Grand Valley State University Institutional Review Board (IRB)	
Title: *IRB protocol review*	
Section: 900	This policy and procedure supersedes those previously drafted
Approved: 10/13/2014 Revised by HRRPPC: 04/24/2018 Revisions Approved by HRRPPC: 10/23/2018 Revisions Approved by IRBPPC: 03/26/2019	Approved: 10/13/2014 Revisions approved by AIO/RIO: 05/23/2018 Revisions approved by AIO/RIO: 12/19/2018 Revisions approved by AIO/RIO: 03/28/2019
Effective Date: 01/21/2019	
Related Documents: *121: Review standards for research not covered by FWA* *910: Continuing review and approval of selected non-exempt protocols* *911: Exemption determinations and research ethics standards*	

Policy

1. The IRB chairperson and members are responsible for conducting review of protocols involving the use of human subjects. Under certain conditions, authorized Office of Research Compliance and Integrity (ORCI) staff members may make exempt determinations without additional review by the IRB.

2. Role and authority of the IRB chair in protocol review:
    a. The chair may be consulted by any committee or staff member for assistance in reviewing any aspect of any protocol.
    b. The chair may review and make an approval or other determination for any protocol under exempt or expedited review procedures at any time without a second reviewer, such as, but not limited to, initial submissions, revisions, amendments, and continuing review.
    c. For expedited reviews, if the reviewers disagree on the proper action, the chair will serve as a third reviewer. If the chair disagrees with the recommended action he or she will refer the matter to a vice-chair or other discipline expert IRB member for additional review until a majority agreement is reached.
    d. The chair will fulfill the same roles and responsibilities as the committee members as noted below.

3. Role and responsibilities of committee members in protocol review:
    a. IRB members are to become familiar with and maintain current familiarity with pertinent Federal regulations, State law and University policies related to use of human subjects in research.
    b. IRB members are to make approval recommendations on all research proposals to which they are assigned for review by the deadline specified, unless prior notification to the ORCI is submitted.
    c. IRB members are to review assigned materials and prepare for, attend, and actively participate in all regular and special meetings of the IRB, unless excused by the chair, or are unable to participate because of emergency situations, teaching conflicts, or disclosed conflicts of interest.

Procedures

1. The IRB reviews research proposals in accordance with the applicable regulatory criteria for approval as well as state law, university, and ORCI policies. The IRB chair votes as a regular member of the committee at will. IRB members are assigned protocol submissions by the IRB chair or ORCI.

2. For review purposes, there are two designations of committee members: Reviewers-in-training and designated reviewers (DRs). Reviewers-in-training are members still in training and with less experience reviewing protocols. They are assigned protocol reviews as a second reviewer on exempt studies or third reviewer on expedited studies until the IRB Chair determines that they have sufficient expertise and protocol review experience to warrant the status of DR. The chair and/or ORCI will provide training and mentoring for committee members as appropriate.

3. Review of Exempt Protocols
   Determination of exempt status may be made by either a DR or an authorized ORCI staff when reviewing research protocol submissions to the IRB for approval. In addition, selected ORCI staff may re-grade a protocol as not research, as not involving living human subjects or upgrade the review category to expedited review or full board review based upon their administrative review. The IRB Chair determines when ORCI staff members display sufficient expertise to become authorized to independently review exempt protocols.

4. Review of Expedited Protocols
   a. For expedited reviews, DRs are authorized to serve as one of a pair of reviewers for expedited protocols, and to make approval decisions regarding initial submission, minor or major amendments or revisions to previously approved protocols, including continuing reviews. DRs may not suspend, terminate or disapprove a protocol submission but may refer it to the full board for further consideration.

   b. Expedited protocol files are assigned to a minimum of two DRs for review and status recommendation to the Chair for concurrence and inclusion or objection and explanation in the final review determination letter. If necessary, the IRB Chairperson may serve as the second reviewer. ORCI staff do not conduct expedited reviews or approve any major changes to approved protocols.

5. Reviewer Actions
   a. For each protocol, of any level of review, each assigned reviewer will state the reviewer's analysis regarding protocol-specific findings and provide justification for the determination.
   b. Reviewers may make a motion for one of the following actions:
      i. **"Approve**": The initial, continuing, or modification submission meets all the criteria for approval.

