Overview of the Revised Common Rule

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Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services
HHS Office for Human Research Protections (OHRP)

OHRP provides leadership in protecting the rights, welfare, and wellbeing of human subjects in research conducted or supported by HHS

OHRP has a distinct role from NIH and FDA (although both are HHS agencies)

• **FDA** – regulates clinical investigations involving drugs, devices, and biologics

• **NIH** – conducts and supports research, some of which falls under the HHS regulations
OHRP’s Role

OHRP holds regulatory authority for the HHS Regulations for the Protection of Human Subjects at 45 CFR 46:

Subpart A – The Common Rule
Subpart B – Pregnant women and fetuses
Subpart C - Prisoners
Subpart D – Children
Subpart E – IRB Registration

• HHS regulations apply to non-exempt human subjects research conducted or supported by HHS

Revisions to the Common Rule published January 19, 2017

No current revisions to other subparts
Why Revise the Common Rule?

• Originally promulgated in 1991
• Revisions needed to meet the challenges of the rapidly changing landscape of research

• Goals:
  • To **better protect research subjects**
  • To **reduce administrative burdens** so that IRBs can better serve their role
Summary of Key Changes

Promote individual autonomy
- Change requirements of informed consent
- Add broad consent option for secondary research

Reduce administrative burden, streamline IRB processes
- Remove activities from the definition of research
- Expand exempt research
- Update and simplifying expedited review
- Eliminate certain continuing reviews
- Use single IRB review
General Implementation of the Transition Provision

Transition date for revised Common Rule

Pre-2018 Rule applies to all studies

Studies initially “approved” before **July 19, 2018**:
- **Presumption**: Pre-2018 rule applies
- Institution may elect to apply the revised Common Rule. IRB must document this in writing.

Studies initially “approved” on or after **July 19, 2018**:
The revised Common Rule applies

**July 19, 2018**

The requirement for single IRB review in multi-institutional studies goes into effect **January 20, 2020**
When Do the Regulations Apply?

To determine if your project is non-exempt human subjects research...

Ask these questions in this order:

1) Does the activity involve research?
2) Does the research involve human subjects?
3) Is the research with human subjects exempt?
Determining When the Revised Common Rule Applies

Legend: New with the revised Common Rule

- **Is it research?**
  - Yes, or Activities deemed not to be research
  - **NO**

- **Does it involve human subjects?**
  - Yes
  - **STOP**
  - No

- **Is it exempt?**
  - Yes
  - Requires limited IRB review to determine that necessary conditions are satisfied
  - No
  - **STOP**

- **Does it involve exemptions 2(iii), 3(i)(C), 7, or 8?**
  - Yes
  - **STOP**
  - No

**Proceed to IRB review**
Question 1: Does the Activity Involve Research?

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

Revised Common Rule

• Citation moved from §46.102(d) to §_.102(l) in the revised rule
• Four types of activities are specifically deemed not to be research
Activities Deemed Not to be Research in the Revised Common Rule

1) Scholarly and journalistic activities

[Government functions with separately mandated protections]

2) Public health surveillance activities

3) Information collection for criminal justice purposes

4) Operational activities for national security purposes

§__.102(l)
Scholarly and Journalistic Activities

Collection and use of information focused directly on the specific individuals about whom the information is collected

- Examples include oral history, journalism, biography, literary criticism, legal research, and historical scholarship
- Excludes certain activities, not entire academic fields
Public Health Surveillance Activities

*Limited to activities conducted, supported, requested, ordered, required or authorized by a “public health authority”*

Defined as:

...agency or authority of the United States, a state, territory, political subdivision of a state or territory, Indian tribe, foreign government, or a person/entity acting under the authority of such an agency, including employees or agents of the public agency or its contractors, or granted authority responsible for public health matters by official mandate
Public Health Surveillance Activities

Limited to activities conducted by a public health authority and:

• Are necessary to allow a public health authority to **identify, monitor, assess, or investigate** potential public health signals, onsets of disease outbreaks, or conditions of public health importance, including **trends, signals, risk factors, patterns of diseases, or increases in injuries** from consumer products

• Provide **timely situational awareness and priority setting** during the course of an event or crisis that threatens public health

§__102(l)
A team of physicians sees a patient with an unusual constellation of symptoms. They run a variety of diagnostic tests and procedures. Results of the test do not yield a known diagnosis. They write a case summary of their observations and submit it to a medical journal for publication.

**Is this research?**

A. Yes  
B. No  
C. I don’t know
A political science professor wishes to write a book about a former governor of his state. He plans to conduct extensive interviews with the former governor and several people who worked with her.

Is this research?

