# Texas State University

# Institutional Review Board (IRB)

# Operations Handbook

June 2023

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Federal Wide Assurance (FWA): # 00000191

IRB Organization (IORG) # IORG0000482

Texas State University IRB website:

https://www.research.txst.edu/orc/irb-resources.html

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# Section 1: Introduction

## 1.1 Background Information

Scientific inquiry, scholarly contributions, creativity, and academic accomplishment can take many forms and may vary among disciplines. All Texas State University (TXST) faculty and staff are ultimately responsible for the scholarly character, accuracy, reliability of their own research, safeguarding of research subjects and the research environment in which they work pursuant to federal regulations, state regulations, university policies, funding agency requirements, and contractual commitments.

TXST, by action of the President, has established an Institutional Review Board (IRB). The IRB protects the rights and welfare of human subjects who choose to participate in biomedical or social behavioral science research. Central to this program, the University maintains a Federal Wide Assurance (FWA) of Compliance (hereafter referred to as "Assurance") with the Department of Health and Human Services' Office for Human Research Protections (OHRP) (FWA # 00000191). [Appendix 12]

This Assurance is renewed every 5 years but updated periodically as required. It commits the University to abiding by all federal regulations and guidelines with respect to its research activities involving human subjects. Based on the principles of the Belmont Report [Appendix 1] - Respect for persons, Beneficence, and Justice - the over-arching goal of the Human Research Protections Program (HRPP) is to protect the rights and welfare of human research subjects at the University. Noncompliance with this assurance means losing eligibility for all federal and other forms of sponsored funding. Additionally, it may cause financial and reputational damage to our institution.

The institution expects full cooperation of all researchers to fulfill the research mission of the institution and societal needs. The TXST IRB board is supported by Research Integrity and Compliance (RIC).

This IRB operations handbook provides the guidelines and regulations governing research with human subjects. The IRB Researchers Guidelines and best practice handbook, a separate document, will outline requirements and best practices for submitting research proposals for review by TXST's IRB(s). Handbooks and University policies are updated periodically or

whenever a change is required due to regulatory changes. The IRB Director or his/her designee will review and approve the revised handbooks and policies.

The Institutional Official (IO) will review relevant policies and procedures. The Research Integrity and Compliance (RIC) department will keep the Institution's research community apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website. Changes to the policies and procedures are communicated to PIs, research staff, IRB members, and IRB staff through IRB website announcements at a minimum, email communications, or meeting announcements.

The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. It consists of various individuals and committees such as: the IO, the RIC Director, RIC staff, the campus IRB committee(s), departments, investigators, and research staff. The objective of this system is to assist TXST in meeting ethical principles and regulatory requirements.

The IO, Vice President for Research and RIC Director will review the activity of the campus IRBs and make a determination as to the appropriate number of IRBs that are needed for the institution.

The policies and procedures set forth in this manual are applicable to all TXST employees and TXST students who propose to conduct human subjects research. The authority also includes research conducted by non-Institution's employees who use Texas State University as a research site.

### 1.2 General Principles

Human subject research is an important area of TXST's research enterprise. Protecting research subjects, their rights, and their welfare is paramount to research growth, and advancing knowledge to improve human health is paramount to the TXST research mission. TXST has embraced protecting human subjects as fundamental to the ethical and responsible conduct of human subject research. Protection can only be achieved if our administrative units, faculty, and students work collaboratively with the common goal of understanding and implementing appropriate regulatory and safety standards remaining in compliance with regulations. To comply with regulations, TXST provides an "Assurance" to the Office for Human Research Protection to comply with federal regulations to the title §45 CFR 46, also known as the Common Rule [Appendix 7] endorsed by several federal funding sources as well as the specific Terms of Assurance that identify certain requirements TXST agrees to fulfill under the FWA.

Also, TXST is committed to complying with titles §21 CFR 50 and 56 [Appendix 5 & 6] if research is to test drugs, biologicals, and devices. These commitments apply to all human subject research conducted by all employees, students and external researchers at the university. TXST is compelled to provide appropriate guidance to researchers engaging in human subject research so that they keep the research subjects out of harm's way. These guidelines enumerated below meet such requirements.

The mechanisms by which the rights, welfare, and safety are being protected include:

1. A formal process to review, approve and monitor human subject research.
2. Provide sufficient resources for the program to flourish.
3. Educate and train investigators about their responsibility for the ethical and responsible conduct of research.
4. Improve the quality of research by identifying errors that might occur during the implementation of a protocol and taking appropriate corrective measures.
5. Be attentive to research participants' concerns and properly respond to their concerns.

**1.3 Mission**

The mission of TXST is to protect research subjects. The institution accomplishes this mission by:

Empaneling a committee named Institutional Review Board (IRB), composed of faculty, staff, and community representatives with a broad range of expertise to protect research subjects and the institution's research mission. Ergo, the mission requires its faculty and students to accept shared responsibility with the IRB by respecting and protecting the rights of research subjects and to comply with federal regulations.

1. The IRB is provided with adequate resources and administrative support to keep abreast of changing regulations and guidelines.
2. The IRB is equipped to monitor approved research projects to ensure no harm is done to research subjects.
3. The IRB is entrusted with a responsibility to independently assess and evaluate the risks and benefits of the proposed research and ensure that risks to human subjects are kept to an absolute minimum and are justified by potential benefits of the research.
4. The IRB is empowered to conduct local reviews of research projects as required by federal regulations and research actions as guided by the principles outlined in the Belmont report.

**1.4 IRB Authority**

The IRB at an institution has the authority to review, approve initiation of, and conduct continuing review of biomedical, social and behavioral research involving human subjects, and to assure the protection of the rights and welfare of human subjects. IRB's have the authority to ensure that all research proposals comply with the following:

1. Institution's standards for advancing and disseminating scientific knowledge and community interests.
2. Institution's objectives are to advance biomedical and social and behavioral sciences.
3. Institution's compliance with regulations that govern the protection of human research subjects under the revised Common Rule promulgated in 2018, Food and Drugs Administration (FDA) when necessary, and other applicable regulations.
4. Human subject research shall conform to the scientific, legal, and ethical principles which guide all research with acceptable research designs by minimizing the risks and enhancing benefits to research participants.

**1.5 Authority of Texas State University IRB**

The TXST Human Research Protection Program (HRPP) operates under the authority of the Institution's policy UPPS No. 02.02.03 titled "Protection of Human Research Subjects." Appendix #13

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:

1. the research is sponsored by the TXST;
2. the research is conducted by or under the direction of any employee or agent of the TXST in connection with their institutional responsibilities;
3. the research is conducted using any property or facility of TXST;
4. Research activity meets definition of human subject research per regulations;
5. the research involves the use of TXST's non-public information to identify or contact human research subjects or prospective subjects;
6. the research is conducted to support a student thesis or dissertation.

**1.6 Texas State University engaged in Human Research**

In general, an institution is considered engaged in human subject research when its employees or agents regardless of funding source obtain one of the following for research purposes:

1. Data about the subjects of the research through intervention or interaction with them;
2. Individually identifiable private information or identifiable biospecimens;
3. The informed consent of human subjects for the research.;

TXST is considered engaged in an HHS-conducted or -supported non-exempt human subjects research project when its employees or agents for research projects obtain one of the following:

1. Receives an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by non TXST employees or agents;
2. Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures;
3. Data about the subjects of the research through intervention or interaction with them;
4. Individually identifiable private information or identifiable biospecimens;
5. The informed consent of human subjects for the research.;

In general, OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Refer to [Appendix 17] for more information regarding when TXST is considered engaged in an HHS-conducted or -supported non-exempt human subjects research project.

