Human Research Protection Program
UNIVERSITY OF GEORGIA

Policies and Procedures

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1. PURPOSE

1.1. The University of Georgia's Human Research Protection Program (HRPP) develops and implements its written policies and procedures to ensure effective and consistent implementation of the requirements and practices related to the review, conduct, and oversight of **human research** and the protection of **research participants**. These policies and procedures are congruent with federal regulations, state laws, and institutional policies, and best practices at UGA and peer institutions.

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

2. DEFINITIONS

2.1. *HRPP Policies and Procedures*: these are the policies and procedures that describe the requirements and practices related to the review, conduct, and oversight of human research activities at UGA or under its auspices. These also describe the roles and responsibilities of those involved in these activities.

2.2. *Policy*: a formal statement of principles on which action(s) for a specific issue are based.

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

3. POLICY

3.1. UGA HRPP will maintain written policies and procedures to ensure effective functioning and operations of the HRPP and the Institutional Review Board (IRB).

3.2. These policies and procedures are applicable to all research investigators conducting human research at UGA or under its auspices, the IRB members, and Human Subjects Office (HSO) staff.

3.3. The use of the word *must* or *will* in UGA HRPP 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 HRPP 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

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appropriate personnel. It is further recognized that there will be case-specific departures from these policies and procedures.

4. PROCEDURES: HRPP Staff

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 for comment.

4.2. Review and Approval

4.2.1. A Policy Executive Committee will be appointed by the HSO Director to review and approve all new and revised policies and procedures, with input from the Full Board if necessary

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/or HSO Director, with a notification to the Policy Executive Committee if necessary.

4.3. Implementation and Communication

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

4.3.2. The effective date for policy implementation will be the date of the Policy Executive Committee meeting when the policy was reviewed and approved.

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 HRPP website and electronic IRB portal.

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

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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 HRPP 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

5.1. TEMPLATE: Policies and Procedures Style

6. REFERENCES

6.1. OHRP Guidance on Written IRB Procedures, http://www.hhs.gov/ohrp/policy/irbgd107.html

Revision History:
08/15/2014: REV0 New Document
07/12/2017: REV1
02/16/2018: REV2