

Protection of Human Research Subjects

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**Sr. Reviewer: Vice President for
Research**

POLICY STATEMENT
Texas State University is committed to upholding the highest ethical standards in research involving human subjects.

01. SCOPE

01.01 This policy describes Texas State University's commitment to full compliance with the U. S. Department of Health and Human Services (HHS) regulations for the protection of human research subjects ([45 CFR 46, June 18, 1991, as amended June 23, 2005 and thereafter](#)) and describes and references procedures that the university takes to fulfill this commitment.

02. ETHICAL PRINCIPLES

02.01 Texas State is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled [Ethical Principles and Guidelines for the Protection of Human Subjects of Research \(the Belmont Report\)](#), regardless of whether the research is subject to federal regulation or with whom conducted or source of support (i.e., sponsorship).

03. REGULATIONS AND PROCEDURES

* 03.01 To fulfill this commitment, Texas State has developed and submitted to the HHS [Office for Human Research Protections \(OHRP\)](#) a [Federal wide Assurance \(FWA\) for the Protection of Human Subjects](#), following the terms of the FWA specified by HHS. In addition, Texas State has registered with OHRP an Institutional Review Board (IRB), established in accordance with and for the purposes expressed in [45 CFR 46](#). Researchers engaging in approved human subject research studies at Texas State are prohibited from disclosing to research participants any results from diagnostic tests related to their health.

03.02 This FWA delineates the following concepts and procedures:

- a. institutional principle
- b. applicability of the terms of the FWA;
- c. compliance with the federal policy for the protection of human subjects and other applicable federal, state, local, or institutional laws, regulations, and policies;
- d. use of written procedures;
- e. scope of the IRB's responsibilities;
- f. informed consent requirements;
- g. requirement for assurances for collaborating institutions;
- h. written agreements with independent investigators who are not otherwise affiliated with the institution;
- i. the role of the institutional official;
- j. institutional support for the IRB;

- l. a program of training in the protection of human research subjects.

03.03 All research covered by this policy will be reviewed and approved by the IRB, except for those categories specifically exempted or waived by federal regulation, as outlined in [45 CFR, Section 46.101 \(b\)\(1-6\)](#) and [Section 46.101 \(i\)](#). The involvement of human subjects in research covered by this policy will not be permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative, as required by federal regulations ([45 CFR, Sections 46.111, 46.116](#) and [46.117](#)).

Texas State assures that before human subjects are involved in nonexempt research covered by this policy, the IRB will give proper consideration to:

- a. the risks to the subjects;
 - b. the anticipated benefits to the subjects and others;
 - c. the importance of the knowledge that may reasonably be expected to result; and
 - d. the informed consent process to be employed.
- 03.04 IRB approval for all federally-sponsored research involving human subjects will be submitted to the OHRP or the appropriate federal department or agency. Compliance will occur within the time and in the manner prescribed for forwarding certifications of the IRB review to HHS or other federal departments or agencies for which this policy applies. As required by [45 CFR, Section 46.119](#), in the event research is undertaken without the intention of involving human subjects but it is later proposed to involve human subjects in the research, the research shall just be reviewed by the IRB. Human research involvement will not be permitted until IRB approval is received by the appropriate federal department or agency.
- 03.05 As the institutional official named in the FWA, the vice president for Research is responsible for monitoring amendments to these regulations and procedures and for proposing revisions to the FWA. Proposed amendments to the FWA are subject to approval of the provost and executive vice president for Academic Affairs.
- 03.06 These regulations, procedures, concepts, and other relevant communications are published on the [IRB website](#). Maintenance, revisions, and updates of this material are the responsibility of the vice president for Research.

04. APPLICABILITY

- 04.01 This policy applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:
- a. the research is sponsored by the university;
 - b. the research is conducted by or under the direction of any employee or agent of the university in connection with their institutional responsibilities;
 - c. the research is conducted using any property or facility of the university;

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 - d. the research involves the use of the university's non-public information to identify or contact human research subjects or prospective subjects; or
 - e. the research is conducted to support a student thesis or dissertation.
- 04.02 All human subject research that is exempt under [45 CFR, Section 46.101 \(b\) \(1-6\)](#) or [46.101 \(i\)](#) will be conducted in accordance with:
- a. the [Belmont Report](#);
 - b. the university's administrative procedures to ensure valid claims of exemption; and
 - c. IRB staff documentation of such activities.

05. REVIEWERS OF THIS UPPS

05.01 Reviewers of this UPPS include the following:

Position	Date
Assistant Vice President for Research	October 1 E3Y
Director, Office of Research Integrity and Compliance	October 1 E3Y
Chair or Co-Chairs, Institutional Review Board	October 1 E3Y

06. CERTIFICATION STATEMENT

This UPPS has been approved by the following individuals in their official capacities and represents Texas State policy and procedure from the date of this document until superseded. Vice President for Research; senior reviewer of this UPPS

President