### 1.7 TXST Not Engaged in Research

**TXST is not considered engaged in research when its employees or students perform any of the following conditions:**

1. The services performed do not merit professional recognition or publication privileges;
2. The services performed are typically performed by those institutions for non-research purposes; and
3. The institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

Specific examples include TXST employees or students:

1. Providing consulting with an investigator from an engaged institution on elements within a dataset that would meet the investigator's needs;
2. Consulting with an investigator from an engaged institution on analytic strategy;
3. Designing the analysis for an investigator from an engaged institution;
4. Developing analytic code for an investigator from an engaged institution;
5. Interpreting the results of analyses run in data center for an investigator from an engaged institution.

Refer to Appendix 17 for more information regarding when TXST is Not considered engaged in an HHS-conducted or -supported non-exempt human subjects research project.

### 1.8 Cooperative Research

Multiple institutions may be engaged in the same non-exempt human subjects research project. For such cooperative research projects, TXST may enter into joint review arrangements, relying upon the review of another qualified IRB, or serving as the IRB of record to avoid duplication of effort, in accordance with HHS regulations at 45 CFR 46.114.

When an TXST is engaged in only part of a cooperative research project each institution must ensure that the IRB(s) designated under its FWA reviews and approves the part(s) of the research in which the institution is engaged. A project specific Investigator Agreement is coordinated between TXST and the relevant cooperative research institutions by contacting Research Integrity and Compliance.

### 1.9 Relationship Among Institution's IRB Components

All internal or external IRBs under the Institution's Federal Wide Assurance [Appendix 11] function independently. An exception in certain circumstances include when the Chair of one of the IRBs may request that a study scheduled for review or continuing review be referred for review to another Institution's IRB (internal) listed in the assurance document. In order to meet this exception, the reviewing IRB is properly constituted ensuring expertise and membership requirements to approve a study.

### 1.10 Revisions and Maintenance of the Manual

The RIC Office is responsible for maintaining and updating this manual. All new or revised manual materials will be placed on the IRB website by the RIC office

## Section 2: Oversight of Human Subjects Research

### 2.1 IRB Jurisdiction includes the following:

1. All studies involving human subject research.
2. All funded and non-funded research involving biomedical, social, behavioral, and educational projects.

3. All clinical trials sponsored by pharmaceutical companies or other Industries (drugs, biologics, and devices.
4. All internally initiated clinical studies conducted by institutions, faculty, staff, and students with or without protected health information
5. All protocols that involve collaboration with another institution, and the other institution conducts a review, TXST IRB may sign an authorization agreement and vice versa.
6. Single IRB review of multisite studies requests. The IRB offices at the TXST will ensure such sites have an FWA for federally funded studies. Principal IRB conducting multisite research will take into account the local context provided by the Institution.
7. Research that has been reviewed and approved by the IRB may be subject to additional review and disapproval by the officials of the institution. However, these officials do not have the authority to approve a study that has been disapproved by the IRB.

**2.2 Studies Requiring IRB Review**

TXST requires IRB review and approval whenever biomedical, social behavioral or educational research projects are conducted by TXST employees and students. Refer to section about engagement of human subject research. [Appendix 17]

The following list provides areas requiring IRB review since they lead to generalizable knowledge.

1. Clinical trials
2. Surveys and questionnaires;
3. Interviews and focus groups
4. Analyses of existing data;
5. Existing and prospectively collected biological specimens
6. Epidemiologic studies
7. Evaluation of social or educational programs
8. Cognitive and perceptual experiments
9. Medical, clinical, or non-clinical chart reviews and
10. Medical and behavioral interventions (diagnosis and treatment).
11. Research projects and results with an intent to publish later or the research contributes to "generalizable (scholarly) knowledge" are considered human subjects unless the research has been determined to be non-human subject research.

* Participants in research studies deserve protection whether or not the research is published.

**2.3 Studies not Requiring IRB Review**

Studies that do not require IRB review activities are those associated with providing timely, situational awareness and priority setting during the course of an event or crisis that threatens public health including natural and man-made disasters. Even when IRB review is not required, researchers and staff are still required to submit an IRB determination request form located on the IRB website.

According to the OHRP, "Activities Deemed Not to Be Research" include the following:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
2. Public surveillance activities, including the collection and testing of information or biospecimens conducted, supported and requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow public health authority to identify, monitor, assess, or investigate potential public health signals, the onset of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns of disease outbreaks or conditions, or increasing injuries from using consumer products.). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or record by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
5. Private information or biospecimen is not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems if the following conditions are both met.
    a. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals, and
    b. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
        i. The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement).
        ii. There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances until the individuals are deceased; or

iii. There are other legal requirements for the release of the key to the investigators until the individuals are deceased.

6. Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be outlined in the application or proposal (45 CFR 46.118). These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under 45 CFR 46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency
7. If the proposed studies involve a group of individuals who are consultants and have been chosen for their expertise to improve the research design, such consultations are considered non-human subjects research.
8. If the studies involve a group of individuals who are brought in to test a new product (e.g. software, equipment, surveys) to identify "bugs" or problems, the research is considered non-human subjects research because the data collected is about the product and not about the individuals. This is a Beta -Test of the product. However, if the studies involve a group of the eventual target population who is brought in to "pilot test" a new product or intervention before researchers finalize the design of the product or intervention, the research MAY BE considered human subjects research. Pilot tests involve living individuals if the PI conducting research obtains data or individually identifiable private information.
9. Investigators make use of certain data such as Public Use Data (publicly available) and de-identified data Not Derived From Other Research Projects.

**2.4 Who will determine whether human subjects are involved in research?**

When non-human subject research (NHSR) is requested by the investigator, OHRP recommends that institutions adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations [see 45 CFR 46.101(b)].

The investigator is responsible for the initial assessment as to whether an activity constitutes human subjects research based on the definitions of "human subject" and "research" in Section 2 "Definitions." TXST investigators are to complete a Determination Request. Verification of determinations, whether the proposed non-human subject research study qualifies as NHSR, based on OHRP definitions of research and human subjects may be made by the RIC Director, designated RIC staff member, or IRB chair.

Determinations regarding less clear-cut activities will be clarified by the RIC staff through email and/or verbal communication with the investigator.

In cases it is verified by the RIC office or IRB chair proposed activity is not research or human subject research requiring IRB oversight, a determination letter will be emailed to the investigator which states the following:

1. The activities described in this application does not meet the regulatory definition of "research or "human subject's research" provided in §45 CFR 46.102 (l). Therefore, this project does not require IRB oversight.
2. Changes to the project must be submitted to the IRB for review prior to implementation to determine if the changes incorporate elements of human subjects research activities which require IRB oversight.

Documentation of all determinations made through the RIC Office will be recorded and maintained in the RIC Office. Formal submissions will be responded to in writing and a copy of the determination request and determination letter/email will be kept on file.

**2.5 Quality improvement activities (QIA)**

When quality improvement activities (QIA) are not done for research purposes, they may **not** be considered as human subject research. Examples are the following:

1. Implementing a practice to improve the quality of patient care or administrative performance
2. Collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes delivering healthcare or academic activities.

QIA Projects considered as human subject research are per regulations at the following link: (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html). Some examples include the following:

1. Activities such as measuring and reporting provider performance data for clinical, practical, or administrative uses to carry out a quality improvement project and publish the results.
2. Data that are not individually identifiable, such as medication databases stripped of individual patient identifiers, for research purposes.

Introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results

QIA projects that involve research require IRB review at full board or expedited review levels depending upon the level of risk to subjects and private information

QIA projects that are research must also meet all 3 parts of the HIPAA requirements when participant's protected health information is used. Refer to definition of HIPPA

**2.6 Questions or Concerns about Research Subjects and/or Researchers**

Questions or concerns about a study:

Any questions about the study are directed to the Principal Investigator/Faculty Advisor and Student PI if applicable listed on the IRB approved application. Contact information can be obtained through the recruitment material approved, consent form, or contacting RIC.

Rights of a Research Subject:

Any questions about the rights of a research subject are directed to the RIC Office and IRB chair. An individual has the right to request to be anonymous in their inquiry and RIC will maintain identifiable information confidential.

Questions or concerns general:

Faculty, research staff, students, and research subjects or any other person who has a question, concern, complaint, suggestion, or input regarding the HRPP or feels that they have been subjected to coercion or undue influence regarding aspects of human subject's research, or feels that they have observed issues of concern regarding human subjects research, may contact RIC:

Research Integrity and Compliance
601 University Drive, JCK 489
Phone: (512) 245-1423
Fax: (512) 245 - 3847
E-mail: orsp-irb@txstate.edu
RIC Website: https://www.research.txst.edu/orc.html

Any questions or concerns regarding the Human Research Protection Program and all allegations of coercion, undue influence or noncompliance are thoroughly investigated and, if applicable, corrective actions taken to rectify the situation. Ultimately, the RIC Director is responsible for ensuring that all concerns, complaints, and allegations have been addressed appropriately and that input and suggestions related to the HRPP are considered when reviewing the program. If it appears that the concern/complaint could be an incident of noncompliance. At the conclusion of any inquiry into a concern/noncompliance all individuals

involved will be informed of result. Serious matters of noncompliance or unanticipated problems that may impact participant safety or rights will be addressed in writing.

# Section 3: IRB Operations

### 3.1 IRB Operations

The organizational structure for human subject protection is attached [Appendix19]. IRBs are operated by individuals assigned to the roles listed in the organization chart and they are required to comply with all regulatory and ethical standards and practices. IRB operations are primarily conducted using an electronic submission. Review and approval of projects requiring IRB oversight are completed within the Kuali Protocols system. IRB records requiring IRB oversight are maintained electronically within the Kuali Protocol system and non-human subject research activities are maintained in a separate electronic spreadsheet stored on the RIC shared drive.

### 3.2 Institutional Official (IO)

The Institutional Officials (Signatory Official) will be appointed by the Vice President of Research. There is no specific term limit for this position.

The ultimate responsibility of the human subject protection program resides with the IO. The IO for the Texas State University is the Division of Research Associate Vice President of Operations. The IO is responsible for ensuring that the HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Assurances (FWA). The IO cannot approve research that has been disapproved or not yet approved by the IRB.

*The responsibilities of IO include:*

1. Appointing IRB members. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she/they is not fulfilling membership responsibilities and or obligations;
2. Appointing the IRB chair or co-chairs if applicable. Suspending or terminating the appointment of any chair or co-chair if he/she is not fulfilling his/her responsibilities and or obligations;

3. Performing periodic evaluation of the performance of the IRB chairs and co-chairs and administrative staff;
4. Managing and administering funds. Ensuring that adequate personnel, space and other resources are allocated to the HRPP;
5. Reviewing and signing agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
6. Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies as applicable, including reports to federal agencies;
7. Recruiting qualified members to include expert, non-scientific and unaffiliated representation on the IRBI;
8. Reviewing and approving University Policies for the IRB and HRPP

**3.3 HRPP Staff**

Each IRB shall be staffed by at least one (1) full-time administrative staff person. HRPP staff is selected in consultation with IO, IRB Chairs and IRB Director as per TXST Human Resources policies and procedures. HRPP staff is evaluated annually according to Human Resources policies and procedures. The staff members shall assist the IRB by fulfilling all record keeping, notification, recording, preparing agenda, preparing minutes of meetings and other procedural requirements as stated herein. The staff is trained to perform all the administrative duties of the IRB and will be familiar with all applicable regulations and institutional guidelines. The IRB Support Staff is responsible for maintaining complete IRB paper/electronic files, records of all research protocols, preparing IRB agenda, IRB minutes and IRB correspondence. Retaining records for at least 3 years after completion of the research, and ensuring records are accessible for inspection

HRPP staff(s) responsibilities include the following:

1. Assisting investigators in their efforts to carry out Institution's research mission;
2. Developing training requirements as required and as appropriate for investigators, committee members, and research staff, and ensuring that training is completed on a timely basis;
3. Responding to faculty, student and staff questions;
4. Working closely with the IRB chair(s) and leadership on the development of policy and procedures, as well as organizing and documenting the review process.
5. Initial review of documents and screening of research proposals prior to its review by the IRB as well as serving as the liaison between the investigators and the IRB.
6. Monitoring changes in regulations and policies that relate to the human research protection program and providing updates on changes.
7. Implementing the Institution's human subject protection policy;
8. Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;

9. Developing and implementing an educational plan for IRB members, staff and investigators;
10. Recruiting qualified members to include expert, non-scientific and unaffiliated representation on the IRBI;
11. Implementing daily operations of the IRB and HRPP in accordance with the SOPs.
12. Develop and implement IRB outreach programs
13. Implement post monitoring activities

### 3.4 RIC Director and HRPP Senior Staff

IRB Director is responsible for all aspects of the IRB program throughout the review process of a research proposal involving human subjects.
This responsibility includes the following:

1. Reviews the IRB minutes for accuracy and ensures proper documentation of discussions, including controverted issues and actions taken by the IRB during its convened meetings.
2. Advises the IO on key matters regarding research at TXST;
3. Developing, managing and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research.
4. Oversight of the submission, implementation and maintenance of approved FWAs and IRB registration;
5. Securing adequate resources for the management of the program
6. Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program;
7. Serving as the primary contact at the Institution for the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies;
8. Day-to-day responsibility for the operation of the HRPP office, including supervision of IRB staff;
9. Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP
10. Oversee the development and implementation of IRB outreach programs
11. Oversee the Implementation of post monitoring activities

### 3.5 Division of Research – Sponsored Programs

Research Support Services staff review all research agreements with federal, foundation, or non-profit sponsors. This ensures that all terms of the award are in compliance with institutional policies. Only designated senior individuals within Sponsored Programs have the authority to approve research proposals and to execute externally funded research agreements that are on behalf of the institution.

When the grant or contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of the Institution, a subcontract is executed between the Institution and the collaborating institution. The subcontract includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval by submission of an executed Form 310 (as applicable). The collaborating institution must also ensure that key personnel involved in conducting human subject research subjects are in compliance with all applicable regulations (**Common Rule, Appendix 7**), FDA regulations (**Appendix #4** and FERPA (**Appendix 20**) for the protection of human research subjects and provide documentation of education of key personnel to the Institution. If the grant or contract includes multi-sites, the TXST IRB office will facilitate single IRB review for a multisite study, such single IRB review will require consideration of local context and an interinstitutional agreement to rely upon an external IRB or TXST IRB as necessary.

### 3.6 Quality Assurance/Quality Improvement and Compliance Audits

The objective of the TXST HRPP Quality Assurance/Quality Improvement Plan is to measure and improve human research protection effectiveness, quality, and compliance with organizational policies and procedures and applicable deferral, state, and local laws. The Quality Assurance/Quality Improvement Plan and compliance audits will be managed and implemented by the RIC staff.

The RIC conducts routine “not for cause” audits and “for cause” audits. A “not for cause” audit” is conducted to assess, educate and train investigators to remain in compliance with federal, state and local regulations and institution policies. Whereas “for cause” audits are conducted in response to regulatory and institutional concerns. In both cases, auditors are delegated by the RIC Director. Auditors will confirm whether approved protocols are implemented as approved by the IRB by examining investigator’s research records, recruitment and consenting process, observe recruitment and consenting process and other human subject research conduct issues that are pertinent to protect human research subjects. IRB-required audits may include external collaborator’s site or institutions to assess compliance with federal, state and local law and IRB policies and procedures.

