

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>IRB Protocol Review: Full Board Protocols</i>	
Section: 902	
Approved by IRBPPC: 02/02/2022	Approved by AIO/RIO: 02/07/2022
Effective Date: 02/28/2022	
<p>Related Documents:</p> <p><i>020: Conducting IRB Meetings</i></p> <p><i>121: Review Standards for Research not Covered by Federalwide Assurance</i></p> <p><i>150: IRB Use of Outside Expertise (Consultants)</i></p> <p><i>710: Assessing Risk to Research Participants</i></p> <p><i>720: Assessing Risk to Vulnerable Populations</i></p> <p><i>721: Protections for Pregnant Women, Fetuses, and Neonates</i></p> <p><i>730: Collection, Management and Security of Research Information</i></p> <p><i>740: Internet Based Research</i></p> <p><i>750: Recruitment, Selection and Payments to Research Participants</i></p> <p><i>810: Informed Consent: General</i></p> <p><i>812: Informed Assent and Parent Permission</i></p> <p><i>813: Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives</i></p> <p><i>814: Informed Consent for Persons not Fluent in the Primary Language of the Study</i></p> <p><i>820: Waivers, Alterations, and Exceptions to Informed Consent Process and Documentation</i></p> <p><i>901: IRB Protocol Review: Expedited Protocols</i></p> <p><i>910: Continuing Review and Approval of Selected Non-Exempt Protocols</i></p> <p><i>911: Exemption Determinations and Research Ethics Standards</i></p> <p><i>1120: Collaborating Research with Investigators Covered by an External FWA</i></p>	

Policy

1. The IRB reviews research proposals in accordance with the applicable regulatory criteria for approval as well as state law, university policies, and IRB policies.
2. Full board IRB review is required for any IRB protocol that is not eligible for an exempt determination, expedited review, or reliance on an external IRB.
3. Full board IRB review must occur at a convened IRB meeting.
4. Role and responsibilities of IRB 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 and other applicable regulatory determinations on research proposals which they are assigned for review by the deadline specified, unless prior notification to the Office of Research Compliance and Integrity (ORCI) is submitted.
 - c. IRB members may not participate in the review of research where they have a perceived or actual conflict of interest.
5. Role and authority of the IRB Chairperson in protocol review:

The Chairperson will fulfill the same roles and responsibilities as the committee members as noted above. Additionally:

- a. The Chairperson, at their discretion, may assign one or more IRB members to serve as primary reviewers for a submission. Primary reviewers are selected based upon the reviewers' background and expertise. They are responsible for presenting general information about the protocol to the IACUC members, including:
 - i. Study purpose
 - ii. Study design and procedures
 - iii. Safety procedures and considerations
 - iv. Qualifications of the researchers
 - v. Any identified concerns regarding the study
 - b. In the absence of selecting a primary reviewer, the Chairperson will facilitate the discussion of the protocol and ensure that the information in 4.a.i-v is discussed.
 - c. As applicable, the Chairperson may request assistance with persons not otherwise affiliated with the IRB who have relevant knowledge to assist the board in the review of the protocol (*IRB Policy 150: IRB Use of Outside Expertise (Consultants)*).
6. Following discussion of the protocol, any voting member of the IRB may make a recommendation for action. In order for a committee action to pass, a majority vote of voting-eligible members present at the convened meeting must agree.
7. Only the convened IRB may disapprove a research study.
8. All members have access to the entire IRB file for any study.

