1. PURPOSE
   1.1. The University of Georgia Institutional Review Board must receive sufficient information from investigators to provide adequate review of proposed research and to make the determinations required by regulations and institutional policy for IRB review and approval. This policy describes the submission requirements and pre-review process for all submissions.

2. DEFINITIONS
   2.1. Pre-Review: The process performed by IRB staff to determine that a submission for IRB review is complete, including the required responses and materials, and that the institutional requirements, such as completion of human subjects protection training, principal investigator (PI) eligibility, and conflict of interest disclosure, have been met.
   2.2. Minimal Risk: means that the probability and 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.
   2.3. Privacy: is the control over the extent, timing, and circumstances of sharing one’s personal data including but not limited to thoughts, feelings, images, and biological materials with others.
   2.4. Confidential: refers to maintenance of the Researcher’s agreement with the participant about how the participant’s identifiable private information will be handled, managed, and disseminated.

3. POLICY
   3.1. All requests for IRB determinations and reviews will be submitted via the electronic portal, Click IRB.
   3.2. All UGA employees and students can create a submission for review using the electronic portal, Click IRB.
   3.3. Only individuals engaged in a research activity should be included in the study team. See Policy and Procedure: Engagement Determination.
   3.4. All study team members must have valid and current records showing completion of human subjects research training. UGA study team members must complete the appropriate CITI training. Non-UGA collaborators must provide a copy of their completion of CITI or another comparable training.
   3.5. Only UGA Tenured or Tenure-Track, Non-Tenure Track or Temporary Faculty, and Senior Research Associates who have signed an Intellectual Property Agreement are eligible to serve as Principal Investigator on a human subject research protocol. See Policy and Procedure: PI Eligibility.
4. PROCEDURES: Researchers

4.1. The creator of a submission will make an initial determination of the type of review or determination required via responses to trigger questions in the online form. These responses will determine what subsequent forms will be presented. The forms will prompt for responses and relevant attachments that pertain to the type of determination and review being requested.

4.2. The information listed below includes examples of the information and materials that are required for initial or continuing review by the IRB or for review of changes to previously approved research. This is not intended to be an all-inclusive list.

4.2.1. Initial Submissions

- Initial submissions include all applicable information requested in the online form.
- In addition to the responses in the online form, the following additional materials may need to be uploaded where prompted:
  - The complete grant application, funding proposal, or contract
  - All recruitment materials (e.g., ads, flyers, telephone or in-person scripts, internet/social media text)
  - Any materials used during the consent process (e.g., forms, letters, verbal scripts)
  - Data collection or recording materials including all instruments (e.g., questionnaires or surveys, observation protocols, interview protocols)
  - Debriefing materials if a student pool is in the targeted population (if applicable, see appropriate department research pool policy) or if incomplete disclosure or deception is employed
  - HIPAA Authorization forms if PHI (protected health information) will be obtained/used
  - Letters of authorization from external sites
  - Other letters of approval/support from collaborating institutions/organizations

4.2.2. Modifications

- All applicable information requested must be included in the online form
- Revised responses where applicable to the original online form
- Any new or revised versions of the additional materials listed above
4.2.3. **Continuing Reviews**
- All applicable information requested must be included in the online form
- Updated/current IRB approvals/letters of support from collaborating institutions/organizations
- Data and safety monitoring reports or multi-site study reports if applicable

5. **PROCEDURES: IRB Staff**

5.1. The IRB Staff will assign the completed submission to another IRB staff person if there is a **conflicting interest**. See Policy and Procedure: Conflicting Interest of IRB Members.

5.2. The IRB Staff will evaluate the most likely level of review or determination (Non-Committee, Committee, or Administrative—see three alternative review routes directly below).

- **5.2.1.** If the research represents a type of research for which according to “HUMAN RESEARCH PROTECTION PROGRAM PLAN” the organization relies on a qualified external IRB, the IRB Staff will inform the investigator to revise the submission and re-submit.

- **5.2.2.** If the research represents a request for developmental review or determination of human subjects research, the IRB Staff will inform the investigator to revise the submission and re-submit.

- **5.2.3.** For all other research, the IRB Staff will confirm that the submission has been properly auto-assigned by the system; reassign if necessary.

5.3. The IRB Staff will evaluate the submission for completeness by:

- **5.3.1.** Verifying that the Principal Investigator meets eligibility requirements for that role.

- **5.3.2.** Verifying that all study team members meet the training requirements and any additional requirements, such as conflict of interest disclosure.

- **5.3.3.** Verifying that the submission is complete. Use WORKSHEET: Pre-review as a guide.

- **5.3.3.1.** If the study team members do not meet requirements described above or the submission is not complete, the IRB Staff will contact the investigator and offer the investigator the opportunity to address the missing items or requirements.

5.4. The IRB Staff will evaluate the complete submissions where all additional requirements as described above are met to determine if there is sufficient information to determine that the approval criteria at 45 CFR 46.111 have been met (see WORKSHEET: Approval Criteria). WORKSHEET: Pre-Review can be used by the IRB Staff to guide the pre-review process.

- **5.4.1.** If additional information is necessary before a sufficient determination can be made, the IRB Staff will contact the investigator and offer the investigator the opportunity to address the missing items or requirements.

- **5.4.2.** If clarification is required to determine the engagement of the institution, the IRB Staff will contact the investigator and offer the investigator the opportunity to provide additional information. See Policy and Procedure: Engagement and WORKSHEET: Engagement Determination.
5.5. When all requests for clarification or additional information have been sufficiently addressed, the IRB Staff will complete the **pre-review process**.

5.6. The IRB Staff will note the regulatory oversight required.

5.7. The IRB Staff will make an initial assessment of the risk level, which includes but is not limited to **privacy** and **confidentiality**, (see WORKSHEET: Approval Criteria) and the type of **research** to be conducted (Social-Behavioral/Educational or Bio-Medical/Clinical).

### 6. MATERIALS

6.1. WORKSHEET: Pre-Review

6.2. WORKSHEET: Approval Criteria

6.3. WORKSHEET: Engagement Determination

### 7. REFERENCES

7.1. 45 CFR 46 Department of Health and Human Services Protection of Human Subjects

7.2. 21 CFR 50 Food and Drug Administration Protection of Human Subjects

7.3. Policy and Procedure: Conflicting Interest of IRB Members

7.4. Policy and Procedure: Non-Committee Review Preparation and Assignment

7.5. Eligibility to Submit Proposals policy