All audit reports are reported to the IRB committee and the investigator. If an audit review finds that research subjects are exposed to unexpected serious harm, RIC Director will report such findings to the IO, investigator and Department Chair or Dean of specific school or college.

In addition, periodically RIC will determine randomly which study would require verification that study is being implemented as approved by the IRB. Such random selection may include projects that are determined to be high risk, high level of enrollment, vulnerable populations, federally funded, involve an investigator who in the past had failed to comply or the determination by the IRB of possible material changes occurring without IRB approval.

### 3.7 Compliance Review for IRBs

Compliance audits are done when directed due to concerns raised by federal agencies, external sponsors or others. The results may impact current practices and may require additional educational activities or revisions to SOPs, and noncompliance will be reported to the IO, department head and the Dean of the respective college or school. Compliance audits of IRB include the following:

1. Review the IRB minutes to determine that adequate documentation of the meeting discussion has occurred. This review will include assessing the documentation surrounding the discussion for protections of vulnerable populations as well as other risk/benefit ratio and consent issues that are included in the criteria for approval;
2. Assess the IRB minutes to assure that quorum was met and maintained;
3. Assess the current reporting process for unanticipated problems;
4. Assess privacy provisions, according to HIPAA; have been adequately reviewed, discussed and documented in the IRB minutes;
5. Evaluate the continuing review discussions to assure they are substantive and meaningful and that no lapse has occurred since the previous IRB review;
6. Observe IRB meetings or other related activities;
7. Review IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures;
8. Review the IRB database/electronic system to assure all fields are completed accurately;
9. Assess reviews by the IRB members;
10. Verify IRB approvals for collaborating institutions or external performance sites;
11. Review the appropriate metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process;
12. Review IRB member rosters and training records and
13. Other monitoring or auditing activities deemed appropriate by the IRB.

The RIC Director will review the results of internal reviews. If any deficiencies are noted in the review, a corrective action plan will be developed by the Director and approved by the IRB committee. The Director will have responsibility for overseeing the implementation of the corrective action plan and sharing the results with the IO.

### 3.8 Review of Human Subjects Research Activities by Other TXST Ancillary Committees

The TXST IRB(s) coordinate reviews with other institutional committees as described below. None of these committees are a formal part of the Institution's IRB structure, but there is communication between the committees regarding status of review and/or conditions of

approval. Other institutional committees also share the responsibility for following guidelines in the collective effort to protect human subjects; however, the final authority for participation of human subjects in research falls on the IRB.
Researchers are not required to wait for the approval of the other institutional review committees before submitting a proposal to the IRB. These reviews are generally conducted in parallel when IRB is conducting its review.

**3.9 Radiation Safety Committee (RSC)**

The RSC provides expertise with regards to accepted radiation protections regulations and practices. For human subject-related radiation safety issues, the RSC managed by TXST Environmental, Health, Safety, Risk, and Emergency Management reviews and makes appropriate decisions under their jurisdiction. The RSC reviews any research that involves the use of X-ray, radioisotopes, lasers, or infrared or near infrared devices. The IRB may request investigators to implement changes to their IRB protocol based on advice from the RSC if it will minimize risk to research participants. A review by the two committees may occur concurrently. If RSC review is completed after the IRB review, the IRB chair reviews any RSC comments. If the chair believes the suggested changes are appropriate and qualify as minor modifications, the IRB chair reviews these through an expedited process. If changes exceed minor modifications, the IRB chair refers the application back to the full board for review. If the chair determines that full-committee review is necessary, RIC staff through email communication will notify the investigator and the Radiation Safety Officer that the study has been placed on administrative hold until the concerns are addressed by the IRB.

To ensure protection for human subjects against radiation, research proposals are categorized and reviewed as follows:

**Class 1:** Radiation Exposure or application of radioactive material as related to a standard clinical procedure that the individual as a patient would have received anyway. The radiation Safety Officer (RSO) will approve such projects.

**Class 2:** Radiation exposure or application or a radioactive material due to a standard clinical procedure that the human subject would not have normally received but which is part of proposed research protocol.

**Class 3:** Radiation exposure due to a non-standard procedure

Procedure for approval is dependent on particular class under which the proposed protocol involving human use falls:

**Class 1:** Radiation Safety Committee review will be necessary.

**Class 2:** Application and associated consent form will receive a summary review jointly by the IRB and the Chair of the RSC. The Radiation Safety Officer shall ensure that the radiation doses are appropriately documented. Full review by the RSC will be necessary, but the action taken will be reported, for the record, at the next Radiation Safety Committee.

**Class 3:** The full IRB and the RSC must review Application and associated consent forms. There may be a separate RSO for EHSREM to conduct independent reviews to

approve or disapprove research protocols involving radiation. Recommendations from RSC will be forwarded to the IRB for discussion at the time of the review to ensure that subjects are protected from harm induced by radiation.

### 3.10 Institution Biosafety Committee (IBC)

Since TXST receives NIH funding this Committee reviews research protocols that involve potentially biohazardous materials and agents, recombinant and synthetic nucleic acids, and the use of tissue isolated from vertebrates. The purpose of these reviews is to ensure that all activities involving these materials, and the facilities used to conduct such work, are in compliance with all applicable external regulations and University policies. Any questions regarding IBC requirements can be directed to ricibc@txstate.edu.

### 3.11 Cooperative Research Projects

Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. When the institution is engaged in cooperative research it will rely upon approval by a single IRB for that portion of the research that is conducted elsewhere in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. The following research is not subject to this provision:

1. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
2. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
3. For research not subject to 2.10.B. of this section, the Institution may enter into joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication.

When the Institution relies on another IRB, the HRPP staff will review the policies and procedures of the IRB providing the review to ensure that they meet Institution's standards. If the other institution holds a FWA, it will be assumed that Institution's standards are being met.

When the Institution reviews research conducted at another institution the particular characteristics of each institution's local research context must be considered, either

(i) through knowledge of its local research context by the Institution's IRB or

(ii) (ii) through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other IRB members.

If the Institution's IRB is the coordinating facility, the Principal Investigator must document how the important human subject protection information will be communicated to the other participating facilities engaged in the research study. The investigator is responsible for serving as the single liaison with outside regulatory agencies, with other participating facilities, and for all aspects of internal review and oversight procedures. The investigator is responsible for ensuring that all participating facilities obtain review and approval from their IRB of record and adopt all protocol modifications in a timely fashion. The investigator is responsible for ensuring that the research study is reviewed and approved by any other appropriate committees at the coordinating facility and at the participating facilities (e.g. VA Research and Development Committee approval) prior to enrollment of participants.

The PI must follow these procedures when the Institution is the coordinating facility:

1. During the initial IRB submission of the multi-site study, the investigator indicates in writing on the IRB application form or in an email to orsp-irb@txstate.edu that the Institution is the coordinating facility of a multi-site study.
2. The investigator submits the following information in their IRB application materials:
    a. Whether research activities at participating institutions are defined as engagement;
    b. Name of each participating facility;
    c. Confirmation that each participating facility has an FWA (including FWA number);
    d. Contact name and information for investigator at each participating facility
    e. Contact name and information for IRB of record at each participating facility
    f. Method for assuring all participating facilities have the most current version of the protocol;
    g. Method for confirming that all amendments and modifications in the protocol have been communicated to participating sites;
    h. Method for communicating to participating facilities any serious adverse events and unanticipated problems involving risks to subjects or others
    i. Method of communicating regularly with participating sites about study events
3. The investigator submits approval letters from all of the IRBs of record for all participating sites.
4. The investigator maintains documentation of all correspondence between participating sites and their IRBs of record.

