

**Georgia College and State University  
Institutional Review Board Official Policies**

I. Identity and Mission

- A. The primary mission of the GCSU IRB is to protect the rights and welfare of human subjects through interdisciplinary review of research proposals. The IRB strives to minimize the potential for physical, mental, or social harm to research participants.
- B. The GCSU IRB uses the [Code of Federal Regulations](#) as the basis for its own policies, though the GCSU IRB reserves the right to impose restrictions on research to exceed these minimum requirements. While not exhaustive, examples of such additional restrictions are delineated throughout this document.
- C. The GCSU IRB is the independent and final authority on research involving human subjects for researchers affiliated with and research conducted at Georgia College and State University.

II. Board Membership

A. Chair

- i. The Chair of GCSU IRB shall be a tenured (associate or full) faculty member who is a current member and has served a year as a Chair-elect (see below in Chair-elect).
- ii. After their term as Chair-elect, the Chair shall be appointed by the GCSU IRB and approved by the office of Provost.
- iii. The Chair's term of service is two consecutive years. During the 2<sup>nd</sup> year of the Chair's term, a Chair-elect is elected to be mentored by the Chair. When the Chair-elect becomes the IRB Chair, the outgoing Chair will continue to support the new IRB Chair by becoming a past-Chair for a year.
  - This results in a four-year term (one year as Chair-elect, two years as Chair, and one year as Past-Chair).
- iv. After completing their term as a Past Chair, the former chair is then eligible to be elected by GCSU IRB as the Chair-elect for a second 4-year term.
- v. The Chair may choose to remain as an IRB regular member, following regular membership policy, after the 4-year term ends.
- vi. The active Chair assumes 75% of the total IRB Chair workload.

B. Chair-Elect

- i. The GCSU IRB Chair-elect shall be a tenured (associate or full) faculty and an IRB member who has served at least one full term as a regular member of the IRB by the time of appointment.
- ii. The Chair-elect is elected to assist the IRB Chair through a formal voting of two-thirds of the full GCSU IRB.
- iii. The Chair-elect assumes the Chair's responsibilities after a year of being mentored.
- iv. The Chair-elect expects to serve a four-year term, starting as the Chair-elect.
- v. Chair-elect carries approximately 25% of the IRB Chair workload.

C. Chair-Council

- i. The GCSU IRB Past Chair shall have served one year as Chair-elect and two years as a Chair.
- ii. The term of service is one year. During the term of service, the Past Chair will serve as a mentor to the Chair and carry approximately 25% of the IRB Chair workload.

#### D. Faculty Members

- i. There shall be a minimum of 12 faculty members on the GCSU IRB. Where possible, representation from each college shall be equitable. Additional members may be added, based on the volume of project submissions.
- ii. These members should represent theoretical perspectives, substantive areas, and research methods that are inclusive of the research submitted to the GCSU IRB.
- iii. Members shall have human participant research experience prior to joining the IRB.
- iv. When a member seat becomes vacant, the GCSU IRB Chair shall solicit two nominations from the department chair or dean in a given area. The board shall review the curriculum vitae of the nominees and elect one of the nominees by voting of two-thirds of the full GCSU IRB board.
  - If nominations are not forthcoming, the board may make its own nomination(s).
  - Additional recruitment of members will be done yearly by the chair.
- v. Faculty are appointed to the IRB. A commitment of three years of service is preferred.
- vi. A faculty member may only be removed before the end of her or his term by resignation or a two-thirds vote of the full GCSU IRB.

#### E. Legal Affairs Representation

- i. Legal Affairs appoints a representative to the GCSU IRB.
- ii. There is no term limitation for the legal affairs representative.
- iii. This is a non-voting member.
- iv. Must be present when full IRB reviews are scheduled.

#### F. Community Representation

- i. One member of the board shall be a resident of Milledgeville/Baldwin County not otherwise affiliated with nor part of the immediate family of a person affiliated with Georgia College and State University.
- ii. The community representative term of service shall be three years, with the possibility of reappointment by the IRB Board.
- iii. This is a voting seat and shall conduct full reviews.
- iv. Community representatives must have current CITI training.

