Creighton UNIVERSITY

CU IRB and Me:

CRITERIA FOR APPROVAL (PART 1 OF 3)

Agenda

- Criteria for approval
- CITI webinars
- IRB website
- Revised guidance documents
- Q & A

Criteria for IRB approval of Research 45 CFR 46.111

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result
- Selection of subjects is equitable
- Informed consent will be obtained and documented (unless waived) accordingly
- There are adequate provisions for data monitoring to ensure safety of subjects if appropriate
- There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data if appropriate
- There are additional safeguards to protect the rights and welfare of subjects likely tobe vulnerable to coercion or undue influence

Criteria for IRB Approval of Research – 45 CFR 46.111

1. **Risks to subjects are minimized:**

   (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

   (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Example 1: Interview-Based Research

(i) Using procedures consistent with sound research design that do not unnecessarily expose subjects to risk

Risks may include psychological discomfort, breach of confidentiality, or social/professional consequences depending on the topic.

1. Minimize Psychological or Emotional Risk

- Avoid unnecessarily sensitive topics unless central to the research question. If interviews involve potentially distressing topics (e.g., trauma), provide participants with relevant support resources.
- Inform participants in advance about the general nature of questions.
- Allow participants to skip any question.
- Allow participants to stop the interview at any time without penalty.

Example 1: Interview-Based Research *(cont.)*

2. Reduce Risk of Social or Professional Harm

- De-identify transcripts (remove names, locations, job titles if identifying).
- Use pseudonyms in transcripts and publications.
- Report findings in aggregate or paraphrased form.
- Avoid including unique quotes that could indirectly identify participants.

3. Ensure Voluntary Participation

- Clearly state that participation is voluntary.
- Emphasize that declining or withdrawing will have no negative consequences.
- Avoid recruiting through direct supervisors or authority figures when possible.

Example 1: Interview-Based Research *(cont.)*

4. Protect Confidentiality

- Conduct interviews in a private setting (in-person or secure virtual platform).
- Store audio recordings on encrypted, password-protected systems.
- Limit access to recordings and transcripts to authorized research personnel.
- Destroy recordings after transcription if not needed long-term.

5. Limit Recording Risk

- Obtain explicit consent for audio recording.
- Offer the option to participate without being recorded (e.g., note-taking only), if feasible.

Example 1: Interview-Based Research *(cont.)*

Example Protocol Language

Risks to participants are minimal and primarily involve potential discomfort when discussing personal or professional experiences. To minimize risk, participants will be informed that they may decline to answer any question and may withdraw from the study at any time without penalty. Interviews will be conducted in a private setting, and all audio recordings will be stored on encrypted, password-protected servers accessible only to the research team. Transcripts will be de-identified and after the contents of the transcripts has been verified the recordings will be deleted. Any potentially identifying details will be removed or generalized.

Example 2: Educational Research

(i) Using procedures consistent with sound research design that do not unnecessarily expose subjects to risk

Minimize risk focused on confidentiality, voluntary participation, and reducing academic pressure.

1. Minimize Risk of Coercion

- Make clear that participation is voluntary and will not affect grades, evaluations, employment, or standing in the school.
- If the researcher is also the instructor, use a third party to distribute and collect surveys.
- Delay access to identifiable data until after grades are submitted.

2. Protect Confidentiality

- Do not collect names, student ID numbers, or other direct identifiers unless necessary.
- Avoid collecting combinations of demographic information that could identify individuals (e.g., “only 1 male student who is over 50 years of age).
- Report findings only in aggregate form.
- Assign study ID numbers instead of using identifying information.

Example 2: Educational Research *(cont.)*

3. Limit Psychological Risk

- Avoid unnecessarily sensitive questions (e.g., trauma, family income, disciplinary history) unless directly relevant to the research question.
- Allow participants to skip any question.
- Provide access to school counseling resources if sensitive topics (e.g., stress, bullying) are discussed.

4. Reduce Burden

- Keep surveys brief (e.g., 10–15 minutes).
- Pilot test instruments to eliminate redundant or confusing items.

5. Obtain Proper Permissions

- Obtain parental consent and student assent when working with minors.

Example 2: Educational Research *(cont.)*

(ii) Using procedures already being performed for diagnostic or administrative purposes (when appropriate)

Minimize additional burden

1. Use Existing Academic Data

Analyze grades, attendance, or standardized test scores already collected by the school instead of creating additional assessments.

2. Use Existing Assignments

Analyze assignments, reflections, or classroom work already completed as part of normal coursework rather than requiring new tasks.