When the TXST is engaged in only part of a cooperative research project, the Institution's IRB only needs to approve the part(s) of the research in which the investigator is engaged. For example, if the Institution is operating the statistical center for a study that receives identifiable

private information from multiple other institutions, the Institution's IRB reviews and approves the research activities related to the receipt and processing of the identifiable private information by the statistical center.

### 3.12 Cooperative agreements for FDA-related research

The Food and Drug Administration (FDA) and Department of Health and Human Services (HHS) regulations permit institutions involved in multi-institutional studies to use reasonable methods of joint or cooperative review **[21 CFR 56.114 and 45 CFR 46.114, respectively.** While the IRB assumes responsibility for oversight and continuing review, the clinical investigator and the research site retain the responsibility for the conduct of the study.

The regulatory provision for cooperative review arrangements may be applied to different types of cooperative clinical investigations. Examples include research coordinated by cooperative oncology groups and participation by investigators and subjects in a clinical study primarily conducted at or administered by another institution. Often, one institution has the primary responsibility for the conduct of the study and the responsibility for administrative or coordinating functions. At other times, multi center trials may be coordinated by an office or organization that does not actually conduct the clinical study or have an IRB.

The cooperative research arrangements between institutions may apply to the review of one study, to certain specific categories of studies or to all studies. A single cooperative IRB may provide review for several participating institutions, but the respective responsibilities of the IRB and each institution should be agreed to in writing.

The Institution may agree to delegate the responsibility for initial and continuing review to another institution's IRB. In turn, the IRB agrees to assume responsibility for initial and continuing review. The institution, when delegating the responsibility for review, understands that it agrees to abide by the reviewing IRB's decisions. In that case, the Institution remains responsible for ensuring that the research conducted within its own institution is in full accordance with the determinations of the IRB providing the review and oversight.

If the Institution's IRB agrees to review studies conducted at another institution, then the Institution bears the responsibility for initial and continuing review of the research. In that case the Institution's IRB takes into account the required criteria for approval, the facilities and capabilities of the other institution, and the measures taken by the other institution to ensure compliance with the IRB's determinations. The reviewing IRB needs to be sensitive to factors such as community attitudes.

The agreement for IRB review of cooperative research will be documented. Depending upon the scope of the agreement, documentation may be simple, in the form of a letter, or more complex, such as a formal memorandum of understanding. In the case of studies supported or

conducted by HHS, arrangements or agreements may be subject to approval by HHS through the Office for Human Research Protections (OHRP) and will be executed in accordance with OHRP's instructions. Whatever form of documentation is used, copies will be furnished to all parties to the agreement, and to those responsible for ensuring compliance with the regulations and the IRB's determinations. The IRB's records will include documentation of such agreements.

When an IRB approves a study, it notifies (in writing) the clinical investigator and the institution at each location for which the IRB has assumed responsibility **[21 CFR 56.109(d)]**. All required reports from the clinical investigators will be sent directly to the responsible IRB with copies to the investigator's institution, as appropriate.

Another form of cooperative research activity is a multi-institutional IRB that oversees the research activities of more than one institution in a defined area, such as a city or county. Such an IRB will be formed by separate but cooperating institutions and eliminates the need for each facility to organize and staff its own IRB. A variation of this is an IRB that is established by a corporate entity to oversee research at its operating components, for example, a hospital system with facilities at several locations.

# Section 4: IRB(s), IRB Chairs, Membership

### 4.1 IRB

TXST has established an Institutional Review Board (IRB) to ensure the protection of human subjects in human subjects research conducted under the auspices of the Organization. TXST IRB apply appropriate policies and procedures described in this document. In addition, TXST outsources some projects approved by the IO for certain clinical studies or industry sponsored research.

1. Advarra: The use of Advarra as an option is available to TXST clinical investigators who conduct industry-initiated, industry-sponsored research activities in which all activities are conducted at TXST sites and by TXST personnel.

The external IRB listed above serves as the IRB-of-record for TXST on a project-to-project basis. RIC HRPP staff will provide project-specific instructions to researchers if the IO approves of the review being outsourced.

**4.2 Membership of the IRB Committee**

The TXST board is comprised of members from each TXST academic college and at least one nonaffiliated member. The committee is comprised of both regular and alternate members selected based on the research objectives and corresponding expertise of the individuals. The number of representatives from each academic college may vary depending on the volume and types of human research to be reviewed for each college. All members will have varying backgrounds, experience, expertise, and professional competence as necessary to promote a complete and adequate review of research activities at Texas State University.

1. Roster: The Membership roster is developed and maintained by RIC and is posted on the IRB website. A list is also provided to the Division of Research annually and updated with OHRP in accordance with HHS regulations at 45 CFR part 46, subpart E.
    a. A membership roster with contact information is available to committee members in CANVAS. The internal roster contains the member's name, role, title, department, and non-public contact information.

2. Composition: The board will be comprised of a diverse group of individuals taking into consideration, expertise, gender, diversity, and advocates of vulnerable populations The IRB board must be comprised of at least five members being comprised of at least one scientist member, one non-scientist, and one nonaffiliated member of diverse experience per Common Rule. A licensed medical physician serves on the board per Texas law 25 TAC 289.226 and TAC 289.231 (b). The RIC Director serves as a voting member.

3. IRB membership: will be periodically evaluated by RIC and the IRB Chair to determine if an adjustment of the membership or composition is necessary to meet the institution's research objectives, pertinent regulations, and guidelines. The Institutional Official is informed of changes in IRB membership. New members identified are recommended to the IO for approval by RIC staff. If approved, a letter signed by the Vice President of Research (IO?) notifying them of acceptance to serve on the committee will be provided to the new member. Administrative offices and affiliate institutions such as the IO and legal counsel may not serve as voting members of the IRB or carry out day-to-day operations of the review process. Individuals from these offices may provide information to the IRB and attend IRB meetings as guests/ex officio members.

On an annual basis the RIC, with input from the chair, will evaluate the individual IRB member performance currently serving in the board in terms of attendance, timeliness, and overall review quality. The Institutional Official(VP?) is informed of changes in IRB membership. Recognition letters based on length/quality of service are also provided to members as applicable. Members are rotated off the committee after completion of one 3-year term to allow other TXST faculty to serve, bringing fresh perspectives. Former members are placed on a

waiting list for a minimum of 1 year in which they are eligible for reconsideration to serve on the committee if a vacancy is available and it meets the committee's current needs..

### 4.3 IRB Chair Duties

The IO, with input from RIC and others as designated, evaluates IRB Chairs' performance on an annual basis. The Institutional Official or designated person is responsible for addressing performance issues with the IRB Chair(s) and for selecting new Chair(s) and Co-Chairs (if applicable) when necessary. Recognition letters based on length/quality of service are also provided to IRB Chairs as applicable.

Chairs are monetarily compensated for their time as determined appropriate by the Institutional Official and Division of Research Vice President of Research. The IRB Chair workload model using course release is no longer applied as compensation.

