

STEPHEN F. AUSTIN
STATE UNIVERSITY
Office of the General Counsel

POLICY SUMMARY FORM

Policy Name: Human Research Subjects Protection

Policy Number: 8.4

Is this policy new, being reviewed/revised, or deleted? Review/Revise

Date of last revision, if applicable: 1/26/2016

Unit(s) Responsible for Policy Implementation: President; Provost and Vice President for Academic Affairs

Purpose of Policy (what does it do): To establish university guidelines on how research involving human subjects must be conducted

Reason for the addition, revision, or deletion (check all that apply):

- Scheduled Review Change in law Response to audit finding
 Internal Review Other, please explain:

Please complete the appropriate section:

Specific rationale for new policy:

Specific rationale for each substantive revision: This policy has been thoroughly revised to (1) incorporate 2017 changes in federal law, (2) clarify language, (3) remove most procedures by placing them in the university's research handbook, and (4) eliminate duplication.

Specific rationale for deletion of policy:

Additional Comments:

Reviewers:

Academic Policy Committee

Steve Bullard, Provost and Vice President for Academic Affairs

Damon Derrick, General Counsel

Human Research Subjects Protection

Original Implementation: April 30, 2002

Last Revision: ~~January 26, 2016~~April 24, 2018

I. Introduction

Stephen F. Austin State University (SFA) seeks to protect the welfare of every person who may be a subject of a research activity. In doing so, the university complies with appropriate federal, state, and local laws, including regulations by the Department of Health and Human Services (DHHS) for the Protection of Human Subjects in Research (45 CFR Part 46, as amended). Documentation of procedures is required for all protocols that are government funded. SFA follows the ethical principles regarding all research involving humans as subjects 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 Subjects of Research (the "Belmont Report"), and in the Code of Federal Regulations (CFR).

II. Institutional Policy

~~All research and research-related activities involving humans as subjects will be reviewed by the university's Institutional Review Board (IRB). A human subject is defined as a living person about whom an investigator conducting research obtains data through intervention or interaction with the individual (e.g., surveys, interviews) or identifiable, private information.~~

~~Program assessment, journalistic inquiries, oral histories, and activities that do not generalize beyond the scope of an investigation are not considered research appropriate for IRB review. For purposes of this policy, research means a systematic investigation designed to develop or contribute to knowledge that can be generalized.~~

All research projects involving human subjects conducted by SFA faculty, staff, and/or students, on or off campus, must have prior approval of the Institutional Review Board (IRB). For purposes of this policy, the following definitions apply:

- **Research** is a systematic investigation designed to develop and/or contribute to generalizable knowledge. It includes research development, testing, and evaluation.
- A **human subject** is defined as a living individual about whom an investigator (whether professional or student) is conducting research.
- **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

Failure to obtain written IRB clearance may result in the imposition of restrictions on the investigator's research activities at SFA. Once IRB approval is obtained, the investigator(s) must abide by several conditions:

~~All research projects subject to IRB review involving human subjects conducted by SFA faculty, staff, and students, on or off campus, must have prior approval of the IRB if any of the following conditions are met:~~

1. ~~The research is conducted by, or under the direction of, an employee or agent of SFA in connection with institutional responsibilities, including student research under the direction of a faculty sponsor;~~
 2. ~~The research is conducted by, or under the direction of, an employee or agent of SFA using any property or facility of the institution;~~
 3. ~~The research involves the use of SFA's non-public information to identify or contact human research subjects or prospective subjects;~~
 4. ~~The research is conducted by or under the direction of an employee or agent of another institution who is using research subjects associated with SFA or its facilities and/or property under written agreement with appropriate university officials.~~
- A second review may be required if more than twelve months has elapsed between the initial IRB review and the beginning of the project or the principal investigator wishes to change procedures or research focus ~~after the proposed project has been reviewed by the IRB~~;
 - All approved research is open to continuing review at intervals appropriate to the degree of risk, ~~but not less than once per year~~;
 - No investigator can abdicate ethical and legal responsibility merely by complying with this policy.;
 - *Records of research data will be retained by the researcher for three years. Failure to obtain prior, written IRB clearance may result in the imposition of restrictions on the investigator's research activities at SFA.*

The chair of the IRB will forward copies of all IRB-approved research protocols and approval letters *to the investigator(s) with copies placed in the SFA electronic repository*.~~that involve research funded by the Office of Research and Sponsored Programs (ORSP) using Research Enhancement, Research Development, or Comprehensive Research funds, or funded by an external entity to ORSP for compliance documentation and appropriate records retention. Multi-institutional studies only require one IRB approval. Multi-institutional studies will be considered on a case-by-case basis to determine the major responsibilities of each institution engaged in the research.~~

III. Guiding Principles to the Ethical Use of Human Research Subjects

~~All qualifying activities as defined in section H research activities involving humans as~~

subjects must provide for the safety, health and welfare of every individual. Additionally, all legal rights, including the right to privacy, must not be infringed. The direct or potential benefits to the subject or the importance of the knowledge to be gained must outweigh the potential risks to the individual. No human subject can participate in a research project until the IRB has approved the research protocol and written informed consent has been obtained from the subject.

