University of the Virgin Islands

Human Research Protection Program Policy

Policy Title: Human Research Protection Program Policy	**Policy Number:** OSP-002	
	Office of Accountability: Office of Sponsored Programs	
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SCOPE

The UVI IRB (Institutional Review Board) is an administrative body established to protect the rights and welfare of Human Subjects recruited to participate in Research activities conducted under the auspices of UVI. All human subject's research conducted at UVI is guided by the principles as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "Ethical Principles and Guidelines for the Protection of Human Subject of Research (Belmont Report)" and the Common Rule. The purpose of this document is to describe UVI's ethical and regulatory requirements for the conduct and oversight of human subject's research (whether funded or not funded).

POLICY STATEMENT

Institutional Authority & Commitment

UVI commits to institutional resources and infrastructure to the protection of Human Subjects. In so doing, the IRB has the authority to suspend or terminate research according to federal regulations.

All research conducted by the university's faculty members, staff members, and students that meets the federal definition of human subjects research must be reviewed and approved by the UVI IRB, or its designated reviewing authority, prior to any research engagement with human participants.

POLICY OBJECTIVES

- To safeguard and promote dignity and well-being of participants in research conducted at or by UVI by assuring their rights, safety and welfare are protected.
- To provide timely and high-quality review and monitoring of human subjects research.
- To facilitate excellence in human subjects research by providing accurate guidance and education to UVI investigators, IRB members, and research officials.
- To ensure compliance with all regulatory and ethical obligations involved in Human Subjects Research conducted at or by UVI.

DEFINITIONS

<u>Human Subject</u>

A living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens or 2) obtains, uses, studies, analyzes or generates identifiable private information or

identifiable biospecimens. Human Subject under U.S. Food and Drug Administration research means an individual who is or becomes a participant in research, either as a recipient of the test article (medical device or drug) or as a control. A human subject includes an individual on whose specimen an investigational medical device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the U.S. Food and Drug Administration define the unidentified tissue specimens as human subjects.

Human Subjects Research

A systematic investigation about living individuals where information is obtained through intervention or interaction including research, development, testing, and evaluation designed to develop or contribute to general knowledge.

Federal Wide Assurance (FWA)

An FWA is the documentation of an institution's commitment to comply with Federal regulations and maintain policies and procedures for the protection of human subjects.

Intervention

Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction

Communication or interpersonal contact between investigator and subject.

Institutional Review Board (IRB)

The IRB is a committee used in research that has been formally designated to approve, monitor, and review biomedical, behavioral or other research involving human subjects.

Institutional Official (IO)

The Institutional Official is delegated the legal authority to represent UVI and all components listed on the UVI FWA on matters related to human research.

Principal Investigator (PI)

For the purposes of Institutional Review Board activities and this document, the principal investigator is the faculty member, post-doctoral associate, graduate student, medical student, or other suitably trained individual responsible for the conduct of a particular research project. Any given project may have additional co- or sub-investigators. Undergraduate students may not act as the principal investigator; the faculty supervisor must serve as the principal investigator and the undergraduate student is listed as a co-investigator.

Private Information

Information about behavior that occurs in a context in which an individual can reasonably exact 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.

Identifiable Private Information

Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable Biospecimen

A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Human Research Protections Administration (HRPA)

The HRPA consisting of the Institutional Official, Office of Sponsored Programs, and the Institutional Review Board Committee provides leadership in protection of the rights, welfare, and wellbeing of human subjects involved in research.

Protocol

A document that outlines the proposed research, including a research design that clearly states the objectives, background, methodology, and significance of the study.

U.S. Food and Drug Administration (FDA)

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. They also provide accurate, science-based health information to the public.

Governance Structure

The IRB is independent of the university and supported by the compliance function within the Office of Sponsored Projects. The Institutional Official is responsible for promoting an overall positive environment for human subjects' research at UVI and reports to the President.

ROLES AND RESPONSIBILITIES

1. **Principal Investigator**
    a) Submit fully detailed research plans.
    b) Ensure that no human subject is recruited or enlisted without prior informed consent.
    c) Take all necessary safeguards to minimize risks and to protect the interests of vulnerable populations.
    d) Maintain the confidentiality of human subject data.
    e) Promptly report, in writing and verbally to IRB Chairperson, IRB Coordinator, and OSP Director any injuries or other unanticipated problems.

f) Assure the adequate training of personnel including Human Subjects Training and Adverse Event procedures.
g) Adhere to high ethical standards; and
h) Read, electronically sign, and comply with the affirmations and certifications on the applicable IRB Application Form.