The IRB Chair duties include the following:

1. Work collaboratively with board members and RIC to maintain and improve the Human Research Protection Program (HRPP), by promoting ethical and responsible conduct of research climate at the University.
2. Chair IRB meetings.
3. Understand and apply the principles of the Belmont Report and the federal regulations related to the protection of human subjects.
4. Serve as a designated expedited/exempt limited reviewer.
5. Assist RIC in IRB educational activities such as presentations to researchers when necessary.
6. Keep abreast of regulations and policies governing IRB review of research and the conduct of human subject research.
7. Provide leadership to the IRB to help ensure the rights and welfare of human subjects participating in the research reviewed by the IRB.
8. Collaborate with investigators and administrators to resolve controversial and/or procedural matters relating to research approval and conduct of research as needed.
9. Annually completing the electronic Financial Conflict of Interest Form in Kuali.
10. Disclosing any potential conflicts before IRB review of the research for which a conflict may exist. If the chair's own research is being reviewed, they will recuse themselves and a temporary co-chair will need to facilitate the meeting.
11. Assist in managing any conflict of interest by ensuring the IRB member(s) with conflicts are not present for review of research for which a conflict may exist.
12. Maintain confidentiality of all IRB-related information.
13. Assist in administering board decisions and maintaining the independence of the IRB.
14. Participate in the development of meeting agendas, policies, procedures, and education efforts to support the human research protection program.
15. Maintain communication with the RIC regarding IRB issues.

16. Participate in the development of policies, procedures, and institutional efforts to promote a culture of shared responsibility for the safety and welfare of research participants.
17. Facilitate discussions with the board members.
18. Provide support and advice to board members.
19. Assist in the resolution of disagreements between board members.
20. Guide committee members and investigators through resolving complex, controverted, ethical, and regulatory issues and disputes.

Below are the preferred qualifications:

1. Experience serving on an IRB.
2. Experience with developing IRB applications as a principal investigator.
3. Experience with managing an externally funded project with IRB oversight.
4. Experience in directing a student thesis or dissertation involving IRB oversight.

**4.4 IRB Chair(s) selection**

The chair(s) are appointed by Division of Research Vice President for Research upon recommendation by the Institutional Officer based on experience, expertise, and recommendations. Chairs must obtain their department chairs approval prior to accepting the position.

The RIC formally informs current and former IRB members of the IRB chair(s) vacancy via email. Members can nominate themselves or others for consideration. Nominees must apply for the position by submitting a CV and 500-word letter explaining their interest, their vision for the board, and any relevant experience to serve as the Chair.

The anticipated length of service is a 3-year term (with renewable terms of one to three years). The minimum attendance requirement is for at least 70% of the meetings scheduled. In the event the chair is unable to attend the meeting or has a conflict of interest he/she should notify RIC immediately. The IRB chair can identify and suggest a current member to serve as temporary Cochair in consultation with RIC if one is not appointed to serve for the length/parts of the convened meeting. The meeting can be rescheduled for another time or day if a temporary chair cannot be identified.

**4.5 IRB Co-Chair**

TXST currently does not have a formal appointed Co-chair. IRB co-chairs are identified in consultation with the IRB Chair, and the RIC staff. Co- chair will be an active committee member

with at least one year experience and fulfill all of the responsibilities of the chair when chair is not available or when the chair is conflicted with the review process.

### 4.6 IRB Primary/Alternate Committee Member Selection and Duties

RIC will recruit prospective members recommended by current members, Department chairs, IRB chair, RIC, and IO. If the prospective member is interested the Institutional Official (IO) will inform the Vice President for Research of the recommendation. If the nominee is accepted by the IO and Vice President of Research a letter will be sent to the new member informing them of the acceptance to serve on the committee.

The anticipated length of service is 3-year term (with renewable terms of one to three years) The minimum attendance requirement for Primary members is at least 70% of the meetings scheduled. If unable to commit to 70% the member RIC staff should be notified, and arrangements can be discussed to determine if they can serve as an alternate or switch positions with their alternate equivalent.

Committee Members are not compensated for their time.

Committee Primary/Alternate Member duties:

1. Attending IRB meetings and actively participating in the review of research.
2. If unable to review or attend the meeting, make appropriate arrangements with RIC so your alternate can review and attend the meeting.
3. Primary members are required to attend 70% of all meetings
4. Alternates can attend any meeting but are not required to attend 70% of the meetings.
5. Completing initial CITI training on human subject protection for IRB members and GCP training with continuing education every three years if your IRB membership is continuing past the initial Triennial training.
6. Understanding and applying the principles of the Belmont Report and the federal regulations related to the protection of human subjects.
7. Providing timely written comments on research undergoing IRB review
8. Disclose any potential conflicts before the IRB review of the research for which a conflict may exist.
9. Maintaining confidentiality of IRB-related information.
10. Participating in educational efforts for investigators, research staff, and new IRB members.
11. Participating in the discussion of issues affecting the human research protection program and contributing to policy development, as appropriate.
12. Reviewing and approving research by exempt Limited and expedited procedures, when designated by RIC or Chair to perform this review.

### 4.7 Alternate Member's Appointment and Duties

Federal regulations allow organizations to appoint an alternate(s) to substitute for an IRB member(s) who is unable to attend so that IRB business may move forward promptly. Alternates are appointed by the same process and for the same length of time as IRB members.

IRB alternates function as regular board members when they are in attendance. An alternate may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Alternates and IRB members have equal responsibilities. However, an alternate member cannot vote if the primary member is present at the meeting. For responsibilities of alternate members, please read the primary/alternate member's responsibilities above (vide Supra)

### 4.8 Member Conflicts of Interest

An IRB member can be an investigator. In each convened IRB meeting, all members in attendance are reminded verbally to recuse themselves from discussions and voting if they have a conflict in reviewing protocols. No member of the IRB shall participate in any way in the initial or continuing review of any project in which the member has a conflict of interest as determined under governmental or institutional policies, except to provide information requested by the IRB. In the event that the Chair has the conflict, the Vice Chair or other senior member of the IRB shall preside over the meeting.

The following circumstances may render members having conflict of interest for reviewing research:

1. Where the member or consultant is involved in the design, conduct, and reporting of the research.
2. Where an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research.
3. Where the member holds significant financial interests related to the research being reviewed.
4. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

### 4.9 IRB Subcommittees

Some of the IRB functions may be performed by IRB sub-committees appointed by the Chair(s) of the IRB or RIC. Members of the IRB Subcommittee must be experienced members of the IRB and should be matched as closely as possible with their field of expertise to the study assigned

to the IRB Subcommittee. The number and composition of the IRB Subcommittee members shall depend on the authority delegated by the IRB Chair to such IRB Subcommittee. IRB subcommittees can create policies, investigate non-compliance and make appropriate recommendations to the full IRB. The Full Board committee may delegate a subcommittee the authority to approve, recommend conditions to be met for approval, or recommend disapproval of protocols. An update of the subcommittee's decision is provided to the Full Board committee at the next scheduled convened meeting.

### 4.10 Consultants

Research that requires expertise beyond or in addition to that available on the IRBs, or involves a vulnerable population where no IRB member is knowledgeable about or experienced in working with these participants will be present at the meeting, one of the following will occur:

1. RIC staff may identify the need for review by a consultant during the preliminary screening of a protocol submission and discuss with the chair. The ORIC staff will invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.
2. The secondary reviewers may identify the need for a consultant during their review. The secondary reviewer(s) will notify ORIC and/or IRB Chair to invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.

Consultants with potential conflicts of interest may not provide information to the IRB. Conflicts will be identified by querying the individual at the time of assignment to review. The use of a consultant and the result of the consultant's review will be shared with the IRB by either having the consultant attend the convened IRB or by having the consultant provide a written summary to the RIC staff who will share with reviewers. Written statements of consultants will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes and Kuali pro.

Consultants are non-voting members. The IRB Office will ensure that all relevant materials are provided to the outside reviewer prior to the convened meeting.

### 4.11 IRB Member Training

The IRB chair, members, and RIC staff involved with the Human Subject Protection Program receive human subject protection education related to federal regulations and guidance, HRPP policies and procedures, and IRB review processes.

