

UNIVERSITY OF SOUTHERN INDIANA

Institutional Review Board By-Laws

Article I. Mission Statement

The University's IRB, or Institutional Review Board, is a federally mandated committee of faculty, administrators, and community representatives, which is charged to review and approve all research protocols involving humans as participants and created by anyone affiliated with the University of Southern Indiana (USI).

The mission of the USI IRB is to ensure protection of the rights of human subjects who participate in research activities conducted by the University community. The IRB is committed to the standards that ensure research is conducted in an ethical manner and complies with government regulations, ensuring the safety and wellbeing of human subjects at the highest level of excellence. USI complies with the ethical principles set forth in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. In addition, USI complies with federal regulations (45 Code of Federal Regulations [CFR] Part 46) concerning research involving human subjects, regardless of the source of funding, as outlined in the Office of Human Research Protections (OHRP) by the United States Department of Health and Human Services (DHHS). USI is committed to standards of excellence for all research activities from the University community.

Article II. Authority

The USI has delegated authority to the IRB which will be empowered to:

1. Review all funded and unfunded research by faculty, students, or staff that involves the use of human subjects prior to the beginning of the research
2. Ensure that researchers have procedures in place to fully inform subjects about the nature, purposes, risks, and benefits of the research, and obtain informed consent as applicable
3. Educate the university community as to the responsibilities and duties of those conducting sound and ethical research
4. Determine the type of review (exempt, expedited, or full board) the research requires
5. Disapprove, recommend modification, or approve research proposals based upon the protection of human subjects
6. Suspend or terminate any human subjects research that is not proposed or conducted as approved by the IRB
7. Require progress reports and/or monitoring as deemed necessary.

Article III. The Board

The IRB is considered a standing committee of USI. The IRB will be comprised of no fewer than nine (9) members who are committed to serving three-year renewable terms. A member may run for re-election an unlimited number of times. Members shall be removed only for stated cause, non-participation and/or non- attendance.

1. Composition

The IRB will have at least one member to represent the scientific community, the nonscientific community, the community not affiliated with USI in any direct way, and the vulnerable population community.

The composition of the membership of the IRB will be at least two representatives from each USI college unit, at least one community member, and at least three at large members. At large members come from other USI units such as David L. Rice Library, University Division, and the Center for Applied Research. Members are elected to serve the IRB. Any member of a USI college unit who would like to serve on the IRB should indicate his/her interest to his/her chair, director, and/or dean.

Elections will be held in the spring semester with each college electing their representative. In cases where there are not enough candidates to fill all open positions, then positions will be filled by appointment. Appointments will be made by a college dean or unit director.

Individuals interested in serving as an at large member should contact the Office of Sponsored Projects and Research. At large positions can be filled by appointment or through an election with the appropriate unit electing their representative.

The community member will be appointed by the IRB.

The Director of Sponsored Projects and Research will be designated as the Institutional Official. The Office of Sponsored Projects and Research staff (e.g., Grant Administrators and Director) are non-voting *ex-officio* members.

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. A representative from USI's General Counsel may serve as legal consult as needed. Special consultants provide expertise and may not vote with the IRB.

2. Membership

The IRB will be composed of members who are:

- Tenured or tenure-track faculty (only required for college units)
- Current with Human Subjects Assurance Training
- Representative in diversity of race, sex, and professional expertise

Duties of Members include:

- Attend Board meetings
- Review and evaluate all assigned protocols within stated timeframes
- Complete and maintain current, approved training for research with human subjects
- Become familiar with federal and state regulations, USI policies, and IRB guidelines and procedures
- Serve on *ad hoc* subcommittees of Board

Failure to attend three (3) consecutive meetings or failure to respond to three (3) IRB submissions by the stated deadline will constitute cause for removal if no valid excuse is provided. Replacement by another individual will be through appointment by a college dean or unit director.

3. The Chair

The Chair will:

- Be elected from the Board members to hold a two-year term
- Have at least one year's experience as an IRB member when elected to serve
- Preside at all regular and special sessions of the Board
- Represent the Board in dealings with the University and the public
- Perform all functions of a Board member
- May designate an Associate Chair to act in his or her absence
- Have the authority to authorize emergency changes to a protocol to avoid an immediate hazard to subjects
- Have the authority to appoint an *ad hoc* committee

4. The Office of Sponsored Projects and Research

Under the terms of the university's current Federal-wide Assurance, the Executive Director of the Office of Sponsored Projects and Research serves as the Human Protections Administrator.