3. Avoid Additional Testing

Do not introduce extra exams or quizzes if current assessments sufficiently measure the outcome of interest.

Example 2: Educational Research *(cont.)*

Example Protocol Language

Risks to participants are minimal and primarily involve potential discomfort when answering questions about their educational experiences. Participation is voluntary and will not affect grades, evaluations, or standing within the institution. If the researcher is also the instructor, a third party will administer the survey, and identifiable data will not be accessed until after grades are finalized. No direct identifiers will be collected, and results will be reported only in aggregate form. Participants may skip any question or withdraw at any time without penalty. Where feasible, existing academic and administrative data will be used to avoid additional testing or burden. All data will be stored on encrypted, password-protected systems accessible only to the research team.

Criteria for IRB Approval of Research – 45 CFR 46.111

2. **Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.**

   In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

   The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

The concept of Risk

The concept of risk is the possibility that something unpleasant or unwelcome will happen. It is generally not objectively quantifiable. It is inherently imprecise, subjective, and value dependent.

- Minimal Risk: The **probability and magnitude** of harm or discomfort anticipated in the research are **not greater in and of themselves than those ordinarily encountered** in daily life or during the performance of routing physical or psychological examinations or tests.
- Greater than Minimal Risk: Anything that does not fit the definition of Minimal Risk.
- Risk is a function of the **magnitude** (how severe) and **probability** (how likely).

What IRB's Consider When Reviewing a Submission

a. Types of risks: Physical, psychological, social, economic, legal, dignity
b. Circumstances for risk: Recruitment, informed consent, performing a research activity, identifiability of responses
c. Who is impacted: Research subjects, others
d. Minimizing risk:
    i. Alternative procedures/methods that are less risky
    ii. Precautions that decrease the likelihood of harms occurring
    iii. Contingency procedures to address harms if they do occur
    iv. Adding onto clinical care procedures that will be done regardless of the research
e. What to consider as the researcher:
    i. Is the hypothesis clear?
    ii. Is the study design appropriate to prove the hypothesis?
    iii. Is the research designed with appropriate measures to minimize risks to participants?
    iv. Is there appropriate use of the exclusion criteria and does the exclusion criteria minimize risks?

Risk to Subjects – What IRB's Consider

Questions reviewers might ask

a. What are the risks that may result from the research?
b. What is the prospect of direct benefit that may result from the research and what might this mean?
c. What is the knowledge that may be gained?
d. Are the risks reasonable to the benefits taking into consideration the importance of the knowledge that could be gained?

Weighing risks against benefits

- Identifying risks
- Forecasting benefits
  - Benefits to subjects – direct or indirect
  - Benefits to others – importance of knowledge, significance of benefits

Risk/Benefit Analysis

- No direct benefit: Serious risks may be justified only if knowledge to be gained is important and cannot be obtained otherwise
- Direct benefit: Reasonable amount of risk may be justifiable

Criteria for IRB Approval of Research – 45 CFR 46.111

3. **Selection of subjects is equitable.**
    - **In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.**
    - **The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.**

- Vulnerable Population: When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects

Criteria for Approval

The concept of equitable selection of subjects is rooted in the fundamental ethical principle of Justice from the Belmont Report.

- The Belmont Report principle of Justice focuses on fairness in the **distribution of research benefits and burdens.** It ensures that no group is unfairly targeted for risky research or excluded from potential benefits. Researchers must **select subjects equitably**, avoiding exploitation of vulnerable populations and ensuring that all groups have equal access to the advantages of research participation.

