Institutional Review Board

Policies and Procedures

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Introduction

At Glenville State University, all research involving human subjects must be approved by the Institutional Review Board (IRB). An IRB is a federally mandated entity that oversees the protection of human subjects in scientific research. The purpose of the IRB is to mitigate the potential harm to subjects, including physical and psychological well-being, autonomy and right to refuse consent, and privacy/confidentiality. The IRB at Glenville State University reviews all research involving human subjects to ensure that risks have been minimized. The potential harm to subjects must be evaluated against the potential benefit before human subjects participate in the research. The IRB also requires that human subjects only volunteer to participate in research studies after they have been provided legally effective informed consent. Investigators may not begin recruiting subjects or collecting data until written approval from the IRB has been provided to the principal investigator. All research studies are required to undergo annual review unless granted an exemption by the IRB. All research studies by students at Glenville State University must be supervised by an appropriate faculty member. In addition to this manual, IRB information and forms can be found on the GSU webpage.

Note: In this document, the terms of Institutional Review Board, IRB, and Board are synonymous.

A. The Purpose of the IRB

The primary role of the institutional review board is to protect the rights and welfare of human subjects/participants. The IRB ensures adherence to research ethics as outlined in the Code of Federal Regulations (45 CFR 46, and 21 CFR 50) and Title 133, Series 31 of the West Virginia Higher Education Policy Commission.

B. Membership of the IRB

1. The IRB consists of at least 5 members.

2. All but one of the members shall be full-time employees of the university. The majority of members shall be full-time faculty members of GSU whose academic discipline requires IRB approval for human research.

3. One voting member shall be a community member who receives no financial remuneration from Glenville State University.

4. The Provost or their designee/proxy is an additional member of the IRB. The Provost or their designee/proxy will only vote in the event of a tie within the IRB.

5. Except for the Provost or their designee/proxy, members of the IRB (including the community member) shall serve two-year terms. Members can serve multiple terms.

6. At the expiration of a member's term or when there is an expected vacancy on the IRB, the IRB chair in consultation with IRB members will recommend faculty or community member to the Provost. Appointment of new members and reappointment of continuing members will be approved by the Provost or their designee.

7. The chair of the IRB will be annually selected by a majority vote of the current IRB members.

8. Additional Responsibilities of the IRB Members:
    a. Conflict of interest: Any IRB member that has a conflict of interest on a research proposal must recuse themselves from the IRB process involving the conflict and may only participate in the process as an applicant/co-applicant. The chair may appoint a designated alternate, if necessary, to serve in that IRB member's stead for any review involving the conflict.

    b. IRB members should have an understanding of the regulatory requirements, including policies and procedures, of the IRB.

C. Authority of the IRB

1. All academic and scientific research that involves human subjects that involves or represents Glenville State University in any way must acquire approval of the Glenville State University IRB.
    a. Opinion polls and surveys may be exempt from the IRB process, subject to IRB review.

    b. Voting polls, such as faculty senate and student government elections, are exempt from the IRB process.

    c. Federally mandated surveys and polls and exempt from the IRB process.

    d. Data collected for the purpose of accreditation is exempt from the IRB process.

    e. When a GSU faculty or staff member are completing an advanced degree at another college or university, and they are required to complete a dissertation or thesis that is approved by the IRB at that college or university, and the dissertation or thesis does not include GSU faculty, staff, or students, then that dissertation is exempt from GSU's IRB process. However, those faculty and staff members completing a dissertation or thesis at another institution are required to submit to the GSU IRB the following information:
        i. A copy of the original IRB application for the other college or university

        ii. A copy of the IRB approval they obtained from the other college or university

        iii. Notification that their dissertation or thesis has been completed and accepted or approved

    f. If a GSU faculty, staff, or student are conducting research in cooperation with individuals from other colleges, universities, or other institutions, and the GSU-affiliated individual is not the primary investigator, then the GSU IRB must be informed of the research and the following information provided:
        i. A copy of the original IRB application for the other college, university, or institution

        ii. A copy of the IRB approval they obtained from the other college, university, or institution

        iii. A list of all researchers and their affiliations that are conducting the research

iv. Any research that involves GSU faculty, staff, or students as research subjects/participants must gain GSU IRB approval

v. Notification that their dissertation or thesis has been completed and accepted or approved

If there is any question about whether the activity requires IRB approval, that question should be formally submitted to the IRB for consideration. If the IRB finds that the activity in question does require approval, the activity may not proceed until formal approval from the Board has been granted.

2. All GSU faculty, staff, and students must obtain approval of the GSU IRB prior to beginning any research that falls under the authority of the GSU IRB as noted in C.1.

3. All research involving investigators who are not affiliated with GSU, but that use GSU students, faculty, or staff as subjects must obtain GSU IRB approval.

4. The GSU IRB may require revision and resubmission prior to granting approval of any research application.

5. The GSU IRB may deny approval of any research application.

6. No recruitment of subjects or data collection may begin until final GSU IRB approval has been granted.

D. Advisory Questions

1. Any IRB-related question must be submitted to the IRB in writing to the chair of the IRB.

2. The IRB will consider the question and provide an official answer from the IRB.

3. Individual members can answer advisory questions but may not make any decisions regarding studies independent of the team.