The Human Protections Administrator and the Office of Sponsored Projects and Research have the following duties:

- Keep current on federal and state guidelines for research with human subjects and communicate that information to the Chair, the Board, and to faculty, staff, and students who do human subjects research
- Organize and participate in educational activities related to IRB policies and procedures
- Post IRB guidelines, forms, minutes, logs, and related materials electronically
- Maintain records for all protocols
- Distribute protocols appropriately

- Post meeting notices on the Office of Sponsored Projects and Research website, IRBNet and via faculty email
- Keep on file IRB correspondence, guidelines, forms, minutes, logs, human research training certificates, and all other relevant information
- Participate in on-site reviews by federal inspectors
- Provide assurances to federal agencies of approval of protocols to be supported by federal funds
- Act as liaison between federal agencies and investigators regarding human subjects issues

5. Meetings

To establish a quorum, at least half plus one of the voting members must be present.

The IRB will meet monthly during the academic year.

The dates of the IRB Meetings will be posted on the USI Office of Sponsored Projects and Research website.

Article IV. Procedures for IRB Review of Protocols

The IRB does not review research protocols which come from outside of the USI community. All research protocols to be reviewed by the IRB must come from within the USI community and have a designated USI faculty or staff sponsor for said protocol.

Research that has been reviewed and approved by the IRB may be subject to further review and disapproval by officials of the institution. Those officials may not, however, approve research if it has been disapproved by the IRB. (HHS OHRP *IRB Guidelines*, 3)

Approved research is subject to continuing IRB review and must be reevaluated at least annually. (HHS OHRP, *IRB Guidelines*, 3)

Exempt Protocols

Exempt protocols will be reviewed by a member of the Board or the Office of Sponsored Projects and Research. Results of review will be communicated to the Principal Investigator (PI) via IRBNet.

If the protocol meets exempt criteria, and is found to be in compliance with Office of Human Research Protection (OHRP) regulations, then the Reviewer can approve the protocol. If minor revisions are required, the Reviewer will indicate whether the protocol is approved or approved

pending minor revision and will communicate this via IRBNet to the PI and the USI Office of Sponsored Projects and Research.

The Office of Sponsored Projects and Research will review and approve the revised and resubmitted protocol to assure appropriate revisions have been made. Results of the final review will be communicated to the Principal Investigator by IRBNet.

The initial review process for Exempt Protocols may take up to 7 business days, not accounting the time for revisions to be made by the PI and additional reviews to be completed by the IRB of the revisions requested.

Expedited Proposals

Expedited proposals will be reviewed by the Office of Sponsored Projects and Research for completeness.

Two members of IRB shall be delegated to perform the Review. If no one on the IRB has appropriate expertise, the IRB Chair may seek a consultation with an expert who will serve in an *ad hoc* capacity to advise on the review of the protocol.

If the protocol meets expedited criteria, and is found to be in compliance with OHRP regulations, then the designated reviewer can approve the protocol. If minor revisions are required, the Reviewer will indicate whether the protocol is approved or approved pending minor revision and will communicate this via IRBNet to the Principal Investigator (PI) and USI Office of Sponsored Projects and Research.

The Office of Sponsored Projects and Research will review and approve the revised and resubmitted protocol to assure appropriate revisions have been made. Results of the final review will be communicated to the Principal Investigator by IRBNet.

The initial review process for Expedited Protocols may take up to 10 business days, not accounting the time for revisions to be made by the PI and additional IRB reviews of the revisions requested.

Convened (Full) Proposals

If the protocol does not meet either expedited or exempt criteria, the protocol shall be reviewed by the full membership of the IRB. Proposals can be accepted, rejected, or returned to Principal Investigator with recommendations for revision to be in compliance with OHRP regulations.

A protocol requiring full board review will need to wait for the next IRB meeting to fulfill the full board review requirements. IRB applications should be submitted at least four weeks prior to a scheduled IRB meeting date.

Results of review will be communicated to the Principal Investigator by USI Office of Sponsored Projects and Research.

Review of Renewals and Revisions

Review of Renewals and Revisions shall be completed by the USI Office of Sponsored Projects and Research. Any revisions that change the project's review type will be subject to the review process for that type. Results of the review will be communicated to the Principal Investigator by IRBNet.

Article V. Conflicts of Interest

No member of this Board may take part in any reviews of any project or activity in which that member has an active role or in which there may be a conflict of interest.

No IRB member may participate in the discussion of a protocol for which he or she is an investigator unless invited to do so by the IRB. No IRB member may vote on a protocol for which he or she is an investigator or has any conflict of interest.

Article VI. Amendment

Amendments to these Bylaws may be proposed by a member of the Board. Revised Bylaws will be sent to members for discussion. The amendment may be adopted by majority vote. Any amendments that are mandated by the federal government will be made immediately.