



Human Research Protection Program

Plan

Dated: September 4, 2014



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Scope

Throughout this document “Organization” refers to University of Miami.

Purpose

This Organization is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Organization’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Organization’s Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program is based on all individuals in this Organization along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Definitions

Agent

An individual who is an employee is considered an agent of this Organization for purposes of engagement in Human Research when that individual is on-duty in any capacity as an employee of this Organization.

An individual who is not an employee is considered an agent of this Organization for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this Organization.

Volunteer Policy A040 outlines the requirements for individuals who perform services directly related to the business of the University but who are not employees of the institution.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Organization.

Clinical Trial

A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

Phase I. Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).

Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.



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Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Engaged in Human Research

In general, this Organization is considered engaged in Human Research when this Organization's employees or agents for the purposes of the Human Research 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 Organization follows OHRP guidance on "Engagement of Institutions in Research"¹ to apply this definition and exceptions to this definition.

Human Research:

Any activity that either:

- Is "Research" as defined by DHHS and involves "Human Subjects" as defined by DHHS ("DHHS Human Research"); or
- Is "Research" as defined by FDA and involves "Human Subjects" as defined by FDA ("FDA Human Research").

Human Subject as Defined by DHHS

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).

¹ <http://www.hhs.gov/ohrp/policy/engage08.html>



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- **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

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 whose specimen (identified or unidentified) a medical device is used.

Investigator

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 at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.²

Research as Defined by FDA

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet 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;
- Must meet 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 Miami HRPP is:

- to promote the rights and welfare of participants in human subject research
- to facilitate excellence in human subject research, and

² 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.



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- to provide high quality education, monitoring, and quality assurance for human subject research

The University of Miami HRPP adheres to the principles of [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research](#).

Ethical Requirements

In the oversight of all Human Research, this Organization (including its investigators, research staff, students involved with the conduct of Human Research, the Organization’s Institutional Review Boards (IRBs), IRB members and chairs, IRB staff, the Institutional official, and employees) 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

Legal Requirements

This Organization commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research must undergo review by one of the organizationally designated IRBs. Activities that do not meet the definition of Human Research do not require review and approval by one of the Organization’s IRBs and do not need to be submitted to one of the Organization’s IRBs unless there is a question regarding whether the activity is Human Research.

When this Organization 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 Organization commits to apply the regulations of that agency relevant to the protection of Human Subjects.

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

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the Human Subject Research Office as defined in the Investigator Manual.

Other Requirements

When reviewing research that involves community based research, the IRB obtains consultation or training.

All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research



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- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and language considerations
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

For clinical trials, this Organization commits to apply the “International Conference on Harmonisation – Guideline for Good Clinical Practice E6.” (ICH-GCP)

This Organization 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 Department of Justice (DOJ), this Organization commits to apply 28 CFR §22. When Human Research is conducted with the Federal Bureau of Prisons (BOP), the Organization commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), this Organization commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D³. This Organization will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.

When Human Research is conducted or funded by the Department of Education (ED), this Organization commits to applying 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.

When Human Research is conducted or funded by the Department of Energy (DOE), this Organization commits to applying the Department of Energy (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.”

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Organization commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

³ Quick applicability table for DHHS Subparts:

	DHHS	DOD	ED	EPA
Subpart B	X	X		X
Subpart C	X	X		
Subpart D	X	X	X	X



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Sponsored Human Research

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

Scope of Human Research Protection Program

The categories of Human Research overseen include:

- International research
- Research conducted or funded by the Department of Defense (DOD)
- Research conducted or funded by the Department of Education (ED)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Energy (DOE)
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.
- Research involving *in vitro* fertilization.
- Federally funded research
- Research involving fetuses.
- FDA-regulated research.
- Research involving drugs that require an IND.
- Research involving devices that require an abbreviated IDE.
- Research involving devices that require an IDE issued by FDA.
- Investigator held abbreviated IDE.
- Investigator held IND or IDE.
- Research involving pregnant women as subjects.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving children as subjects.
- Emergency use of a test article in a life threatening situation.
- Activities involving humanitarian use devices.
- Research using the short form of consent documentation.
- Classified Research (Classified research is secret research to which access is restricted by law to a particular hierarchical class of people. A security clearance is required to review classified research.).

The categories of Human Research not overseen include:

- Research conducted or funded by the Veteran Administration (VA)
- Research involving a waiver of consent for planned emergency research.

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available on the following Web site: www.hsro.miami.edu.



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Human Research Protection Program Components

Institutional Official

The Vice Provost for Research is designated as the Institutional Official.
 The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire research review staff.
- Determine what IRBs the Organization 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 Human Research Protection Program that are binding for the Organization.
- Suspend or terminate research approved by one of the Organization’s IRBs.
- Disapprove research approved by one of the Organization’s IRBs.

The Institutional Official has the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- 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 requirement.
- Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
- 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 one of the IRBs designated by the Organization.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- 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 Research protection program.
- Ensure that the Human Research 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 (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.



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All members of the Organization

All individuals within the Organization have the responsibility to:

- Be aware of 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 an IRB designated by the Institutional Official.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Institutional Official.
- Report allegations or findings of non-compliance with the requirements of the Human Research Protection Program to the IRB.

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

IRBs

The list of IRBs designated by the Institutional Official to be the IRBs relied upon by the Human Research Protection Program and the scope of review of these IRBs is listed in the IRB rosters available from the Human Subject Research Office (HSRO). The Associate Vice Provost of Human Subject Research provides day-to-day oversight of the HSRO and IRBs.