Procedures

1. Submission of Full Board Protocols
 - a. The Principal Investigator (PI) is responsible for submitting a completed protocol submission form in the ORCI's electronic management system. This submission should also include the following documents, as applicable:
 - i. The funding letter, sponsor's agreement or human subjects portion of the grant/application
 - ii. Written permission from data collection sites indicating support of the research
 - iii. Written recruitment materials, such as flyers, posters, emails and social media posts
 - iv. Written permission from the GVSU Athletic Director, if the research will target varsity athletes for inclusion
 - v. Written permission from the Office of Institutional Analysis, if that office will be distributing recruitment emails on behalf of the researchers
 - vi. Informed consent and assent documents

- vii. HIPAA authorization form, if separate from the informed consent document
 - viii. Surveys, interview questions and data collection forms
 - ix. Any other documentation that may be relevant to IRB review
- b. Protocols may be referred to full board review via one of three methods:
- i. The PI may make a preliminary determination that a protocol requires full board review.
 - 1. If this is selected on the protocol submission form, the Chairperson will verify that full board review is the most appropriate level of review. If the Chairperson determines the protocol is eligible for either exempt or expedited review, the review process corresponding to the appropriate level of review will be followed. If the Chairperson confirms full board review is required, the protocol submission form is sent to all members for review.
 - ii. The PI does not indicate that full board review is needed, but the ORCI determines that the protocol is not eligible for any other review pathway. The rationale for this determination is documented on the protocol submission form and forwarded to the Chairperson for confirmation and further distribution to the members for review.
 - iii. Any IRB member may refer any initial, continuing, or modification submission to the full board for review.
2. Pre-IRB meeting activities
- a. IRB members are provided a copy of all documents submitted by the researchers at the time the protocol is assigned for review.
 - b. Members are typically provided two weeks to complete a pre-review of the submitted materials. Upon completing their pre-review, members can submit questions and comments in the ORCI's electronic management system for the PI to address prior to the IRB meeting.
 - c. Approximately two weeks prior to the IRB meeting, the IRB Chairperson coalesces these questions into a single document and forwards to the PI.
 - d. The PI is given one week to provide a written response. This response is provided to all IRB members and included in the electronic management system. If no response is received, the protocol is reviewed in its original state at the IRB meeting.
 - e. The Chairperson or IRB members can request the PI or other member of the research team to attend the IRB meeting. The PI can also volunteer to attend the IRB meeting in order to present the research and answer questions from the members. The ORCI is responsible for coordinating guest attendance at IRB meetings.
 - f. IRB meeting agenda
 - i. The deadline to include protocols on the IRB meeting agenda is four weeks prior to the scheduled meeting.
 - ii. The ORCI prepares and distributes the agenda to all IRB members at least one week prior to the scheduled meeting.

3. IRB Actions

- a. For each protocol review, the IRB will review the protocol submission, document their analysis regarding protocol-specific findings, and provide justification for the determinations.
- b. The IRB may recommend 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 Chairperson without considering the criteria for approval.
 1. For initial and continuing review, include in the motion the period of approval.
 2. Summarize the IRB’s required modifications and reasons.
 - iii. **“Request Clarifications/Changes”**: The initial, continuing, or modification submission does not meet the criteria for approval, and substantial changes or additional information is needed.
 1. Summarize the IRB’s reasons (required clarifications and modifications) and, if any, recommendations.
 - iv. **“Disapprove”**: The initial, continuing, or modification submission does not meet the criteria for approval, and the IRB considers the research to have extensive deficiencies.
 1. Summarize the IRB’s reasons and, if any, recommendations.
 - 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. Include in the motion if currently enrolled participants will need to be informed about the suspension, and if so, how that information will be communicated to the participants
 5. Summarize the IRB’s reasons and recommendations.
 6. Refer to the 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. Include in the motion the method by which the study will be terminated. This should be done in an orderly manner and include the following considerations:
 - a. If currently enrolled participants will need to be informed about the termination, and if so, how that information will be communicated to the participants.
 - b. If the study or study participants should and will be transferred to another study, and if so, how that information will be communicated to the participants.
 - 2. Summarize the IRB’s reasons for termination.
 - 3. Refer to the RIO. Follow *IRB Policy 1050: Suspension or Termination of Research Activities*, including all reporting requirements.
 - vii. **“Lift Suspension”**: Based on a modified submission or new information, the previously suspended research meets the criteria for approval.
 - 1. Summarize the IRB’s reason(s) for lifting the suspension.
 - viii. **“Table”**: The initial, continuing, or modification submission is insufficiently prepared and lacking essential information.
 - 1. Summarize the IRB’s reason(s) for tabling the protocol.
 - ix. Options for IRB members present, but not voting, on a motion.
 - 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.
 - 2. **“Recuse”**: Due to a previously declared conflict of interest or other real or apparent competing influence, the member excuses themselves from the discussion and voting on the initial protocol submission or any subsequent submissions (*IRB Policy 140: IRB Member Conflict of Interest*).
- c. Determination of Continuing Review
- i. Unless the IRB determines otherwise, continuing review of research is not required for 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:
 - 1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - 2. 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.
 - iii. The following criteria should be considered by the IRB, as applicable, when determining the continuing review interval of the proposed research: the nature of the study; the degree of uncertainty of the risks involved; the

