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## HUMAN SUBJECTS RESEARCH

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### **A. Purpose**

The University of Texas Rio Grande Valley (UTRGV) maintains a program for the protection of human subjects who are recruited for or participate in research conducted at UTRGV or by UTRGV investigators. This policy describes the ethical standards and institutional commitments applicable to the conduct of human subjects research, whether the research is conducted on or off UTRGV's physical campuses.

### **B. Persons Affected**

This policy applies to:

1. All UTRGV faculty, visiting faculty/researchers, staff, or students engaged in or assisting with research involving human subjects, internal or external to UTRGV, in connection with his or her institutional role.
2. All UTRGV faculty, visiting faculty/researchers, staff, or students responsible for administering human subject research, even when a subcontractor or collaborator not affiliated with UTRGV carries out all activities involving human subjects.
3. Any individuals not affiliated with UTRGV, who are conducting research involving the participation of UTRGV students, faculty, staff, or UTRGV patients as human subjects.

### **C. Policy**

1. UTRGV will maintain a human subject protection program conducted in compliance with applicable federal and state laws, regulations and UTRGV policies and procedures. Regulations governing human subject research include, but are not limited to, the Department of Health and Human Service and the Food & Drug Administration regulations for the Protection of Human Subjects (45 CFR 46 and 21 CFR 50, respectively) and those related to Institutional Review Boards (21 CFR 56).
2. UTRGV expects all human subjects research activities to be guided by the ethical principles of respect for persons, beneficence, and justice, as set forth in the [Belmont Report](#) of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979, created by the National Research Act (Pub. L. 93-348).
3. The Executive Vice President for Research, Graduate Studies and New Program Development is designated as the Institutional Official (IO) responsible for the human research protection program at UTRGV. The IO has the authority to delegate the performance of certain oversight and operational duties to one or more individuals.
  - a. The IO is responsible for establishing and enforcing relevant policies and procedures to ensure:
    - i. the protection of research participants and compliance with state and federal laws;
    - ii. the autonomy of the Institutional Review Board(s);

- iii. the human research protection program has sufficient resources for conducting activities under its jurisdiction;
  - iv. the number of IRB members is adequate to address the volume and types of human research to be reviewed;
  - v. an annual review of the human research protection program is conducted, including but not limited to, reviewing number and composition of the IRB depending on volume and types of research, and performance of IRB researchers and staff; and
  - vi. without limitation, other policies and procedures necessary to monitor, evaluate, and continually improve the protection of human research subjects.
- b. The IO has the authority to:
- i. create and approve policies and procedures, including those dealing with conflicts of interest, governing the human research protection program;
  - ii. establish or modify IRB(s);
  - iii. provide resources, including budgetary authority, for IRB(s);
  - iv. take action if persons responsible for the protection of human participants are unduly influenced;
  - v. suspend or terminate research including disapproving a protocol or research activity approved by the IRB; and
  - vi. place administrative sanctions on investigators for non-compliance, such as requiring investigators to undergo additional training as a condition of continuing research, or appointing independent persons to monitor ongoing research.
4. All research covered by this policy, whether funded or non-funded, will be reviewed and approved by an Institutional Review Board for the Protection of Human Subjects in Research (IRB) in accordance with applicable regulations. Research involving human subjects must not be performed unless federal and state regulations have been satisfied and a written certification of UTRGV IRB's review, reliance, or approval of the research is obtained.
- a. The IRB is an autonomous oversight committee responsible for the general oversight, evaluation, and compliance of UTRGV's human research protection program. The IRB is responsible for safeguarding the rights and welfare of subjects who participate in the research activity as well as ensuring compliance with UTRGV's policies and procedures.
- b. The IRB has the following authority:
- i. approve or rely on other IRB for approval, require modifications to secure approval, or disapprove all human subject research activities overseen and conducted by UTRGV or on its behalf;
  - ii. suspend or terminate approval of research not being conducted in accordance with IRB requirements or associated with unanticipated events related to research involving human subjects;

