



# **Handbook of Operating Procedures**

**Section:** 4.10.8  
Originally Approved: 04/10/2008  
Last Amended: 12/12/2013  
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## **HUMAN SUBJECTS RESEARCH**

### **A. Purpose**

The purpose of this policy is to set forth guidelines for conducting research involving human subjects at The University of Texas-Pan American (UTPA), whether University faculty, staff, or students are involved as researchers or as subjects.

### **B. Persons Affected**

This policy applies to:

1. All University faculty, visiting faculty/researchers, staff, or student researchers conducting or assisting in research involving human subjects in connection with his or her institutional role.
2. All Principal Investigators responsible for administering human subjects research even where all activities involving human subjects are carried out by a subcontractor or collaborator not affiliated with the University.
3. All research seeking to recruit University students, faculty, or staff as human subjects that is conducted by individuals not affiliated with the University.

### **C. Policy**

The policy of the University is to protect human subjects involved in research in accordance with applicable ethical principals and other requirements. Accordingly:

1. All human subjects research protocols must be submitted to, and approved by, the Institutional Review Board (IRB) prior to the recruitment or involvement of human subjects, regardless of whether the research may qualify for an exemption from [Code of Federal Regulations Title 45 Part 46](#) (45CFR46).
2. All human subjects research conducted solely by individuals not affiliated with the University will need to be submitted to the University IRB for local IRB clearance. In such cases, the research must have been previously reviewed and approved by the IRB at the investigator's Federalwide Assurance (FWA)-holding institution. In such cases, the IRB will review the proposal for human subjects protections. Approval for the use of University facilities must be obtained from department chairs, college deans, or the University Provost, as appropriate.
3. A student may serve as Principal Investigator on human subjects research provided his or her IRB proposal is cosigned by a faculty mentor who is responsible for providing



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appropriate oversight and guidance for the protection of human subjects and is responsible for the maintenance of accurate human subject and research records in accordance with this *Handbook of Operating Procedures (HOP)* Section 4.10.8.

### **D. Definitions**

1. *Research*. A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2. *Human subject*. A living individual about whom an investigator conducting research obtains either:
  - a. Data through intervention or interaction with the individual, **or**
  - b. Identifiable private information.
3. *Ethical Principals and Other Requirements*. Ethical principals and requirements applicable to Human Subject Research as established in the documents below:
  - a. The University's current Federalwide Assurance (FWA) document. This document is an agreement with the U. S. Department of Health and Human Services Office for Human Research Protections (OHRP), and is required in order for the University to participate in federally funded Human Subject Research.
  - b. Documents specifically referenced in the FWA:
    - i. OHRP Federal Regulations for Protection of Human Subjects ([45CFR46](#))
    - ii. FDA Federal Regulations for Protection of Human Subjects ([21CFR50](#) and [21CFR56](#))
    - iii. Belmont Report
  - c. Additional documents
    - i. Family Educational Rights and Privacy Act ([FERPA](#))
    - ii. Health Insurance Portability and Accountability Act ([HIPAA](#))
    - iii. Protection of Pupil Rights Amendment ([PPRA](#))



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- iv. *HOP* [Section 8.9.1](#)- Policy for the Use and Protection of Information Resources
- v. *HOP* [Section 5.2.3](#) - Family Educational Rights and Privacy Act
- vi. UTPA’s Institutional Radiation and Biosafety Committee ([IRBC](#)).
- vii. UTPA’s Bloodborne Pathogen Exposure Control Plan ([BPECP](#))

### **E. Responsibilities**

#### 1. Researchers

All individuals engaged in conducting human subjects research activities, including research assistants, are responsible for the following:

- a. protecting human subjects;
- b. carrying out research involving human subjects in accordance with protocols approved by the IRB;
- c. immediately notifying the IRB and Office of Research Compliance at the Office of Research if human subjects involved in research projects are harmed. The term “harm” includes any physical or psychological injury, adverse events, improper disclosure of private information, economic loss, and any other harmful or potentially harmful occurrences.
- d. submitting evidence of appropriate human subject protection training;
- e. complying with FERPA where research involves student educational records;
- f. complying with the HIPAA where research involves medical records; and
- g. for obtaining any necessary approvals from the University’s Institutional Radiation and Biosafety Committee (IRBC) and for complying with UTPA’s Bloodborne Pathogen Exposure Control Plan for studies using or collecting any microbiological/infectious agents (including saliva and/or blood samples) and/or recombinant DNA molecules.



