

HUMAN RESEARCH PROTECTION PROGRAM PLAN

HRP 101
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Human Research Protection Program
UNIVERSITY OF GEORGIA

706-542-3199 | irb@uga.edu | <https://research.uga.edu/hrpp/>

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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 strategy 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 research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Engaged in Human Research

In general, UGA is considered engaged in a human subjects research activity when its employees or agents obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for 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: (i) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For this definition:

- **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** includes communication or interpersonal contact between investigator and subject.
- **Private Information** includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- **Identifiable Information** is private information for which the subject's identity is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen is a biospecimen for which the subject's identity is or may readily be ascertained by the investigator or associated with the biospecimen.

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 HHS regulations at 45 CFR part 46 use the term "investigator" to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. If a team of individuals conducts Human Research, the

investigator is the responsible leader of the team and is usually referred to as the Principal Investigator. The "Lead Investigator" is the person responsible for the conduct of the Human Research at one or more sites.

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.

The FDA has defined "clinical investigation" to be synonymous with "research."

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 this Institution oversees.

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 including students
- Institutional Review Board (IRB) Members and Chairs
- Human Subjects Office (HSO)/IRB Staff
- The Institutional Official
- Employees

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

Legal and Regulatory Requirements

- All exempt Human Research must receive determination by the HRPP.
- All non-exempt Human Research activities must undergo review by the IRB.
- Activities that do not meet the definition of 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 required whether the activity is research involving human subjects. For additional information, see *Policy and Procedure: Determination of Human Subject Research*.
- When UGA is engaged in Human Research conducted, funded, or otherwise subject to regulations by a federal department or agency that is a signatory of the Common Rule, this Institution commits to apply the relevant regulations of that agency to the protection of Human Subjects. UGA applies different requirements as described in HRPP policy and procedures to research that is not DHHS regulated.
- When UGA is engaged in FDA Human Research, this Institution commits to apply the relevant FDA regulations to the protection of Human Subjects.
- UGA applies the revised Common Rule only to research approved after January 21, 2019.

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.
- When serving as the reviewing IRB for other entities, UGA IRB will conduct a review of the research, including initial review, continuing review, and review of modifications to previously approved research, to determine if that research is ethically justifiable and is conducted according to all applicable regulations and laws.
- The European Union has passed a data privacy regulation applicable throughout the entire European Union ("EU") and to those who collect personal data about people in the EU. The European Union General Data Protection Regulation ("EU GDPR") imposes obligations on entities, like the University of Georgia, that collect or process Personal

Data about people in the EU. The EU GDPR applies to Personal Data collected or processed about *anyone located in the EU*, regardless of whether they are a citizen or permanent resident of an EU country. The UGA Enterprise Information Technology Services (EITS) policy on GDPR can be found on their website:

https://eits.uga.edu/access_and_security/infosec/pols_regs/policies/eu_gdpr/

- 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 was 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 research.]
 - Department of Defense (DOD) - DOD Directive 3216.02, 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 , 10 CFR 745.103, DOE Directive DOE O 443.1B and ethical standards outlined in the Human Subjects Protection (HSP) Resource Book – [https://science.energy.gov/~media/ber/human-subjects/pdf/education-and-resources/doeresources/DOE_HSR_Resource_Book_2012_Update.pdf], and the DOE Requirements for Protecting Personally Identifiable Information [<https://science.energy.gov/ber/human-subjects/regulations-andrequirements/>] M 471.3-1; and DOE M 205.1-8) 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 research results 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 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
<https://research.uga.edu/hrpp/policies-and-procedures/>.

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 following 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 the IRB has not approved
- 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 remove individuals from involvement in the HRPP
- Ensure that the HRPP has sufficient resources, including that the number and constitution of IRBs, conflict of interest review, quality improvement program, and sponsored programs, appropriate for the volume and types of Human Research to be reviewed, so that key critical functions 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 undertaken 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 responsible for business development are prohibited from serving as IRB Members and from carrying out the review process's day-to-day operations.

IRBs

All non-exempt Human Research is reviewed by one of UGA's IRB, unless UGA has entered into an authorization agreement with an external institution with a federal wide assurance (FWA), and whose IRB is judged by UGA's HSO Director as 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. Officials of this Institution may not approve Human Research that the IRB has not approved.
- Suspend or terminate approval of Human Research not being conducted according to an IRB's requirements or 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.
- Determine if an activity is exempt from regulation.
- 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 are responsible for following 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. In addition, the Human Subjects Office Director is responsible for registering IRBs when required by regulatory agencies using the process in HRPP policy: [IRB Formation](#).

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 IRB requirements, 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 is responsible for ensuring that grants or funding proposals involving Human Research have received IRB review and approval before the commencement of Human Research activities.

Director, Conflicts of Interest Review and Management (COI Director) and Conflict of Interest Committee

The Institution's COI Director 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 and all HRPP Policies and Procedures 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 involved

in clinical trials must maintain their Good Clinical Practice (GCP) training every three years through the CITI refresher course. This training can be accessed at <https://pep.uga.edu/>.

HSO/IRB Staff also train IRB members on the Policies and Procedures, 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
(706) 542-3199

Reporting and Management of Concerns

Questions, concerns, complaints, allegations or findings of non-compliance, or input regarding the HRPP may be reported by any individual orally or in writing. Allegations of undue influence may be reported by individuals responsible for the oversight of human research orally or in writing. In addition, 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 is responsible for investigating all other reports and taking corrective actions as required.

Employees who report possible compliance issues in good faith should not be subjected to retaliation or harassment due to 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:

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

Employees and investigators should notify the Institutional Official or the IRB Office of any negative actions by a government oversight office, any litigation, arbitration, or settlements related to human research protections, and any negative press coverage regarding the HRPP. These notifications should be made as soon as possible to allow the IRB Office to report the information to AAHRPP within 48 hours.

Monitoring and Auditing

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. For-cause 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.

All open research studies are tracked through the electronic IRB Portal, including determinations of not-human research, developmental activities, and those studies under the oversight of external IRBs. Records are maintained and archived according to the HRPP Policy: [IRB Records and Records Retention](#).

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 and the UGA Associate Vice President for Research Compliance Integrity & Safety 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. Therefore, the Associate Vice President for Research Integrity & Safety has the responsibility to review this plan periodically. This review assesses whether

the plan provides the desired protections of research subjects in a fully compliant, ethical, and efficient manner and identifies needed changes.