- iii. observe, or have a third party observe, the consent process; and
  - iv. observe, or have a third party observe, the conduct of research.
- c. The IRB has jurisdiction over all research involving human subjects, regardless of funding source or performance site, conducted under the auspices of UTRGV. The IO may enter into reliance agreements to rely on the IRB at other institutions and organizations for review, approval, and oversight of single projects or categories of projects. When UTRGV or its affiliated institutions agree to rely on another IRB, the UTRGV human subjects program remains responsible for ensuring compliance with the reviewing IRB's determinations and with the terms and conditions of the Federalwide Assurance (FWA) for the protection of human subjects.
  - d. UTRGV recognizes the independence of the IRB. Research reviewed and approved by a UTRGV IRB may be subject to further review and possible disapproval by other review bodies or officials of the institution or its affiliated institutions; however, no person or organization may override the IRB's disapproval determination.
- 5. A significant burden of responsibility rests with investigators when engaged in human subjects research. The responsibilities of an investigator under this policy include, without limitation:
    - a. assuring human subjects research are performed in accordance with funded proposal (if any) and IRB approved protocols;
    - b. ensuring IRB approvals have been obtained prior to beginning research;
    - c. providing updates to the IRB for continuing review at least annually or more frequently as required by the IRB; and
    - d. ensuring changes to protocols have been approved by the IRB in accordance with IRB policies, prior to the implementation of such changes.
  - 6. All known or suspected non-compliance with this policy must be reported promptly to the Office of Research Compliance.
  - 7. All institutional and non-institutional performance sites, domestic or foreign, will be obligated by this policy to conform to ethical principles which are at least equivalent to those of UTRGV.
  - 8. Failure to comply may result in disciplinary action, up to and including termination of employment.

#### **D. Procedures**

Procedures governing the IRB actions and protections of human subjects are compiled in the UTRGV Human Subjects Protection Handbook, which may be amended from time to time. All human subjects research must be conducted in accordance with this handbook.

#### **E. Definitions**

- 1. Human Subject - Two definitions are applicable in this policy:

- a. The Department of Health and Human Services (DHHS) defines a human subject as a “living individual about whom the investigator (whether professional or student) conducting research obtains:
  - i. data through intervention or interaction with the individual, or
  - ii. identifiable private information.” (45 CFR 46.102(f))
- b. The Food and Drug Administration (FDA) defines a human subject as an individual “who is or becomes a participant in research, either as a recipient of the test article (any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other test article subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act) or as a control. A subject may be either a healthy individual or a patient.” (21 CFR 56.102 (e))
2. Human Subject Research - Any activity that is either (a) “research” as defined by DHHS regulations that involves “human subjects” as defined by DHHS, or (b) “research” as defined by FDA regulations that involves “human subjects” as defined by the FDA.
3. Institutional Official (IO) - The UTRGV official responsible for ensuring that UTRGV’s human subject protection program has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent UTRGV, is the signatory official for all assurances, and assumes the obligation of the institution’s Federalwide Assurance. The IO is the point of contact for correspondence addressing human subjects research with the Office of Human Research Protections, the Food and Drug Administration, and affiliated institutions.
4. Investigator - An individual performing various tasks related to the conduct of human subject research activities such as:
  - a. obtaining information about living individuals by intervening or interacting with them for research purposes.
  - b. obtaining identifiable private information and/or specimens about living individuals for research purposes.
  - c. obtaining informed consent of individuals to be subjects in research.
  - d. studying, interpreting, or analyzing human subject data, including but not limited to identifiable private information and/or specimens, for research purposes.
5. Research - Two definitions are applicable in this policy:

- a. Research, as defined by DHHS, is as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46.102(d))
- b. Research, as defined by FDA (synonymous of the term Clinical Investigation), is an activity that involves a drug or device, other than use of a market drug in the course of medical practice, or the use of a device to evaluate safety and effectiveness of that device, and data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.

**F. Related Statutes or Regulations, Rules, Policies, or Standards**

[Code of Federal Regulations, Title 45 – Public Welfare, Part 46: Protection of Human Subjects](#)

[Code of Federal Regulations, Title 21 – Food and Drugs, Part 50: Protection of Human Subjects and Part 56: Institutional Review Boards](#)

[Belmont Report](#) of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979

**G. Dates Reviewed or Amended**

Not Applicable.