E. Governing Principles

1. The rights and welfare of all participants must be adequately protected, including the physical and psychological wellbeing of participants.

2. The rights of informed consent, self-determination, and privacy must be protected.

3. Risk must be minimized by using procedures and methods that are consistent with scientific research design and do not expose participants to unnecessary risk.

4. Risks must be reasonable in relation to the anticipated benefits to the participants and to the importance of the anticipated knowledge to be gained by the research.

5. Researchers must monitor the data collected during the research to ensure the safety of participants.

6. In general, deception should not be incorporated into a research design. When deception is necessary, it is the responsibility of the researcher to provide a detailed analysis of why deception is necessary for the study, detailing how participants will be protected from unnecessary risk, as well as how participants will be debriefed once their participation has completed, or at the end of the study if the debriefing would compromise the integrity of study. All studies using deception must debrief participants and inform them of the deception.

7. If extra credit is offered as an incentive for research participation, students must be able to obtain equivalent extra credit by means other than research participation. The effort and time requirements for the alternative extra credit must be comparable. It is a violation of IRB policy for students to receive an academic penalty for not participating in research. Investigators should be extremely cautious in offering extra credit to students in their courses to avoid even the appearance of coercion. Further, investigators are reminded that all participants, including those receiving extra credit, are free to discontinue participation at any time without penalty.

F. Application Procedure

1. Individuals wishing to apply to the GSU IRB for research must check the IRB page on the GSU website to ensure they are using the current form.

2. The initial application shall be made to the IRB by submitting the following materials to the IRB email address at IRB@glenville.edu.
    a. The current application form, with all sections completed. If a section does not apply, that should be noted by the principal investigator with the words, "not applicable," or the initials, "N/A."

    b. A copy of the consent form that participants will sign to signify that they are voluntarily participating in the research.

    c. A copy of all survey instruments being used in the research. If the research is a qualitative study, the list of interview questions must be included. Researchers should ensure that they have the proper permissions for all instruments used in the study. Use of copyrighted or licensed measures must have formal approval from the copyright or license holder.

    d. A copy of the participant recruitment materials.

    e. A description of all data collection methods (e.g., Survey Monkey, physiological apparatus, or hardcopy questionnaires) that will be used.

3. The IRB chair will assign the application a control number. This number will include the school year and term number, with an appended number for each application. For example, the second IRB application submitted in the spring of 2026 would be numbered GSU-2025-S26-V1. Numbering will restart each academic year. The IRB chair will keep digital records of all IRB applications.

4. The IRB chair will determine if the proposed categorization of the research as exempt, expedited, or full review is correct. Following this determination, the chair will follow the appropriate set of procedures below. If the chair disagrees with the proposed characterization of the review needed, the chair will consult with the IRB Committee, and the appropriate categorization will be made and communicated to the researcher.

G. IRB Categories

1. *Exempt Review*
    a. Definition: Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn or the assessment of educators.

    b. The IRB chair (or designee determined by the chair) will be the screening member and review applications that fit this category. That member can escalate the application to either expedited or full review if the determination is made that the study is not exempt.

    c. Process:
        i. Studies or surveys previously approved by the IRB for which no meaningful changes were made (e.g.; subjects, data collection methods, data storage) within a two-year period meet the criteria for Exempt Review.

        ii. The IRB chair (or designee determined by the chair) will be the screening member and review applications that fit this category. That member can escalate the application to either expedited or full review if the determination is made that the study is not exempt.

        iii. If the screening member agrees that the project is exempt, a memo to the IRB committee should be prepared, affirming the research's exempt nature and recommending approval. The remaining committee members will have 24-48 hours to provide feedback to the screening member.

        iv. Upon acceptance of this memo, the PI (and advisor, if relevant) should be informed in writing of the action of the committee (and the expiration date of approval, if approved) by the chair.

    d. Examples (Defined by the U.S. Department of Health and Human Services):
        i. Research in standard educational settings involving normal educational practices (e.g., classroom research on instructional strategies).

        ii. Research involving anonymous data collection (e.g., surveys without identifying information).

        iii. Studies with minimal psychological or physical risk where subjects give informed consent (e.g., studies on decision-making with non-invasive methods).

iv. Research using datasets that are publicly available or have no identifiers linked to individuals.

2. *Expedited Review*
    a. Definition: Activities where the probability and magnitude of harm or discomfort are no greater than those encountered in daily life.

    b. Process:
        i. Once the classification of expedited is confirmed by the chair, the full committee will review the application.

        ii. These decisions made by the committee will be (approval, request for modifications or more information, or rejection) recorded and communicated in writing to the PI (and advisor, if relevant) by the same process as exempt reviews.

    c. Examples (Defined by the U.S. Department of Health and Human Services):
        i. Clinical studies of drugs and devices without Investigational New Drug (IND) applications or investigational device exemptions (IDEs).

        ii. Collection of blood samples from healthy, non-pregnant adults or children within certain limits.

        iii. Non-invasive procedures (e.g., MRIs, EEGs, or routine physical examinations).

        iv. Data collection via voice, video, digital, or image recordings.

        v. Behavioral or social science research involving surveys, interviews, focus groups, or similar methods that do not involve sensitive information or vulnerable populations.

