

# HUMAN RESEARCH PROTECTION PROGRAM PLAN

HRP 101  
June 2017



**Human Research Protection Program**  
**UNIVERSITY OF GEORGIA**

706-542-3199 | [irb@uga.edu](mailto:irb@uga.edu) | <https://research.uga.edu/hso/>

---

# Table of Contents

Scope.....	2
Purpose.....	2
Definitions .....	2
<i>Agent</i> .....	2
<i>Clinical Trial</i> .....	2
<i>Engaged in Human Research</i> .....	2
<i>Human Research</i> .....	2
<i>Human Subject as Defined by DHHS</i> .....	3
<i>Human Subject as Defined by FDA</i> .....	3
<i>Investigator</i> .....	3
<i>Research as Defined by DHHS</i> .....	3
<i>Research as Defined by FDA</i> .....	4
Mission .....	4
<i>Ethical Principles</i> .....	4
<i>Legal and Regulatory Requirements</i> .....	5
<i>Other Requirements</i> .....	5
<i>Sponsored Human Research</i> .....	6
<i>Scope of Human Research Protection Program</i> .....	6
<i>Human Research Protection Program Policies and Procedures</i> .....	6
Human Research Protection Program Components .....	6
<i>Institutional Official</i> .....	6
<i>All Members of the Institution</i> .....	7
<i>IRBs</i> .....	8
<i>Human Subjects Office (HSO)</i> .....	8
<i>Investigators and Research Team Members</i> .....	8
<i>Legal Counsel</i> .....	9
<i>Deans/Department Chairs</i> .....	9
<i>Sponsored Projects Administration</i> .....	9
<i>Research Integrity Officer and Conflict of Interest Committee</i> .....	9
Education and Training .....	10
Questions and Additional Information for the IRB .....	10
Reporting and Management of Concerns .....	10
Monitoring and Auditing.....	11
Disciplinary Actions .....	11
Approval and Revisions to the Plan.....	12

## Scope

Throughout this document “Institution” refers to the University of Georgia.

## Purpose

The University of Georgia (UGA) is committed to protecting the rights and welfare of human subjects in research. The purpose of this plan is to describe UGA’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research. UGA’s Human Research Protection Program (HRPP) is a comprehensive system designed and implemented to ensure the Institution meets its obligation to protect the rights and welfare of human subjects in its research activities.

## Definitions

### ***Agent***

An individual is an “agent” of the Institution if, in the performance of Human Research, the individual (a) acts on behalf of the institution; (2) exercises institutional authority or responsibility; and/or (3) performs institutionally designated activities.

### ***Clinical Trial***

A biomedical or behavioral research study of human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new diagnostic procedures or therapeutic interventions are safe, efficacious, and effective.

### ***Engaged in Human Research***

In general, UGA is considered engaged in a human subjects research activity when its employees or agents: (1) intervene or interact with living individuals; or (2) obtain individually identifiable private information about the subjects of the research. This Institution follows *OHRP Guidance on Engagement of Institutions in Human Subjects Research* to determine if it is engaged in human subjects research.

### ***Human Research***

Any activity that either:

- Is “Research” as defined by the Department of Health and Human Services (DHHS) and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or

- Is “Research” as defined by the Food and Drug Administration (FDA) and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

### ***Human Subject as Defined by DHHS***

A “human subject” is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

- **Intervention** means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

### ***Human Subject as Defined by FDA***

A “human subject” is an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whom or on whose specimen (identified or unidentified) a medical device is used.

### ***Investigator***

The “investigator” is the person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals, the investigator is the responsible leader of the team and is usually referred to as the Principal Investigator.

### ***Research as Defined by DHHS***

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

### ***Research as Defined by FDA***

Research is any experiment that involves a test article and one or more human subjects, and must meet any one of the following:

- The requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act, meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- The requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act, meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

### **Mission**

The mission of the University of Georgia's Human Research Protection Program is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Institution.

### ***Ethical Principles***

In the oversight of all Human Research, the University of Georgia follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report":

- Respect for Persons
- Beneficence
- Justice

The following categories of individuals are expected to abide by these ethical requirements:

- Investigators
- Research Team Members
- Institutional Review Board (IRB) Members and Chair
- Human Subjects Office (HSO)/IRB Staff
- The Institutional Official
- Employees

## ***Legal and Regulatory Requirements***

The University of Georgia commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research activities must undergo review by the IRB. Activities that meet the definition of Human Research are reviewed using the applicable Worksheets and Checklists located in the IRB Portal.

