

Montana State University Billings

Institutional Review Board

Bylaws

The Institutional Review Board of Montana State University Billings (IRB 000001622) is an official board established by the U.S. Department of Health and Human Services under a letter of Federalwide Assurance (FWA 00000978 Montana Ste U-Billings) dated May 20, 2009 and expiring May 21, 2017.

Purpose

The MSU Billings Institutional Review Board (IRB) ensures that the rights, safety, and welfare of human subjects in research are protected, consistent with applicable legal, ethical, and institutional guidelines established in federal, state, and institutional policies and to ascertain compliance with the policies of MSU Billings for research involving human subjects.

Guiding Principles

IRB decisions are guided by the overarching ethical principles developed in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report and established in the Code of Federal Regulations Title 45: Public Welfare, Subtitle A Health and Human Services, Part 46-Protection of Human Subjects (45 CFR 46) and Code of Federal Regulations Title 21: Food and Drugs Part 56-Institutional Review Boards (21 CFR 56), and all applicable state and institutional guidelines.

Central to all IRB decisions are the three basic principles established in the Belmont Report <http://hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

- a. Respect for all persons, evidenced by informed consent, full consideration of privacy and confidentiality, and all additional protections necessary to safeguard vulnerable populations,
- b. Beneficence, evidenced when possible benefits are maximized and possible risks are minimized for all participants, and
- c. Justice, evidenced by equitable selection of participants.

Authority / Responsibilities

The IRB has the responsibility to:

- Prospectively review any research involving human subjects to be conducted by MSU Billings faculty, staff, or students or conducted on the MSU Billings campus by unaffiliated agents,
- Determine the type of review (exempt, expedited, or full) appropriate to any research proposal,
- Approve, modify, or disapprove all research proposals, based upon evaluation of the protection afforded human subjects in the research proposal,
- Suspend or terminate any research project,
- Require progress reports and perform such monitoring as is necessary to fulfill IRB responsibilities for the protection of human subjects.

* Research includes any systematic investigation including development, testing, or evaluation designed to develop or contribute to generalized knowledge. Any research involving animals rather than human subjects should be submitted for review to the MSU Billings Institutional Animal Care and Use

Committee (IACUC), to which the IRB refers inquiries. Relevant information for such research is available at <http://www.iacuc.org/index.htm>.

In meeting its responsibilities, the IRB, consistent with the information available to it, determines the extent to which the following conditions are achieved in any research project being reviewed:

- risks to subjects are minimized by the use of procedures consistent with sound research design that exposes subjects to no unnecessary risk, and when possible, research uses procedures that already are being used for other purposes,
- risks to which subjects are exposed are reasonable in relation to (1) anticipated benefits and (2) the importance of the knowledge that may reasonably be expected to result,
- subjects are selected equitably and special attention is given to protect people in vulnerable populations,
- informed consent, when necessary, will be obtained from each prospective subject (or legal representative) by means of a written document reviewed by the IRB to assure that it contains required elements of informed consent and is understandable to potential subjects,
- the research plan makes adequate provisions for ensuring the safety of subjects, and
- adequate provisions are established to protect the privacy of subjects and to maintain the confidentiality of data.

When appropriate to the research project, the IRB shall determine if the type of data and safety monitoring proposed by the principal investigator is sufficient for the (1) level of risk to which subjects will be exposed and (2) satisfactory with regard to an adverse event reporting system.

Relationship to University

The IRB shall be directly responsible to the Director(s) of Grants and Sponsored Programs, who, as the Institutional Officer(s) are ultimately responsible for overseeing the protection of human subjects, establishes and maintains all necessary support for the IRB, research investigators, and staff to meet their shared responsibility for the ethical conduct of research. The campus shall provide the IRB with needed clerical support, files, copying facilities, supplies, equipment, and space.

Membership

The IRB shall consist of the following members, appointed by the Director(s) of Grants and Sponsored Programs:

- One faculty member from each college,
- Four off campus members, representing the following constituencies: Community Science Researcher, Community Ethicist, Community Non-Scientist, and a Community at Large representative.

In making appointments to the Committee, reasonable steps to achieve diversity in race, gender, cultural backgrounds, and professional qualifications should be considered. All IRB members shall be appointed for three-year terms and, though members may be reappointed, that is not the expected norm. Membership terms shall be staggered, with new members appointed at the last meeting of the spring semester. Any vacancies that arise shall be filled in the same manner as initial appointments. Members shall be removed only for stated cause. Failure to attend four (4) consecutive meetings may constitute cause for removal and replacement by another individual designated by the Director(s) of

Grants and Sponsored Programs. Alternates shall be appointed to serve when needed. Members receive no compensation but shall be covered for liability under the MSUB umbrella coverage.

