

USF System   USF   USFSP   USFSM   USFP

**Number: 0-305**

**Subject: Use of Human Subjects in Research**

Date of Origin: 12-06-89

Date Last Amended: 02-02-09

Date Last Reviewed: 02-02-09

---

## I. INTRODUCTION (Purpose and Intent)

The University of South Florida System (USF System) requires from faculty, staff, and students the responsible conduct of research and the ethical treatment of human subjects in research. The USF System has a systematic and comprehensive Human Research Protection Program (HRPP) that is designed to protect the rights, dignity, and welfare of human subjects who participate in the research programs of the USF System and its affiliated institutions. The program is based on the ethical principles outlined in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report.

## II. STATEMENT OF POLICY

The HRPP includes the USF System Institutional Review Boards (IRB) and other duly constituted, relied-upon IRBs as set forth in the USF System Federalwide Assurance. All research involving human subjects must receive IRB review and approval prior to initiation and must be conducted in accordance with the policies and procedures of the USF System, the Code of Federal Regulations governing the use of humans in research, and the applicable regulations set forth by the International Harmonisation Council. Related policies and procedures are available on the Office of Research & Innovation and the Division of Research Integrity & Compliance website: <http://www.research.usf.edu/cs/hsp.htm>.

The President has delegated authority and responsibility of the HRPP to the Vice President for Research & Innovation. The Vice President serves as the

Institutional Official for the USF System Federalwide Assurance and is responsible for oversight and the compliant operation of the HRPP.

The IRBs are granted authority through federal regulations to review research proposals and take any of the following actions:

- Approve.
- Require modification to secure approval.
- Disapprove.
- Suspend or terminate approval.
- Observe or have a third party observe consent processes or the conduct of research.
- Conduct Quality Assurance evaluations and for-cause audits of on-going and closed research studies involving human subjects.

Research covered by this policy that has been approved by a USF System IRB may be subject to further appropriate review and approval or disapproval by officials of the University. However, these officials may not approve the research if it has not been approved by an IRB.

### **III. RESPONSIBILITIES**

#### **A. The USF System Vice President for Research & Innovation:**

- Serves as Institutional Official and is ultimately responsible for oversight and the compliant operations of the HRPP.
- Maintains open and direct channels of communication with IRB members and staff, investigators and research staff, and administration to address questions, concerns, or suggestions regarding the HRPP.
- Provides the IRB with sufficient meeting space, staff, and budgetary resources to support review and record keeping responsibilities. A program report drafted by the Director of Research Integrity & Compliance is reviewed annually to ensure adequate resources are available to support required activities.

- Notifies the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the Office of Research Oversight (ORO, for VA-regulated research) of serious or continuing noncompliance with IRB policies or regulations and suspensions or terminations of IRB approval.
- Protects IRBs from undue influence or threat of retaliatory actions so that IRBs can function independently, basing decisions on ethical principles, regulations, and institutional policies. IRB members and staff shall report any instances of undue influence to the Director of Research Integrity & Compliance. The Director will investigate the matter and report findings and recommendations for resolution to the Vice President for Research & Innovation.
- Approves recommendations and appoints IRB members, alternates, ex-officios, and consultants.
- Evaluates all IRB members, chairpersons, staff, board composition, and number annually to ensure adequate resources, program continuity, and scientific and professional expertise of members relevant to the business conducted. The Director of Research Integrity & Compliance will prepare the annual report to present to the Vice President for Research & Innovation.

**B. The USF System Director of Research Integrity & Compliance:**

- Serves as the overall administrator for the HRPP and is responsible for ensuring that the IRBs function and operate in compliance with all federal, state, and local laws and regulations that govern the protection of human subjects in the conduct of research.
- Notifies the Vice President for Research & Innovation and as applicable, other administrative and affiliated officials of any injury, breach of trust, unanticipated problems involving risks to subjects or others, serious or continuing non-compliance with requirements by research investigators, or suspension of IRB approval.

- Investigates all issues of undue influence or threats of retaliation directed to the IRB members and staff and provides recommendations for resolution to the Vice President for Research & Innovation.
- Presents an annual report to the Vice President regarding the status of the HRPP programs that includes review of resources, continuity of IRB operations, and adequacy of scientific and professional expertise available to carry out requirements of the HRPP.
- Delegates operational authority to the USF System HRPP Manager as appropriate.

**Authorized and signed by:**

**Karen A. Holbrook, Vice President for Research & Innovation**  
**Judy Genshaft, President**