A. Yes
B. No
C. I don’t know
A physician reports what appears to be an outbreak of an unusual type of meningitis. A public health authority in the area plans to collect the patients’ medical and demographic information to document trends, and identify signals and risk factors as a way to better manage this potential public health crisis.

**Is this research?**

A. Likely yes  
B. Likely no  
C. I don’t know
Question 2: Does the Research Involve Human Subjects?

**Human subject**: a living individual about whom an investigator conducting research

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

§102(e)(1)

**Revised Common Rule**: no substantive changes in interpretation, only clarifying
Associated Terms & Concepts

Changes make OHRP’s current interpretation explicit

- **Intervention**: includes physical procedures by which information or biospecimens are gathered and manipulations of the subject or subject’s environment for research purposes

- **Interaction**: includes communication or interpersonal contact between investigator and subject

- **Identifiable biospecimen**: biospecimen for which the identity of subject is or may readily be ascertained by the investigator or associated with the information

- **Identifiable private information**: private information for which the identity of subject is or may readily be ascertained by the investigator or associated with the information
The Evolving Concept of “Identifiability”

- **Identifiable**: the identity of the subject is or may readily be ascertained by the investigator or associated with the [materials]
- Federal agencies commit to collaborate at least every four years to:
  - Re-examine the meaning of identifiability
  - Determine analytic techniques capable of generating identifiable private information or biospecimens

§__.102(e)(5)-(7)
An investigator receives survey data on the use of opioid pain medications from an outside source. The data were obtained for a previous and unrelated research study, not the current research. The investigator cannot identify the survey participants.

Is this human subjects research?

A. Yes
B. No
C. It depends
D. I don’t know
A researcher forms a hypothesis about certain groups of individuals and their responses to current events in the news. She wants to study public tweets related to those current events to establish a correlation and predict behavior.

Is this human subjects research?

A. Yes  
B. No  
C. I don’t know
Research with Biospecimens or Private Information
That is *Not* Human Subjects Research

If research involves *only* coded biospecimens or private information *and* meets both of the following:

1) is not collected specifically for the research in question, **AND**
2) investigator(s) cannot readily ascertain identity of the individual(s) to whom data/specimens pertain,

then it is *not* human subjects research.
Question 3: Is the Human Subjects Research Exempt?

Pre-2018 Rule
• 6 exemptions, §46.101(b)(1)-(6)

Revised Common Rule
• 8 exemptions, §_.104(d)(1)-(8)
• Exemptions 3, 7, and 8 – new
• Exemption 1, 2, 4, and 5 – modified
• Exemption 6 – no change
## Summary of Changes to Exemptions

<table>
<thead>
<tr>
<th>Pre-2018 Rule (Current)</th>
<th>Revised Common Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Educational practices</td>
<td>Restrictions added</td>
</tr>
<tr>
<td>2. Educational tests, surveys, interviews, observation of public behavior</td>
<td>Expanded</td>
</tr>
<tr>
<td>3. Research on public officials</td>
<td>Removed and replaced with new</td>
</tr>
<tr>
<td>4. Research on existing data</td>
<td>Expanded old and added new</td>
</tr>
<tr>
<td>5. Public benefit service</td>
<td>Expanded with changes</td>
</tr>
<tr>
<td>6. Taste and food evaluations</td>
<td>No change</td>
</tr>
</tbody>
</table>

- New Exemption # 7
- New Exemption # 8
- New limited IRB review
# Exemptions Applicability Subparts C & D

<table>
<thead>
<tr>
<th>Subpart C</th>
<th>Prisoners Research</th>
<th>Pre-2018 Rule (Current)</th>
<th>Revised Common Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None apply</td>
<td></td>
<td>Research expanded: Exemptions do not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners</td>
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</table>

<table>
<thead>
<tr>
<th>Subpart D</th>
<th>Research with Children</th>
<th>Pre-2018 Rule (Current)</th>
<th>Revised Common Rule</th>
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<tbody>
<tr>
<td></td>
<td>Exemption 2 does not apply for research involving survey or interview procedures or observations of children by investigators who participate in the activity being observed</td>
<td>Same restrictions as before for exemption 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other exemptions apply</td>
<td>Plus new provision §_.104(d)(2)(iii) also not applicable (identifiable information obtained, and limited IRB review)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>New exemption 3 does not apply</td>
<td></td>
</tr>
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</table>
Exemption 1: Restrictions Added

- Normal educational practices in established or commonly accepted educational settings
- New:
  Research that involves normal educational practices that are not likely to adversely impact
  - Students’ opportunity to learn required educational content, or
  - Assessment of educators who provide instruction

§__104(d)(1)
A study team wants to test whether adding an hour of physical education (PE) per week reduces disciplinary actions for student behavior. In half of the schools in a district, students will have an additional hour of PE each week, which will occur in place of one hour of their regular science instruction.

