in the NPRM

• Explanation of Public Comment Process and Current Status
## Regulatory Developments

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1974</td>
<td>HEW Regulations on the Protection of Human Subjects</td>
</tr>
<tr>
<td>1974</td>
<td>National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research</td>
</tr>
<tr>
<td>1979</td>
<td>National Commission’s Belmont Report</td>
</tr>
<tr>
<td>1981</td>
<td>Revised HHS Regulations</td>
</tr>
<tr>
<td>1991</td>
<td>Common Rule</td>
</tr>
<tr>
<td>2011</td>
<td>Common Rule Advance NPRM</td>
</tr>
<tr>
<td>2015</td>
<td>Common Rule NPRM (September 8, 2015)</td>
</tr>
<tr>
<td>2016 (est.)</td>
<td>Final Common Rule</td>
</tr>
</tbody>
</table>
The “Common” Rule

• Followed by 18 Federal Departments and Agencies

  1. Dept. of Agriculture
  2. Dept. of Commerce
  3. Dept. of Defense
  4. Dept. of Education
  5. Dept. of Energy
  6. Dept. of Health & Human Services
  7. Dept. of Homeland Security
  8. Dept. of Housing and Urban Development
  9. Dept. of Justice
  10. Dept. of Transportation
  11. Dept. of Veterans Affairs
  12. Agency for International Development
  13. Central Intelligence Agency
  15. Environmental Protection Agency
  16. National Aeronautics & Space Administration
  17. National Science Foundation
  18. Social Security Administration

• Will be joined by the Department of Labor
Why Modernize?

• Research has changed dramatically since 1991:
  – Expansion in clinical trials
  – Diversification of social sciences research with participants
  – More research conducted in clinical settings
  – More studies involving multiple institutions
  – Greater scientific data sharing
  – Increasing ability to extract information from biospecimens

• New initiatives such as the President’s Precision Medicine Initiative are advancing a more participatory model of research
Overarching Goals

Two main goals of the update:

- Enhance safeguards and respect for research participants
- Simplify the current oversight system and reduce inappropriate administrative burdens
Major Reforms

• Match oversight to level of risk
• Require consent for research with biospecimens
• Allow broad consent
• Simplify consent documents
• Increase privacy and security safeguards
• Streamline IRB review of research
Matching Oversight to Level of Risk – Expansion, Exclusions, and Exemptions
Matching Oversight to Risk

**Increasing risk to participants**

<table>
<thead>
<tr>
<th>Current Common Rule</th>
<th>Not covered</th>
<th>Exempt</th>
<th>Exempt</th>
<th>Covered</th>
<th>Covered</th>
<th>Covered</th>
<th>Covered</th>
<th>Not covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed Common Rule</td>
<td>Excluded</td>
<td>Excluded</td>
<td>Exempt</td>
<td>Exempt</td>
<td>Exempt</td>
<td>Exempt</td>
<td>Covered</td>
<td>Covered</td>
</tr>
</tbody>
</table>
Expansion of Scope

• Proposes to cover clinical trials that are not currently subject to Federal regulation:

  – Conducted at an institution that receives federal funding for non-exempt human subjects research; and,

  – Conducted at an institution in the U.S.
Exclusions – Not Research

- Oral history, journalism, biography, and historical scholarship focusing on specific individuals
- Collection of data and biospecimens for intelligence or national security activities
- Collection of data and biospecimens for criminal justice activities
- Public health surveillance
- Collection of data and biospecimens for institutional internal monitoring and program improvement
- Quality assurance / quality improvement for the delivery of an accepted practice or service
Exclusions – Low-Risk Research

• Research involving information originally collected for other purposes (research or clinical) if information is:
  – publicly available; or
  – non-identified, and investigator will not contact or re-identify

• Research gathering non-identified or non-sensitive* information through educational tests, surveys or interviews, or observation of public behavior

*Unlikely to pose risk of criminal or civil liability, or damage financial standing, employability, educational advancement, or reputation
Exclusions – Low-Risk Research with Other Adequate Protections

• Research conducted by a federal agency that is subject to protections in the Paperwork Reduction Act, E-Government Act, Privacy Act:
  
  – gathering identifiable, sensitive information through educational tests, surveys or interviews, or observation of public behavior
  
  – using information generated or collected by the government for non-research purposes, including criminal history data

• Research involving collection and analysis of identifiable health information if regulated as health care operations, research, or public health activities by HIPAA
Exclusions – Low-Risk Biospecimen Research

• Research involving non-identified biospecimens that will not reveal new information about an individual, e.g.:

  – test and assay development and validation

  – quality assurance and control activities, and

  – proficiency testing (i.e., for laboratory performance)
Exemptions – Some Protections Required

- Standard tool or expert with knowledge of the Common Rule determines exemption status; records must be kept
- Safeguards apply to protect information and biospecimens
- Limited IRB Review of consent process
- Broad consent using an approved template
Exemption – Low Risk Research

• Research in educational settings/practices unlikely to adversely impact students’ opportunity to learn

• Research and demonstration projects supported by the federal government to evaluate public benefit or service programs

• Research involving benign interventions or video recording if the information is non-identified or not sensitive

• Taste and food quality evaluation

☐ Exempt determination made and recorded
Exemption – Research with Sensitive Information

- Non-interventional research gathering identifiable, sensitive information through educational tests, surveys or interviews, or observation of public behavior

