IRB Revised Common Rule

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Changes in the Revised Common Rule

• Definition of “research;” other definitions
• Informed Consent
• Continuing Review
• Changes to Exemptions
• Secondary Research & Broad Consent
Why revise the Common Rule?

• Clarifications of existing rule
• Changes in research practice (biospecimens, secondary research, internet)
• Reduction of administrative burden
Definition of “research”

The following activities are deemed not to be research subject to IRB review:

1) **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), …that **focus directly on the specific individuals** about whom the information is collected.

2) **Public health surveillance activities** …**by a public health authority.**

3) **Collection and analysis of information…by or for a criminal justice agency …for criminal justice or criminal investigative purposes.**

4) **Authorized operational activities…in support of …**national security missions.
Other Definitions

See Appendix D for a complete list.

1. "Written, or in writing" now includes writing in an electronic format.

2. Definition of "human subject" clarified to include identifiable biospecimens and biospecimens obtained through interactions with the individual.

3. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.
Changes to Informed Consent

The informed consent process and consent form must:

1. Provide the information a reasonable person would want to have in order to make an informed decision about whether to participate.

2. Present the information in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate.

3. Provide at the beginning of the form the key information about the study: the purpose, the risks, the benefits, and alternatives.
Changes to Informed Consent

The informed consent form must include new required elements:

1. A notice about whether the data collected as part of the current research might be stripped of identifiers and used for other research in the future.

2. If applicable, a notice about:
   a. possible commercial profit,
   b. whether clinically relevant research results will be returned to the subjects, and
   c. whether research activities will or might include whole genome sequencing.
Other Changes to Informed Consent

1. Additional allowed condition for alteration or waiver of informed consent.

2. Changes to informed consent for screening & recruitment.

3. Additional condition for waiver of documentation of consent.

4. Posting of informed consent forms used in clinical trials, including social, behavioral and education research.

There is a checklist of basic and additional items required for informed consent on the IRB website.
Continuing Review

Under the Revised Common Rule, continuing review is not required for:

1) Research that is eligible for **expedited review**, 
2) Exempt research that requires **limited IRB review**, 
3) Research that has completed all interventions and now **only includes analyzing data**, even if the information or biospecimens are identifiable, 
4) Research that has completed all interventions and now **only includes accessing follow-up clinical data** from clinical care procedures.

The IRB can override this default and require continuing review, as long as the IRB documents the decision and the rationale for this decision. PIs must notify IRB of changes.
Changes to Exemption Categories

What does it mean if your research is exempt?

• The IRB does not do a review to determine if you are following ethical research practices, but does issue a memo documenting a review to determine the research is exempt.

• It is the PI’s responsibility to follow ethical research practices.

• Protocols that have been granted exemption from IRB Review may still be subject to review by study sites, schools, or collaborating institutions.
Changes to Exemption Categories
See Appendix B of IRB Guide

**Exemption 1** (research in educational settings):

- **Added a new restriction to the applicability of Exemption 1**: the research must not be likely to adversely impact the student’s opportunity to learn required educational content or the assessment of educators who provide the instruction.
Changes to Exemption Categories

Exemption 2 (research involving educational tests, surveys, interviews, public observations):

→ Added “only” to first line to clarify that Exemption 2 applies to research that “only includes interactions”...

→ Added new limitation to the applicability criteria: “educational advancement.”

→ Added a new exempt category of research (2(iii)) using identified data, with a limited review by the IRB (A limited review means that the IRB review is limited to protections for privacy and confidentiality).
Changes to Exemption Categories

New Exemption 3 (benign behavioral interventions)

Benign behavioral interventions are brief in duration, harmless, … and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

- Examples would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If at least one of the following criteria is met:

(A) [Unidentified data]

(B) [Identified data, but no risk to subjects]; OR

(C) [Identified data], and an IRB conducts a limited IRB review … of protections for privacy and confidentiality.

- cannot use this exemption if deception is involved unless have prior consent to deception
Changes to Exemption Categories

Exemption 4 (secondary research with unidentified data):

- Added (ii) Information…is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained…., the investigator does not contact the subjects, and the investigator will not re-identify subjects;

- Added two new criteria
  (iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information…for the purposes of “health care operations” or “research” …or for “public health activities and purposes”; or
  (iv) The research is conducted by …a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, [under certain conditions]
Changes to Exemption Categories

Exemption 5 (research on public benefit or service programs):

→ Expanded to cover R&D on public benefit or service programs that is supported by a Federal department or agency.

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants....
Changes to Exemption Categories

**Exemption 6 (taste and food quality):**

→ The revised Common Rule made no changes to Exemption 6.
Changes to Exemption Categories

Do exemptions apply to protected populations?

1. The exemptions are applicable to research with **pregnant women, fetuses, and neonates** (subpart B) as long as the conditions of the exemptions are met.

2. The exemptions **do not apply to research with prisoners** (subpart C), except for research aimed at involving a broader subject population that only incidentally includes prisoners.

3. Most exemptions **can apply to research with children** (subpart D) as long as the conditions of the exemptions are met.
   - Exemption 2 (educational tests, etc.): 2(i) and 2(ii) do not apply for interviews or surveys with children. Exemption 2 (iii) may not be applied to research with children.
   - Exemption 3 (benign behavioral interventions) does not apply to research with children.
Almost done!
Exempt Secondary Research

In addition to Exemption 4 (unidentified data):

**New Exemption 7.** Storage or maintenance of identifiable information or biospecimens for secondary research.

**New Exemption 8.** Secondary research with identifiable private information or identifiable biospecimens.

- Both require **broad consent**
- Both require that an IRB conduct a limited IRB review … the IRB review is limited to protections for privacy and confidentiality and broad consent.
Non-Exempt Secondary Research

Reminder: Secondary research must comply with the criteria for IRB approval of research, which includes the requirement for seeking the informed consent from every prospective subject or legally authorized representative, unless informed consent is waived by the IRB.
Non-Exempt Secondary Research

Three options for secondary research that does not qualify for an exemption:

1. Apply for and obtain a waiver of the requirement for informed consent from the IRB [must meet conditions for waiver];

2. Seek and obtain the study-specific informed consent of each potential subject or legally authorized representative for the study in question;

3. Seek and obtain the broad consent of each potential subject or legally authorized representative for the study in question.

→ or use nonidentifiable information/biospecimens, which is exempt under #4.
Broad Consent

- **Broad consent** is a new type of informed consent pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens.

- If an individual was asked and refused to provide broad consent, the IRB cannot waive informed consent to the use of the subject’s identifiable private information or identifiable biospecimens in a secondary study.
Unique elements of broad consent (in addition to standard ones):

- Description of types of research that may be done with stored data ...
- Description of identifiable private data that might be used or shared, and with which types of institutions or researchers.
- Description of the period of time the materials may be stored, maintained, or used.
- Information on who to contact about subject rights, storage & use of materials, research-related harm.
- Statement that subjects will not be informed about specific studies and that they might have chosen not to consent to some of these studies.
- Statement that clinically relevant research results might not be disclosed to the subject.

For more information
Recap

- Clarifications of activities that are not “human subjects research” subject to IRB review
- Clarification of “human subjects” to include biospecimens
- Changes to informed consent requirements to promote research participants’ understanding
- Revisions of exemption categories & addition of limited review
- Addition of prospective broad consent to facilitate secondary research with identified data
- Continuing Review only for research that receives a full committee review
Before you go...

- Where can you find more information? The IRB website
- Other common questions – student research
- Questions?