

OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE
Texas State University
HUMAN RESEARCH PROTECTION PROGRAM

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Texas State IRB website: <http://www.txstate.edu/research/orc/IRB-Resources.html>

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ARTICLE 1

**INSTITUTION'S MISSION, REGULATIONS, ETHICAL PRINCIPLES, ASSURANCE
AND INSTITUTIONAL AUTHORITY ON HUMAN SUBJECT PROTECTION
PROGRAM**

Texas State University has prepared this manual to guide investigators on IRB Policies and Procedures to conduct human subject Research. The manual provides the requisite information for investigators to conduct human subject research and comply with regulations and ethical principles enumerated in the Belmont Report. This guidance manual also serves as the operational manual for HRPP. Institution abides by the federal policy for the protection of human subjects, known as the Common Rule, whenever 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 institutional policies. This manual is updated periodically consistent with changes to regulations, guidelines and university policies and procedures.

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

Institution, by action of the President, has established an institutional review board (IRB) to review human subjects research. The IRB reviews research conducted or supported by the Institution's faculty, students, or staff to determine that the rights and welfare of human subjects are adequately protected. The Human Research Protection Program (HRPP) at the Institution is an integrated system managed by the Office of Research Integrity under the auspices of the Office of Research. Various components of HRPP include compliance, training, education, quality assurance, research integrity, and research protocol reviews by the Institutional Review Board (IRB) and other relevant committees.

3. Federalwide Assurance (FWA)

It is the assurance provided to the Office of Human Research Protection (OHRP) concerning federally supported research. The Institution has specifically provided in its assurance to comply with the ethical principles of 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"), applicable professional and ethical standards and codes, and carried out in compliance with applicable federal laws, state laws, University policies or procedures.

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

The Institutional Official (IO) under this authority has the responsibility to initiate and update the Assurance. HRPP staff will assist IO in submitting and communicating with OHRP. Assurance will be updated anytime changes are made to the assurance including membership changes and reliance on another institution. 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. Regulations

A. United States Food and Drug Administration Regulations

The U.S. Food and Drug Administration, within the Department of Health and Human Services, regulates drugs, medical devices, and biologics. FDA regulations 21 CFR Part 50 (Protection of Human Subjects), and 21 CFR Part 56 (Institutional Review Boards) must be adhered to when studies are conducted using drugs, medical devices, or biologics. FDA regulations are not entirely consistent with the common rule; however, they are taking steps to harmonize the clinical research regulations with the common rule. At Institution, FDA regulations apply to studies involving, test drugs, biologics, and devices.

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) (<https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>), 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 the faculty, staff, and students. FERPA gives parents certain rights concerning their children's educational records. Therefore, for researchers to access student records, and survey responses to evaluate students' ability to learn using computers or other technology, the effectiveness of teaching, etc., parent permission is required.

This means Institution 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 is primarily concerned with information generated while providing 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 is a person, business, agency, or healthcare provider and therefore a covered entity. Since a great deal of health research is also subject to FDA and the common rule, IRB needs to know these rules to protect research subjects.

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

D. Clinical Laboratory Improvement Amendments (CLIA)

The Clinical Laboratory Improvement Amendments of 1988, a statute was amended in 2003 to the Public Health Services Act. This statute was revised by the US Congress for the federal program for certification and oversight of clinical laboratory testing. In general terms, the CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for diagnosis, prevention, or treatment of disease or health assessment. Our Institution's laboratories are not CLIA-certified; however, Institution researchers may use commercial laboratories for testing biospecimen for research purposes.

5. Ethical Principles

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

The ethical codes the IRB members must follow include the following. At the Institution, the Belmont Report is the principal ethical standard that governs research. The other ethical

standards the Institution adopts are the Nuremberg Code and the Declaration of Helsinki. These ethical codes were fundamental to establishing regulations protecting human research subjects.

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." The Belmont Report sets forth the

basic three ethical principles expected to be followed when doing research involving human subjects. Each of these ethical principles is described below.

<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

Respect for Persons - requires individuals (research subjects) to be treated as autonomous agents, and individuals with diminished autonomy are also entitled to protection as well. In other words, research participants have the autonomy to make decisions on whether to participate in research.

Beneficence - is understood as not harming research subjects, maximizing benefits, and minimizing harm. 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.

Justice – This 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** – This was developed following the Nuremberg Military Tribunal which judged

Nazi doctors conducting human experimentation. The code emphasized that "the voluntary consent

of the human subject is essential." The code further underscores this capacity of participants to

consent, participants' rights to participate or not, freedom from coercion, no withdrawal penalty if subjects decide not to participate in the study, and comprehension of the risks and benefits

involved. https://en.wikipedia.org/wiki/Nuremberg_Code#cite_ref-ushmm_6-1.

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 on 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. (<https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/>.)

6. 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 under this authority has the responsibility to maintain the Assurance. In the assurance, on behalf of the Institution, the IO has committed to comply with the Common Rule for federally supported research. The IO has also made an additional commitment as an addendum to FWA to comply with DOD-funded research. The ultimate responsibility of the human subject protection program resides with the IO. The Institution has charged the IRB with reviewing responsibilities of any human subject research conducted by faculty, students, and staff at the Institution's campuses. Any collaborative research conducted by Institution's faculty, students, and staff at another institution. The authority also includes research conducted by non-Institution's employees who use Institutions facilities as a research site.

