

HUMAN RESEARCH PROTECTION PROGRAM POLICIES AND PROCEDURES

1. Overview

Policies and procedures are developed and implemented to ensure effective and consistent operation of the Human Research Protection Program (HRPP). These policies and procedures are often mandated by state/federal legislation or regulations, recommended by federal guidance, and/or are reflections of best practices among peer institutions.

Policies and procedures differ in their scope and applicability to research involving human subjects, including:

- University policies and procedures
- College, School, or Department policies and procedures
- Institutional Review Board (IRB)/Office of Responsible Research Practices (ORRP) policies and procedures
- Office of Responsible Research Practices desk procedures.

The focus of this document is on the policies and procedures of the IRBs and ORRP.

2. Definitions

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

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

HRPP Policies and Procedures: Policies and procedures of the Office of Research, IRBs, and ORRP that apply to the conduct, review, and oversight of human subjects research and describe the roles and responsibilities of those involved in these activities.

3. Scope of HRPP Policies and Procedures

The scope of policies and procedures for the Human Research Protection Program includes, but is not limited to, research submission and review criteria, review and approval procedures, education and outreach activities, oversight and compliance processes, and quality improvement initiatives.

4. Policy and Procedure Recommendation

Research stakeholders, including University faculty, administrators, investigators, research staff, students, IRB members, and ORRP staff, may make recommendations

for new policies and procedures or changes or revisions to existing policies and procedures to the IRB Chairs, Office of Responsible Research Practices, IRB Policy Committee (IPC), and/or the Office of Research.

5. Policy and Procedure Development

The Office of Responsible Research Practices is responsible for drafting new or revised policies and procedures after review of the regulations, guidance, and best practices at peer institutions and in consultation with the Office of Legal Affairs and/or Office of Research Compliance. Policies and procedures will reflect available information and are written in sufficient detail to describe the actions that are followed to achieve the intended outcome.

6. Policy and Procedure Review and Approval

The IRB Policy Committee is authorized by the Vice President for Research to review and approve all HRPP policies and procedures. The IPC will forward HRPP policies and procedures or recommendations for policies and procedures to the Vice President for Research and/or Senior Associate Vice President for Research (Institutional Official) for review and approval, as applicable, based on the scope of the policy.

7. Implementation of HRPP Policies and Procedures

The Office of Responsible Research Practices is responsible for the implementation and communication of HRPP policies and procedures. Policies and procedures and accompanying materials (e.g., forms, guidance) will be posted and made available on the ORRP website. Communication will be made about new or revised policies and procedures through University communication mechanisms. The IRB Policy Committee will set an effective date for policy implementation. When a policy and procedure represents a significant change to existing policy, process or procedures, the effective date will be set to allow for communication, including education and planning for operational changes.

8. Policy and Procedure Maintenance

The Office of Responsible Research Practices is responsible for maintaining HRPP policies and procedures. The IRB Policy Committee will review existing policies and procedures at least every three years. In addition, policies and procedures will be developed (as described above) or updated as needs are recognized or change. Research stakeholders will recommend needed revisions or additions.

9. Applicable Regulations/Guidance

AAHRPP Evaluation Instrument for Accreditation (updated 06/01/07)