~~Participation in projects must be voluntary. Informed consent must be obtained from all subjects unless waived by the IRB. A subject's informed consent must be obtained through methods that are consistent with federal law (45 CFR §§ 46.116 -117) and appropriate to the risks of the project. Whenever possible, consent should be obtained directly from the participants. If a subject is not legally or physically capable of giving informed consent, a legally authorized representative may do so.~~

~~An individual does not abdicate any rights by consenting to serve as a research subject. A human subject has the right to withdraw from a research project at any time or can refuse to participate; in either case, the subject must not experience any loss of benefits for withdrawing from a research project. Further, a human subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.~~

The principal investigator has the obligation of safeguarding information obtained as part of a research project. When the principal investigator is a student, the faculty sponsor is responsible for the ~~conduct of the research and the supervision of human subjects~~ *IRB application, training for the research protocol, research activities, supervision of human subjects, and reporting any changes to the IRB, as well as unanticipated consequences from the research.*

IV. **IRB Membership and Institutional Responsibilities**

The IRB at SFA has the responsibility and authority to review, approve, disapprove, or require changes in research activities and methodology of research involving human subjects.

~~The IRB will have at least six members: one community representative not associated with the university, four faculty members knowledgeable about applicable laws and standards of professional conduct and practice in the use of human subjects in research, and one faculty member from a non-scientific department. All members are appointed by the president of the university for indefinite terms. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues, but these individuals will have no voting rights. The IRB chair is appointed by the provost and vice president for academic affairs of the university from among the faculty members.~~

~~on the IRB. Whenever possible, the chair of the IRB shall be granted reassigned time equivalent to three TLC each semester. The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted at the institution. The membership of the IRB is based on the following criteria:~~

- At least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
- At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- An ex-officio, non-voting representative from the Office of Research and Graduate Studies (ORGs);
- Invited, non-voting individuals at the discretion of the IRB who have competence in specialized areas of research.

Appointments to the IRB are made by the president of the university for indefinite terms. The IRB chair is appointed by the provost and vice president for academic affairs from among the faculty members of the IRB. Whenever possible, the chair of the IRB will be granted reassigned time equivalent to one three hour course each semester.

ORGSP is responsible for maintaining the registration status of the IRB with the DHHS Office for Human Research Protections (OHRP) and for ~~reporting changes in the IRB chair and membership, and for~~ monitoring the status of a university Federal Wide Assurance (FWA) as applicable.

V. Conflicts of Interest

Conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. This definition applies to any IRB member or his/her immediate family member (within the second degree of affinity or third degree of consanguinity). No individual involved in the conduct and/or supervision of a specific project can participate in IRB review of the proposal, except to provide information. Any IRB member who has a conflict of interest, or a perceived conflict of interest, in any research application must recuse himself or herself from the vote and must disclose the conflict of interest. Conflicts of interest include any substantial interest in or other arrangement that might benefit the IRB member privately or might result in a financial benefit to the IRB member or any member of their immediate family (within the second degree of affinity or third degree of consanguinity). If a quorum is present without the recused member, then a vote can proceed. Otherwise, an substitute alternate IRB member must be present to proceed to a vote. If there is a conflict of interest for the outside committee member, then an alternate outside member must be utilized for the vote. No individual conducting and/or supervising a specific project can participate in IRB review of the proposal, except to provide information.

~~The IRB will meet once each month or as needed to ensure a thorough and speedy assessment of applications. An expedited review procedure is possible for applications that involve minimal risk to subjects and that either fall under one of the research categories eligible for expedited review or fall under the categories exempted by federal regulations. A risk is considered minimal when the harm anticipated in the proposed research is not greater in either probability or magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.~~

~~Final determination whether a project is eligible for expedited review can only be made by the IRB. The IRB shall weigh the following factors in making its determination whether to approve a proposal:~~

- ~~1. The rights and welfare of the subjects will be adequately protected.~~
- ~~2. The risks to the subjects are reasonable in relation to anticipated benefits of the study.~~
- ~~3. The written informed consent of subjects will be obtained by adequate and appropriate methods.~~

VI. Informed Consent

A subjects informed consent must be obtained through methods that are consistent with federal law (45 CFR §§46.116-.117). An individual does not abdicate any rights by consenting to serve as a research subject. A human subject has the right to withdraw from a research project at any time or can refuse to participate; in either case, the subject must not experience any loss of benefits for withdrawing from a research project. Further, a human subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety or harassment.

The legal age of consent for research purposes in the State of Texas is eighteen (18) years of age. For human subjects under 18, consent must be given by a legally authorized representative, an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research procedure(s). *Additionally, the human subject under 18 must assent to the research.*

If the subject is a minor, written consent by a legally authorized representative is required unless waived by the IRB. Such waivers will be granted by the IRB only if the principal investigator can provide adequate justification for the request [45 CFR §46.116(c)] and demonstrate assent of the minor, unless the IRB acknowledges the minor is incapable of giving assent.

