

Human Research Subjects Protection

Original Implementation: April 30, 2002

Last Revision: February 2, 2021

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).

Institutional Policy

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. The application must be signed and submitted electronically to the IRB. Once IRB approval is obtained, the investigator(s) must abide by several conditions:

- 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;
- All approved research is open to continuing review at intervals appropriate to the degree of risk;
- 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.

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. 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.

Guiding Principles to the Ethical Use of Human Research Subjects

All 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.

The principal investigator has the obligation of safeguarding information obtained as part of a research project. The principal investigator must be a faculty or staff member even though it may be student research, the faculty sponsor is responsible for the 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.

IRB Membership and Institutional Responsibilities

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

- 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.

ORGS is responsible for maintaining the registration status of the IRB with the DHHS Office for Human Research Protections (OHRP) and for monitoring the status of a university Federal Wide Assurance (FWA) as applicable.

Conflict 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). An 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. If a quorum is present without the recused member, a vote can proceed. Otherwise, an alternate IRB member must be present to proceed to a vote. No individual conducting and/or supervising a specific project can participate in IRB review of the proposal, except to provide information.

Informed Consent

A subject's 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 a human subject's legal rights, including any release of the institution or its agents from liability for negligence. Requirements and guidelines for informed consent can be obtained from the ORGS website.

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).

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.

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: Provost and Executive Vice President for Academic Affairs

Contact for Revision: Dean, Research and 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 Committee

Revision History: April 24, 2018
January 26, 2016
April 23, 2013
July 20, 2010