Overview of Important Changes to the Final Rule

45 CFR 46

Bowling Green State University Research Compliance Office
Created 1/7/2019
Transition Dates

January 19, 2017  The Department of Health and Human Services (HHS) published the Final Rule

January 21, 2019  Effective date for all changes (except cooperative research)

January 20, 2020  Effective date for cooperative research
## Transition provisions

<table>
<thead>
<tr>
<th>Research Study Initiation Date</th>
<th>Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research initially approved by an IRB, waived pursuant to [former subsection] 101(i), or determined to be exempt [under former subsection 101(b)] before January 21, 2019</td>
<td>These studies are by default subject to the pre-2018 rule (the Common Rule as published in the 2016 edition of the CFR). However, an organization engaged in such research may choose to comply with the Final Rule (2018 requirements) for such a study (the grandfathered research) if the organization applies the Final Rule to the study and an IRB documents this determination. Further guidance is pending to determine if the IRB must document this per study even if the institution issues an institutional policy applying the Final Rule to all research.</td>
</tr>
<tr>
<td>Research initially approved by an IRB, waived pursuant to [former subsection] 101(i), or determined to be exempt on or after January 21, 2019</td>
<td>These studies are subject to the Final Rule (2018 requirements).</td>
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Updates to Definitions- New and Revised Terms

- **New Terms Added:**
  - Clinical Trial
  - Public Health Authority (also includes tribal law)
  - Written or in Writing (includes electronic format)

- **Revised Existing Terms:**
  - Vulnerable (pregnant women and “handicapped” removed; replaces “mentally disabled” with “individuals with impaired decision-making capacity”)
  - Human Subject (includes biospecimens)
  - Research (defines what’s NOT research: certain journalistic, public health, surveillance, and criminal justice or intelligence activities)
  - Legally Authorized Representative (LAR)
Updates to Informed Consent Process and Document

- These changes are meant to facilitate subjects’ understanding of the reasons to participate (or not) in the research.

- Requires that key information essential to decision-making receive priority by:
  - Being presented first in the consent discussion;
  - Appearing at the beginning of the consent document

  If you have questions about how to apply the new "key information" requirement for a particular project, please contact the Research Compliance Office for advice.

- Prospective subject (or Legally Authorized Representative) must be provided with the information that a reasonable person would want to have to make an informed decision about whether to participate, and be given an opportunity to discuss that information.

- Broad consent may be obtained in lieu of informed consent obtained only for storage, maintenance, and secondary research uses of private information and identifiable biospecimens. **NOTE**: BGSU will not implement the new regulatory "Broad Consent" option as an informed consent process at this time. Exemptions 7 & 8, which rely on Broad Consent, also will not be implemented.
# New Consent Elements
for projects involving biospecimens, clinical trials, and genome sequencing

<table>
<thead>
<tr>
<th>When your project will involve...</th>
<th>Include in the informed consent...</th>
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<tbody>
<tr>
<td>The collection of identifiable private information or identifiable biospecimens</td>
<td>A statement indicating whether:</td>
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<td></td>
<td>- identifiers may be removed, and</td>
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<td></td>
<td>- de-identified information or biospecimens may or may not be used or shared for future research</td>
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<tr>
<td>Use of biospecimens</td>
<td>A statement indicating whether:</td>
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<td></td>
<td>- biospecimens may be used for commercial profit, and</td>
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<td></td>
<td>- the subject will share in that profit</td>
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<tr>
<td>Clinically relevant results</td>
<td>A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions</td>
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<tr>
<td>Whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)</td>
<td>A statement indicating that the research will or might include whole genome sequencing</td>
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Updates to Exempt Categories- and meaning of “Limited IRB Review”

- The Final Rule establishes new exempt categories of research. Under some of the new exempt categories (specifically, categories 2 and 3), research is required to undergo “limited IRB review,” which at BGSU is similar to the expedited review process.

- “Limited IRB review” focuses especially on ensuring there are adequate confidentiality and privacy safeguards.
Changes to Exempt Categories 1, 2, and 4

- Category 1 includes an added clause for educational research, “practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.”

- Category 2 includes research involving education tests, survey or interview procedures, or observation of public behavior. This allows for collection of potentially sensitive or harmful identifiable private information from adults if an IRB conducts a “limited IRB review.”

- Category 4 expands secondary research and no longer requires that the secondary data be existing at the time of the IRB submission.
Changes to Exempt Category 3

- **Benign behavioral interventions (Category 3)**
  - Only for behavioral research, not biomedical research.
  - Children are specifically excluded.
  - “Benign behavioral interventions” are defined as “brief in duration, harmless, painless, not physically invasive, not likely to have an impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.”
  - Allows for collection of potentially sensitive or harmful identifiable private information from adults if an IRB conducts a “limited IRB review.”
  - The new “limited IRB review” is intended to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.
New Exemptions - Categories 7 and 8

*NOTE: BGSU will not be implementing the “broad consent” categories until further guidance is provided by OHRP.

- **Storage or maintenance for secondary research for which broad consent is required (Category 7)**
  - Covers activities that involve storage or maintenance for secondary research use of private information or identifiable biospecimens
  - Limited IRB review required to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens

- **Secondary research for which broad consent is required (Category 8)**
  - Covers research that involves the use of private information or identifiable biospecimens that have been stored or maintained for research use
  - Limited IRB review required to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens
Can Research Regulated by the Subparts be Exempt?

- **Subpart B - Additional protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research**
  - Yes, all exemption categories apply

- **Subpart C - Additional Protections Pertaining to Biomedical & Behavioral Research Involving Prisoners as Subjects**
  - Only for research aimed at involving a broader subject population that only incidentally includes prisoners

- **Subpart D - Additional Protections for Children Involved as Subjects in Research**
  - Yes, for exemptions at paragraphs 46.104(d)(1),(4),(5),(6),(7), and (8)
  - Only for research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed for paragraphs 46.104(d)(2)(i) and (ii)
  - No, for exemption at paragraph 46.104(d)(2)(iii) of this section
Updates to Expedited Review Process

- Although the The Final Rule removes the requirement that IRBs conduct continuing review of ongoing research for studies that undergo expedited and “limited review,” Bowling Green State University’s IRB policy will continue to require periodic reviews for expedited studies and exempt studies whose privacy and confidentiality concerns require them to undergo “limited review.”
Multi-Site Research Using Cooperative Review and Single IRB (sIRB) Review

- The Final Rule creates a new requirement for U.S. institutions engaged in multi-site (more than one) cooperative research to use a sIRB for that portion of the research that takes place within the U.S., with certain exceptions.

- This requirement becomes effective three years after publication (20 January 2020).

- Note: For studies that must comply with the National Institutes of Health (NIH) policy on sIRB review, the effective date was 25 January 2018 (with certain exceptions).
Some of the content for this presentation taken from the handout, “Overview of Important Changes to the Final Rule,” made available to help the research community understand the revisions to the Common Rule. This handout, and others were developed with the assistance of expert authors and peer reviewers and are available by the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org. Bowling Green State University is a subscriber of the CITI program.