The Common Rule (IRB) Changes and What it means for Research Administrators

Wednesday, May 15, 2019

The Good, The Bad, the Ugly, and everything in-between
Key Areas of Change

- Definitions
- Informed Consent
- Continuing Review
- Exemptions & Exclusions
- Limited Review
- Privacy & Security
Definitions

Human Subject

a living individual about whom an investigator conducting research:

• (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
• (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Previous Definition:

• are living individuals about whom an investigator obtains either: Data through intervention or interaction with the individual; or identifiable private information
Vulnerable subjects are mentioned but limit their scope to vulnerability to coercion and undue influence.

- Children
- Prisoners
- Individuals with impaired decision-making capacity
- Economically/Educationally disadvantaged persons

**NOT Research**

- Public Health Surveillance
- Operational Activites for Homeland Security, Defense and Other Security Missions
- Biospecimens, Records and Analysis of Information for Criminal Justice Agencies

**Scholarly and Journalistic Activities**
Informed Consent

- Informed consent must begin with a “concise and focused presentation of the key information” that is most likely to help a potential subject or authorized representative to understand why he or she may or may not want to participate in the research.

- Requires that investigators post on a publicly available federal website an IRB-approved informed consent form for each clinical trial that is conducted or supported by a Common Rule Agency.
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- To be used for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
- Collected for either research studies other than the proposed research or non-research purposes.

Broad Consent

Continuing Review
Continuing Review

- is eliminated for the following types of studies:
  - Expedited review **
  - Research that has progressed to the point that it involves only data analysis
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

** Studies that were approved as expedited may still have continuing review ONLY if the reviewer explicitly justifies why continuing review would enhance protection of research subjects
Exemption 1 - Revised

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2 - Revised

Added: that only includes

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)
Exemption 3 - **NEW!**

Research involving benign behavioral interventions in conjunction with the collection of information from an ADULT subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

Exemption 4 - Revised

Secondary research for which consent is not required:
Secondary research uses of identifiable private information or identifiable biospecimens.
Exemption 5 - 

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 7 - 

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § _.111(a)(8).
Exemption 8 - NEW!

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use.
Limited Review

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

<table>
<thead>
<tr>
<th>The use of the information;</th>
<th>The likely retention period or life of the information;</th>
<th>The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified</th>
</tr>
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<tbody>
<tr>
<td>The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;</td>
<td>The security controls that are in place to protect the confidentiality and integrity of the information;</td>
<td>The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption;</td>
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Privacy & Security

[Image of SRA International logo]
https://na01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fohrp%2Fregulations-and-policy%2Fguidance%2Ffaq%2F2018-requirementsFaqs%2Findex.html&amp;data=02%7C01%7Ccmyles%40research.uu.edu%7C5f7debad6c144b8c3eac08d67cd377d1%7C63ec59cb94a24e6b8090be2f81176596%7C0%7C636833645022454413&amp;sdata=pyYV%2BD53OrRJnmXk3PQQDapY%2FDATvMTkcV%2BwdpBKKlc%3D&amp;reserved=0
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