Overview of the New Common Rule

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Disclaimer

This presentation is the interpretation of the University of Pittsburgh HRPO team of the Final Rule. It is based on extensive reading of the new regulations and the Preamble that accompanies it, as well as various educational sessions and interpretations by national experts. It is expected that interpretation, analysis and application of the Final Rule will evolve as implemented and with the emergence of Federal guidance.
What is the Common Rule?

- Federal Policy for the Protection of Human Subjects
- 45 CFR 46
- Enforced by the Office for Human Research Protections (OHRP)
What’s in a Name?

The Common Rule: Published in 1991 and codified in separate regulations by 15 Federal departments and agencies

- Agriculture
- Energy
- NASA
- Commerce
- Consumer Product Safety Commission
- Education
- Housing and Urban Development (HUD)
- Justice
- Defense
- Agency for International Development (USAID)
- Transportation
- EPA
- Health and Human Services
- National Science Foundation
- Veterans Affairs (Office of Research Oversight, Office of Research and Development)
Why change it?

1991

2017
Highlights of What’s to Come

• Single IRB Review for Multi-Site Studies
• Broad consent for data or biospecimens
• Public posting of consent forms of federally funded studies and clinical trials
• Key elements of consent: provide subjects a clear picture of the scope of the research and risks and benefits
• New exempt categories
• Removal of Continuing Review in limited circumstances
Highlights of What’s to Come

• Promoting Autonomy
  • Revised requirements of informed consent
  • Broad consent for secondary research
  • Public posting of consent forms of federally funded studies and clinical trials

• Reducing burden, streamlining administration
  • New definitions
  • Expanding exempt categories
  • Eliminating certain continuing reviews
  • Single IRB review
Definitions §102

- **New: Clinical trial**
  - **What does it mean to me:** Clinical trials are required to publicly post an IRB approved consent form

- **Revised: Research**
  - **What does it mean to me:** specifically names activities that are *not* subject to the Rule

- **Revised: Human subject**
  - **What does it mean to me:** clearly covers biospecimens and data in various scenarios
Research §102(l)

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

New: Deems activities not to be research:

1. Scholarly and journalistic activities that focus directly on the specific individuals about whom the info is collected: oral history, journalism, biography, legal criticism, legal research, and historical scholarship

2. Public health surveillance activities limited to those conducted, supported, requested, ordered, required or authorized by a public health authority for public health importance (includes “timely situational awareness”)

3. Criminal justice or criminal investigational purposes

4. Authorized activities in support of intelligence, homeland security, defense or other national security
Human Subject \(\S102(e)\)

**Current**

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

**New**

Human subject means a living individual about whom an investigator (whether professional or student) 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.
Unidentifiable today. Identifiable tomorrow.

Identifiable: the identity of the subject is or may readily be ascertained by the investigator or associated with the [information][biospecimen]

Re-examine the meaning of “identifiable private information” and “identifiable biospecimen” within 1 year and then at least every 4 years after

- Addresses advances in technology and science
Informed Consent
Changes to Informed Consent

• Additions and changes to the General Requirements for Informed Consent
• Broad Consent
• Posting of consent forms for clinical trials
• Waivers and alterations of informed consent
General Requirements for Informed Consent §116

- Subjects must be provided information that a reasonable person would want to make an informed decision and opportunity to discuss the information
- Must begin with a concise and focused presentation of key information
- Be organized to facilitate comprehension, not merely provide a list of isolated facts, to allow one to decide to participate or not
Basic Elements of Informed Consent

New: Notice of future use of identifiable private information or identifiable biospecimens §116(b)(9)

- Identifiers might be removed and the de-identified information or biospecimens could be used for future research without additional informed consent,
  or
- The information or biospecimens will not be used or distributed for future research even if identifiers are removed.
Additional Elements of Informed Consent
§116(c)

New:

• Notice that biospecimen research may result in commercial profit and whether the subjects will share in the profit or not
• Notice of under what conditions clinically relevant research results will be returned to subjects
• Notice if biospecimen research will include whole genome sequencing
**Broad Consent §116(d)**

- **Optional** alternative to traditional informed consent
- Certain new exempt categories added for administration of Broad Consent
- Used only for “storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens…”
- Includes basic elements: risks, benefits, confidentiality, voluntary, commercial profit, and whole genome sequencing
**Broad Consent §116(d)**

**Must be tracked:**
- Who was asked
- What were they asked
- Did they say yes or no
- What biospecimens or data were collected under the broad consent
- What did it allow
- What did it limit

**If refused:**
- May be asked again in the future
- IRB cannot waive informed consent if a person refused broad consent for storage, maintenance and use of private identifiable information and identifiable biospecimens

**Exemptions 7 and 8:**
- **7:** storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary use under limited IRB review
- **8:** Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if certain criteria are met

