Research Integrity and Compliance
Human Research Protection Program

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Texas State University has prepared this operational manual to guide investigators on Institutional Review Board (IRB) policies and procedures governing human subjects research (HSR). It describes the operations of the university's Human Research Protection Program (HRPP) as is based on the ethical principles described in the Belmont Report. This institution abides by the Federal Policy for the Protection of Human Subjects, known as the "Common Rule," in the conduct of federally supported research, research collaborations, and use of federal funds for research. This manual will be updated every three years or whenever there are changes to the regulations, guidance, and/or institutional policies.

1. Mission Statement

Texas State University hither to known as "Institution", is a public research university that has grown into one of the largest universities in the United States. The university is dedicated to advancing scientific discovery and innovation in the applied research arena to find multidisciplinary innovative and practical solutions to real-world problems that affect the people of Texas and the rest of the world.

The mission of the Institution is to foster scientific inquiry and scholarly, and creative activities conducted by the faculty, staff, students, and others. The institution is committed to conducting these activities responsibly while safeguarding the research environment, research integrity, and research subjects by following ethical principles, federal, state, and local laws and regulations, university policies, and funding agency requirements. As part of this mission, the Institution is committed to protecting the rights and welfare of research subjects. Furthermore, the investigators at the Institution and the university leadership assume joint responsibility to protect the rights and welfare of research subjects.

2. Institution's Commitment to Protect Human Research Subjects
The institution, by action of the President, has established an institutional review board (IRB) to review HSR. The IRB reviews research conducted or supported by the Institution's faculty, students, or staff to ensure that the rights and welfare of human subjects are adequately protected. The HRPP at the Institution is an integrated system managed by Research Integrity and Compliance under the auspices of the Division of Research. Various components of the HRPP include compliance, training, education, quality assurance, research integrity, and research protocol reviews by the IRB and other relevant committees.

3. Federalwide Assurance (FWA)
The Institution holds a Federalwide Assurance, accepted by the Office of Human Research Protection (OHRP) in the Department of Health and Human Services (HHS). It covers all federally supported HSR. The Institution has committed to comply with the ethical principles of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report, titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (the "Belmont Report"), and applicable professional and ethical standards and codes. HSR will be conducted in compliance with applicable federal laws, state laws, university policies, or procedures.

Federally supported research means the Institution is engaged in research using federal funds or support provided by the U.S. Government for the conduct of research either directly or indirectly through collaborations and contracts with external entities. The research may involve intervention or interaction conducted by Institution employees and students or use of individually identifiable information or biospecimens obtained for federally supported research.

Assurance will be updated every three years. HRPP staff will assist the IO in the submission of this Assurance and other documentation, as needed, to OHRP. This Assurance will be updated anytime changes are made to the membership of the IRB, or to the changes are made to the membership of the IRB, or when the institution adds or removes external IRBs upon which it agrees to rely. If there are no changes to the FWA, the IO through HRPP submits the renewal of FWA every three years. HRPP is responsible for recordkeeping.

4. Authority of the Institution

The president, under the authority of the Board of Trustees, has appointed an Institutional Official (IO) to administer the Human subject Research Protection Program (HRPP). The IO has the responsibility to maintain Assurance. In the Assurance, on behalf of the Institution, the IO has committed to complying with the Common Rule for federally supported research and, when applicable, the additional requirements governing Department of Defense (DoD)-supported human subjects research. The ultimate responsibility of the HRPP resides with the IO. The IO may not be appointed to the IRB. The IRB is responsible for the review and oversight of all human subjects research involving the institution's faculty, staff, or students; research conducted using institutional facilities; and collaborative research conducted in partnership with other institutions, regardless of where the research takes place.

Oversite of HSR is a shared responsibility involving many key individuals, including the Vice President of Research (VPR), Assistant Vice President for Research Compliance, IO, IRB Chair and HRPP staff. Furthermore, HSR may involve components subject to review by other institutional committees. These include the Radiation Safety Committee (for research involving the use of radiological materials); the Institutional Biosafety Committee (for research involving the use of biological materials); and the Conflict of Interest Committee.

5. Regulations

Additional federal laws and regulations may apply to HSR and help guide IRB review and compliance at the Institution.

A. United States Food and Drug Administration Regulations

Research involving the use of drugs, medical devices, and/or biologics must comply with Food and Drug Administration (FDA) regulations 21 CFR Part 50 (Protection of Human Subjects) and 21 CFR Part 56 (Institutional Review Boards). FDA regulations are not entirely consistent with the Common Rule; however, steps are being taken to harmonize the regulations. When there is a discrepancy between the Common Rule and the FDA Regulations, the latter shall prevail when applicable.