Activities that do not meet the definition of Human Research do not require review and approval by the IRB and do not need to be submitted in the IRB Portal unless a determination is needed whether the activity is Human Research. For additional information, see *Policy and Procedure: Determination of Human Subject Research*.

When UGA is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Institution commits to apply the relevant regulations of that agency to the protection of Human Subjects.

When UGA is engaged in FDA Human Research, this Institution commits to apply the relevant FDA regulations to the protection of Human Subjects.

## ***Other Requirements***

All policies and procedures are applied equally to all Human Research regardless of whether the research is conducted domestically or in other countries.

UGA may agree to follow the “International Council on Harmonization – Good Clinical Practice E6 (ICH-GCP)” for clinical trials where required by a sponsor.

This Institution prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”).

When Human Research is conducted or funded by the following federal agencies, the Institution commits to comply with associated regulation:

- Department of Justice (DOJ) - 28 CFR §22.
- Bureau of Prisons (BOP/DOJ) - 28 CFR §512. [Note that for research conducted within the Bureau of Prisons, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.]
- Department of Defense (DOD) - DOD Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D. Department of the Navy - SECNAVINST 39000.39D.
- Department of Education (ED) - 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

- Department of Energy (DOE) - DOE O 443.1A and to use “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the Department of Energy (DOE) Requirements.”
- Environmental Protection Agency (EPA) or when the results of research are intended to be submitted to or held for inspection by EPA - 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

### ***Sponsored Human Research***

For both sponsored and non-sponsored Human Research, UGA abides by its ethical principles, regulatory requirements, and its policies and procedures.

### ***Scope of Human Research Protection Program***

All forms of Human Research are overseen except for Research conducted or funded by the Veterans Administration (VA).

### ***Human Research Protection Program Policies and Procedures***

Policies and procedures for the HRPP are available on the following Web site <http://research.uga.edu/hso/irb-guidelines/>.

## **Human Research Protection Program Components**

### ***Institutional Official***

The Vice President for Research is designated as the Institutional Official.

The Institutional Official has the authority to take the following actions or delegate these authorities to the Associate Vice President for Research Compliance:

- Create the HRPP budget
- Allocate resources within the HRPP budget
- Appoint and remove IRB members and IRB Chairs
- Hire and fire HSO staff
- Determine what IRBs the Institution will rely upon
- Approve and rescind authorization agreements for IRBs
- Place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research
- Create policies and procedures related to the HRPP that are binding on the Institution
- Suspend or terminate research approved by the Institution’s IRB
- Disapprove research approved by the Institution’s IRB

The Institutional Official has the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the HRPP
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirements
- Ensure the provision of regular, effective, educational and training programs for all individuals involved with the HRPP
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Institution cannot approve research that has not been approved by the IRB
- Implement a process to receive and act on complaints and allegations regarding the HRPP
- 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 HRPP
- Ensure that the HRPP has sufficient resources, including that the IRB is 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 (FWA) and addenda
- Fulfill educational requirements mandated by OHRP

### ***All Members of the Institution***

All individuals within the Institution have the responsibility to:

- Be aware of the activities that meet the definition of Human Research
- Consult the IRB 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 the IRB
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the Institutional Official
- Report allegations or findings of non-compliance with the requirements of the HRPP to the IRB

Individuals who are responsible for business development are prohibited from serving as IRB Members and from carrying out day-to-day operations of the review process.



## ***IRBs***

All Human Research is reviewed by UGA's IRB, unless UGA has entered into an authorization agreement with an external institution that has a federal wide assurance (FWA), and whose IRB is judged by UGA's HSO Director to be qualified to review the research.

Reliance on an external IRB for non-exempt Human Research requires an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU), and a local review for compliance with UGA's institutional policies. For additional information, see *Policy and Procedure: Reliance on an External IRB*.

The UGA IRB and IRBs relied upon by UGA have the authority to:

- Approve, require modifications to secure approval, and disapprove Human Research overseen and conducted by the Institution. All Human Research must be approved by an IRB. Officials of this Institution 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 an 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 HSO/IRB staff have the responsibility to follow HRPP policies and procedures that apply to IRB members and staff.

