Human Research Protection Program

Plan[1]

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[1] This document satisfies AAHRPP elements I.1.A-G, I-2, I-3, I.4.B-C, I.5.A, I.5.C, I.5.D, I.6.B, I.7.A, I.7.C, I-9, II.1.B, II.2.C, II.2.G, II.2.H, II.2.E-II.2.E.2, II.3.C-II.3.C.1, II.3.E, II.3.F, III.1.A, III.1.C, III.2.A, III.2.D

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Scope

Throughout this document "Institution" refers to University of Miami.

Purpose

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

This Institution's Human Research Protection Program 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 Institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Definitions

Agent

An individual who engages in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this Institution.

Clinical Trial

Refer to HRP-001: SOP Definitions and HRP-103: Investigator Manual.

Engaged in Human Research

Refer to HRP-001: SOP Definitions and HRP-103: Investigator Manual.

Human Research

Refer to HRP-001: SOP Definitions and HRP-103: Investigator Manual.

Human Research as Defined by DHHS

Refer to HRP-001: SOP Definitions and HRP-103: Investigator Manual.

Human Research as Defined by FDA

Refer to HRP-001: SOP Definitions and HRP-103: Investigator Manual.

Mission

The mission of this Institution's Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Institution.

Ethical Requirements

In the oversight of all Human Research, this Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution's institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional

Official/Organizational Official (IO/OO), and employees) will adhere to all ethical, regulatory and legal requirements for human research.

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

Legal Requirements

When this Institution 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 regulations of that agency relevant to the protection of Human Subjects.

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

All Human Research must undergo review by one of the institutionally registered IRBs or IRB-Designee. If activities do not meet the definition of Human Research, refer to HRP-103: Investigator Manual.

Other Requirements

If the Human Research requires additional regulatory and legal considerations, the institution will apply rules as necessary. Refer to HRP-103: Investigator Manual for more details on additional requirements.

Sponsored Human Research

For both sponsored and non-sponsored Human Research this Institution abides by its ethical principles, regulatory requirements and its policies and procedures. Refer to HRP-103: Investigator Manual.

The categories of Human Research not overseen include:

- Research conducted or funded by the Veteran Administration (VA)
- 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.)

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program can be found here.

Human Research Protection Program Components

Institutional Official/Organizational Official (IO/OO)

The Vice Provost for Research and Scholarship is designated as the IO/OO.

The IO/OO 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 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 Human Research Protection Program that are binding on the Institution.
- Suspend or terminate research approved by one of the Institution's IRBs.
- Disapprove research approved by one of the Institution's IRBs.
- Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the studies in an emergency/disaster scenario (e.g., natural disasters, man-made disasters, infectious disease pandemics, etc.).

The IO/OO 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 Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- Ensure that the IRB Chair(s) and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.

- Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.
- 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.

IRBs

The list of IRBs designated by the IO/OO 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 HSRO. IRB members and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

Relying on an External IRB

Refer to HRP-103 - INVESTIGATOR MANUAL.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in HRP-103 - INVESTIGATOR MANUAL.
- Comply with all determinations and additional requirements and regulatory authorities of the IRB, the IRB chair, and the IO/OO.
- Develop and implement emergency/disaster response procedures for their research depending on location and nature of the research.
- Different sites have different rules and expectations. Know your site and follow appropriate guidelines.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide consult upon request to the IO/OO, IRB, and other individuals involved with the Human Research Protection Program.
- 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.

Department Chairs

Department Chairs have the responsibility to:

- Oversee faculty, staff, students, and visitors engaged in research in the department/center/institute/program in their department or school. This includes, but not limited to, ensuring protocol quality, timeliness, accountability, responsiveness, and oversight of students, when applicable.
- Ensure research objectives of the department, school, and University are consistent.
- Forward complaints and allegations regarding the Human Research Protection Program to the IO/OO.
- Ensure that each Human Research study conducted in their department or school has adequate resources. The Department Chair's approval of a protocol avers that (a) this research is adequate to move forward and (b) the PI has the capacity and the time to conduct the research in keeping with Human Subjects Protections standards.

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

This plan is made available to the human research community via the HSRO website and HRP-103: Investigator Manual. To maintain awareness of Human Research Protection Program policies and procedures, new information, revised materials and opportunities for continuing education are communicated to the Institution by way of various email list-serve groups targeted to appropriate audiences.

IRB members, IRB staff, and others involved in the review of Human Research, including the IO/OO, must complete initial and continuing training utilizing the Collaborative Institutional Training Initiative (CITI) human subjects online training program or Certified IRB Professional (CIP) successful licensure. Training is valid for a three-year period, after which time refresher training must be completed. If training was obtained via CIP, refer here for maintaining licensure.

Investigators research staff, and community health workers or other community members must complete the initial and continuing training. Additional training modules may be required based on the type of research. All training requirements are described in HRP-103 - INVESTIGATOR MANUAL.

Emergency Preparedness

The organization routinely assesses potential emergency scenarios and threats to the institution to improve its emergency preparedness and response plan. The organization is responsible for notifying research teams when the organization's emergency response plan is activated. Depending on the nature of the event, the HSRO Director will collaborate with institutional

leadership to determine the types of research that might continue and the types that the organization may need to temporarily postpone. Human Research Protection Program staff will also coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the organization. The organization proactively identifies external IRBs on which it can rely on temporarily during an emergency.

For more information on emergency preparedness refer to HRP-065: SOP: Response Plan for Emergencies-Disasters Impacting the HRPP, HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning and HRP-352: WORKSHEET: Additional Emergency-Disaster Review Considerations.

Questions and Additional Information for the IRB

The HSRO welcomes your questions, information, and feedback. You may find information on HSRO staff, office hours and resources here.

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 are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, HSRO, IO/OO, Legal Counsel or Department Chairs.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The IO/OO 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 because of the reporting. Concerns about possible retaliation should be immediately reported to the IO/OO or designee.

To make such reports, contact the IO/OO at Vice Provost for Research + Scholarship.

Monitoring and Auditing

Internal or external auditors who have expertise in federal and state statutes, regulations and institutional requirements may conduct periodic audits to monitor and ensure compliance. 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 IO/OO may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the IO/OO 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 President of this institution. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO/OO has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the IO/OO, the President has the authority to amend this plan as deemed necessary.

Approved:

Julio Frenk, M.D.
President
<Date>