#### G. Optional Membership

- i. Staff Representation  
One member of the board may be a non-faculty staff employee of Georgia College and State University, nominated by the Staff Council. The board shall review the curriculum vitae of the nominee(s) and elect by a two-thirds vote of the full GCSU IRB. The staff representative term of service shall be no longer than three years. The staff representative may be re-nominated and re-affirmed. This is a non-voting seat and shall not conduct reviews.
- ii. Student Representation  
One member of the board may be a currently enrolled GCSU undergraduate or graduate student. Potential student members will express formal interest and will be selected by committee vote. The student representative term of service shall be no longer than one year, with the possibility of reappointment. This is a non-voting seat and shall not conduct reviews.

### III. Meetings

- A. The GCSU IRB shall meet at least once every fall and spring semester. Additional meetings may be called by the Chair as necessary.
- B. Board decisions may be made electronically, between in-person meetings, at the Chair's discretion.
- C. A quorum shall be a simple majority (greater than 50%) of the total current membership, not including open seats, and is necessary for decisions requiring a vote.
- D. Full review of research (see "review" section for definition) may only be conducted at formally called meetings. When full reviews are being considered, these meetings will be closed.
- E. All meeting minutes shall be retained permanently by the IRB.

#### IV. Review

- A. Investigations that (1) involve human participants and (2) contribute to generalizable knowledge must obtain approval from GCSU IRB. Investigations or other research that does not meet both of the aspects of the Federal definition of research need not be submitted to the GCSU IRB for consideration.
  - i. Research projects conducted in courses are subject to this policy if they qualify for research as indicated in point A and must follow all ethical and review policies contained herein. For research projects in courses that do not qualify as research as defined in point A, faculty members are still responsible for ensuring that students behave ethically and responsibly in completing their course projects or assignments.
- B. Each researcher involved in a given project must register certification of human subject ethics training completed within three years of approval of the application. Researchers include the principal investigator (PI), any co-investigators or partners in the research, and any research assistants.
  - i. Acceptable certifications include:
    - Collaborative Institutional Training Initiative (CITI)
      - a. Human Subjects Research (HSR)
        - i. biomedical track as appropriate
        - ii. social, behavioral, and educational track as appropriate
      - ii. A certification number/learner ID number and a completion date are required to be listed in the submission portal, along with the certificate image file which should be uploaded and attached to a researcher's profile.
- C. For research conducted by students, a faculty supervisor is required and shall be indicated on the research proposal.
  - i. It shall be the faculty supervisor's duty to act as a preliminary human subjects' ethics reviewer.
  - ii. Faculty supervisor of a student research project should ensure the proposal meets the general ethical standards of one's field, the requirements of the Code of Federal Regulations, and the particular policies of the GCSU IRB and that all necessary information and documents are included.
  - iii. Faculty supervisors should also ensure that proposals submitted to the IRB are complete, accurate, and in final draft form.
- D. Exempt status is granted solely and preemptively by the GCSU IRB based on federal guidelines. That is, researchers may not determine on their own that their research is exempt but, instead, must apply to the GCSU IRB for exempt status approval.
  - i. Exempt status is not to be confused with a waiver of general requirements for consent.
  - ii. Research involving minors can be exempt by the typical criteria so long as it is strictly observational--the researcher(s) does not interview or survey the children, and the researcher is not him/herself a student participant in the classroom.

