INSTITUTIONAL REVIEW BOARD

Policies and Procedures

Adopted: 28 April 2020

200 High Street • Glenville, WV 26351 • (304) 462-7361 • www.glenville.edu

Introduction

At Glenville State College all research involving human or animal subjects must be approved by the Institutional Review Board (IRB). An IRB is a federally mandated entity that oversees the protection of human and animal 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 College reviews all research involving human and animal subjects to ensure that risks have been minimized. The potential harm to subjects must be evaluated against the potential benefit before human and animal 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 principle 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 College must be supervised by an appropriate faculty member.

In addition to this manual, IRB information and forms can be found on the GSC webpage.

Note: In this document the terms 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 and non-human vertebrate subjects/participants. The purpose of the IRB is to ensure 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 5 members.

2. Four of the 5 members shall be faculty members who are employed full-time by GSC whose academic discipline requires IRB approval for the conducting of human and vertebrate animal research.

3. One of the 5 members shall be a community member who receives no financial remuneration from Glenville State College.

4. The Provost, or their designee/proxy, is a 6th member of the IRB. The Provost or their designee/proxy will only vote in the event a tie vote within the IRB.

5. Except for the provost or their designee/proxy, members of the IRB shall serve 2-year rotating terms. Members may serve more than one term, but must have at least one year between terms on the IRB.

6. When there is an expected vacancy on the IRB, the IRB chair will recommend faculty or community member to the Provost, under consultation from the IRB. Appointment of new members will be approved by the Provost, or their designee.

7. The chair of the IRB will be selected by a majority vote of the current IRB members, and will serve until the end of their term on the Board expires.

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 polices and procedures, of the IRB.

C. Authority of the IRB

1. All academic and scientific research that involves human and vertebrate animal subjects that involves or represents Glenville State College in any way must acquire approval of the Glenville State College 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 GSC 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 GSC faculty, staff, or students, then that dissertation is exempt from GSC's IRB process. However, those faculty and staff members completing a dissertation or thesis at another institution are required to submit to the GSC 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 GSC faculty, staff, or student are conducting research in cooperation with individuals from other colleges, universities, or other institution, and the GSC affiliated individual is not the primary investigator, then the GSC 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 GSC faculty, staff, or students as research subjects/participants must gain GSC IRB approval
v. Notification that their dissertation or thesis has been completed and accepted or approved

g. 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. Any research involving non-human vertebrate animals must also acquire WV Institutional Animal Care and Use Committee approval ***in addition to*** GSC IRB approval.

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

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

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

6. The GSC IRB may deny approval of any research application.

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

D. Advisory Questions

1. Any IRB-related question must be submitted to the IRB as a formal request for information via email or paper submission to the chair of the IRB.

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

3. Neither the chair, nor any individual IRB member has the individual authority to answer questions for the IRB.

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 right 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. If the IRB believes that deception may result in immediate psychological or emotional distress, the IRB can require the researcher(s) to debrief immediately after participation.

F. Review Categories

There are three (3) types of IRB review according to 45 CFR 46: exempt, expedited, and full review.

1. **Exempt review** is for research that involves minimal risk to participants and meets any of the criteria listed below:

a. 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 required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b. Research that **only** includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

c. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

d. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA as "health care operations," "research" or "public health"; or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities and the information is subject to federal privacy standards and other requirements specified in the exemption [Refer to 45 CFR 46.104(d)(4) of the revised Common Rule]

e. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

f. Taste and food quality evaluation and consumer acceptance studies.

g. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials. [Refer to 45 CFR 46.104(d)(7), 46.111(a)(8), and 46.116(d) of the revised Common Rule.]

h. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

i. Broad consent is obtained from the subjects for the secondary research use of their identifiable materials,

ii. Documentation or waiver of documentation of informed consent is obtained,

iii. An IRB conducts a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and

iv. The investigator does not include returning individual research results to subjects as part of the study plan. [Refer to sections 45 CFR 46.104(d)(8), 111(a)(7) and 46.116(d) of the revised Common Rule]

2. **Expedited review** is for research that involves minimal risk where the "magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests," (45 CFR 46). A study may be eligible for expedited review if it meets any of the following criteria.

a. Collection of data from voice, video, digital, or image recordings made for research purposes.

b. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

c. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as for medical treatment or diagnosis).

d. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving X-rays or microwaves.

e. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) research on drugs for which an investigational new drug application (21 CFR Part 312) is not required (b) research on medical devices for which (i) an investigational device exemption application (21CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

f. Collection of blood samples by finger stick, heel stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection

procedure, the amount of blood to be collected, and the frequency with which it will be collected.

g. Prospective collection of biological specimens for research purposes by noninvasive means.

h. Minor changes to research previously approved by the Lafayette IRB may also qualify for expedited review.

