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### 1. PURPOSE

- 1.1. This **policy** describes the submission requirements and pre-review process for all submissions.

### 2. DEFINITIONS

- 2.1. **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.
- 2.2. **Minimal Risk:** a level of risk wherein 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. **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.
- 2.4. **Privacy:** is the control over the extent, timing, and circumstances of sharing one's personal data with others, including but not limited to thoughts, feelings, images, and biological materials.

### 3. POLICY

- 3.1. All requests for IRB determinations and reviews will be submitted via the electronic portal.
- 3.2. All UGA employees and students can create a submission for review using the electronic portal.
- 3.3. Submissions for human research projects must include sufficient information to make the determinations required by regulations and institutional policy.

### 4. PROCEDURES: Researchers

- 4.1. The person creating 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. Submissions of non-Exempt human research must include the following additional materials, when applicable. This is not intended to be an all-inclusive list.
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**4.2.1. Initial Submissions**

- 4.2.1.1. Initial submissions include all applicable information requested in the online form.
- 4.2.1.2. In addition to the responses in the online form, the following additional materials may need to be uploaded where prompted:
  - 4.2.1.2.1.
  - 4.2.1.2.2. All **recruitment materials** (e.g., ads, flyers, telephone or in-person scripts, internet/social media text)
  - 4.2.1.2.3. Any materials used during the **consent process** (e.g., forms, letters, verbal scripts)
  - 4.2.1.2.4. Data collection or recording materials including all instruments (e.g., questionnaires or surveys, observation protocols, interview protocols)
  - 4.2.1.2.5. 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
  - 4.2.1.2.6. **HIPAA Authorization** forms if **protected health information (PHI)** will be obtained/used
  - 4.2.1.2.7. **Letters of authorization** from **external sites**
  - 4.2.1.2.8. Other letters of approval/support from collaborating **institutions/organizations**

**4.2.2. Modifications**

- 4.2.2.1. All applicable information requested must be included in the online form
- 4.2.2.2. Revised responses where applicable to the original online form
- 4.2.2.3. Any new or revised versions of the additional materials listed above

**4.2.3. Continuing Reviews**

- 4.2.3.1. All applicable information requested must be included in the online form
- 4.2.3.2. Updated/current IRB approvals/letters of support from collaborating institutions/organizations
- 4.2.3.3. Data and safety monitoring reports or multi-site study reports if applicable

**5. PROCEDURES: IRB Staff**

- 5.1. The IRB Staff will assign the submission to another IRB staff person if there is a conflicting interest. See *Policy and Procedures: Conflicting Interests of IRB Members and Consultants*.
- 5.2. The IRB Staff will evaluate the most likely level of review or determination and will reassign if



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necessary.

5.2.1. If study will require **Full Board Review**, the IRB Staff selects the appropriate IRB that will review the research based on the study design and objectives, targeted population, study procedures or interventions, the nature of the research risks, and the expertise of the reviewing IRB.

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. See *Policy and Procedures: PI Eligibility*.

5.3.2. Verifying that all study team members meet the training requirements. See *Policy and Procedures: Investigator Training*.

5.3.3. Verifying that all members of the study team have provided responses pertaining to conflict of interest. See *Policy and Procedures: Financial Conflicts of Interest*.

5.3.3.1. If any member of the study team indicates they have a conflict of interest and the research is externally funded, the study team member will be reminded to complete an updated Grants Portal Disclosure and informed that any required management plan will have to be approved by the IRB.

5.3.3.2. If any member of the study team indicates they have a conflict of interest and the research is not externally funded, a description of the nature of the financial interest and how it relates to the research will be obtained and provided to the RIO for determination if a management plan is required.

5.3.4. Verifying that the source of funding is identified, if applicable.

5.3.5. Verifying that the submission is complete using *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.

5.3.5.1. If clarification is required to determine the engagement of the institution or collaborators, the IRB Staff will contact the investigator and offer the investigator the opportunity to provide additional information and will consult with the IRB Director and Office of Research Legal Counsel as needed. See *Policy and Procedures: Engagement Determination* and *WORKSHEET: Engagement Determination*.

5.3.5.2. If clarification is required to determine if the study design represents research involving human subjects, the IRB Staff will contact the investigator and offer the investigator the opportunity to provide additional information and will consult with the IRB Director or designee as needed. See *Policy and Procedures: Determination of*



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*Human Research.*

- 5.4. The IRB Staff will evaluate the submission where all requirements as described above are met and decide if there is sufficient information to determine the level of review or to determine that the approval criteria at 45 CFR 46.111 can be met (see *WORKSHEET: Approval Criteria*). *WORKSHEET: Pre-Review* can be used by the IRB Staff to guide the pre-review process.
- 5.5. If the submission involves the use of a test article (drug or device, including a humanitarian use device), IRB staff will document the lack of, or insufficient, information pertaining to IND, IDE/HDE, and/or provisions to control the drug(s) or device(s) in the Comments section of CHECKLIST – 401 – Pre-Review and will communicate the request for additional information necessary to complete IRB review to the study team. (*WORKSHEET – 306 – Drugs and WORKSHEET – 307 - Devices will be used to support this part of the pre-review.*)
- 5.6. When all requests for clarification or additional information have been sufficiently addressed, the IRB Staff will complete the **pre-review** process.
- 5.7. The IRB Staff will note the regulatory oversight required.
- 5.8. The IRB Staff will make an initial assessment of the type of research to be conducted (Social/behavioral/educational or Biomedical/clinical).

**6. MATERIALS**

- 6.1. WORKSHEET: Pre-Review
- 6.2. WORKSHEET: Criteria for Approval
- 6.3. WORKSHEET: Engagement Determination
- 6.4. WORKSHEET: Drugs
- 6.5. WORKSHEET: Devices
- 6.6. CHECKLIST – Pre-Review

**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 Procedures: Conflicting Interests of IRB Members and Consultants
  - 7.4. Policy and Procedures: Engagement Determination
  - 7.5. Policy and Procedures: Investigator Training
  - 7.6. Policy and Procedures: Non-Committee Review Preparation and Conduct
  - 7.7. Policy and Procedures: Principal Investigator Eligibility
  - 7.8. Policy and Procedures: Determination of Human Research
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## Pre-Review of IRB Submissions

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