- Secondary research using identifiable, sensitive information collected for non-research purposes if:
  - Prior notice was given to the individuals that the information might be used in research
  - The secondary investigator uses the information only for the research for which they received it

Exempt determination made and recorded
Safeguards to protect information
Exemption – Research with Biospecimens and Identifiable Data

• Collection of biospecimens and identifiable information for the establishment of databases and biobanks

- Exempt determination made and recorded
- Safeguards to protect information and biospecimens
- Broad Consent
- Limited IRB Review

• Secondary research with biospecimens or identifiable information when there are no plans to return individual research results

- Exempt determination made and recorded
- Safeguards to protect information and biospecimens
Exclusions and Exemptions – Application to Vulnerable Populations

• Exclusions apply to all vulnerable populations except:
  – Non-interventional research with children involving educational tests, surveys, interviews, or observation of public behavior

• Exemptions apply to research involving pregnant women and neonates

• Certain research involving children cannot be exempt:
  – Research involving benign interventions or video recording if the information is non-identified or not sensitive
  – Non-interventional research gathering identifiable, sensitive information through educational tests, surveys or interviews, or observation of public behavior

• Research involving prisoners cannot be exempt unless the research incidentally involves some prisoners
Requiring Consent for Research with Biospecimens
Require Consent for Research with Biospecimens

• Change in definition of human subject requires consent when an investigator obtains, uses, studies, or analyzes biospecimens for research

• Applies regardless of whether biospecimens are identified or non-identified (with some exceptions)

• Would not apply to collection and use of biospecimens for non-research (e.g., clinical) purposes, unless used for research
Require Consent for Research with Biospecimens: Alternative Proposals

• In recognition of the significant change of the proposal, two alternative proposals are included in the NPRM

• Alternative A:
  – Requires consent for research involving generation or use of whole genome sequence data, whether non-identified or not

• Alternative B:
  – Requires consent for research involving generation or use of data that is unique to an individual and could be used to identify them if combined with publicly available data, whether non-identified or not
IRB Waivers of Consent

• Additional criteria have been added for waiving consent for research involving biospecimens
  – There must be compelling scientific reasons
  – Research could not be conducted with other biospecimens for which there is consent

• Waiving consent not allowed for research with biospecimens or identifiable information if individual was asked to consent and declined

• Waiving consent is expected to be rare
Allowing Broad Consent
Defining Broad Consent

• Allows and defines broad consent for collection and use of biospecimens and identifiable information for future, unspecified research
  – Must use approved template (to be developed by the Secretary with public comment)
  – May be used:
    • in conjunction with a specific consent for research
    • In a clinical setting
Broad Consent Elements

• General description of types of research that may be conducted

• Description of the scope of the consent, i.e., what will be collected and for how long (may be up to 10 years or date of legal age of consent; indefinite for research)

• Time period of availability for secondary research (can be indefinite)

• Statement that participation is voluntary, refusal will involve no loss of benefits, and that the participant may request to withdraw consent

• Option to decline inclusion of non-identified data in a publicly accessible database
Simplifying Consent Documents
Simplify Consent Processes and Documents

• Informed consent documents must first include the required elements of consent
  – All other information may only be provided after
  – If combined with HIPAA authorization forms, must be presented in the consent and not appendices

• Participants must receive:
  – information a reasonable person would need to make an informed decision about participation, and
  – an opportunity to discuss that information
Increasing Privacy and Security Safeguards
Privacy and Security Standards for Biospecimens and Identifiable Data

• Research would be required to follow:
  – Specific measures to be published by the Secretary; or
  – Measures required by the HIPAA Privacy and Security Rules (limitations on disclosure, and administrative, physical, and technical safeguards)

• Sharing permitted for:
  – Other research with equivalent safeguards, IRB-approval (if required), and no further sharing
  – Public health purposes
  – Any other purpose with participants’ consent

• IRB review of safeguards is not required
Streamlining IRB Review
Multi-site Research

• Institutions located in the US engaged in cooperative research must rely upon approval by a single IRB unless:
  – Local IRB review is required by law
  – The Federal Department or Agency determines that a single IRB would not be appropriate for a particular study

• IRBs, rather than research institutions, will be held responsible if IRBs fail to follow the regulations
Review Efficiencies

• IRBs will no longer review grant applications

• Continuing review would be eliminated for:
  – Research eligible for expedited review
  – Studies that progressed to only data analysis or accessing follow-up data from standard clinical care for participant’s condition

• If IRBs conduct continuing review when not required, rationale must be documented
Other Efficiencies

- List of activities eligible for expedited review are now considered minimal risk unless review finds otherwise.

- For other minimal risk determinations, a list of minimal risk research activities will be published.

- Requirement to report changes in IRB membership to department or agency heads would be eliminated.
Transition Provisions

• Effective date is 1 year after publication of the final rule

• Research begun before the effective date would not subject be to the new requirements

• Biospecimens collected before the effective date would be grandfathered if non-identified

• Compliance date of 3 years after publication allowed for:
  – New consent requirement for biospecimens
  – Mandate for single IRB in cooperative research
Next Steps
Next Steps

✓ Public comment period closed January 6, 2015
  – 2,172 comments were submitted to the docket
  – Comments represented diverse perspectives and interests

✓ Consideration of public comments underway

• Development of the final rule

• Publication of the final rule
Thank You