**Limited IRB Review §111(a)(8):** broad consent must be obtained and documented, any changes made to the storage/maintenance of information/specimens must be adequate to protect privacy and confidentiality
Other Considerations
Screening, Recruiting, Determining Eligibility §116(g)

**New:** An IRB may approve a protocol where an investigator will obtain information or biospecimens for screening, recruiting, or determining eligibility without informed consent:

- Information is obtained through oral or written communication with the prospective subject or LAR, or
- The investigator will obtain private identifiable information or identifiable biospecimens by accessing records or stored identifiable specimens

Effectively eliminates the need for the IRB to grant waivers for screening and recruitment, consistent with FDA regulations and HIPAA
Documentation of Informed Consent §117

• Includes electronic formats as written informed consent. A copy must still be given
• Allows, specifically, consent forms to be read to the subject
• Waiver to obtain a signed informed consent still remains, a 3rd option is included for situations where obtaining written informed consent would be culturally inappropriate
Posting of Clinical Trial Consent Form §116(h)

**New:** One IRB–approved consent form used to enroll subjects must be posted on a publicly available federal website

- Federal department or agency “may permit or require” redactions
- Posted after the clinical trial has closed to recruitment no later than 60 days after the last study visit by any subject

Per the preamble: Intended to increase transparency and play a key role in justifying the public trust in the integrity of the clinical trial enterprise
Removal of Continuing Review §109(f)

**New:** Continuing review is not required in the following circumstances:

- Research eligible for expedited review
- Research reviewed under limited IRB review
- Research that now involves only one or both
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - Accessing follow-up clinical data from procedures that subjects would undergo as a part of clinical care
Requirement for Single IRB Review §114

**New:** U.S. institutions engaged in cooperative research must rely upon a single IRB for review

- The reviewing IRB will be identified by the Federal Department or Agency supporting the research or proposed by the lead institution
- May not be required if supporting Federal department or agency deems a single IRB inappropriate in a particular context
- Effective January 20, 2020
Exempt Research §104

A bunch of revisions and three new categories (3), (7), and (8)
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<thead>
<tr>
<th>Exemption</th>
<th>Action</th>
<th>Differences</th>
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<tbody>
<tr>
<td>1  Normal educational practices in established or commonly accepting</td>
<td>Restrictions added</td>
<td>Not likely to adversely • Impact students’ opportunity to learn required content, or</td>
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<td>educational settings</td>
<td></td>
<td>• The assessment of educators who provide instruction</td>
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<td>2  Educational tests, surveys, or observation of public behavior</td>
<td>Broadened</td>
<td>• Information recorded cannot identify subjects directly or indirectly</td>
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<td></td>
<td></td>
<td>• Disclosed information would not place subjects at risk</td>
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<td></td>
<td></td>
<td>• Identifiable information can be recorded and the IRB conducts a limited review</td>
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<tr>
<td>3  Educational tests, surveys, or observation of public behavior with</td>
<td>Removed and Replaced</td>
<td>Research involving <strong>benign behavioral interventions</strong> with written or verbal collection of information (more on this later!)</td>
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<td>public officials</td>
<td></td>
<td></td>
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<tr>
<td>4  Collection or study of <strong>existing</strong> data, documents, records, and</td>
<td>Broadened</td>
<td>• Removes “existing”</td>
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<td>specimens when publicly available or recorded with no identifiers</td>
<td></td>
<td>• Can be used if the use is regulated under HIPAA as “health care operations,” “research,” or “public health”</td>
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<td></td>
<td>• Research on behalf of Federal department/agency using government-generated or collected information</td>
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<td>5  Research and demonstration projects about public benefit or service</td>
<td>Broadened</td>
<td>• No longer limited to federally conducted research, can be used for federally supported</td>
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<td>programs</td>
<td></td>
<td>• Must be posted on a Federal website or other approved location</td>
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<td>6  Taste and food quality evaluation and consumer acceptance studies</td>
<td>Unchanged</td>
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Research Involving Benign Behavioral Interventions §104(d)(3)

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

- Subject must prospectively agree, and
  - Information is recorded so that identity cannot be readily ascertained directly or indirectly,
  - Any disclosure of information would not place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
  - Recorded info is identifiable but the IRB has conducted a limited IRB review
So what exactly is a “benign behavioral intervention”?

• §104(d)(3)(ii): ...are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing
  • Examples: online games, puzzle solving in various conditions, decision making cash allocation

Further information and guidance an educational tools, on this topic and others, are available on the website for SACHRP (Secretary’s Advisory Committee on Human Research Protections)
Now What?

• Upcoming sessions will cover implementation of consenting changes and exemptions in more detail
• HRPO is working to determine how implementation will take place and how to transition
• Policy changes will be forthcoming
Questions?