TITLE: **Institutional Components and Authority**

PURPOSE: Description of components in the HSPP office

RESPONSIBILITIES: HSPP Staff

HUMAN SUBJECTS PROTECTION PROGRAM COMPONENTS

Organizational Official

The Senior Vice President for Research (SVPR) is designated as the Organizational Official.

The Organizational Official has the authority to:

- Create the HSPP budget
- Allocate resources with the Human Subjects Protection Program budget
- Appoint and remove IRB members and IRB chairs
- Hire and fire HSPP staff
- Determine what IRBs, the organization, will rely upon
- Approve and rescind IRB authorization agreements
- Place limitations or conditions on an investigator's or research staff's privilege to
- conduct Human Research
- Create policies and procedures related to the Human Subjects Protection Program that are binding on the organization
- Suspend or terminate IRB approval of research
- Disapprove research approved by the

The IRB Organizational Official also has the authority to:

- Oversee the review and conduct of Human Research under the jurisdiction of the
- Human Subjects Protection Program
- Periodically review this program to assess whether it is providing the desired results and recommend amendments, as needed
- Establish policies, processes, and procedures designed to increase the likelihood that
- Human Research will be conducted in accordance with ethical and legal requirement
- Institute regular, effective, educational, and training programs for all individuals involved with Human Research
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the organization cannot approve research that has not been approved by an IRB designated by the organization
- Implement a process to receive and act on complaints and allegations regarding the
- Human Research
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas
- Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Subjects Protection Program

- Ensure that the Human Subjects Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner
- Review and sign federal assurances and addenda.

All members of the organization

All individuals within the University of Arizona are accountable for the following:

- Be aware of the definition of Human Research
- Consult the HSPP when there is uncertainty about whether an activity is Human
- Research
- Not conduct Human Research or allow Human Research to be conducted, without review and approval by an IRB designated by the Organizational Official
- Report allegations of coercion or undue influence regarding the oversight of the
- HSPP or concerns about the HSPP to the Organizational Official
- Report allegations or findings of non-compliance with the requirements of the HSPP
- to the IRB.

IRBs

The list of IRBs designated by the Organizational Official is available on the HSPP website.

The IRBs relied upon by the Organizational Official have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the organization. All Human Research must be approved by an IRB designated by the Organizational Official. Officials of the organization may not approve Human Research that has not been approved by the IRB
- Suspend or terminate approval of Human Research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects
- Observe, or have a third party observe, the consent process and the conduct of the
- Human Research
- Determine whether an activity is Human Research
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.

IRB members and HSPP staff are responsible for following applicable HSPP policies, processes and procedures that apply.

Investigators and Research Staff

Investigators and research staff will do the following:

- Follow the HSPP requirements described in this manual
- Follow the HSPP policies and processes that apply
- Comply with all determinations and additional requirements of the IRB and the
- Organizational Official.

Legal Counsel

The Office of General Counsel (OGC) will do the following:

- Provide advice upon request to the Organizational Official, IRB, and other individuals involved with the Human Subjects Protection Program
- Determine whether someone is acting as an agent of the organization
- Resolve conflicts among applicable laws.

College/School/Department/Center/Section Administrators

College and department administrators will do the following:

- Oversee the scholarly review, scientific merit and conduct of Human Research in their college, school, department, center or section
- Forward complaints and allegations regarding the HSPP to the Organizational Official
- Ensure that each Human Research study conducted in their college, school, department, center or section has adequate resources.

MATERIALS:

- Investigators Manual

REFERENCES:

- http://ogc.arizona.edu/

REVIEW/REVISIONS: From 05/28/15 version of the Investigators Manual.