Creighton UNIVERSITY

CU IRB and Me:

CRITERIA FOR APPROVAL (PART 2 OF 3)

Agenda

- Criteria for approval – informed consent
- Waivers
- Revised consent templates
- CITI webinars
- IRB website
- 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

4. **Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.**

5. **Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.**

Informed Consent

- Belmont Principle of Respect for Persons
- The concept of informed consent means that ***prior to participating in research***, every potential subject has to be provided with all necessary information about the research and provide their voluntary consent to participate.
- It is the duty of the research team to ensure the potential subjects is fully informed about the study's purpose, procedures, potential risks and benefits, and their right to withdraw at any time before obtaining their consent to participate.

General Requirements for Informed Consent

- Obtain legally effective informed consent of the subject or subject's legally authorized representative (LAR)
- Informed consent should only be obtained when the subject has sufficient opportunity to discuss and consider whether or not to participate
  - The possibility of coercion or undue influences should be minimized at all times
- Information provided to subjects is given in a language that is understandable to them
- Informed consent should begin with a concise and focused presentation of the key information
  - Most likely to assist a subject in understanding the reasons why one might or might not want to participate
- Informed consent, as a whole, must present information in sufficient detail

Required Elements of Informed Consent

- 9 Basic Elements of Consent
- 9 Additional Elements of Consent
- Senior IRB Administrators will review the consent during the pre-review process to ensure all elements of Informed Consent are present
- Our consent templates include all Basic and Additional Elements of Consent

Basic Elements – 45 CFR 46.116(b) and 21 CFR 20.25

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. Description of any risks or discomforts to subjects
3. Description of any benefits
4. Alternative procedures or courses of treatment
5. Statement about confidentiality of records
6. For greater than minimal risk (GMR) studies, whether compensation for injury is available or not
7. Contact information for answers to questions about the research or who to contact in the event of a research-related injury
8. Statement that participation is voluntary
9. If the research involves the collection of identifiable information, one of two statements are included:
    i. A statement that identifiers might be removed and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject; **or**
    ii. A statement that the subject's information or biospecimens, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements – 45 CFR 46.116(c)

When appropriate, one or more of the additional elements of informed consent are required to be provided to each subject or their LAR.

1. Risks to fetus
2. Circumstances in which subject participation may be terminated
3. Cost to the subject
4. Consequences of a subject's decision to withdraw
5. Significant new findings
6. Number of subjects involved
7. Biospecimens used for commercial profit
8. Disclosure of clinically-relevant research results
9. Biospecimens – whole genome sequencing

Researchers and Informed Consent

- Informed consent is a process – researchers must communicate their intentions throughout the study
- Establish a trustworthy relationship with participants
- Make informed consent meaningful
  - Interactive communication
    - Comprehension
    - Accessibility
  - Research approachability
    - Autonomy to participate or withdraw
  - Frame as ongoing dialogue rather than a one-time agreement
    - Periodic updates
    - Incorporate feedback mechanisms and regular check-ins

What IRBs Consider When Reviewing Informed Consent

a. Does the consent form contain the general and basic required elements, and any additional elements, if applicable?
b. The purpose of the research and the setting in which the research will be conducted.
c. The study summary/activities match in the protocol and consent form.
d. Participant recruitment and enrollment procedures.

Documentation of Informed Consent – 45 CFR 46.117

- Informed consent should be documented by the use of a written informed consent form (ICF) approved by the IRB
- ICF signed by the subject or the subject's LAR (including in an electronic format)
- Copy given to the person signing the ICF
- The subject or the subject's LAR should have an adequate opportunity to read the ICF before signing

Waiver of Documentation – 45 CFR 46.117(c)(1)

The IRB may waive the requirement for signed informed consent for some or all subjects if the IRB finds any of the following:

- The only record linking the subject and the research would be the ICF and the risk would be potential harm resulting from a breach of confidentiality;
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; **or**
- If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Note: If the waiver is granted, the IRB may require the investigator to provide subjects or LARs with a written statement regarding the research.

Requirements for Waiver or Alteration of Consent

The IRB must have the following information to document and approve a waiver or alteration of consent to satisfy the five criteria of 45 CFR 46.116(f):

- The research involves no more than minimal risk
- The research could not practicably be carried out without the requested waiver or alteration
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
- The waiver or alteration will not adversely affect the rights and welfare of the subjects
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

Justification for Impracticable

- Waiver criterion: The research could ***not practicably*** be carried out without the requested waiver or alteration.
- In some research projects, it would not be practicable to perform the research if informed consent was required. For example:
  - The sample size required is so large (for example, with epidemiological studies) that including only those samples/records/data for which informed consent could be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
  - The subjects for whom records would be reviewed may be lost to follow-up. Individuals likely to have relocated or died may be significant percentage of the proposed subject population, thus decreasing the statistical power of the study if informed consent was required.
  - Disclosure of the study purpose would bias the research subjects so that study results are not meaningful.
  - There is a risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek informed consent.
  - There is a risk of inflicting psychological, social, or other harm by contacting individuals or families with particular conditions.

Note: In general, investigator inconvenience or cost does not determine "impracticality" and there should be a clear rationale why the research could not be conducted with a population from whom informed consent could be obtained.

Justification for Not Adversely Affected

- The waiver or alteration ***will not adversely affect*** the rights and welfare of the subjects
  - This justification should be based on the “reasonable person” standard; that is, whether or not a reasonable person in the subject’s position would consider the waiver as adversely affecting their rights and welfare.

