

Institutional Review Board (IRB)

PURPOSE:

- The IRB ensures that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB reviews all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research.
- Proposals for all human subjects research must be submitted to the IRB for review before any data collection can begin.
- Whenever FHSU becomes engaged in human subjects research (i.e., whenever any FHSU employees or students engage in any form of data collection through interaction or intervention with individual humans or the gathering of identifiable private information about individual humans from existing documentation, or any FHSU employees or students are the subjects' of data collection, for the purposes of contributing to generalizable knowledge) actions taken will be in accordance with the terms of the *Federal Wide Assurance (FWA)* for institutions within the U.S.A.
- The IRB (a) determines and certifies that all projects reviewed by the IRB conform to FHSU policies and all applicable regulations regarding the health, welfare, safety, rights, and privileges of human subjects; and (b) assists the investigator in complying with federal, state, and Fort Hays State University regulations and policies.
- The IRB is guided in its decision-making by ethical principles, and federal, state, and University regulations regarding research with human subjects. The primary responsibility of the IRB is the protection of research subjects from undue risk and from deprivation of personal rights and dignity.

MEMBERSHIP:

- According to federal regulations, the IRB shall have a minimum of 5 members with varying backgrounds who are:
 - sufficiently qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects;
 - not entirely of members of one profession;
 - represent diversity in race/ethnicity, gender, and academic discipline, and exercises sensitivity to community attitudes;
 - includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas, and;
 - includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- Leadership
 - The Chairperson is elected by the IRB for a term of one year at the last meeting of the academic year who will take office at the first meeting of the subsequent year, and is responsible for running convened meetings of the IRB.
 - The Secretary is elected by the IRB to serve for a renewable 3 year

term, and records the minutes of convened IRB meetings.

- Other
 - The designated Institutional Official is the Provost.
 - The Coordinator of the Office of Scholarship and Sponsored Projects provides administrative support for the IRB, including all recordkeeping, correspondence, managing submission and approvals, and training.

HOW APPOINTED:

- IRB members are selected from the faculty and from the community-at-large to ensure representation of professional expertise and community attitudes. Nominations for Secondary Reviewers are generally obtained from IRB members, deans, department chairs, or from self nominations. The IRB Administrator and the IRB review the nominations, and the names of recommended candidates are forwarded to the IO. The final decision in selecting a new member is made by the IRB.
- A Secondary Reviewer is eligible to apply for appointment to the IRB after a minimum of one year of service. Appointments to the IRB depend upon the availability of an open position. Appointments must maintain diversity (Scientist vs. Non Scientist, type of discipline, gender, ethnicity, etc.).
- On an annual basis, the IO and IRB Administrator review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.
- Alternates may serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.
- All IRB members are required to complete the CITI training for IRB members.

ROTATION:

Appointments are made for a renewable three-year period of service. There is no limit on the number of terms any individual may serve. Reappointment decisions may take into account the past performance of the member and the need for maintaining diversity of the IRB. Any change in appointment, including reappointment or removal, requires written notification. Members may resign by written notification to the IRB Administrator.

WHEN APPOINTED:

Applications for Secondary Reviewers are accepted on an ongoing basis. Decisions regarding appointment to the IRB as a Full member are typically made in the spring, prior to the beginning of the next Fiscal Year.

**MEETING
FREQUENCY:**

The IRB meets monthly during the academic year, and at least once during the summer.

**PARLIAMENTARY
PROCEDURE**

Quorum shall be met when a simple majority, that is 50% of the committee plus one, is present. No business can be conducted without a quorum present. A modified form of Robert's Rules is used for voting and decision making.