2. **Undergraduate Student Investigators** can serve as a Co-Investigator on human research protocol, but there must be a Faculty Member serving as the main Faculty Advisor/Principal Investigator of the project. The IRB cannot give retroactive approval to any project.

3. **Graduate Student Investigators** can serve as a Principal Investigator on human research protocol; however, the Faculty Advisor and/or Dissertation Chair must be listed and approve the IRB application. Data that is obtained without IRB approval may be deemed unusable for a Master's Thesis or PhD Dissertation. The IRB cannot give retroactive approval to any project.

4. **Faculty Advisors** are responsible for providing students with:
    a. Timely information and guidance regarding proposal preparation, conduct and responsibilities; and
    b. Information to foster responsible research conduct and compliance.

    In order to adhere to proper timelines in the preparation and conduct of research, it is imperative that faculty advisors:

        i. Complete the Human Subject training required by UVI and federal regulations.
        ii. Remain up to date with IRB procedures and policies as well as those of the Graduate School.

    It is important to note that delinquency in the submission of requested information and forms or approvals by a particular faculty advisor and his/her students may delay the review of IRB proposals; and

    Faculty Advisors are required to have the necessary expertise to advise and supervise students performing human subject research.

5. Office of Sponsored Programs shall:
a. Establish a formal process to monitor, evaluate and continually improve the protection of human research participants.
b. Educate investigators and research staff about their ethical responsibility to protect research participants.
c. When appropriate, intervene in research and/or respond directly to concerns of research participants.
d. Ensure that the research review process is independent and free of undue influence.
e. Maintain records of compliance actions as per the federal requirement.
f. Notify the investigators of all UVI IRB final protocol decisions and any ensuing stipulation as required; and

g. Report to the University President and the Institutional Review Board any deficiencies in research projects as a result of failures to adhere to the provisions in this Policy.

6. Institutional Review Board

a. Review and approve, require modification, disapprove, or table any research activity, including proposed changes in previously approved Human Subject Research.
b. Require that information given to subjects as part of the informed consent is in accordance with CFR 46.116 and documentation of informed consent in accordance with CFR 46.117, unless a waiver is issued.
c. Make determinations of eligibility for exempt, expedited and limited review procedures. Expedited review and limited review of research activities are not permitted where full board review is required.
d. Require progress reports from investigators, including continuing review at intervals appropriate to the degree of risk, but not less than once per year.
e. Suspend or terminate approval of research not being conducted in accordance with applicable federal regulations and/or IRB requirements, or that has been associated with unexpected serious harm to subjects.
f. Place restrictions on studies and/or ensure certification that Principal Investigators are qualified to conduct research.
g. Actively recruit and assure a sufficient number of alternates and categories required for membership.
h. Provide reports to the Vice President for Research or University President regarding any suspension, termination or restrictions occurring as a result of violations of this Policy.

7. Institutional Official

a. Oversee compliance with all applicable federal regulations and guidance, state law and institutional policies.
b. Signatory authority for the Federal Wide Assurance submitted by UVI to HRPA.
c. Serve as a knowledgeable point of contact for HRPA, FDA and other governmental and non-governmental agencies regarding human research protections.
d. Ensure effective institution-wide communication and guidance on human subject protection issues.
e. Oversee processes to ensure that investigators fulfill their responsibilities under applicable regulations.
f. May accept external IRB committee with evidence of approval from that external IRB after consultation with the IRB Chair
g. Investigate allegations of potential undue influence and take corrective actions as appropriate.
h. Facilitate participation by the research community in human subjects' protection educational activities.
i. Designate one or more IRBs that will review research covered by the UVI FWA;
j. Arrange for sufficient resources, space, and staff to support the IRB's review and record keeping duties.

k. Appoint/remove, with or without cause, either directly or through a designee, the IRB Chairperson and IRB committee members; and
l. Conduct an annual review of the Human Research Protection Program.

Complaints or Questions

Any concerns or complaints regarding IRB processes may be addressed to the Director of Compliance, the IRB Chair or the IO, and held in confidence.

RELATED INFORMATION

21 Code of Federal Regulations (CFR), Part 50, Protection of Human Subjects
21 Code of Federal Regulations (CFR), Part 56, Institutional Review Boards
21 Code of Federal Regulations (CFR), Part 312, Investigational New Drug Application
21 Code of Federal Regulations (CFR), Part 314, Application for FDA Approval to Market a New Drug
21 Code of Federal Regulations (CFR), Part 600, Biological Products
45 CFR Part 46 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

RELATED DOCUMENTS

University of Virgin Islands IRB Federal-Wide Assurance and IRB Registration