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### 2. Principal Investigators

Principal Investigators have the following responsibilities in addition to those applicable to researchers in general:

- a. accurately describing proposed human research protocols;
- b. identifying proposals needing IRB approval (via the proposal routing process);
- c. obtaining IRB approval prior to initiating any human subjects research;
- d. obtaining IRB approval for any alterations to the approved protocols (including changes in recruitment, procedures, or informed consent) prior to implementation of the changes.
- e. obtaining continuing review and approval of the protocol prior to the expiration of IRB approval where the research (including analysis of identifiable private information) will extend past the IRB approved expiration date;
- f. knowing and ensuring compliance with international, federal, and state laws and policies applicable to the proposed research;
- g. ensuring compliance with IRB policies; and
- h. retaining signed consent forms and research data for a minimum of 3 years after the completion of the study.

### 3. The Institutional Review Board (IRB)

The IRB is responsible for reviewing all human subjects research conducted by University faculty, visiting faculty/researchers, staff, or students in connection with their institutional role and for reviewing all research conducted solely by non-affiliated researchers if the research involves faculty, staff, or students of the University as human subjects. In this capacity it is authorized to:

- a. Approve, disapprove, or require modifications to proposed research in order to provide appropriate protection for human subjects;
- b. Conduct continuing reviews;
- c. Observe/verify changes;



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- d. Suspend or terminate approval;
  - e. Observe the consent process and the research procedures ; and
  - f. Develop procedures for handling noncompliance.
4. The IRB Chair (or designee)

The IRB chair is responsible for determining whether research can be considered exempt from [Code of Federal Regulation Title 45 Part 46](#) (45CFR46), based on the list of established exemption categories, whether it falls under one or more of the categories of research eligible for expedited review (review by the IRB chair and/or another experienced IRB committee member), or whether the research must be reviewed by the full IRB committee at a convened IRB meeting. If an expediting reviewer believes that a protocol should not be approved, it must be referred to the full IRB for consideration.

5. The Office of Research Compliance (ORC) at the Office of Research

The ORC is responsible for providing administrative and logistical support for the activities of the IRB.

### **F. Procedures**

1. Submission and review of human subjects research.

The procedures for submission and review of human subjects research are provided on the IRB website.

2. Notification of IRB action.

Notification of IRB action, including exemption, modification, approval, or disapproval of the proposed protocol will be provided to the Principal Investigator(s) and the ORC. Protocols are approved for a maximum of one year.

3. Payments to human subjects.

If a Principal Investigator will be authorizing participant stipends to a single individual in the same calendar year totaling more than \$50, these stipends are to be paid by University check issued through Accounts Payable. If the total amounts will be less than \$50 to the same individual in the same calendar year, they may be paid directly by either cash or gift card, provided:



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- a. the Principal Investigator provides Accounts Payable with a certifying statement to support how the funds will be used in compliance with the terms of the sponsored project and the “gift card purchase waiver” requirement of IRB.
- b. the Principal Investigator maintains research records that are consistent with the certifying statement.

### **G. Review**

The Divisional Head for this policy is the Provost/VPAA and this policy shall be reviewed every five years or sooner if necessary by the following Stakeholder Review Team members:

1. Vice Provost for Research– Senior Reviewer
2. Faculty Senate Chair
3. AAET
4. Staff Senate Chair
5. Student Government President
6. Chair of the Institutional Review Board