This Organization may rely upon IRBs of another organization provided one of the following is true:

- The IRBs are part of an AAHRPP accredited organization.
- This Organization's investigator is a collaborator on Human Research that is primarily conducted at another organization and the investigator's role does not include interaction or intervention with subjects.
- The Organization is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

Reliance on an external IRB requires an Institutional Agreement for IRB review (IAIR) and a local review for compliance with local policies of the organization.

The UM IRBs and IRBs relied upon by this Organization 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 one of the IRBs designated by the Institutional Official. Officials of this Organization may not approve Human Research that has not been approved by one of the Organization's IRBs.
- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects.



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- 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 whether Human Research is exempt according to Subpart A, Subpart B and Subpart D of the DHHS regulations.
- Confirm that a test article has an IND, IDE, or meets an exemption.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan defined by the Institutional Conflict of Interest Committee (ICOIC), if any, allow the Human Research to be approved.

The IRBs are informed of additional considerations for Human Research studies by ancillary committees designated by the Organization to review the studies. These components of the HRPP provide support to researchers in the protection of Human Research participants. Components communicate with each other based on the particular needs of Human Research proposals. Communication is done via the IRB electronic protocol submission and tracking system, in-person meetings, or via email and conference calls.

IRB members and HSRO staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
- Comply with all determinations and additional requirements of the IRB, the IRB chair, the Associate Vice Provost for Human Subject Research, and the Institutional Official.

Legal Counsel

In addition to compliance with federal regulations, the University of Miami and its IRBs are committed to compliance with applicable state and local laws. In taking these and federal regulations into account in its review and oversight of human subject research, the IRB may seek guidance from attorneys in the UM Office of General Counsel especially when there appears a need for resolution of differences among federal, state and local laws. UM legal counsel shall advise the IRB on any issue/concern that the IRB believes is appropriate to its responsibilities for human subject protection in research.

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Official, IRB, and other individuals involved with the Human Research Protection Program.



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- Provide advice on the application of laws relevant to Human Research based on the localities where UM researchers conduct Human Research.
- Determine whether someone is acting as an agent of the Organization.
- Determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

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

Office of Research Administration

The Office of Research Administration has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

Education and Training

All new employees engaged in Human Research are to review this plan as part of initial orientation. The Human Subject Research Office is to provide refresher training to current employees as needed to maintain awareness of this policy.

Investigators and research staff must complete the initial and continuing training described in the INVESTIGATOR MANUAL (HRP-103) and as defined below.

Upon initial involvement in Human Research, investigators and research staff involved in the design, conduct, or reporting of the research must complete at least one of the four “Core” courses of the Collaborative Institutional Training Initiative (CITI) human subject online training program. Human research protections certification from other equivalent programs may be approved by the Associate Vice Provost for Human Subject Research. Upon successful completion of the appropriate CITI course, research personnel will be “CITI-certified” for a period of two years. Re-certification is required within two years of the initial CITI-certification.

Investigators new to clinical research at UM must also complete the New Investigator training offered by the Office of Clinical Research Operations and Regulatory Support (CRORS), when applicable, prior to IRB approval of the Human Research.

IRB members, HSRO staff, and others involved in the review of Human Research must complete initial and continuing training defined within the CITI program (Group 5). IRB members who are not Human Research investigators and HSRO staff who complete Group 5



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training will be "CITI-certified" for a period of three years. Re-certification is required within three years of the initial and/or last CITI-certification. HSRO staff and others who are not Human Research investigators and who are Certified IRB Professionals (CIP) are exempt from the CITI re-certification requirement as CIP re-certification is required every three years. The HSRO reviews CITI certification for all Human Research personnel at the time of initial and continuing review, and at the time a modification is submitted to add new research personnel. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects. The HSRO will not release approval documents until documentation that all study personnel have current CITI certification or have otherwise completed the training requirements.

Questions and Additional Information for the IRB

The Human Subject Research Office wants your questions, information, and feedback. Contact and location information for the Human Subject Research Office is:

Amanda Coltes-Rojas
 Director of Regulatory Affairs
 Suite 1002
 1500 NW 12th Avenue
 Miami, FL 33136
 Email: acoltes@med.miami.edu
 (305) 243-3195

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees may use 'Cane Watch' to report concerns on an anonymous basis via the web or by telephone at 877-415-4357. Concerns may be reported to the Associate Vice Provost for Human Subject Research, the Vice Provost for Research or any other compliance official.

The Institutional Official and/or IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Institutional Official has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report in good faith possible compliance issues 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 designee.

To make such reports, contact:

John Bixby
 Vice Provost for Research
 Dominion Towers 1205J-R64
 1400 NW 10th Avenue
 Miami, FL 33136



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Email: jbixby@miami.edu
Phone: (305) 243-7587
Fax: (305) 243-3549

Auditing

To ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and Institutional requirements will conduct periodic audits. Internal compliance audits are conducted by the Office for Research Compliance and Quality Assurance (RCQA). 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

This Human Research Protection Program Plan is to be approved by the Vice Provost for Research (Institutional Official), University of Miami. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the Institutional Official, the Associate Vice Provost for Human Subject Research has the authority to amend this plan as deemed necessary.

Approved:

John L. Bixby, PhD
Vice Provost for Research, University of Miami
9/4/2014