What IRB's Consider When Reviewing Equitable Selection of Subjects

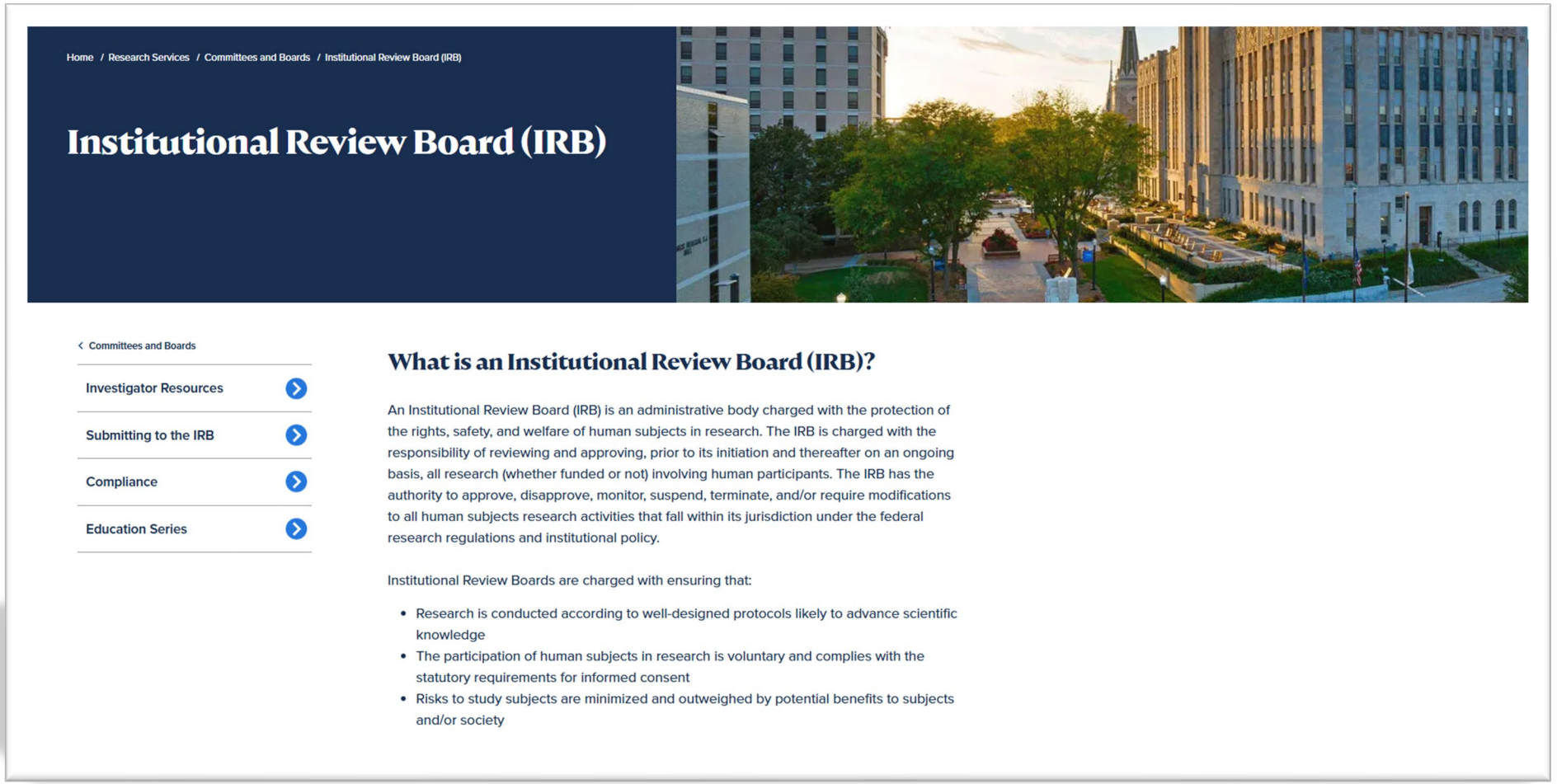
a. The purpose of the research and the setting in which the research will be conducted
b. If prospective participants would be vulnerable to coercion or undue influence
c. The inclusion and exclusion criteria
    i. Who is the target population?
    ii. Is the target population appropriate for answering the questions the protocol addresses?
    iii. Is the inclusion criteria sufficiently inclusive?
    iv. Are the reasons for exclusion scientifically valid?
d. Participant recruitment and enrollment procedures
e. Are potentially vulnerable populations involved?
f. Can measures (adequate additional safeguards) be taken to minimize the risk of vulnerable populations?

CITI Webinars

Available webinars relevant to today's topics

- Working with Your IRB (ID: 317832)

CU IRB Website



https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb

Revised Guidance Documents

Guidance Document

- Quality Improvement Projects and Not Human Subjects Research Requirements
- Checklist: Case Study or Human Subjects Research?
- Flowchart: Human Subjects Research Decision Tree **NEW**
- Guidance Document: Do I Need to Submit to the IRB?
- Guidance Document: IRB Requirements for Recruitment Materials

https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb/investigator-resources

Help us help you

Our goals

- Provide meaningful education and guidance to the research community
- Support researchers for the lifetime of their studies

IRB Booking Page

Suggestions for future CU IRB and Me sessions

Next CU IRB and Me Session:
Criteria for Approval (2 of 3)
on 18-Mar-26 at 12 PM (Central)

Q & A

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Thank you.

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