- E. Research proposed by faculty and staff who are not affiliated with Georgia College and State University must have a Georgia College and State University adviser, supervisor, or co-investigator/partner to remain under the purview of Georgia College and State University.
- i. This includes institutional research requests from individuals not affiliated with Georgia College and State University.
- F. All research proposed for sites on and off of Georgia College and State University's campus and university-owned property (e.g., local elementary schools) must include a site permission letter signed by an administrator of that site on official letterhead and included as a scanned pdf or picture for inclusion in their project application.
- G. All research requires an informed consent process, regardless of exempt, expedited, or full status, which must be described (and documentation included) in research proposals unless a waiver is requested.
- i. Informed consent must meet Federal guidelines for required elements of informed consent. Informed consent must include contact information for the researcher and GCSU IRB Chair or Georgia College and State University Legal Affairs.
  - ii. A waiver of the requirement for informed consent may be considered, but is not guaranteed, under specific criteria.
    - Either both (for justification under point (c) of the federal guidelines) or all four (for justification under point (d) of the federal guidelines) criteria in the Code of Federal Regulation must be met for the chance of a waiver. No single criteria or subset of criteria are sufficient for waiver.
  - iii. The researcher must retain a copy of the informed consent document signed by the human subject (or a legal representative), except with permission from the GCSU IRB when the research presents no more than minimal risk.
    - Even when the signature requirement is waived, informed consent must always be shared with the human subject.
  - iv. Minor Assent
    - When the human subject is 8 to 17 years old, both age-appropriate signed assent from the minor and signed permission from a parent/legal guardian are required.
    - When the human subject is 5 through 7 years old, both age-appropriate oral assent from the minor (script required) and signed permission from a parent/legal guardian are required.
    - For minors for whom written assent is not appropriate, oral assent from the minor (script required) and signed permission from a parent/legal guardian are required.
    - When the human subject is under 5 years old, only signed permission from a parent/legal guardian is required; however, any reasonable objection to participation from the human subject in this situation should be construed as a refusal to participate, and data collection with this subject should halt immediately.
    - For research involving institutionally grouped minors of varying age (e.g. a classroom with some 7-year-olds and some 8-year-olds), the researcher may consider the mean age of the children in determining consent/assent/permission requirements.
  - v. Signed consent/assent/permission documents must be retained by the researcher for at least three years.
- H. The Chair has the latitude unilaterally to approve research that is currently approved by an external, registered, peer institutional review board.
- I. International Research

- i. GCSU IRB approval/exemption of research using the policies stated in this document is sufficient for research conducted outside of the United States for the purposes of Georgia College and State University.
  - Researchers are responsible for meeting the ethical and legal requirements particular to international locations that may differ from GCSU IRB standards and need not notify the GCSU IRB of these differences.
- ii. If the Chair determines that the procedures prescribed by an international institution afford protections that are at least equivalent to those provided in this policy, the Chair may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.

## V. Record Retention

### A. Records retained by the IRB

- i. Minutes of IRB meetings and final research reports shall be retained permanently by the IRB.
- ii. Records relating to research shall be retained by the IRB for three years after completion of research in accordance with the USG policy. Records to be retained by the IRB include:
  - applications for approval by the review board
  - descriptions of protocols
  - approved study instruments
  - Protection of Human Subjects forms (OMB-0531-0009)
  - Protection of Human Subjects C Assurance/ Certification/Declaration forms (OMB-0925-0637)

### B. Records retained by the investigator

- i. The final research report must be retained by the investigator permanently.
- ii. Records relating to individual research shall be retained by the investigator for three years after completion of the research in accordance with the USG policy. Records to be retained by researchers for three years include:
  - applications approved by the review board
  - descriptions of approved protocol(s)
  - signed consent forms
  - study instruments
  - data collected (to be stored in accordance with USG policy and in manner approved by IRB)

## VI. Research Non-Compliance

### A. The following shall be identified as non-compliance with acceptable research practices:

- i. providing any fraudulent information to or withholding any relevant information from the GCSU IRB
- ii. conducting research as an affiliate of Georgia College and State University, on the property of Georgia College and State University, or on human subjects defined by their affiliation with Georgia College and State University without prior and formal approval or exemption by the GCSU IRB
- iii. departing from the protocol of approved or exempt research, particularly in a way that increases the risk to human subjects
- iv. other ethically questionable issues identified by the GCSU IRB

### B. When the GCSU IRB becomes aware of any non-compliance:

- i. the GCSU IRB shall formally (electronically or otherwise) notify the researcher(s) and their supervisor(s) (e.g., student's advising faculty and Chair, faculty member's Chair, etc.) and instruct them to cease any and all data collection
- ii. the researcher(s) shall have 7 calendar days from the date of notification to apprise the GCSU IRB formally of the status of the research

- iii. the researcher(s) have the right to request a formal meeting with the GCSU IRB but must request such a meeting within 14 calendar days from the date of notification
- C. The GCSU IRB has the authority at any time to investigate both ongoing and completed research.
- D. The GCSU IRB may take any of the following actions:
  - i. issue a warning to a researcher
  - ii. censure a researcher
  - iii. rescind research approval or exemption for a given project
  - iv. require data to be destroyed
  - v. refer the researcher to Academic Affairs for further disciplinary actions.

Approved by the IRB: 1-6-17; Revised 8/31/2018

Reviewed and revised by the IRB: 11/2/2023