Revised Common Rule Overview of the Key Changes

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Final Revisions to the Common Rule

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protections of Human Subjects (the Common Rule). It implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

Implementation Date: January 21, 2019
What’s Not Changing?

Minimal change to IRB review of projects that involve:

- More than minimal risk
- Drugs/biologics/medical devices (FDA-regulated)
- Collection of biospecimens
- Children
- Prisoners
Key Changes

- **Removes certain activities** from the definition of research
- **Eliminates continuing review** for most minimal risk research
- **Expands exemption categories** and changes the review process
- **Reframes informed consent information** and adds required elements
- **Requires single IRB review** of research involving external collaborators
A project must meet the definition of “research” and “human subject” to be human subject research – requiring IRB review.
Remove certain activities from the definition of research
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

Four types of activities are specifically deemed not to be research:

- Scholarly and journalistic activities
- Public health surveillance activities
- Information collection for criminal justice purposes
- Operational activities for national security purposes
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 specific activities, not entire academic fields
Public Health Surveillance Activities

Limited to activities conducted, supported, requested, ordered, required or authorized 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 of injuries from consumer products.

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

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.
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. Obtain, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
Clarifications

**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 biospecimens or identifiable private information:** biospecimens or private information for which the identity of subject is or may readily be ascertained by the investigators or associated with the information.
Test Your Knowledge

An investigator plans to analyze the GPA of students in intramural sports teams at a small college. The records will contain only the students’ GPA, date of birth, gender, and race.

Are these records identifiable information under the Common Rule?

A. Likely yes
B. Likely not
C. Undecided
**When to Apply the Revised Common Rule?**

1. **Is it research?**
   - **No** or Activities are deemed not to be research
   - **Yes**

2. **Does it involve human subjects?**
   - **No**
   - **Yes**

3. **Is it exempt?**
   - **No**
   - **Yes**

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

   - Requires limited IRB review to determine that exemption conditions are satisfied

   - **Submit IRB Exemption Application in IRBNet**

4. **Submit Appendix E for documentation purposes**
Eliminates continuing review for most minimal risk research
Changes to Continuing Review

- Continuing review is eliminated for studies reviewed via expedited review
  - The IRB can require continuing review for a study if there is cause

- Also eliminated for full board projects once subject interaction is complete

- Amendments and Adverse Event/Reportable Events are still required

- Investigators will receive reminders about submitting continuing review reports for full board review only

- Implementation of Post Approval Monitoring Program
Expands exemption categories and changes the review process
Exemption Category Changes

Revisions to Exemptions

- New restrictions have been added to the old exemptions – only category 6, the taste and food quality study exemption remains the same
- New uses and restrictions on exemptions for research involving children
- New exemption categories 2, 3, 7, & 8 require a “limited IRB review”

New Exemptions

- Research involving *benign behavioral interventions* in conjunction with the collection of information from adults
- Secondary research uses of identifiable private information or identifiable biospecimens
- Storage or maintenance for secondary research use of private information or identifiable biospecimens
- Research involving the use of private information or identifiable biospecimens that have been stored or maintained for research use
Limited IRB Review

Exemption with “limited IRB review” – new regulatory category

- For projects collecting sensitive, identifiable data, the IRB must review privacy/confidentiality protections (review by an IRB member)

- “Limited IRB review” will be conducted through an expedited review process to ensure adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data.

- An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under 45 CFR 46.104 for which limited IRB review is a condition of exemption (exemption categories 2, 3, 7 & 8)
Exemption 1: Restrictions Added

Normal educational practices in established or commonly accepted education settings

What’s new?

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
Test Your Knowledge

An investigator wants to study whether middle school students improve their math scores by adding more math lessons during the school week. One group of students will take 20 hours of math and 10 hours of English lessons in a week, and the other group will take the regular curriculum of 15/15 hours of math and English.

Would this research meet the criteria for exemption 1 in the revised common rule?

A. Yes
B. No
C. It depends
Exemption 2: Expanded

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

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
Exemption 3: New Exemption category

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:

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

“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
An investigator wants to study whether calming music improves cognitive performance in adults. One group of subjects will take a cognitive test in a quiet room, and the other group will take it in a room with calming background music. The investigator will collect the tests without any individually identifiable information.

Would this research meet the criteria for exemption 3?

A. Likely yes  
B. Likely no  
C. It depends  
D. Undecided
Exemption 4: Expanded Secondary Research Uses of Identifiable Information or Biospecimens

What is **Secondary Research**?

Research use of information or biospecimens collected for:

- Research studies other than the one proposed, or
- Non-research purposes (e.g., clinical care, public health, education)
Exemption 4: Secondary Research
Uses of Identifiable Information or Biospecimens

Materials no longer need to be “existing”

Exempt if:

i. Identifiable materials are **publicly available**, OR

ii. Information, which may include information about biospecimens, is **RECORDED** by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, and the investigator **does not contact the subjects or re-identify subjects**, OR

iii. Investigator’s use is regulated under HIPAA as “health care operations,” “research,” or “public health,” (NOTE: HIPAA does not apply to biospecimens) OR

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

Last year, an investigator collected videotaped interviews of Amazonian indigenous tribes to study anthropology. Now the same investigator wants to analyze this data again for a study in linguistics.