## ***Human Subjects Office (HSO)***

The Human Subjects Office or IRB Office is the coordinating office for the HRPP. It facilitates the IRB review process, provides education and training, and conducts post-approval monitoring.

## ***Investigators and Research Team Members***

Investigators and research staff have the responsibility to:

- Follow the HRPP requirements described in the *INVESTIGATOR MANUAL (HRP-103)*.
- Follow the HRPP policies and procedures that apply to IRB members and staff.

- Comply with all determinations and additional requirements of the IRB, the IRB Chair, and the Institutional Official.

### ***Legal Counsel***

Legal Counsel has the responsibility to:

- Provide upon request legal advice to the Institutional Official, IRB, and other individuals involved with the Institution's HRPP.
- Assist in determining whether an individual is performing Human Research as an agent of the Institution when there is uncertainty or disagreement.
- Determine the applicable definitions of "legally authorized representative," "children," and "guardians" when necessary for Human Research conducted in jurisdictions not addressed by Institution's policies and procedures.
- Provide legal advice to assist in resolving conflicts among applicable laws and regulations relevant to Human Research.

### ***Deans/Department Chairs***

Deans and Department Chairs have the responsibility to:

- Ensure the review and conduct of Human Research in their department or school.
- Forward complaints and allegations regarding the HRPP to the Institutional Official.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

### ***Sponsored Projects Administration***

UGA's Sponsored Projects Administration has the responsibility to ensure that grants or funding proposals involving Human Research has received IRB review and approval prior to the commencement of Human Research activities.

### ***Research Integrity Officer and Conflict of Interest Committee***

The Institution's Research Integrity Officer evaluates or ensures that the Institution's Conflict of Interest Committee evaluates any conflict of interest with the conduct of Human Research as defined by UGA Policy on Conflicts of Interest in Sponsored Projects.

The IRB has the final authority to determine whether conflicts of interest and its management allow the research to be approved. For additional information, see *Policy and Procedure: Financial Conflicts of Interests*.

## Education and Training

All new HSO/IRB Staff members are to review this plan as part of initial employee orientation.

Investigators, Research Team Members, IRB Members, and HSO/IRB Staff must complete the applicable modules in the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Training is valid for five-years, after which time a refresher CITI course must be completed. However, NIH-funded investigators and research staff who are involved in clinical trials are required to maintain their Good Clinical Practice (GCP) training every three years through the CITI refresher course. This training can be accessed at <http://research.uga.edu/hso/citi-training/>.

HSO/IRB Staff also train IRB members on the SOPs, Checklists, and Worksheets applicable to IRB members including regulatory and guidance requirements noted in the section “Other Requirements.”

## Questions and Additional Information for the IRB

The IRB Office seeks your questions, information, and feedback. Contact and location information is below:

Human Subjects Office  
Tucker Hall  
University of Georgia  
310 East Campus Road, Athens, GA 30602-1589  
Email: [irb@uga.edu](mailto:irb@uga.edu)  
(706) 542-3199

## Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, Institutional Official, Research Integrity Officer, Legal Counsel, Deans, or Department Chairs.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Institutional Official or the Associate Vice President

for Research Compliance has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report possible compliance issues in good faith should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or the Associate Vice President for Research Compliance.

To make such reports, contact:

David Lee, Ph.D.  
Vice President for Research and Institutional Official  
University of Georgia  
150B Coverdell Center, Athens, GA 30602  
706.542.5969  
Email: [dclee@uga.edu](mailto:dclee@uga.edu)

Or

Christopher King  
Associate Vice President for Research Compliance  
University of Georgia  
214 Tucker Hall, Athens, GA 30602  
706.542.4016  
Email: [cking@uga.edu](mailto:cking@uga.edu)

## **Monitoring and Auditing**

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and Institutional requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

## **Disciplinary Actions**

The Institutional Official may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the Institutional Official such actions are required to maintain the Human Research Protection Program.

## **Approval and Revisions to the Plan**

The Institutional Official, as well as the UGA Associate Vice President for Research Compliance, have both reviewed and approved this Human Research Protection Program plan. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Associate Vice President for Research Compliance has the responsibility to review this plan periodically to assess whether it is providing the desired protections of research subjects in a fully compliant, ethical, and efficient manner, and to initiate modifications as needed.