New Human Subjects Rule

AN OVERVIEW

IRB Review: The Old Rule

- Three categories: Exempt, Expedited, Full
- Never exempt: Children, Prisoners, Pregnant women
- Approval good for one year only
- Multi-institutional research? Storing and maintaining data for secondary use?
- Is oral history covered?

New rule

- New definition of research & new exempt categories
- "Exempt with limited review"
- Some research on minors is exempt (and pregnant women no longer a vulnerable category)
- Expedited research need not reapply after 1 year
- Multi-institutional research, storing data, oral history addressed
- Plus some stuff on consent

Carleton Policy vs. Federal Rule

Carleton Policy:

All persons involved in conducting research have an obligation to respect the dignity and integrity of the persons beings studied, including their right not to be the subject of potentially harmful research.

Where possible, potential subjects should be provided the opportunity and means to decide freely whether to participate.

Researchers who promise confidentiality are responsible for maintaining it and for informing subjects of the limits of their capacity to meet that responsibility.

Research procedures should minimize the risk of harm and maximize the possible benefits to the subject and to society.

Subjects should be selected for reasons directly related to the problem being studied, not because of their easy availability, their compromised position, or their manipulability.

Multi-institutional Research

- One IRB To Rule Them

(unless you're doing research in another country)

"Not research"

- Research: Systematic investigation designed to contribute to generalizable knowledge.
- The following are **not** research:
- "**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.**"

Exempt categories

The major ones for us are:

- Cat 1: Normal educational research
- Cat. 2: Low-risk social research*
- Cat. 3: Behavioral experiments*
- Cat. 4 & 8: Secondary research on (identifiable data or biospecimens)
- Cat. 7: Collecting (identifiable data or biospecimens) for secondary use*

*Requires “limited review” if you’re collecting data that are both sensitive and identifiable

1: Educational research

Research conducted in established or commonly accepted educational settings, involving normal educational practices **that are not likely to impact students' opportunity to learn required educational content**.

Note: We are proposing additional safeguards if a professor wants to study her or his own students. We'll discuss that next.

Pedagogical Research Using One's Own Students—Carleton policy

- When making adjustments to a class, professors often wish to study the learning outcomes of their own students. This is both admirable and a hallmark of sound pedagogy. For the most part, these activities are considered to be exempt from IRB oversight (note that it is the IRB that must determine "exempt" status). That said, a pillar of human subjects research is voluntary, uncoerced, informed consent of the participants. Due to the inherent power dynamics between a professor and the students *currently in their classes*, it is the opinion of Carleton's IRB that students cannot fully consent. In order to protect our students, and to preserve their right to opt out of human subjects research, we ask the following of our faculty:

Pedagogial Research: Continued

- Please enlist a faculty partner, who is not in any way associated with the class in question, to handle the consent forms and administer the activities or surveys in question. This faculty partner will hold all documents, files, or outcomes related to the study in their possession until grades have been assigned and the course is complete. In this way, the professor of the course being studied cannot know which students do and do not consent to participate in the research until a time when this knowledge cannot affect the grades of any students. Knowing this allows the students more freedom to opt out of the study without negative impacts. We require that their consent be obtained before the study, which necessitates that we designate these studies not “Exempt,” but rather “Limited Review.”

2: Low-risk social research

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observations of public behavior…. If at least one of the following criteria is met:

- Identity of subjects can't be readily ascertained (data aren't identifiable), or
- Disclosure wouldn't put subjects at risk (data aren't sensitive), or
- **The data are sensitive and identifiable but: IRB conducts a limited review to make the determination that there are adequate provisions to protect the privacy of subject and confidentiality are protected**

See IRB website for more info on protecting your data

Low-risk social research on minors?

Exempt:

- Surveys & interviews, if data are not sensitive or not identifiable;
- Educational tests & observations of public behavior if data are not sensitive or not identifiable **AND** you're not interacting directly with minors

Not exempt:

- You're doing educational tests or observations of public behavior and interacting directly with minors; or
- You're collecting sensitive, identifiable data

This sort of research can be expedited, but you will need parental consent

3: Behavioral experiments

Research involving benign behavioral interventions in conjunction with the collection of information from an **adult** subject or audiovisual recording if (1) subject **agrees to intervention**, (2) there's **no deceit** involved (or the subject agrees to be deceived) and at least one of these conditions is met:

- Identity of subjects can't be readily ascertained (data isn't identifiable), or
- Disclosure wouldn't put subjects at risk (data isn't sensitive), or
- **The data are sensitive and identifiable but: IRB conducts a limited review to make the determination that there are adequate provisions to protect the privacy of subject and confidentiality of data**

4 & 8: Secondary research

Secondary research using potentially identifiable private information **or biospecimens:**

Cat. 4: Fully exempt if:

- The data are publicly available, or
- The information is recorded in manner that subject's identity isn't readily ascertained and investigator won't contact or re-identify subjects

Cat. 8: If data **or biospecimens** will remain identifiable, the IRB will review to ensure that:

- Subjects consented to this sort of use; and
- Privacy and confidentiality of data is protected.