vulnerability of the subject population; the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor; the projected rate of enrollment; and whether the study involves novel therapies.

- d. If the submission includes additional required determinations, such as requests for waiving consent or the inclusion of minors in the research, these determinations will be documented by the IRB in accordance with the applicable IRB policy.
4. Chairperson Actions
 - a. The Chairperson will prepare the response to the PI, delineating the conditions of approval or requested changes. This response will be routed to the PI through the ORCI's electronic management system.
 5. ORCI Actions
 - a. ORCI staff do not conduct full board reviews nor approve any modifications to previously approved full board protocols.
 - b. For protocols that have been conditionally approved: At the Chairperson's discretion, ORCI staff may verify that the conditions required for approval have been satisfied. This verification can be done without requiring further review by the IRB members or the Chairperson. (Note: This is a verification process, not an "approval"; the protocol has already been determined to meet all of the criteria for approval at the time of conditional approval.)
 6. PIs may resubmit disapproved protocols, but are not advised to do so without first consulting the ORCI and IRB Chairperson first.
 7. IRB Approval
 - a. The IRB approval letter is sent to the PI, the PI's Authorizing Official, and the Office of Sponsored Programs (if applicable).
 - b. For protocols approved via full board review, the approval date is the date of the convened meeting, and the approval period (for protocols requiring continuing review), if applicable, is calculated based on this date. For protocols that are conditionally approved, the approval is not effective until the Chairperson or designee confirms the approval conditions have been satisfied.

Guidance

1. Criteria for Approval

Regulatory criteria for approval of research; applies to initial, continuing and amendment reviews:

- a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

1. Applicable protocol components: Objective, Purpose, Background, Resources available to conduct the research, Inclusion and exclusion criteria, Procedures involved in the research, and Additional protections for vulnerable populations.
 2. Questions to consider: Is there another way to do the research that will reduce risks to subjects that does not affect the science? Can less risky procedures answer the question? Can fewer procedures answer the question? Are the procedures needed at all? Can additional procedures reduce risk? Can different exclusion criteria reduce risk? Are the research staff qualified? Consider physical, psychological, legal, social, and economic risks.
- b. Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. (N/A if no such procedures.)
1. Applicable protocol components: Objective, Purpose, Background, Resources available to conduct the research, Inclusion and exclusion criteria, Procedures involved in the research, and Additional protections for vulnerable populations.
 2. Questions to consider: Are procedures that will answer the scientific question being done anyway? If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm? Consider physical, psychological, legal, social, and economic risks.
- c. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits subjects would receive even if not participating in the research.
1. Applicable protocol components: Background, Inclusion and exclusion criteria, Risks to participants, Potential benefits to participants, and Additional protections for vulnerable populations.
 2. Questions to consider regarding importance of knowledge expected to result: Is the study designed in such a way that the results will likely be useful for advancing knowledge? Is there good scientific design? Are there adequate resources? What are research staff qualifications? Is there adequate time? Adequate personnel? Adequate participant pool? What will be its importance?
 3. Questions to consider regarding the overall risks and benefits: What are the risks to participants? What are the anticipated benefits? What is the importance of the knowledge that may reasonably be expected to result? Are the risks reasonable in relationship to the benefits and the importance of the knowledge that may result?