1. For initial and continuing review, include in the motion the period of approval.

ii. **"Approve with Conditions"**: The initial, continuing, or modification submission will meet the criteria for approval with minor or prescriptive changes or requirements that can be verified by administrative staff or chair without considering the criteria for approval.
    1. For initial and continuing review, include in the motion the period of approval and the level of risk.
    2. Summarize the IRB's required modifications and reasons.

iii. **"Defer" (i.e. table)**: The initial, continuing, or modification submission does not meet the criteria for approval and also does not meet the criteria for "Disapprove".
    1. Summarize the IRB's reasons (required clarifications and modifications) and recommendations, if any.
    2. If required clarifications are *major*, Approve with Conditions does not apply and the response to tabling letter must be accepted or declined by the IRB or Vice-Chair acting as chair or the full board.

iv. "**Disapprove**": The initial, continuing, or modification submission does not meet the criteria for approval and the full IRB at a convened meeting considers the research to have extensive deficiencies.
    1. This motion is not available FOR EXEMPT OR EXPEDITED REVIEWS.
    2. Motion for disapproval should be referred to full board for review.
    3. Summarize the IRB's reasons and recommendations, if any.

v. "**Suspend**": Based on new information the previously approved research no longer meets the criteria for approval, but some research activities meet the criteria for approval or the IRB has recommendations that may make the research meet the criteria for approval.
    1. Include in the motion which research activities must stop or be modified.
    2. If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion to stop all research procedures (except as noted below) and stop enrollment.
    3. If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion which subjects can continue and what procedures can be performed.
    4. Summarize the IRB's reasons and recommendations.
    5. Refer to the full board and to Research Integrity Officer (RIO). Follow *IRB Policy 1050: Suspension or Termination of Research Activities*, including all reporting requirements.

vi. "**Terminate**": Based on new information the previously approved research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable.
    1. Must be referred to full board.
    2. If termination is approved, reports to affected federal agencies (e.g., OHRP, FDA, NSF, etc.) may also be required.
    3. Summarize the IRB's reasons for termination.
    4. Refer to the full board and RIO. Follow IRB Policy 1050: *Suspension or Termination of Research Activities*, including all reporting requirements.

vii. "**Lift Suspension**": Based on a modified submission (Change in protocol) or new information, the previously suspended research meets the criteria for approval.
    1. Requires full board approval at a convened meeting[1].

viii. **"Decline to Review"**: If reviewer(s) determines submission is insufficiently prepared, and Chair concurs, the motion is to Table without action, the status is withdrawn, and the determination letter states "Decline to Review."
    1. Summarize the IRB's reason(s) for declining to review

ix. "**Waiver or alteration" of consent process or documentation of consent**: The reviewer(s) determines waiver or alteration of consent process or documentation of consent is appropriate
    1. Must be documented as a separate vote from the protocol approval itself.
    2. Waiver or alteration could be requested by PI or deemed appropriate to suggest to the PI by an IRB reviewer.
    3. **Expedited review**. Approval requires majority reviewer agreement including a final review and determination by the chair or vice-chair. Requires three votes if using DR, two votes if only chair and vice-chair.
    4. **Full board review**. Approval of a waiver or alteration of the consent process or documentation requires majority vote of members present at convened meeting[1] and documented as a separate vote from the protocol approval determination.

x. Options for IRB members present, but not voting, on a motion.

[1] Convened meeting indicates quorum has been met; recusals count as absences and therefore may not contribute to quorum. Abstentions are not absences and do count toward quorum, but as a 'no' vote. Quorum is achieved by the presence of one over half of the full voting members and must include at least one non-scientist. An alternate member may count toward quorum when any full voting member is absent. Votes involving prisoners as study subjects must include the prisoner representative.

1. **"Abstain"**: Based on lack of opportunity to formally review and form measured judgments concerning the protocol submission the member does not participate in the voting.
    a. The abstention is not global to the protocol; it may affect only initial application or any subsequent submission of the same protocol.

2. **"Recuse"**: Due to a previously declared conflict of interest or other real or apparent competing influence, the member excuses him or herself from the discussion and voting on the initial protocol submission or any subsequent submissions.
    a. Recusal is global to the protocol file.

6. Exception: Approval of required modifications for full board reviewed protocols for which initial approval was deferred (i.e. tabled).
   The IRB may authorize the chair or a subcommittee of the board to approve, under expedited review procedures, *minor* required modifications and/or clarifications to a full board reviewed protocol. This authorization must be recorded as a separate vote at the time that approval of the initial submission was deferred pending required modifications. Both the full board vote to defer (i.e. table) approval and the full board vote to authorize approval of required modifications under expedited procedures must be recorded in the meeting minutes.

7. IRB-required modifications and corrections
   When the IRB requires modifications or clarifications to a protocol in order to comply with federal regulations, research ethics standards, or the minimization of risks to research subjects, it shall inform the researcher of the required modifications and/or clarifications in writing. Required submission of a revised protocol application or other materials shall be at the discretion of the reviewers.

8. Additional considerations for reviewers
    a. Determination of continuing review requirements
        i. Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:
            1. Research eligible for expedited review in accordance with 45 CFR 46.110;
            2. Research reviewed by the IRB in accordance with limited IRB review;
            3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
                a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
                b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

ii. If continuing review is determined to be necessary by the IRB upon protocol approval, the IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, not less than once per year.

b. Non-exempt studies, regardless of whether or not a continuing review is required, require official closure for recordkeeping purposes (e.g., data retention).

References

21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
45 CFR §46.109, §46.116, §46.117.