7: What if you're collecting & storing data for secondary use?

This is covered by category 7:

Storage and maintenance for secondary use of identifiable data or identifiable biospecimens is technically exempt, **but not really**. IRB will review for

- "Broad consent" from subjects;
- Privacy and confidentiality of data is protected.

- *"Broad consent"? What's that? We'll get to that in a minute….*

Participant Observation?

Probably not exempt (unless it's limited to public observation & interviews only)

Please look at the guidance on the IRB website on how we review participant observation research

Wait, what about 5 & 6?

Cat. 5: evaluation of federal public service or benefit projects, if they are approved by federal dept. head

Cat. 6: Taste test, food quality studies

Summary

- FULLY EXEMPT: most low-risk research collecting info that isn't sensitive **or** isn't identifiable
- LIMITED REVIEW: most low-risk research collecting info that is sensitive **and** identifiable.
- MIGHT NOT BE EXEMPT, EVEN IF LOW-RISK: Research on minors, participant observation, deceptive experiments
- ALWAYS FULL REVIEW: More than minimal risk, research on prisoners

Consent

Key Points

Why Consent?

- The aim of requiring consent is to make sure participation is voluntary
- Subjects of special concern:
  - children
  - prisoners
  - persons with impaired decision making abilities, and
  - persons who are economically or educationally disadvantaged
  - (for us): students of the Principal Investigator, who may feel coerced

Informed Consent

All consents form should:

- Begin with a concise, focused presentation of the key information needed to make this decision;
- Present the information in a way that facilitates comprehension of why one might and might not want to participate; and
- Contain no exculpatory language (waiving of legal rights).

Include *only if relevant:*

An "informed consent" form should also include:

- An explanation of the research, duration and procedures subjects will experience;
- Reasonably foreseeable risks to subjects;
- Reasonably foreseeable benefits to subject or others of the research;
- The extent to which subjects' info will remain confidential;
- Contact info for researcher & IRB;
- A statement that participation is voluntary and subject can discontinue participation at any time without loss of any benefits to which the subject is entitled.
- If you're collecting identifiable information, you also have to explain whether it may be de-identified, saved and used for additional research in the future without getting subject's consent.

Broad consent

When you're collecting data or specimens to be stored for secondary use by other folks, you may need to secure **broad consent**. Explain:

- the kind of research that may be conducted with the data or biospecimens;
- whether you'll be sharing this stuff with other institutions, and what types of researchers or institutions might use it;
- how long it will be maintained and used; and
- whether the subjects will receive reports on any research using this stuff.

Again, only if relevant:

You should also:

- describe foreseeable risks to subject from the research;
- describe any benefits to the subject or others from the research;
- describe how confidentiality of the records identifying the subject will be maintained; and
- tell subjects whom to contact about storage & use of the stuff, and whom to contact about any harms resulting from the research.

Also, if relevant (this applies only to biospecimens):

- whether the biospecimens will be used for commercial profit and
- whether the research will or might include whole genome sequencing

Waiving consent

Informed consent can be waived by the IRB if

- the research involves no more than minimal risk,
- the subjects' rights and welfare won't be affected,
- the research couldn't be carried out without the waiver, or
- the subjects will be given pertinent information after they participate (when appropriate).

Broad consent:

If subject was asked to consent to storage or private identifiable information and refused, the IRB **cannot** waive consent (although it can waive documentation of consent in appropriate circumstances).

Waiving documentation of consent

The IRB can waive documentation of informed and broad consent for minimal risk research for any of these reasons:

- To secure privacy: If the consent form is the only record linking the subject to the research, and the principal risk of harm from the research is breach of confidentiality. In this case, you must ask the subject whether they want documentation linking the subject with the research. The subject's wishes will govern.
- Written consent isn't the norm: The research involves no procedures for which written consent is normally required outside the research context.
- The subjects don't do forms: the subjects are members of a distinct cultural group in which signing forms is not the norm. In this case, you must use an alternative way to document informed consent (like noting it in your field notes).

Additional resources:

CITI resources on the new rule (link to CITI is on IRB website)

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