B. Family Educational Rights and Privacy Act (FERPA)

The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. FERPA is applicable when the research at the Institution is designed to study the effectiveness of an instruction method, techniques, curricula, or classroom management by faculty, staff, and students. FERPA gives parents certain rights concerning their children's educational records. Parent permission is required when researchers request access to student records and survey responses to evaluate students' ability to learn using computers or other technology; effectiveness of teaching; etc.

Investigators cannot use students' records or student's identifiable information to recruit them for a research study.

C. Health Information and Portability and Accountability Act (HIPAA)

The HIPAA Privacy Rule protects information generated in the provision of healthcare services, and it is not primarily concerned with research. The rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. A covered entity health plan; health care clearinghouse; or health care provider who transmits any health information in electronic form in connection with transactions covered under 45 CFR Part 162.

Institution is not a covered entity at present; therefore, HIPPA regulations do not apply.

D. **Clinical Laboratory Improvement Amendments (CLIA)**

The Clinical Laboratory Improvement Amendments are a set of standards to improve the quality of clinical laboratory testing in laboratories that conduct testing on human specimens for assessment of health or the diagnosis, prevention, or treatment of disease. CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue. This Institution's laboratories are not CLIA-certified; therefore, any laboratory testing intended to support clinical decision-making or the return of individual test results to participants must be conducted through a CLIA-certified laboratory, as required by applicable regulations.

6. Ethical Principles

A key area of the institution's research enterprise is HSR. Protecting research subjects, their rights, and their welfare is paramount to its research mission and growth. Protection can only be achieved if the administrative units, faculty, and students work collaboratively with a common goal of understanding and implementing appropriate regulatory, ethical, and safety standards and complying with all applicable regulations.

The ethical principles that govern HSR, which are incorporated into the institution's policies and procedures, include the Belmont Report, the Nuremberg Code, and the Declaration of Helsinki.

A. **Belmont Report** -In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report)." The Belmont Report sets forth three ethical principles governing research involving human subjects. Each of these ethical principles is described below.
    a. **Respect for Persons** - Individuals (research subjects) are to be treated as autonomous agents, and those with diminished autonomy are entitled to protection. They have the autonomy to make decisions on whether to participate in research.

    b. **Beneficence** - Two obligations exist: 1) do not harm people; and 2) maximize possible benefits and minimize possible harms. Persons are treated ethically not only by respecting their decisions and protecting them from harm but also by making efforts to secure their well-being. The obligations of beneficence affect both the individual investigators and society at large. The prospect of benefit may be directed to the participant, or the prospect of benefit may apply to society in general.

    c. **Justice** – The principle of justice emphasizes "who ought to receive benefits of research and bear its burden? This means "sharedness of burden," "equal share," "fairness in distribution", or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unjustifiably.

B. **Nuremberg Code** – The Nuremberg Code was developed following the Nuremberg Military Tribunal which judged Nazi doctors who had conducted human experimentation in Germany in the 1930s and 1940s. The code states that "the voluntary consent of the human subject is essential" and emphasizes the importance of voluntary, informed consent; freedom from coercion; freedom to withdraw from the study at any time, without penalty; and comprehension of the risks and benefits involved.

C. **Declaration of Helsinki** - The World Medical Association (WMA) developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research involving identifiable human material and data. This declaration has been revised many times, and the version contains thirty-seven different principles. Although the Declaration is addressed primarily to physicians, the WMA encourages researchers conducting clinical research involving human subjects to adopt the principles of the Helsinki Declaration.

7. IO Responsibilities

The responsibilities of the IO include the following:

A. Establish a culture of safety and ethical practices for the conduct of HSR, in which responsibilities are shared among investigators, the IRB, HRPP staff, and others.
B. Establish an IRB and authorize the IRB to approve, require modifications to secure approval, or disapprove proposed research studies.
C. Complete the required training to understand regulations, ethical standards, and the institution's policies and procedures.
D. Appoint IRB Chairs and members.
E. Ensure that the IRB is operating independently.
F. Periodically evaluate the HRPP and provide adequate resources (e.g. space, personnel, etc.) as needed.
G. Institutional officials with responsibilities for promoting, negotiating, or managing research funding or business partnerships shall not serve as appointed or ex officio members of the IRB to preserve the IRB's independence and avoid conflicts of interest.
H. Ensure that study disapprovals by the IRB are not overturned at any level of the organizations.
I. Ensure that the IRB has the authority to conduct additional reviews of an approved study at any time.

