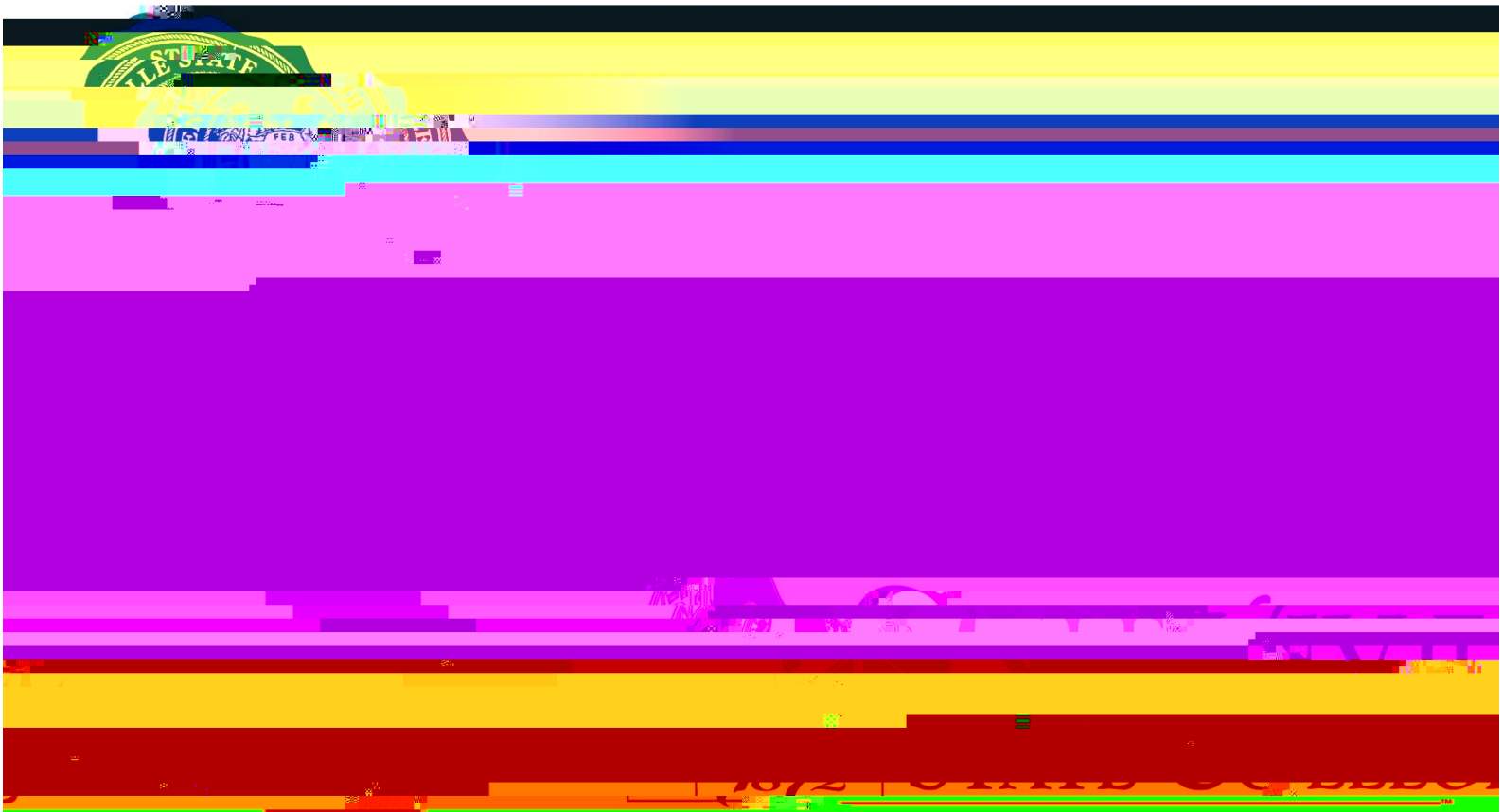

INSTITUTIONAL REVIEW BOARD

Policies and Procedures

Adopted: 28 April 2020

200 High Street, Glenville, WV 26351 (304) 462-8361

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

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.

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**

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

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

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 investiga

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

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

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

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)

   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