3. **Full review**, sometimes called quorum review, is required for all research that does not qualify for exempt or expedited review. Full review is required when the participants represent a vulnerable population, such as prisoners, and anyone under the age of 18 years old. If the research involves any of the following, it will be subject to full review.

a. Children under the age of 18 years

b. Prisoners

c. Individuals with impaired decision-making capacity

d. Economically or educationally disadvantaged persons

e. Procedures that might cause physical harm

f. Procedures that might cause significant psychological/emotional distress

g. Collection of information about highly sensitive topics

h. Collection of information about illegal behavior

i. Collection of information that could seriously harm the participant legally, socially, financially, or other, if other people could identify them

j. While oral histories are not subject to IRB approval, case study research requires full review.

G. Application Procedure

1. Individuals wishing to apply to the GSC IRB for research must check the IRB page on the GSC website to ensure they are using the most 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 principle 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.

d. Any survey instrument that may be copywritten, be the intellectual property of another, or otherwise have any question regarding its legal use in the research be proposed must have the provost's approval. A copy of the provost's approval letter must be submitted with the initial application.

e. A copy of the participant recruitment materials.

f. A description of all data collection instruments 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 fall of 2020 would be numbered GSC-IRB-2020-01-02. The IRB chair will keep a record, via spread sheet (such as Excel) of all IRB applications.

The IRB members will have two weeks to review the materials. The application will be discussed by the IRB at its next regularly scheduled meeting after the two weeks review period.

4. If there are no questions or concerns regarding the autonomy and safety of subjects, the IRB will return the application with a notice of approval and the type of review (Exempt, Expedited, or Full).

5. If the IRB has questions or concerns regarding the autonomy and safety of subjects, the IRB will submit a request for further information, or for revision of the research design to be consistent with protection of human and non-human vertebrate subjects.

6. In the event the IRB requests that the principle investigator make revisions or answer questions, the IRB members will have at least one week to review the principle investigator's

responses and will discuss those responses at the next regularly scheduled meeting after the one-week review period.

7. The IRB shall provide three opportunities for revisions before rejecting an IRB application. In the event that an IRB application is rejected by the IRB, the IRB chair will provide written notice to the principle investigator detailing the concerns for the protection of subjects.

8. If the principle investigator disagrees with the IRB's findings, they may appeal the decision per the appeals process outlined in Section H of these policies and procedures.

9. Once the IRB has made a determination to either accept or reject an application, in addition to transmitting the findings to the principle investigator, the findings will also be transmitted to the provost.

10. Any significant changes to the research design that occurs after the IRB has approved the application, must be submitted to the IRB and be subject to this application procedure. The changes shall be detailed in a memo of revision.

11. Once an application has been approved, the approval may be rescinded for the following reasons:

a. The researchers fail to follow the research protocol that was accepted.

b. A complaint is provided to the IRB that subjects/participants are subjected to undo risk or direct harm.

c. Significant changes are made to the research design, such as a change in the data collection method, that was not submitted to the IRB for further approval.

12. The IRB may require that principle investigators undergo training related to the protection of human and/or non-human vertebrate animals, especially for student researchers. If the IRB requires such training, it will explicitly state the name of the training and the method of acquiring it in a memo to the principle investigator.

H. Appeals Procedure

1. If an investigator disagrees with an IRB decision or action, they may request reconsideration of the decision or action by one of the following methods: appearance before the IRB or advisory review panel. 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 very rare need for appeals, as investigators may always modify their research to meet the protection needs of their subjects.

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 is decision. If the investigator is dissatisfied with 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 and the grounds of the appeal.

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

5. Composition of the Advisory Review Panel (ARP): The ARP shall consist of 3 faculty, appointed by the provost, who teach in fields commonly known to engage in human or non-human vertebrate animal research, such as, but not limited to, biology, psychology, or criminal justice. Preference shall be given to professors who teach in the subject matter related to the research, if possible, unless there is a conflict of interest. The IRB Chair shall be an ad hoc member of the ARP.

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 and the IRB chair. It is the duty of the ARP to make findings solely based on the purpose of the IRB, the protection of the rights and welfare of human and non-human vertebrate 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 2 weeks of receipt of the ARP's report, and issue a final decision.

9. Within 7 days of the meeting to consider the ARP's report, the IRB chair will provide written notice to the principle investigator, the department chair/head, 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 and engage the IRB process with the new application.

I. Finalizing of 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 (7) 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.

I. Revisions to the IRB Policies and Procedures

1. Any member of the IRB, or any faculty member, including adjunct faculty and instructors, may propose additions or revisions to the IRB procedures.

2. Once a revision is proposed, the IRB members shall have at least two weeks to review the proposal or proposals.

3. The IRB shall discuss the benefits and costs of the revision or revisions prior to voting on the proposal to be forwarded to Administration.

4. A simple majority vote from the IRB shall move the proposal forward to Administration for consideration.