



University of Idaho Institutional Review Board Standard Operating Procedures Manual

Procedure and Guideline	Last Revised: November 3, 2020
Expiration of Protocols	Effective Date: December 1, 2020

IRB Procedures: Protocol Review Process

Protocol Review Processes

All requests to utilize human subjects in research must be submitted by the Principal Investigator to the IRB via a protocol form and approved by the IRB prior to recruiting, consenting, or performing human subjects' research. The IRB may approve new, renewing, or modified/amended protocols through Full Board Review, Expedited Review, or Exempt Review.

For all reviews, in addition to the Submission form, the following materials may be necessary to complete the review process. The IRB Office will review application packets to ensure completion prior to member review:

- Submission form
- Recruitment material(s)
- Consent or assent document(s)
- Survey questions
- Interview questions
- Additional relevant materials

Research involving vulnerable populations, medical procedures, tribal relations, or other novel research, may require additional review by experts with experience with the population or procedure being performed. Any member can call for additional, expert reviewers. UI IRB standard is that all prisoner protocols require review by a non-conflicted prisoner IRB representative, protocols involving Native American Tribal entities are reviewed by the UI office with oversight of tribal relations, and protocols with complex or novel medical procedures are reviewed by a non-conflicted medical IRB representative. Other expert opinions may be solicited based upon need.

All IRB members receive training on the Designated Member Review policy and procedure during new member orientation. Additionally, all members are required to sign the "Member Acceptance of Responsibilities" stating they agree with the process described above and understand that Designated Member Review may be assigned by the Chair or the Chair's designee, usually the IRB office.

a. Full Board Review (FBR)

Protocol review by the full committee is conducted by a quorum of the IRB at a convened meeting. The purpose of FBR is for all IRB members to be involved in protocol review and decision-making through interactive discussion. Absent members may provide review comments prior to a convened meeting, however these may not be counted toward a vote or considered as part of the quorum. Additional expert opinion may be solicited as needed.

b. Expedited Review

Expedited Review may be used to perform protocol reviews outside of a convened meeting, if the protocol submitted falls within one of the nine categories allowable by expedited review.

Additionally, the following criteria must be met (45 CFR 46 & 21 CFR 56):

- Participant risks are minimized when appropriate, or reasonable in relation to anticipated benefits
- Equitable selection criteria is used
- Safety monitoring criteria is in place, when appropriate
- Adequate provisions for privacy are in place, when appropriate
- Adequate provisions for confidentiality are in place, when appropriate
- Additional safeguards are in place for vulnerable populations, when appropriate
- Consent is properly obtained or a waiver from the IRB is received
- Risk to participants meets the definition of “minimal risk” in 45 CFR 46.102(i)

Expedited review can also be used to finalize the review and approval of a protocol that was initially reviewed by FBR but required modifications to secure approval, or when the Board has determined that a FBR protocol only needs Expedited Review in the future

- **Expedited review process:** The IRB office may provide a copy of the new protocol or amendment to the Chair and request a determination on the review process, either FBR or Expedited if needed.
- The Chair, or designee such as IRB office, appoints one or more qualified IRB members to act as Expedited reviewer(s).
- The Expedited reviewer(s) may:
 - Approve the protocol or significant change as submitted,
 - Require modifications to the protocol or significant change in order to secure approval, or
 - Refer the protocol to the full committee with or without modifications for FBR.
- If more than one Expedited reviewer is assigned, they must be unanimous in any decision. Reviewers receive identical versions of the protocol. Requested modifications are sent to the Primary Investigator for review and response
- IRB members are informed of the protocol approval at the next meeting.

The following procedures describe the Expedited process used after FBR:

- When the committee votes to require modifications to a protocol, the members present at a convened meeting must decide whether to finalize the review by Expedited review or Table for review at the next convened meeting.
- If the quorum of members are in unanimous agreement for Expedited Review, the chair appoints one or more designated member reviewers. This is documented in the meeting minutes.
- If more than one designated member reviewer is used, they must be unanimous in the decision to approve. If the designated member reviewers cannot come to a unanimous decision, the Chair may make the final decision, or return the protocol back to the Full Board for a decision.
- The IRB Office provides the Principal Investigator (PI) the requested modifications for review and response.
- Once a response is received, the IRB coordinator forwards the revised protocol materials to the reviewer(s).

- The reviewer(s) may approve the changes, require additional modifications to secure approval, or request the revised protocol be review by additional subject matter experts or at the next convened meeting.
- Investigators may not proceed with the project until all committee requests have been clarified and approved.
- Any member of the IRB may, at any time, request to see the revised protocol or request FBR.

c. Amendments of Full Board protocols that are allowable by Expedited review

Minor changes in ongoing research projects originally reviewed by Full Board Review may be reviewed and approved by the IRB via Expedited review prior to their implementation. Minor changes should not increase the risk of the study participant. Examples of minor changes include:

- Amendments that would fall within Expedited Categories 1-7
- Minor changes to other study documents (surveys, recruitment materials, interview questions, etc.)
- Additional study documents that are similar to those previously approved
- Changes in payment to subjects that are insubstantial enough as to not cause undue influence
- Decrease in number or volume of sampling as long as it does not increase the risk to the participant
- Editorial changes for clarification in any of the study documents, including Consent forms
- Addition of translated versions of previously approved study documents

Examples of major changes that could require Full Board review include:

- Changes that increase the risk to the participant
- Addition of new subject populations
- Changes to exclusion or inclusion criteria that could adversely impact the risk/benefit ratio
- New or significantly changed study document, such as including new risks
- Complex changes to a protocol
- Changes to the informed consent documents that adversely affect the rights and welfare of study participants

Final decision of whether an Amendment should be reviewed as Expedited or Full Board will be left up to the Chair with guidance from the IRB Coordinator.

d. Exempt Review & Certification

Members of the IRB office perform exempt protocol review and certification.

The IRB office may require consultation with the IRB Chair or other members of the IRB committee should questions arise associated with exempt category applicability to a study.

e. Administrative Changes

The members of the IRB office may administratively process minor changes to an approved protocol. These requests must be made by in writing by the PI but need not be approved by the IRB. Examples of administrative changes include:

- Contact information updates; and
- Changes in personnel other than the PI;
- Request for closure of a protocol.

f. Changes that do not require IRB notification

Investigators may use fewer subjects than approved or on expedited or exempt protocols may choose not to perform approved procedures, as long as this does not change the risk profile to the participant. These do not require IRB approval, notification, consultation, or administrative handling unless they increase the risk to the participant.