Consent must be voluntary and must be given without coercion or undue influence. This includes provisions for payments or other incentives to participate in a research study [Payments to Human Research Subjects (8.8)]. The information provided to the subject or to the subject's legally authorized representative must be in simple, easily understood language. If the human subject does not understand English, the informed consent must be presented in the appropriate language.

Informed consent cannot waive or limit ~~in appearance or in fact~~ a human subject's legal rights, including any release of the institution or its agents from liability for negligence. ~~Informed consent forms must include a statement that concerns may be addressed to the Office of Research and Sponsored Programs.~~ Requirements and guidelines for informed consent can be obtained from the ORGSP website.

VII. Exempted Research

All qualifying research with human subjects, as defined in section II, must be reviewed by the IRB. A principal investigator cannot claim exempt status in order to bypass IRB review. The IRB is responsible for determining whether a research project falls within one of the exempted categories as defined in 46 CFR 101(b)(1)-9(b)(6).

VIII. Expedited Review

Certain research projects may be eligible for expedited review. In making this determination, the research protocol will be reviewed by the IRB chair and/or experienced IRB members selected by the chair. *All members of the IRB will be advised on research proposals that have been approved under expedited review at each IRB committee meeting. This review is limited only to the question of whether an expedited review is appropriate; research protocols cannot be disapproved without a full IRB review.*

~~Six categories of research can be considered for expedited review. Research protocols that qualify for expedited review by the IRB are the following.~~

- ~~1. Minor modifications or additions to existing approved studies.~~
- ~~2. Research on individual or group behavior or characteristics of individuals (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior, game theory, and test development); research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, when the investigator does not manipulate subjects' behavior or involve procedures that impose stress on the subjects.~~
- ~~3. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.~~
- ~~4. Collection of data from voice, video, digital, or image recordings made for research~~

~~purposes.~~

5. ~~Moderate exercise by healthy subjects.~~
6. ~~Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice.~~

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1. ~~Research conducted in established or commonly accepted educational settings that involve common educational practices.~~
2. ~~Research involving the use of educational tests (e.g., cognitive diagnostic, aptitude, achievement) where information is recorded in a manner that does not identify subjects, directly or indirectly.~~
3. ~~Research involving survey or interviewing procedures, except where any of the following conditions exist:~~
 - a. ~~responses are recorded in a manner that subjects can be identified, directly or indirectly;~~
 - b. ~~the subjects' responses, if they become known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing or employability;~~
 - c. ~~the research deals with sensitive aspects of the subjects' own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol;~~
 - d. ~~the research involves the use of children, minor age students, or other vulnerable groups as subjects.~~
4. ~~All research involving survey or interview procedures when the respondents are elected or appointed public officials or candidates for public office.~~
5. ~~Research involving the observation (including observation by participants) of public behavior, except where any of the following conditions exist:~~
 - a. ~~observations are recorded in a manner that the subjects can be identified, directly or indirectly;~~
 - b. ~~the observations recorded about individuals, if they become known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing or employability;~~
 - c. ~~the research deals with sensitive aspects of the subjects' behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol;~~
 - d. ~~the research involves the use of children, minor age students, or other protected or vulnerable groups as subjects and the principal investigator is a participant in the activities being observed.~~

- ~~6. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the principal investigator in a manner that subjects cannot be identified, directly or indirectly.~~
- ~~7. Research and demonstration projects that are conducted by or subject to the approval of the DHHS, and which are designed to study, evaluate, or otherwise examine:~~
 - ~~a. programs under the Social Security Act or other public benefit or service programs;~~
 - ~~b. procedures for obtaining benefits or services under those programs;~~
 - ~~c. changes in or alternatives to those programs or procedures;~~
 - ~~d. changes in methods or levels of payment for benefits or services under those programs.~~

IX. Full Review

Research protocols that include any protected populations must be reviewed by the full IRB committee. Protected populations include prisoners, children (unless the study is normal educational practice), employees, terminally ill subjects, AIDS/HIV subjects, human fetuses, and neonates. The IRB committee may reject the application, accept the application with minor revisions, or request significant changes with the request for an additional full committee review.

Cross Reference: Ethical Principles and Guidelines for the Protection of Human Subjects in Research: The Belmont Report; 45 CFR §§ 46.101-.505; Payments to Human Research Subjects (8.8).

Responsible for Implementation: President; Provost and Vice President for Academic Affairs

Contact for Revision: Director, Office of Research and Sponsored Programs
Graduate Studies

Forms: Application for Approval of Research Involving the Use of Human Subjects; Conflict of Interest Disclosure Form for IRB Members; Workload Reassignment Request

Board Committee Assignment: Academic and Student Affairs