1. PURPOSE

1.1. The University of Georgia Institutional Review Board (UGA IRB) develops its written policies and procedures according to HHS regulations at 45 CFR 46. Policies and procedures are developed and implemented to ensure effective and consistent operation of UGA’s IRB and its human research protections program. These policies and procedures are often mandated by federal, state or institutional regulations or guidance, and/or are reflections of best practices at UGA and peer institutions.

1.2. This policy describes how IRB policies and procedures are developed, reviewed, revised, disseminated, and implemented at UGA.

2. DEFINITIONS

2.1. Policy. A formal statement of principles on which action(s) for a specific issue are based.

2.2. Procedure. A series of actions conducted in a certain order or manner; operational method by which policy is put into practice.

2.3. IRB Policies and Procedures. Policies and procedures of the IRB, the Human Subjects Office, and other University units that apply to the review and oversight of human subjects research activities that are being conducted under the auspices of UGA. These also describe the roles and responsibilities of those involved in these activities.

3. POLICY

3.1. UGA IRB and Human Subjects Office (HSO) will maintain written policies and procedures to ensure effective functioning and operations of the IRB and the human research protections program.

3.2. These policies and procedures are applicable to all research investigators conducting human subjects research under the auspices of UGA, the IRB members, and HSO staff.

3.3. The use of the word must or will in UGA IRB policies and procedures means that something is required under the federal, state, institutional, or other applicable regulations. The use of the word should in UGA IRB policies and procedures means that something is recommended or suggested, but not required.

3.4. Due to the complex nature and wide breadth of human research, these policies and procedures cannot address all possible scenarios or issues. When scenarios/issues arise that are not covered by the policies and procedures, these will be resolved through discussion with the appropriate personnel. It is further recognized that there will be case-specific departures from these policies and procedures.

4. PROCEDURES

4.1. Development
4.1.1. The HSO Director, with advice from HSO staff, IRB Chair, IRB members and/or investigators determines when new policies and procedures or changes or revisions to existing policies and procedures need to be developed.

4.1.2. HSO Director and staff are responsible for drafting policies and procedures after review of the federal regulations/guidance and best practices at peer institutions, and if necessary, in consultation with other stakeholders and/or other applicable University units/departments.

4.1.3. Policies and procedures will be written in sufficient detail and describe the actions that are followed to achieve the intended outcome.

4.1.4. The draft policies and procedures are initially reviewed by the HSO unit.

4.1.5. The final draft is distributed to the IRB members prior to a convened meeting.

4.2. Review and Approval

4.2.1. The IRB will review and approve all new and revised IRB policies and procedures at a convened meeting, with appropriate documentation in the meeting minutes.

4.2.2. Non-substantive revisions to approved policies and procedures (include, but are not limited to, improving its clarity, correcting typographical errors, updating web links, updating federal regulations, or minor procedural changes) will be approved by the IRB Chair and HSO Director, with a notification to the Full Board if necessary.

4.3. Implementation and Communication

4.3.1. HSO is responsible for the implementation and communication of IRB policies and procedures.

4.3.2. The effective date for policy implementation will be the date of the convened meeting when the policy was reviewed and approved by the IRB.

4.3.3. A revised policy and procedure will supersede all previously approved versions, and will be effective on the date of the most recent approval date.

4.3.4. Policies and procedures and accompanying materials (e.g., forms, guidance) will be posted and made available on the IRB website and electronic IRB portal.

4.3.5. Communication will be made about new or revised policies and procedures through IRB communication mechanisms.

4.3.6. When a policy and procedure represents a significant change to existing policy, processes, or procedures, the effective date will be set to allow for communication, including education and planning, for operational changes.

4.4. Maintenance

4.4.1. HSO is responsible for maintaining the IRB policies and procedures. The HSO Director and staff will review existing policies and procedures on a regular basis.

4.4.2. Policies and procedures will be developed or updated as regulations and needs are recognized and/or changed.

4.4.3. Research stakeholders may recommend needed revisions or additions.

5 MATERIALS

Policies and Procedures Style Template

6 REFERENCES