

**Procedures for Initial Review of Research Proposals  
Involving Human Subjects and Live Animals**  
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**Step #1. Initial Assessment**

- A. Proposals for use of human subjects and live animals are to be submitted to the IRB Chair by the Graduate Committee Chairperson before onset of any research activities. The IRB Chair will submit the research proposal to a selected member of the IRB for initial assessment.
- B. Depending on the nature of the research and content of the proposal, the results of the Initial Assessment Reviewer may determine :
  - (1) The research project is exempt from IRB review;
  - (2) The research project is appropriate for an expedited review by one member or a subcommittee of the IRB; or
  - (3) The research project is subject to full review by the IRB.
- C. Upon receipt of the IRB Reviewer's Initial Assessment Report, the IRB Chairperson will finalize a determination as to which type of review is necessary and prepare the written IRB Initial Assessment Report for dispatch.

**Step#2. Dispatch of Initial Determination**

- A. If determined to be exempt, the IRB Approval Form will be signed by the IRB Chair and returned to the researcher immediately with copies sent by email to the Committee Chair and University Administration for the archival record.
- B. If determined that an expedited review is required, the IRB Chair will designate an IRB Expedited Reviewer to evaluate the proposal further. If the Reviewer has questions concerning the proposal, he or she will consult with The IRB Chair to determine whether or not full review is required. After a detailed inspection, the research project can be determined exempt by the IRB Expedited Reviewer, with a written report sent to the IRB Chair. If determined to be exempt, the IRB Exemption Report will be signed by the IRB Chair and returned to the researcher immediately with copies sent by email to the Committee Chair and University Administration for the archival record.
- C. If the IRB Expedited Reviewer determines, in consensus with the IRB Chair that the research project will require a Full Review, the IRB Exemption Report is marked Not Exempt and signed by the IRB Chair and returned to the researcher immediately with copies sent by email to the Committee Chair and University Administration for the archival record.

**Step #3. Full IRB Committee Review**

- A. If . Full IRB Committee Review is required, a copy of the research proposal will be assigned to a voluntary IRB Full Review Preliminary Committee of three faculty members, in good standing , appointed from among the IRB Membership, for a detailed preliminary assessment and written report, initiated at least fifteen days before convening a meeting of the Full IRB Committee. A summary report of the findings from the preliminary reviewers will be prepared by the IRB Chair, and distributed to the Full IRB Committee at least three days prior to the schedule meeting date.

- B. The Full IRB Committee meeting shall be conducted via audio conference arranged by the IRB Chairperson.
- C. At the Full IRB Committee meeting, a majority quorum of the IRB Committee members must be present at the meeting for a full review of any proposal to take place.
- D. The principle investigator shall be invited to attend the meeting to answer questions at about the research.
- E. A majority of the quorum present may approve or disapprove the research.
- F. Members of the IRB who vote to disapprove a proposal must submit their reasons in writing to the IRB Chairperson.

#### **Step #4. Procedures Following Approval by IRB Full Review Committee**

If the IRB Full Review Committee determines, in consensus with the IRB Chair that the research project is approved, the IRB Full Review Committee Report is marked “approved” and signed by the IRB Chair and dispatched to the researcher immediately with copies sent by email to the Committee Chair and University Administration for the archival record.

#### **Step #5. Procedures Following Disapproval by IRB Full Review Committee**

If the IRB Full Review Committee determines, in consensus with the IRB Chair that the research project is disapproved, the IRB Full Review Committee Report is marked “disapproved” and signed by the IRB Chair and dispatched to the researcher immediately with copies sent by email to the Committee Chair and University Administration for the archival record. Further, together with the report of disapproval, the researcher will be notified in writing, with clearly itemized reasons for the disapproval, and will be given an opportunity with complete instructions, to respond in writing and make requisite changes, corrections and upgrades to the research proposal and re-submit for review within a designated period not to exceed 90 days, with a deadline date provided.

#### **Step #6. Chronological Follow-Up Activities**

Ongoing research, which has previously been approved must be resubmitted for review within one calendar year, of its last approval. A new review form must be used for this resubmission, and the full process is re-engaged.