Under this authority provides a list of key individuals, units, and their relationships to manage the HRPP this includes the Vice President for Research (VPR), IO, IRB Chair, HRPP Director, and IRB coordinators. Under this authority, there are other ancillary committees that provide risk assessment to the IRB. These include the Radiation Safety Committee, Conflict of Interest Committee, and Biosafety Committee in matters relating to the use of radiation and use of hazardous agents provided. They operate under the direction of the IO.

7. IO Responsibilities

IO is responsible to:

- A. protecting research subjects and setting a tone for investigators to accept equal responsibility for the proper conduct of human subject research.
- B. Establish an IRB and provide authority to the IRB to approve, require modifications to secure approval, or disapprove a research study.
- C. Ensure that the IRB is operating independently.
- D. Periodically evaluate and provide adequate resources to support HRPP including space and personnel.
- E. Ensure that Institution officials involved in the business development are not serving as members or *Ex-officio* members.
- F. Ensure that the studies disapproved by the IRB at full board, expedited and exempt reviews are not overridden at any level of the organizations.
- G. Ensure that the IRB has the authority to conduct additional reviews of an approved study at any time.
- H. Appointing IRB Chairs and members.
- I. Ensure that all obligations of the HRPP are carried out effectively and efficiently and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects.

- J. Periodically ensure proper communication between the IRB, HRPP, researchers, and the organization.
- K. Soliciting 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. Provide adequate resources to the IRB operations.
- N. Review HRPP and IRB Policies.
- O. Complete the required training to understand regulations, ethical standards, and the institution's policies and procedures.
- P. Avoid serving as the chair or IRB member.
- Q. Terminate IRB members for cause.
- R. Report all incidents, as required by the Institution's FWA, deemed to be serious or continuing noncompliance to the appropriate federal authorities.
- S. Meets regularly with IRB Chairs and the HRPP team to receive regular communication regarding the status of the HRPP and the IRB.
- T. Serve as a liaison to resolve certain disputes between the IRB and the investigator and make recommendations for the IRB and researcher's consideration.
- U. 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 like authorizing someone else to sign 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.

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

The HRPP's role is to protect the rights and welfare of research subjects by providing support, guidance, and education to facilitate human subject research that is ethical and scientifically sound. Individuals in the HRPP program are members of the Institution's research administration. The Director of HRPP reports to the IO and meets with the IO as often as necessary. Multiple units within the Institution provide support to the operations of the HRPP. These include the Office 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. The responsibilities of HRPP staff

- A. Responsibility for enforcing university policies and procedures.
- B. Provide day-to-day oversight of the HRPP.
- C. Serve as the designees to communicate with OHRP and other agencies.
- D. Sign or release approval letters such as approval letters that require modification to secure approval and disapproval after the IRB has decided.
- E. At the discretion of the IO, HRPP staff serve as IRB members.
- F. A good understanding of research administration.
- G. Backgrounds in research administration, diverse types of research, including basic, clinical, educational, psychological, and social sciences.
- H. Ability to work with community members.

- I. Familiarity with relevant regulations and knowledge of institutional policies.
- J. Develop SOPs, policies, and procedures for HRPP and IRB.
- K. Expertise in maintaining websites.
- L. The ability to perform tasks delegated by the IRB and the IO. Work closely with the chair to execute the overall management of the IRB functions.
- M. The expertise for outreach, education, and training to IRB members and investigators.
- N. The expertise to provide researchers with meaningful advice on how to better protect research participants in their studies through effective communication.
- O. The ability to conduct prereviews to ensure clarity, completeness, consistency, and correctness of IRB submissions.
- P. Identify missing documents such as the protocol, consent form, and recruitment material. If incomplete, advise investigators on submitting missing documents.
- Q. 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. Determine and implement reliance agreements and master agreements for research that is more than minimal risk.
- R. If the study falls under FDA jurisdiction, and the study involves multi-site, develop cooperative agreements with outside IRBs for IRB approval.
- S. Provide support for investigators and researchers helping them resolve issues before assigning the study for review.
- T. 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.
- U. Complete CITI training every three years. In addition, receive additional training by attending local and national IRB conferences and workshops.
- V. Expertise to decide the level of review based on the level of risk.
- W. Enter IRB recommendations/comments of the IRB on the database including approval, required modifications to secure approval, and disapproval approval.
- X. Determine and enter in the database approval and expiration dates.
- Y. Expertise in conducting routine quality control audits and for cause audits, reviewing and reporting noncompliance.

10. Participant's Rights, Questions, And Concerns

Research participants may call the investigator or the IRB offices to discuss any questions about the study and their rights. Researcher's names and contact information is provided on the consent form. At the time of consenting, researchers explain the nature and methods used in the study to participants and their rights to participate in the study. Strict confidentiality will be maintained when subjects like to discuss their rights in private. Anonymous Questions/ Complaints by Research Subjects about the study or the research staff can be lodged by calling 512-245-1423 or emailing orsp-irb@txstate.edu.

If researchers have concerns or complaints about the service they received from the IRB Office or the IRB, they have been unable to resolve the problem, they must contact the Institutional Official (IO) using the following contact information.

Michael Blanda, Ph.D.
 Chief Operating Officer-Division of Research
 Professor
 Texas State University

601 University Drive
San Marcos, TX 78666
Phone: 512.245.2314

If the matter is not resolved, researchers may contact the Vice President for Research at the following address:

Shreekanth Mandayam, Ph.D.
Vice President for Research
601 University Drive
JC Kellam Suite 489
San Marcos, TX 78666
Phone: 512-245-2314