3. *Full Review*
    a. Definition: Studies where the likelihood or magnitude of harm exceeds that encountered in daily life or routine tests (e.g., research with substantial psychological risk, potential physical harm, or exposure to sensitive information without confidentiality guarantees).

    b. Process:

i. Once the classification of full is confirmed by the chair, the full committee will review the application.

ii. Once the committee has discussed the application, the PI (and advisor, if relevant) will be invited to the next scheduled meeting to answer any questions.

iii. If the PI cannot attend the meeting (due to a scheduling conflict, etc.), the committee will determine a special meeting time that accommodates the PI.

iv. After meeting with the PI, the committee will make a decision which should be communicated to the PI (and advisor, if relevant) by the same process in the other categories.

c. Examples:
    i. Research involving minors often requires full IRB review due to additional safeguards.

    ii. Participation is subject to specific ethical and legal protections.

    iii. Some research may pose additional risks and hence requires full review.

    iv. May have diminished capacity to provide informed consent.

H. Appeals Procedure

1. If an investigator disagrees with an IRB decision or action, they may request reconsideration of the decision or action by requesting an appearance before the IRB. All appeals decisions must be based solely on the purpose of the IRB – the protection of the rights and welfare of human and non-human vertebrate subjects. In general, there should be a rare need for appeals, as investigators may always modify their research to meet the protection needs of their subjects. Failing a successful appeal to the IRB, the investigator may then request a review by an advisory review panel.

2. Investigator appears before the IRB – The investigator shall request to appear at the next regularly scheduled meeting of the IRB to present information relevant to the application. This method of appeal is initiated by letter to the IRB requesting to be placed on the agenda at the next regularly scheduled IRB meeting. The IRB may uphold, modify, or reverse its decision. If the investigator is dissatisfied with the outcome of this appearance, they may request, within seven calendar days of the IRB notification of the result of this appearance, to proceed to an Advisory Review Panel.

3. Advisory Review Panel – The investigator may request an advisory review panel as further appeal after appearing before the IRB. This method of appeal is initiated by sending a letter of appeal to the Provost outlining the request for an appeal, including the justification for the appeal.

4. The Advisory Review Panel must be formed by the Provost within 14 calendar days of receipt of the letter of appeal.

5. Composition of the Advisory Review Panel (ARP): The ARP shall consist of three external, non-GSU affiliated faculty who teach in fields commonly known to engage in human research, such as, but not limited to, biology, health sciences, psychology, or criminal justice. Preference shall be given to professors who teach in subject matter related to the research, if possible, unless there is a conflict of interest. The IRB Chair shall be an ex officio member of the ARP, with voice but no vote.

6. Duties of the ARP: The ARP will conduct an investigation into the appeal. It will review all information presented by the appellant. The ARP will also review minutes of the discussion by the IRB regarding the research proposal being appealed, including the reasons for the IRB action. The ARP may choose to interview the appellant. It is the duty of the ARP to make findings solely based on the purpose of the protection of the rights and welfare of human subjects.

7. Within 30 days of its formation, the ARP will conclude its investigation and transmit its findings to the IRB chair via a written report of its findings and recommendations.

8. The IRB will consider this report at their next regular meeting, or a special meeting, held within two weeks of receipt of the ARP's report, and issue a final decision.

9. Within seven days of the meeting to consider the ARP's report, the IRB chair will provide written notice to the principal investigator, the department chair/dean, and the provost of the decision of the IRB.

10. The researchers may always modify their research proposal and resubmit as a new IRB application. The researchers are welcome to consult the IRB in preparing the new application.

I. Finalizing the Application

1. The decision of the IRB becomes final under any of the following circumstances:
    a. The investigator chooses not to appeal;

    b. The investigator fails to notify the Office of Academic Affairs (Provost), within seven calendar days of receipt of the IRB's notification, of a decision to appeal;

    c. The investigator fails to appear before the IRB at its next regularly scheduled meeting;

    d. The investigator fails to request information of an advisory review panel within seven calendar days after appearing before the IRB; or,

    e. The investigator fails to make documents concerning the study available to the advisory review panel within seven calendar days of being requested to do so.

2. Once the IRB decision is final, the investigator may initiate a new application to the IRB with modifications to the proposal. (See section H.10)

J. Revisions to the IRB Policies and Procedures

1. At any time, any member of the IRB, or any faculty member, including adjunct faculty and instructors, may propose additions or revisions to the IRB Policies and Procedures.

2. The IRB members shall have at least two weeks to review the proposed revision(s) or addition(s).

3. The IRB shall discuss the benefits and disadvantages of the revision(s) or addition(s) prior to voting on the proposal to be forwarded to Administration.

4. A simple majority vote from the IRB shall move the revision(s) or addition(s) forward to the Provost for distribution.