Certification: All MSUB IRB members are required to complete IRB training from the National Institutes of Health and to have a current certificate of completion on file in the Office of Grants and Sponsored Programs.

Conflict of Interest: No IRB member shall participate in any initial or continuing review when he/she has any conflicting interest; except to provide information requested by the IRB.

Confidentiality: All IRB members operate under the clear expectation that all study materials provided to the IRB are proprietary and confidential; as such, study materials may not be discussed or distributed outside of official IRB business and must be handled consistent with the highest regard for protection of confidentiality.

Officers

The Director(s) of Grants and Sponsored Programs shall (a) appoint a chairperson of the IRB, who shall be a tenured faculty member and functions as a voting member of the IRB and (b) a vice-chair who also shall be a tenured faculty member and voting member of the IRB. The Chair shall serve for two years after having served as Vice-Chair for at least one year preceding appointment as chair. The Chair shall be responsible for seeing that (a) meeting agendas are set, (b) minutes are kept and maintained, (c) business is conducted as effectively and efficiently as is reasonable, and (d) IRB actions are implemented. The Chair shall receive release time, the equivalent of a three (3) credit course during both fall and spring semesters, to allow for the successful completion of IRB Chair duties. The Vice-chair shall fulfill the duties of the Chair if the Chair is absent or recuses him/herself from a review. The Director(s) Grants and Sponsored Programs shall serve as the institutional officer responsible for oversight of all IRB functions and provision of resources necessary for IRB operation.

Meetings

The IRB shall meet as needed throughout the academic year. Meetings will be scheduled for a semester, with respect to member availability; however, the chairperson may call a special meeting upon one week written or telephone notice.

Minutes of each meeting shall be kept by the Administrative Associate to the Director(s) of Grants and Sponsored Programs, with a list of all proposals and actions since the previous meeting attached.

A quorum shall consist of a simple majority that includes at least one member whose primary concerns are non-scientific and a quorum must be maintained to conduct business.

When deemed appropriate by the Chair, business may be conducted electronically or by phone; though such actions shall not replace real-time, face-to-face discussions that are required for certain IRB actions.

On occasion, as needed, the IRB may invite individuals with special expertise and competence to serve as consultants in reviewing a given proposal. Such individuals do not vote, but provide input for IRB deliberations. Additionally, IRB meetings may be attended by persons who are not members – with the consent of the chairperson. Typically, such persons would (1) have submitted proposals which require oral explanation and questioning or (2) have research in progress that requires monitoring.

Records

The chairperson shall see that proper records are maintained. These include:

- Minutes of each meeting with the names of those present, the proposals acted upon, a summary of the discussion, any other IRB actions or discussion, and a list of exempt, expedited, and amended proposals,
- Copies of proposals,
- IRB correspondence, and
- Pertinent print and electronic reference materials, guidelines, and similar information.

IRB members will be provided with the minutes of the last meeting in advance of the next meeting. The minutes shall be kept in perpetuity and all proposals shall be kept for three years following completion of the research.

IRB Decisions / Actions

In meeting its responsibility to approve, disapprove, or modify any research proposal, the IRB shall seek consensus in applying all applicable guidelines for the protection of human subjects, consistent with all applicable federal, state, and institutional statutes, regulations, and policies. Roberts Rules of Order apply in the general sense that the chairperson shall conduct meetings, agendas will set and distributed prior to meetings, previous minutes will be approved or amended, If consensus is not reached, then a simple majority will determine IRB action, with each IRB member having one vote, including the chairperson. The quality of a proposal's methodology shall be considered to the extent that it affects any risk to which participants are exposed.

The IRB Chair or Vice-chair is authorized to act on proposals that qualify for acceptance as exempt or meet the criteria for expedited review; as well as conducting continuing reviews on such projects. All proposals requiring full review must be acted on by the IRB as a whole, and continuing reviews of such projects also must be conducted by the entire IRB.

In accordance with applicable federal, state, and institutional regulations and policies, the IRB shall monitor those research projects which it judges to involve more than minimal risk to the subjects. The IRB may request periodic written or verbal reports or conduct unannounced site visits.

Expedited and full review projects shall be reviewed on at least an annual basis; no approval exceeds one year.

If the IRB becomes aware of any serious or continuing non-compliance or suspends or terminates an approval, written notice of such action will be given to the Director(s) of Grants and Sponsored Programs and, if necessary, to appropriate agencies consistent with OHRP guidelines.