Would this study meet the criteria for the revised exemption 1?

A. Likely yes
B. Likely no
C. I don’t know
Exemption 2: *Expanded*

Research that *only includes* interactions involving educational tests, surveys, interviews, and observations of public behavior, exempt when:

i. Information recorded cannot be readily linked back to subjects, or
ii. Any information disclosure would not place subjects at risk of harm, or
iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §___.111(a)(7)

§___.104(d)(2)
Test Your Knowledge

A professor wants to study whether students’ educational test scores improve if they are exposed to low decibel, calming music during the exam. One group of students will take a test in a normal classroom environment, and the other group will take it in a room with calming background music. The professor will collect the educational tests without individually identifiable information.

Would this research meet the criteria for the revised exemption 2?

A. Yes
B. No
C. It depends
D. I don’t know
An investigator wants to interview residents in a nursing home about sexual activity and romantic relationships among residents. Each resident will be asked to complete the survey within two months of entering the facility, and again one year later. In order to track any differences in responses that occur over time, the investigator will need to identify respondents.

Would this research meet the criteria for the revised exemption 2?

A. It is possible
B. It cannot
C. I don’t know
What Happened to Exemption 3 under the Pre-2018 Rule?

- Removed and replaced
- Pertained to research involving the use of educational tests, survey procedures, or observation of public behavior if:
  - The human subjects are elected or appointed public officials or candidates for public office, or
  - Federal statute requires protection of confidentiality without exception
- Most of these activities are not research. Of those that are, many could apply the new exemption 2. If researchers record sensitive identifiable information about public officials, it must be kept confidential.
Exemption 3: New Exemption

Research involving benign behavioral interventions with adults who prospectively agree, when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, and:

A. Information recorded cannot be readily linked back to subjects, or
B. Any information disclosure would not place subjects at risk of harm, or
C. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §111(a)(7)
Exemption 3 (cont.)

• “Benign behavioral interventions”
  These are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and investigator has no reason to think the subjects will find the interventions offensive or embarrassing

• Includes authorized deception research

  §104(d)(3)(ii)-(iii)

SACHRP’s Recommendations on Behavioral Intervention, July 26, 2017
A professor wants to study whether students’ educational test scores improve if they are exposed to low decibel, calming music during the exam. One group of students will take a test in a normal classroom environment, and the other group will take it in a room with calming background music. The professor will collect the educational tests without individually identifiable information.

Would this research meet the criteria for the revised exemption 3?

A. Likely yes
B. Likely no
C. It depends
D. I don’t know
Exemption 4: Expanded and New

Secondary research use of identifiable private information or identifiable biospecimens if the research falls under one of four provisions.

i. Identifiable private information or identifiable biospecimens are publically available, OR

ii. Information, which may include information about biospecimens, is *recorded* in unidentifiable manner and the investigator does not contact or re-identify the subjects, OR

iii. Investigator’s use is regulated under HIPAA as “health care operations,” “research,” or “public health”, OR

iv. Research is conducted by, or on behalf of, a Federal agency using information collected or generated by the government for nonresearch purposes, and the information is protected by federal privacy standards

*Note: No requirement that all data be “existing” at outset of study*
Exemption 5: Expanded

Public benefit and service programs research and demonstration projects

• Expanded to apply to such federally-supported research; no longer limited to federally-conducted research

• Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research

§__.104(d)(5)
Exemption 6: No Change

Taste and food quality evaluation and consumer acceptance studies

§.104(d)(6)
Exemptions 7 and 8: New

- **Exemption 7**: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research

- **Exemption 8**: Secondary research using identifiable private information or identifiable biospecimens

§_.104(d)(7) and (8)

**Both require**: Broad Consent, Limited IRB Review
Limited IRB Review

• Required for exemptions 2(iii), 3(i)(C), 7, and 8 in the revised Common Rule
• Expedited review can be used
• One time only, no continuing review required
  • Exemptions 2(iii) and 3(i)(C) review:
    • For privacy and confidentiality protection under §_.111(a)(7)
  • Exemptions 7 and 8 review:
    • For safeguards related to privacy and confidentiality protection, and broad consent
Determining When the Revised Common Rule Applies

Legend: New with the revised Common Rule

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Please refer to the text of the revised Common Rule available on OHRP’s website (hhs.gov/ohrp) for a complete and accurate description of the regulatory requirements.
Questions?

• OHRP has developed resources about the Revised Common Rule at: www.hhs.gov/ohrp
• Submit your questions to OHRP@hhs.gov
• Stayed connected! Join our listserv at: https://www.hhs.gov/ohrp/news/sign-up-for-announcements/index.html