



Human Subjects Institutional Review Board BY LAWS

Committee Approved: April, 2018

It is the policy of Ferris State University (FSU) to comply with the United States Department of Health and Human Services, Office for Human Research Protections (Part 46 of Title 45 of the Code of Federal Regulations). To this end, a University Human Subjects Institutional Review Board, hereafter referred to as the IRB, has been established to review all research involving human subjects.

The IRB is responsible for developing and enforcing policies and procedures applicable to research wherein humans may be at a minimal risk or greater as a consequence of participating in an investigation or experimental procedure. Human subject research conducted at or supported by the University will honor the three ethical principles enshrined in the "Belmont Report": respect for persons, beneficence, and justice.

1.0 Oversight

- 1.1 The IRB reports to the Institutional Official (IO), who is assigned by the University President.
- 1.2 Annually, the IRB will provide a report to the IO with the following information: number of applications submitted for initial and continuing review, application review category, if federal funding was involved and if so, to which agency and if materials or products from the Food and Drug Administration (FDA) were involved.
- 1.3 By-laws will be reviewed on as needed basis, or minimally every three years, by the full committee; any proposed amendments made would require a vote with a quorum present.
- 1.4 By-law amendment proposals will be made available to the committee at least 30 days in advance of a committee vote unless changes in regulations necessitate amendments sooner

2.0 Membership

- 2.1 The IRB shall follow the regulations for membership as outlined in 45 CFR 46.107. As such, there will be at least five members serving on the committee at all times, with diverse gender, backgrounds, racial and cultural diversity, and sensitivity to varying issues such as community attitudes, in order to provide complete and adequate review of human subjects' research activities commonly conducted by the University.
- 2.2 Members, as a group, will have sufficient experience, expertise, and knowledge to review human subjects' research within the context of the purpose of the IRB.
- 2.3 There will be at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.
- 2.4 There will be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- 2.5 Excluding ex-officio members, individuals from a single FSU departmental unit or college may not constitute greater than fifty percent (50%) of the total IRB membership.
- 2.6 IRB Chair and committee members will have completed the appropriate training module in the online CITI program and will renew their training, as applicable in order to keep it current while they serve on the committee.
- 2.7 The IRB Chair and members will be encouraged to attend off-site training, sponsored by OHRP and to review OHRP materials on an annual basis in order to stay current with the regulations.
- 2.8 The IO will designate the Chair of the IRB; the Chair is a voting member of the IRB.
- 2.9 In consultation with the Chair, the IO will appoint members to the IRB. The IRB Chair has the right to appeal any appointment provided the grounds are consistent with IRB membership guidelines and policies.
- 2.10 The IO can remove a member from service upon recommendation from the Chair and subject to university policies and procedures.



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- 2.11 The Ex officio member(s) will be a non-voting member(s) of the IRB who will not count towards quorum and include the IO or their designee.
- 2.12 New members will be given application reviews in conjunction with experienced members in order to allow for an opportunity to ask questions on the same application review to the initial reviewer, the Chair and/or another member.
- 2.13 No member will be administratively subordinate to another member, excluding the Chair.
- 2.14 All members will serve on a voluntary basis for three calendar years. Members may be re-appointed for consecutive terms
- 2.15 Should any member wish to step down from their service on the committee, written notice is required.
- 2.16 Members who anticipate four or more absences in a calendar year should contact the Chair to arrange appointment of an alternate member.
- 2.17 The Chair may appoint alternate members from the same college or department of the regular member; terms are concurrent. Only alternate members may serve as voting proxies for regular members. Alternates may attend meetings and participate in discussion, but may not vote when the regular member is in attendance.
- 2.18 Should the Chair be unable to carry out the responsibilities of Chair for a period of time, the Chair may select an interim Chair from among the committee to serve for a set period of time. Interim Chairs must receive approval from the IO.

3.0 Meeting Procedures

- 3.1 The IRB will meet on an ad hoc basis. The first meeting of the year will be determined by the IRB Chair. Remaining meeting times and locations for the academic year will be determined based on member's schedule and distributed.
- 3.2 Members may attend in person or contact the Chair to arrange for attending via video or teleconferencing.
- 3.3 IRB Agenda will be proposed prior to the meeting; members may contribute additional items.
- 3.4 Meeting minutes will be prepared and distributed to all members. Minutes will include all information required by 45 CFR 46.115 (a)(2) and shall reflect, among other items, a record of all members present and absent, members recused, actions and votes for each protocol undergoing initial or continuing review by the convened IRB, the vote on all IRB actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving the research, the determinations regarding risk and approval period and a summary of the discussion of controverted issues and their resolution.
- 3.5 Copies of IRB agendas, minutes and applications will be posted for member review.