Is the new data analysis secondary research?

A. Yes
B. No, because it is the same investigator
C. Undecided
Exemption 5: Expanded

Public benefit and service programs research and demonstration projects:

- Expanded to apply to 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
New Exemptions Applicable to Secondary Research: Exemptions 7 and 8

**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

Investigator does not include returning individual research results to subjects as part of the study plan except when required by law

Both require:

- **Broad consent** for storage, maintenance, and future secondary use of identifiable information or identifiable biospecimens
- **Limited IRB review** for privacy and confidentiality protection, and some aspects of broad consent
Secondary Research Use & Broad Consents
Broad Consent Template

- Allows the individual the right to make a choice whether to allow for the use of their identifiable information or biospecimens for future research use.

- Not required for storage and secondary research use of de-identified data or specimens or for uses consistent with the original informed consent.

- **This consent must be accessible for verification/ tracking if the information will be used and must be managed in order to remove if the individual changes their mind about sharing their information or biospecimens.**
  
  - New Exemption 7 covers the **storage and maintenance** of data/specimens collected with broad consent.
  
  - New Exemption 8 covers the **secondary use** of data/specimens collected with broad consent.
Reframes informed consent information and adds required elements
Informed Consent Changes

- Provide a “concise and focused presentation of key information” up front

  **Key information:**
  - Voluntary participation
  - Summary of research procedures
  - Risks
  - Benefits

- **New consent elements (if applicable)**
  - Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
  - Clinically relevant results will be returned (or not)
  - De-identified data or biospecimens may be shared for future research (or not)

- New templates available on the IRB website and in the Forms & Templates Library in IRBNet.
Instructions to Investigators
Delete the RED text before submitting this form to the IRB.
Consent to Participate in Research

Study Title:

IRBNet #: 

Principal Investigator:

Faculty Sponsor: insert faculty sponsor’s name, credentials if student research

Study Site: Location where study will take place if off campus, at a school or in the community

Sponsor/Funding source: if no funding involved, delete

You are being asked to participate in a research study. Your participation in this research study is voluntary and you do not have to participate. This document contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Purpose
Provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This summary should include:

- The purpose and expected duration
- Requirements of the study
- Other alternatives to participating, if appropriate
Single IRB (sIRB) Review Requirement

- Requires that **all federally-sponsored research with multi-institutional collaborators** be reviewed by one designated IRB of Record

- Requires an **IRB Authorization Agreement** signed by a DU authorized signatory official and other institution

- Not required until **January 2020**
Other Changes Occurring in the DU IRB Office

- IRB submission forms updated to reflect new revised Common Rule changes
- New review processes implemented
- IRB determination/approval letters, templates and notifications revised
- Human Research Protection Program (HRPP)/Institutional Review Board (IRB) policies updated
- New section on IRB website created with revised Common Rule information
Changes to IRBNet Submissions

- **Exemption Application Form** modified to include new exemption categories

- IRB Determination Form – Appendix E revised to reflect **new definitions of “human subject” and “research”** – a form to evaluate whether a project requires IRB review

- Informed Consent templates updated to include **new elements** and require **version control of consent forms**

- **Broad Consent template** added to allow for the use of identifiable information or biospecimens for future research use
How are current EXEMPT projects affected by the revised Common Rule?

- All exempt projects will be assigned a two-year review period. This review period will appear in IRBNet in the “Next Report Due” field.

- No expiration dates will be affixed to exempt consent documents (Exempt Information Letter). Version dates of consent documents will be required.
- Post approval monitoring will occur within 24 months after the study has been granted exempt status.
How are current **EXPEDITED** projects affected by the revised Common Rule?

- All expedited projects will be assigned a **two-year review period**. This review period will appear in IRBNet in the “Next Report Due” field. Project expiration dates will be removed in IRBNet administratively by the IRB Office.

<table>
<thead>
<tr>
<th>Project Status as of: 01/14/2019</th>
<th>Reviewing Board: University of Denver (DU) IRB, Denver, ...</th>
</tr>
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<tbody>
<tr>
<td>Project Status: Active</td>
<td>Project Expiration Date: 01/17/2019</td>
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<tr>
<td>Initial Approval Date: 02/05/2016</td>
<td>Next Report Due:</td>
</tr>
<tr>
<td>Project Risk Level: Minimal Risk</td>
<td></td>
</tr>
</tbody>
</table>

- **Expiration dates** will be removed from consent documents. Version dates of consent documents will be required.

- *Continuing review will no longer be required.*

- **Post approval monitoring** will occur within 24 months after the study has been approved.

* The IRB may require a continuing review for some studies if there is cause.
Federal Common Rule Resources

Federal Policy for the Protection of Human Subjects, Text of New Rule

Secretary’s Advisory Committee on Human Research Protections, August 2, 2017, Letter to the HHS Secretary and Attachments, including:
Attachment B, Recommendations on Benign Behavioral Intervention
Attachment C, Recommendations for Broad Consent Guidance
https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html
QUESTIONS
DU Resources

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IRB Website
www.du.edu/orsp/research-compliance/human-subjects
THANK YOU!

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