Criteria for Waiver of Parental/Guardian Permission

The IRB may allow a wavier of parental/guardian consent (permission) provided the requirements of 45 CFR 46.116(f)(3) and 45 CFR 46.408(c) are met; specifically:

- The research must be designed for conditions or for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects.
- The following are considerations which may justify a waiver:
  - Informing parents or guardians may result in harm to the child.
  - The research is important to the health and well-being of adolescents and the subjects are capable of understanding informed consent at an adult level.
- There is an appropriate mechanism in place for protecting the children who will participate as subjects in the research.
  - The choice of an appropriate mechanism depends upon the nature and purpose of the research activities, the risks and anticipated benefit to the subjects, and their age, maturity, status, and condition. For example, the appointment of an advocate, provisions for referral to counseling or other safeguards, etc.

Upcoming: Revised Informed Consent Templates

Templates

- Revised Informed Consent Template
- Revised Parent/Guardian Permission Template
- Revised Assent for Ages 7-12 Template
- Revised Assent for Ages 13-18 Template

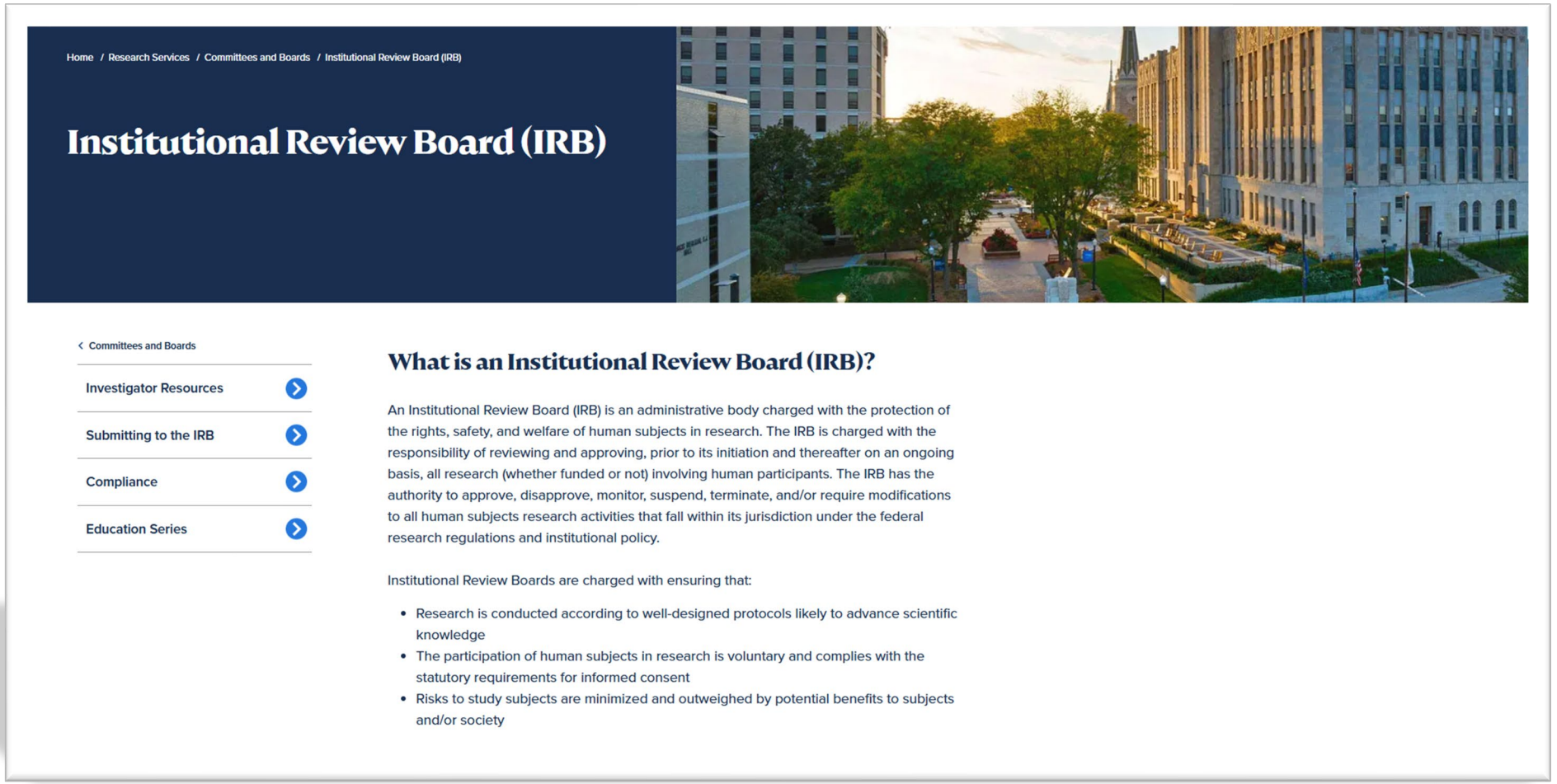
https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb/investigator-resources

CITI Webinars

Available webinars relevant to today's topics

- Working with Your IRB (ID: 317832)
- Advance Research Directives Tools for Supporting People Who Lack Decision-Making Capacity (ID: 317780)
- Improving the Clinical Trial Participant's Experience: From Recruitment through Study Closure (ID:317868)
- Informed Consent and Clinical Investigations: A Focus on the Process (ID:317830)
- Informed Consent and Research with Wearable Tech (ID:317836)
- Remote Informed Consent: The Same, but Different, but Still the Same (ID:317840)
- Revised Common Rule: Revisions to Informed Consent (ID:317817)
- Social Media and Research Recruiting (ID:317823)
- Understanding Consent Requirements and "Key Information" Under the Revised Rule (ID:317820)

CU IRB Website



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

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 (3 of 3)
on 15-Apr-26 at 12 PM (Central)

Q & A

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Thank you.

IRB Office | 402.280.2126 | IRB@creighton.edu