- d. Selection of subjects is equitable. Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment and payment procedures.
 - 1. Applicable protocol components: Purpose, Background, Setting of the research, Recruitment, Inclusion and exclusion criteria, Consent process, and Additional protections for vulnerable populations.
 - 2. Questions to consider: Is subject selection fair, just and equal? Are burdens fairly distributed? Are benefits fairly distributed? Is a population unfairly targeted? Is a population unfairly excluded? Consider women, children, racial minorities, economically disadvantaged, non-English speaking individuals, medically uninsured, international subjects, and people with reduced autonomy.

- e. Informed consent will be sought and documented from each prospective subject or the subject's legally authorized representative, or the IRB has waived or altered the requirement to obtain informed consent or documentation of informed consent.
 - 1. Applicable protocol components: Purpose, Background, Study design (recruitment, procedures involved in the research, and data management), Risks to participants, Potential benefits to participants, Provisions to protect the privacy interests of participants, Provisions to maintain the confidentiality of the data, Consent process, and Additional protections for vulnerable populations.
 - 2. Questions to consider: Will the circumstances of the consent process provide the participant sufficient opportunity to consider whether to participate? Will circumstances of the consent process minimize the possibility of coercion or undue influence? Has the participant been provided enough information to make a decision? Will the person understand the consequences of the decision? Can the person make and communicate that decision? What language does the participant speak? Can the research team communicate in understandable language to the participants? Will written information be in the language understandable to the participants?

- f. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (This criterion is generally not applicable if the research is no greater than minimal risk.)
 - 1. Applicable protocol components: Procedures involved in the research, Provisions to monitor the data collected to ensure the safety of subjects.
 - 2. Questions to consider: Who reviews the data: Investigator, internal associate, medical monitor, internal committee, independent committee (DSMB)? What data is reviewed: Safety data, untoward events, SAEs, IND safety reports, efficacy data? When and how often is data reviewed?

- g. When appropriate, there are adequate provisions to protect the privacy of subjects.

1. Applicable protocol components: Study design (data management), Provisions to protect the privacy interests of participants.
 2. Questions to consider: Will participants have an expectation of privacy? Will participants think that the information sought is any of the researcher's business? Will participants be comfortable in the research setting (consider that people may prefer to talk to the same gender; consider settings/location of interactions-office, hallway, phone; consider type of interaction-survey, physical exam, hidden camera)? What will happen to participants in the research? Will the participants be comfortable with the research situation? Privacy refers to person and their interest in controlling access to themselves.
- h. When appropriate, there are adequate provisions to maintain the confidentiality of data.
1. Applicable protocol components: Study design (data management), Provisions to maintain the confidentiality of the data.
 2. Questions to consider: Will confidentiality be pledged? Are there legal/ethical requirements? Will data release cause risk of harm? What promises have been made about the collected data? What procedures are in place to meet those promises? Consider methods for confidentiality: restricted access using locks/passwords, certificates of confidentiality, error inoculation/random responses, bracketing/top coding, ethical editing of qualitative descriptions, data brokering. Confidentiality refers to agreements with the participant about how data will be handled.
- i. Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. ("N/A" if no vulnerable subjects.)
1. Applicable protocol components: Purpose, Background, Setting of the research, Study design (recruitment and inclusion/exclusion criteria), Risks to participants, Potential benefits to participants, Consent process, and Additional protections for vulnerable populations.
 2. How to determine whether there is a vulnerable population: Is there a power differential? Are there communication issues? Are there decisional issues? Are there excessive motivating factors? Is the recruitment process acceptable? Are advertisements acceptable? Are payment arrangements acceptable? Consider fetuses, neonates of uncertain viability, non-viable neonates, prisoners, children, physical disabilities, mental disabilities, economically disadvantaged, educationally disadvantaged, students, employees, and those with life threatening diseases.
 3. Questions to consider: Is the research of importance to the vulnerable population? Can the research question be answered by using a non-vulnerable population? Is the risk-potential benefit relationship appropriate to the vulnerable population? What additional steps will be

taken to minimize coercion and undue influence of the vulnerable population?