4.0 Review Procedures

- 4.1 Per 45 CFR 46.109, In conducting the initial review of proposed research, the IRB will obtain information in sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111. The IRB Office and/or IRB Committee shall establish and maintain policies and procedures to meet these requirements and review them on an as needed basis or minimally on a 3-year basis.
- 4.2 Per 45 CFR 46.115, applications and application materials, regardless of review category will be made available for all members to view.
- 4.3 Members of the IRB must respect the confidentiality of information about participants and investigators learned while reviewing submitted protocols.
- 4.4 Members with a conflict of interest pertaining to a protocol review, full review or otherwise, must make the



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conflict known and remove themselves from the review and voting process, except when the IRB requests a member to be present in order to provide information. In the event that the conflict involves the chair, an alternate may be assigned to act on behalf of the chair for that protocol review. Removal will be noted in the meeting minutes.

- 4.5 Per 45 CFR 46.110(b)(2), under an expedited review procedure, the review may be carried out by the IRB Chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may only be disapproved only after review in accordance with the nonexpedited procedure set forth in 45 CFR 46.108.
- 4.6 Per 45 CFR 46.108(b), except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
- 4.7 Unless otherwise stated, Expedited reviews are approved for one full year. Applications which undergo a Full Review receive an approval determination on a case by case basis as determined by the committee and may have additional reporting requirements.

5.0 Reporting Procedures

- 5.1 Investigators must at all times respect the confidentiality of participant information in their possession. Research records, including signed consent documents, must be maintained for three years, in accordance with 45 CFR 46.115(b) and 45 CFR 46.117. Investigators must comply with reasonable requests to provide pertinent information to oversight bodies, including the University, consistent with participants' confidentiality rights.
- 5.2 Prior to granting approval, when the IRB requests amendments to the application and/or consent form or amendments be made to any other documents related to the study protocol, new versions of these forms must be submitted in their entirety in order to maintain accurate record keeping.
- 5.3 Any changes from an approved IRB protocol, deemed "major" by the IRB, including changes involving participants, collaborating investigators, informed consent procedures or research instruments, must be reported to and approved by the IRB before implementation. Minor changes, such as word corrections, need not be reported.
- 5.4 Investigators must promptly report unanticipated problems and/ or adverse events to the IRB. Reports must be completed and submitted with a week from the day the event which may cause risk to human subjects/others occurs. Investigators are responsible to understand these terms.
- 5.5 Investigators who wish to continue work on a research project past the approval date, must submit a Request for Extension one month prior to the expiration date of the approved project. Extensions may be granted for one year increments for up to five years, at which time the IRB Office will determine whether additional extensions may be granted or a new protocol submitted.
- 5.6 Descriptions of planned and approved research must not significantly conflict with or deviate from information provided to external funding agencies or other university committees. At any time, the IRB may consult with the appropriate external funding agencies or other university committees to ensure compliance of approval dates and protocol procedures. Inquiries may occur without investigator knowledge.
- 5.7 In order to protect the University and to ensure the safety and protection of those involved in the research project, IRB has the authority to suspend or terminate approval of a protocol at any time.



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- 5.8 In serious situations, the Institutional Official (IO) or the Provost & Vice President for Academic Affairs will have the authority to terminate or suspend a project immediately. In all other cases, the IRB will convene for a full review prior to suspension or termination of any protocol; a quorum must be met and vote to determine further action.
- 5.9 All IRB records including but not limited to IRB agendas, minutes, applications, approval letters, correspondence, and annual reports and final reports will be retained for a minimum of 3 years in order to meet federal regulations. All records relating to research conducted will be maintained for a minimum of 3 years after completion of the research and will be reasonably accessible for inspection and copying by any authorized representatives of HHS.

6.0 Voting

- 6.1 When a decision or recommendation from the IRB is required, the Chair shall request a motion for a vote. Any member may make a motion for a vote.
- 6.2 For applications requiring Full and Continuing Review and other business requiring a vote, a quorum of committee members must be present. A quorum constitutes a simple majority of IRB membership, and must reflect the membership requirements outlined in 2.0. An application approval from the IRB requires a majority vote by committee members when a quorum has been met.
- 6.3 When a quorum cannot be met (e.g. loss of a majority through recusal of members with conflicting interests or early departures, or absence of a non-scientist or community member), the IRB may conduct an electronic vote and quorum is met electronically.
- 6.4 Voting decisions will be documented in meeting minutes, including the total number of votes, and the number of those who approved, denied or abstained.