J. Ensure proper communication among the IRB, HRPP, researchers, and other stakeholders.
K. Solicit input from IRB chairs, members, and staff, as well as researchers and other stakeholders, when necessary.
L. Ensure that records are properly maintained. Verify once a year.
M. Periodically review HRPP and IRB policies to ensure they are current and consistent with all applicable regulations.
N. When warranted, remove IRB members.
O. Report all incidents of serious and/or continuing noncompliance to the appropriate federal authorities.
P. Meet regularly with IRB Chairs and the HRPP team to discuss program status.
Q. Serve as a liaison to resolve certain disputes between the IRB and the investigator and make recommendations for resolving such disputes.
R. The IO may delegate the performance of certain oversight and operational duties to one or more individuals. Any delegation of duty must be in writing. However, certain authorities (e.g. signing the Assurance, ensuring that the IRB functions independently, and ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP) may not be delegated.

8. Human Subject Research Protection Program (HRPP) and Responsibilities

The HRPP's role is to provide support, guidance, and education to faculty, staff, and students to facilitate safe and ethically sound HSR. The HRPP staff shall meet with the IO regularly as needed to discuss the needs of the program. Multiple units within the Institution provide support to the operations of the HRPP. These include the Division of Research, the Office of Sponsored Program, the Division of Information Technology, the Office of General Counsel, the Office of Environmental Health, Safety, and Risk Management, Research Centers, and the Office of the Provost and Academic Affairs.

9. Responsibilities of HRPP Staff

The responsibilities of the HRPP responsibilities include the following:
A. Implement university policies and procedures governing HSR.
B. Provide day-to-day oversight of the HRPP.
C. Serve as designees to communicate with OHRP and other agencies.
D. Serve on the IRB at the discretion of the IO.
E. Understand the principles of research administration as they pertain to diverse types of research (e.g. basic; clinical; educational; psychological; social-behavioral; etc.)

F. Develop SOPs, policies, and procedures for the HRPP and IRB.
G. Work effectively with community members, including researchers and stakeholders, by providing clear guidance on compliance requirements, supporting understanding of policies, and promoting cooperative, ethical practices.
H. Possess a strong understanding of applicable regulations to review research protocols, submissions, and related documentation to ensure compliance with federal regulations (e.g., 45 CFR 46), institutional policies, and ethical standards.
I. Conduct prereviews of IRB submissions to ensure clarity, completeness, consistency, and accuracy, and identify any missing documents (e.g., protocol, consent forms, recruitment materials), advising investigators on needed revisions.
J. Determine the review type for exempt, expedited, and full board review categories, ensuring accurate classification and thorough documentation, based on level of risk and assigning reviews to IRB members.
K. Create approval letters including conditional approval letters that require modification to secure approval and disapproval after the IRB has decided.
L. Help maintain current (or up to date) information on the IRB website.
M. Perform tasks delegated by the IRB and the IO. Work closely with the chair Perform tasks as requested by the IRB and IO and work closely with the Chair to manage all IRB functions.
N. Conduct outreach, education, and training to IRB members and investigators.
O. Serve as a resource to researchers and provide guidance on the safe and ethical conduct of HSR.
P. Determine whether outside IRBs are involved in research, communicate with outside IRBs, and determine if a single IRB (sIRB) review is required for multi-site research and determine the IRB of record.
Q. Determine if there is a need for a reliance agreement and if so, implement such agreements for any research involving more than minimal risk.
R. Establish and maintain cooperative agreements, reliance agreements, and other collaborative arrangements with external IRBs, as appropriate, to facilitate the ethical review and oversight of human subjects research.
S. Arrange IRB meetings and assign protocols at the appropriate level of regulatory review, prepare agendas for the meeting, take minutes of the meetings, and manage correspondence.
T. Complete all required human subjects research protection training and maintain current knowledge through ongoing education and professional development activities related to IRB and human subjects research oversight.

U. Enter IRB recommendations/comments of the IRB on the database including approval, required modifications to secure approval, and disapproval approval.
V. Enter approval and expiration dates into the protocol management system.
W. Conduct routine quality control audits and for-caused audits.

10. Participant's Rights, Questions, And Concerns

Research participants may call the investigator or HRPP staff to discuss any questions about the study and their rights. Researchers' names and contact information are provided on the consent form. At the time of consenting participants, researchers must explain the nature and methods used in the study and ensure participants fully understand their rights. Strict confidentiality will be maintained when subjects want to discuss their rights in private.

Questions, concerns, or complaints about a research study, research procedures, or the study team may be directed to Research Integrity and Compliance at 512-245-1423 or humansubjects@txstate.edu.

Texas State University (TXST) also provides access to EthicsPoint, a secure third-party reporting system that allows individuals to submit reports anonymously or confidentially regarding fraud, waste, abuse, conflicts of interest, research misconduct, or other ethical concerns involving university operations.

Reports may be submitted through the following channels:

Online: TSUS Fraud, Compliance, or Ethics Report Form

Phone: EthicsPoint Hotline at 866-294-0987

If researchers have concerns or complaints about the service they received from HRPP staff or the IRB, or if they have been unable to resolve an issue, they may contact the Institutional Official (IO or the Vice President for Research).