Policy for Review of Human Subject Research

The University complies with the Department of Health and Human Service (DHHS) regulations for the protection of human subjects, 45 Code of Federal Regulations (45 CFR 46) Section 45, Part 46, effective August 19, 1991, as documented in the University’s Federal Wide Assurance (FWA 00001224).

3.1 Ethical Principles

The University’s human subject research program is directed by three basic ethical principles of respect for persons, beneficence, and justice, 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, July 12, 1974.

3.2 Institutional Policy

3.2.1 All research sponsored or sanctioned by the University involving any human subjects, whether funded or non-funded, conducted by faculty, students or staff, using any property or facility owned or controlled by the University, or involving the use of non-public information maintained by the University to identify or contact human research subjects will be conducted in compliance with 45 CFR 46. Research involving human subjects may not be performed unless the requirements of this federal policy have been satisfied and written certification of the University’s review and approval of the research is obtained.

3.2.2 The Vice Provost and Sponsored Projects is authorized to review all proposed research, and decide whether the University will permit the research, as appropriate to the role and scope of the University.

3.2.3 All human subject research will be reviewed by the University’s Institutional Review Board (IRB). The involvement of human subjects in research projects will not be permitted to begin until the IRB has approved the research protocol, the informed consent document, the testing instruments, and the appropriate consents from subjects have been obtained by the Principal Investigator.

3.2.4 The IRB will consider the following criteria before approving the use of human subjects in research covered by 45 CFR 46:
a. the risks to subjects;

b. the anticipated benefits to subjects and others;

c. the importance of the knowledge that may be reasonably be expected to result; and

d. the informed consent process to be used by the Principal Investigator(s).

3.2.5 Notification of IRB action, including exemption, modification, approval, or disapproval of the proposed protocol will be given to the Principal Investigator(s) and The Office of Research and Sponsored Projects. Previously approved protocols must be reviewed annually by the IRB. Interim changes to approved protocols must be reviewed and approved by the IRB prior to implementation. If the protocol is to be considered via full IRB committee review any protocols, amendments, progress reports or informed consent documents not received with at least 10 days lead time will not be considered by the IRB until they have had sufficient time to review.

3.2.6 If human subjects involved in research projects approved by the IRB are harmed, including any physical or psychological injury, any adverse events, improper disclosure of private information, economic loss, and other harmful or potentially harmful occurrences, the Principal Investigator must notify the IRB and the Office of Research and Sponsored Projects immediately. ORSP will, in turn, notify the Office of Human Research Protections, Department of Health and Human Services.

3.2.7 Any person responsible for the design, conduct, or reporting of human subject research that has an economic interest in, or acts as an officer or director of any outside entity whose financial interests would reasonably appear to be affected by the research should be removed from the project, due to conflict of interest as provided in Chapter 2 of this Section of the handbook.

3.3 Applicability

3.3.1 This policy applies to all research involving human subjects, regardless of sponsorship, if:

a. the research is sponsored by the University; or

b. the research is conducted by or under the direction of any employee, or student, or agent of the University in connection with his or her institutional responsibilities; or

c. the research is conducted using any property or facility owned or controlled by the University; or

d. the research involves the use of non-public information maintained by the University to identify or contact human research subjects or prospective student participants.

3.3.2 All human research that is determined by the IRB to be exempt from review under 45 CFR 46 must be conducted in accordance with the Belmont Report of the National Commission for
the Protection of Human Subjects of Biomedical and Behavioral Research and shall remain subject to all University requirements for full submission of all protocol procedures using human subjects, and orderly accounting procedures.

3.4 Institutional Review Board Procedures

3.4.1 An Institutional Review Board (IRB) has been established by the University to review all proposed human research protocols. The IRB will meet at least twice per year upon the call of the Chair.

3.4.2 Principal Investigators must submit to the Office of Research and Sponsored Projects fully detailed protocols of their proposed research involving human subjects before the initiation of any research activities or data collection. Principal Investigators should familiarize themselves with the requirements of Federal regulation CFR 46 and with the University’s Federal Wide Assurance at http://ww.utep.edu/orsp/Compliance/humans.html

3.4.3 Required documentation to be submitted with the protocol includes:

a. informed consents in English and/or Spanish;

b. letters of approval from appropriate school districts, clinics, hospitals, or other outside performance sites;

c. recruiting posters or other advertisements; and

d. testing instruments or survey forms in English and/or Spanish.

3.4.4 The IRB will provide an initial review of the submitted protocol and all supporting documentation to determine whether, in compliance with provisions of 45 CFR 46, the protocol may be exempted from further review, will be given an expedited review, or will be subject to a full review by the IRB.

3.4.5 An exemption, all or in part, to further review by the IRB may be granted for any proposed protocol qualified under the six exemption categories provided in 45 CFR 46, as determined solely by the IRB. Written notice of this determination will be provided to the Principal Investigator and the Office of Research and Sponsored Projects.

3.4.6 Expedited review by the IRB may be provided for any proposed protocol which, under the nine expedited review categories provided in 45 CFR 46, is determined by the Chair of the IRB to involve no more than minimal risk to human subjects. The Chair, or his or her delegate, in consultation with such other members of the IRB as the Chair may deem necessary, will conduct the review and shall provide the Principal Investigator and the Office of Research and Sponsored Projects with a written determination as soon as practical.
3.4.7 Full committee review of research protocols is required when the research project is determined to involve greater than minimal risk to human subjects. A quorum of more than half of the IRB must be convened to act upon a protocol presented for full committee review. If the protocol is to be considered via full IRB committee review any protocols, amendments, progress reports or informed consent documents not received with at least 10 days lead time will not be considered by the IRB until they have had sufficient time to review.

3.4.8 Investigators will implement standard Universal precautions procedures for the protection of human subjects. Principal Investigators will immediately inform the Institutional Coordinator for Research Review in the Office of Research and Sponsored Research of any human subject research injury or adverse event during the course of the project.

3.4.9 Investigators must resubmit protocols to the Office of Research and Sponsored Projects, which require renewal after one year. A research progress report is required for consideration of each renewal request, and all changes to the protocol must be identified in order that an appropriate amendment to the protocol can be filed with the IRB. The Office of Research and Sponsored Projects will send a memo of determination to the PI when the IRB has approved the renewal or amendment of the protocol.

3.4.10 All Principal Investigators are required to have successfully completed a required training course in human subject research requirements and research ethics administered by the Office of Research and Sponsored Projects. A certificate of this course completion must be maintained on file at the Office of Research and Sponsored Projects.