Minimally, initial training in human subject protection, with renewal every three years is required. This is done by completing Collaborative Institutional Training Initiative (CITI) modules. Modules required are IRB Member learning module and Good Clinical Practice (GCP)RIC staff verify CITI training during the onboarding process and at a minimum once a year to verify still current.

Chair, members, and RIC staff also receive additional education/new information via newsletters, email announcements, website postings, in-person training sessions, conferences, and webinars

### 4.12 Allegations and Undue Influence

Institutions research team, faculty, staff, administration or students may report to RIC suspected or actual non-compliance with the approved study's provisions and applicable human research regulations. Complaints can also be sent to the IO, HRPP, IRB Director or any other senior administrators in the Institution. Reports of noncompliance may arrive in the form of a complaint or from the results of an audit.

Research participants, family members of research participants, and other external to the Institution, including regulatory agencies may also report in writing or anonymously suspected noncompliance to the IRB chair, Institution's RIC, Vice President Division of Research to the IO or to the President of the Institution

The reports of research non-compliance, misconduct and whistleblower reports are subject to different rules and they may be referred to the Institution's Legal Counsel.

If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the RIC Director and to the Institutional Official (IO), depending on the circumstances. The official receiving the report will conduct a thorough investigation and determine a corrective action, if indicated, will be taken to prevent additional occurrences.

## Section 5: Meetings

### 5.1 IRB Meeting Schedule

The IRB meets the third Wednesday of each month and deadlines are two weeks prior unless otherwise noted due to holidays or other unanticipated events (natural weather disasters). The annual schedule with meeting dates and submission deadlines is developed and posted on the IRB website before the Fall Semester begins. Deadlines do not apply to reviews that meet exempt or expedited review criteria as determined by RIC. Meetings can occur in person, via Zoom, or hybrid. The meetings may last up to 2 hours depending on the number of protocols and complexity of the reviews.

The IRB will meet monthly or as frequently as is necessary to complete the business of the IRB, with meetings conducted by the IRB Chair or appropriate designee approved by RIC or the IO.

**5.2 Quorum**

RIC staff attending IRB meetings are responsible for determining whether the meetings are appropriately convened before the decision and voting for each review. A quorum is defined as the majority voting members including at least one member whose primary concerns are in nonscientific areas in attendance at a convened meeting (45 CFR 46.108(b); 21 CFR 56.108(c)). If a majority of the voting members are not present, or if a nonscientist is not present, then quorum has not been met. Alternates are not calculated in the quorum as they are substitutes for regular members.

Assuming all applicable committee composition requirements are satisfied (section 4.2) , the number of IRB members necessary for a quorum is calculated by dividing the number of members in half and “rounding up” when there is an odd number of members or “adding one” for an even number. For example (i) If an IRB has 15 members, the quorum is 8 (ii) If an IRB has 20 members, the quorum is 11.

If a quorum is not met, then IRB voting cannot take place; and the items on the agenda will be tabled until the next convened IRB meeting or ad hoc meeting. The comments entered in Kuali protocol and discussed in the meeting will be shared with the researcher to address before the next scheduled meeting the agenda item will be voted.

If a quorum is lost during a convened meeting (e.g., due to a member leaving the meeting), then no further voting can take place; and the remaining items on the agenda will be tabled until quorum/ nonaffiliated member can be restored or the next convened IRB meeting unless the non-affiliated is also a non-scientist. In the case of a drug, biologicals or device study a physician must be present or no further voting can take place; and the remaining items on the agenda will be tabled.

RIC staff attending IRB meetings record the attendance of members as they enter and leave the room. If the quorum is lost, RIC staff will notify the IRB Chair that no further actions can be taken until/unless a quorum is restored.

IRB members with potential conflicts of interest must leave the room before the discussion of the research, except to provide the information requested by the IRB. Members with potential conflicts of interest may not be present for the vote and are not counted toward a quorum for review of the research for which the potential conflict exists.

Comments from members unable to attend a meeting that has been provided in advance (e.g. e-mail or Kuali protocols) may be considered by the attending IRB members.

Any member may participate and vote if unable to attend in person by teleconference or videoconference, provided the member has received all materials before the meeting and can actively and equally participate in the discussion. In certain circumstances, an electronic vote can be utilized. Alternate votes do not count unless they are substitutes for a regular member. (e.g. two members from the Psychology department vote on a protocol. Only the regular member's vote is recorded).

### 5.3 Telephone and Audio-visual (AV) use for meetings

Most IRB meetings for TXST are conducted in hybrid format with the IRB chair and RIC staff member present in the same room. Face-to-face meetings are encouraged for those who can attend at a minimum once a year. When telephone and audio-visual methods are used, the minutes will reflect how members participated in the meeting. All members, irrespective of their mode of participation shall receive all pertinent information prior to the meeting and will be able to participate equally and actively during discussions. When a member leaves the AV conference, that member will not be counted towards the quorum.

### 5.4 Reporting of regulatory changes and guidelines

The RIC staff/Director shall regularly report to the IRB any amendments to or newly applicable FDA or Common Rule regulations as well as any changes in TXST policies and procedures that affect the operation of the IRB and its ability to safeguard the rights and welfare of research subjects. The RIC staff/Director shall also regularly report to the IO any amendments to existing regulations or newly applicable FDA and DHHS regulations, non-compliance/deviations in implementing protocols as approved by the IRB, suspensions and alleged scientific misconduct.

### 5.5 Meeting Procedures

The IRB Chair, or Vice-Chair (in the event that the IRB Chair is absent or conflicted), will call the meeting to order, once it has been determined that a quorum is met. In the event that both the Chair and Vice-Chair are absent, the board members present will vote to appoint a member to serve as Chair for the meeting. This vote will be documented in the meeting minutes. The Chair or Vice-Chair will remind IRB members to recuse themselves from the discussion and vote by leaving the room where there is a conflict. The IRB will review and discuss the IRB Minutes from the prior meeting and determine if there are any revisions/corrections to be made. If there are no changes to be made, the Minutes will be accepted as presented and considered final. If it is determined that revisions/corrections are necessary, the Minutes will be amended.

All members present at a convened meeting have full voting rights, except in the case of a conflict of interest. Alternate members have full voting rights if the primary member is absent. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

It is the responsibility of the HRPP staff to take minutes and record the proceedings of the meeting and present meeting minutes.

**5.6 Guests**

Each Principal Investigator (highly recommended) or his/her representative may be invited to the IRB meeting to answer questions about their proposed research. The Principal Investigator may not be present for the discussion or vote on their research.

Ex-officio guests are individuals who, by virtue of their position and their role in the Institution's research may, regularly attend IRB meetings. Ex-officio guests may fully participate in the IRB discussion and deliberations but may not vote.

Other guests may be permitted to attend IRB meetings at the discretion of the IRB Chair and the RIC staff. Guests, other than ex-officio guests, may not speak unless requested by the IRB. All guests are reminded to maintain confidentiality of IRB discussions.

**5.7 Meeting minutes**

In compliance with the HHS regulations at 45 CFR 46.115(a)(2) and the FDA regulations at 21 CFR 56.115(a)(2) ORIC will prepare and maintain minutes to show:

1. Attendance at the meetings by listing their names.
2. Summary of actions taken by the IRB;

3. The vote on these actions, including the number of members voting for, against, and abstaining;
4. The basis for requiring changes in or disapproving research
5. A written summary of the discussion of issues and their resolution.

# Section 6: IRB Review Process

### 6.1 CFR Regulations to Approve the Submission

To approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied in accordance with §46.111 Criteria for IRB approval of research.

1. Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable taking into account the purposes of the research and the setting in which the research will be conducted. The IRB will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, or mentally disabled persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and to the extent required by §46.116.
5. Informed consent will be appropriately documented by and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, or mentally disabled persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

### 6.2 Proposals Submitted for IRB Review

The IRB is subject to both the HHS and FDA regulations in titles 45 (45 CFR Part 46), and 21 (21 CFR Parts 50 and 56) respectively.

### 6.3 Applicants

Applicants can be Texas State students, faculty, staff, or non-Texas state-affiliated persons. Non-Texas state persons must find a Texas State faculty member to serve as a proxy and contact person on the proposal. Students need a faculty member to be listed on the application as Principal Investigator/Faculty Advisor. The student can list themselves under Key personnel as Principal Investigator – student researcher.

If students are completing a proposal for a thesis and are using data previously approved by a Texas State faculty member, they are not required to submit a new proposal. The original PI should add the student to their proposal as key personnel and the ORIC can issue a letter for the student to provide documentation to the Graduate College. If the student is using the same procedures as previously approved studies but implementing an additional new procedure they will be required to submit a new proposal.

### 6.4 IRB Review Process

The Texas State IRB review process involves submission through the Compliance Kuali system. Once received by the RIC office it will follow the process outlined in Appendix # after verifying it meets the definition of human subject research.

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:

1. the risks to the subjects;
2. the anticipated benefits to the subjects and others;
3. the importance of the knowledge that may reasonably be expected to result; and
4. the informed consent process to be employed.

Please note that only the RIC/HRPP staff assign the level of review based on regulations not the researcher. The three levels of review can be exempt, expedited, or full board. A researcher has the right to submit an IRB determination request located on the IRB website if they feel they do not require IRB oversight.

If the research is categorized as Full Board (FBR), the initial review process is identical to exempt and expedited research, however, it is required to be reviewed at a convened IRB meeting. IRB meetings are traditionally on the 3rd Wednesday of every month unless it is a holiday. Deadlines to submit applications that are categorized as FBR is traditionally the 1st Wednesday of the month and are posted on our website. If at any time before the meeting, the primary reviewer/IRB Chair and IRB admin decide the application is not ready for Full board review the board and RIC reserve the right to delay the FBR until determined fully developed.

All applicants are provided 30 days to reply to the IRB's requested changes. The IRB reserves the right to abandon an application file if responses are not received within the 30 days. A new IRB application will be required for any further review of the proposed research project by the IRB.

Any relevant protocol correspondence from the applicant received in the orsp-irb@txstate.edu or the IRB specialist's mailbox will be documented in the Kuali protocol module system as a file in admin notes and files.

**6.5 Full Board Review Process**

Once the proposal is identified as requiring Full Board Review due to vulnerable populations or risk levels per regulations the applicant will be notified. A content reviewer will be assigned to the proposal to present at the convened meeting based on their expertise. The RIC will work with the applicant before the convened meeting to identify any concerns and clean up the proposal to facilitate a smooth review.

Applicants are expected to attend the meeting to answer any questions the board may have regarding their study to facilitate a faster review. If the applicant is unable to attend, they must notify the RIC before the convened meeting date to determine if a teleconference or phone call can be implemented.

All proposals to be reviewed at the convened meeting will be distributed to board members no later than the Friday before the Wednesday meeting by RIC via the Kuali system. The meeting is to occur on the third Wednesday of every month unless otherwise determined by the Chair and RIC such as during holidays.

The submission deadlines for proposals to be considered for the full board must be submitted and if a student proposal is approved by their faculty sponsor by the deadline (typically the second week before the meeting). Deadlines and meeting dates are posted on the IRB website. RIC will ensure a quorum, a non-scientist, and a non-affiliated member is present during the convened meeting to comply with federal regulations.

**6.6 Procedures during the Convened Meeting**

Quorum is verified by HRPP staff and until quorum is met no agenda items may be voted only discussed. If quorum is lost at any time and items cannot be voted they are tabled for the next convened meeting or an ad hoc meeting is scheduled.

Overall time goal per proposal is approximately 20 minutes but may vary depending on the complexity of the protocol. Additional time is provided to ensure all reviewer and researcher concerns are addressed

Chair Responsibilities:
Conduct meetings per regulations and Roberts Rules of Order.
Encourage discussion focusing on the protocol issues such as volunteering, clarity, risks and benefits, conversion, alternatives, consenting process, and consent form,

HRPP staff/Co-Chair Responsibilities:
Assist in the conducting of meetings
Ensure meetings are conducted per University and Federal regulations.
Assist in keeping meetings on task and time
Take meeting minutes
Serve as a regulation resource

Time Keeper (Voluntary):
Assist in keeping the meeting on time

Content Reviewer (assigned by RIC or Chair) Responsibilities:
Review assigned protocol submission before meeting
Provide a brief overview of the project to members
Highlight key areas
Present questions/ clarifications needed to decide on approval

Committee (primary/alternate) attendee responsibilities:
Familiarize yourself with all protocol submissions before meeting
Listen to content reviewer comments
Add additional comments needed for clarification to decide on approval

Committee attendee Decision options:
Approve
Approve conditionally (Requires revisions to secure approval)
Not approve and request a new submission
Determine IRB oversight is not required
Table for further discussion to make the determination

Applicant Responsibilities:
Attend the meeting (If a student Faculty Sponsor is requested to attend)
Answer the committee questions

Board process:

1. Discuss protocol submission before inviting the applicant into the room.
2. Provide feedback to the applicant.
3. Allow the applicant to leave the room.
4. Deliberate and determine decision.
5. Inform applicant about decision verbally if still in waiting room.
6. HRPP staff will follow up with the applicant in writing about the decision after the meeting if no longer in waiting room.
7. All protocols reviewed a convened meeting needs a second motion.
8. After the meeting the HRPP staff forward the required IRB revisions to the researcher via Kuali. The HRPP and Chair ensure that the revisions are made in concurrence with the Board's recommendations.

To ensure an effective review the IRB prefers to review no more than 3 protocols per meeting. If more than 3 FBR protocols are submitted during the same month the IRB will do one of the following:

- Agree to review the additional protocols during the originally assigned meeting date,
- waive the presentation requirement to experienced researchers or to protocols that do not require major revisions,
- schedule an additional meeting in the same month, or if the research will not be compromised or the researcher does not intend to immediately collect data, the project will be scheduled to be reviewed at the next scheduled meeting.

# Section 7: Post IRB Approval

## 7.1 Expiration Dates

Exempt protocols do not expire. Expedited or Full Board reviews are approved for 12 months or less as stated in the IRB application (anticipated end date) or determined by RIC in consultation with the chair due to risks. Expiration dates in the Kuali system will be standard and will fall on the last day of the month prior to the approval month . (i.e. Applications approved for March 2016 will all have an expiration date of February 28, 2017). Exemptions to this rule are if we rely on another Institution for IRB Jurisdiction our IRB expiration date will coincide with the other Institutions expiration.

Our Institution requests a final report be submitted if all data collection and analysis of identifiable information has been completed to ensure Investigators are not continuing research activities after expiration.

For Expedited and Full Board studies, the Investigator is responsible for submitting a Continuation if more time is required for data collection or analysis of identifiable information. If approval is not extended before the expiration date, all data collection must cease and a new IRB application must be submitted. Data collection may not resume until the new application has been approved. The Kuali system will send an automated notice of expiration the day after the expiration date informing researchers and all protocol personnel listed all research activities should cease. the Kuali system will automatically update the status to expired

## 7.2 Continuation Review and Final Report Review

Texas State IRB voted to continue with annual continuation for expedited and Full board reviews though not required per the new common rule 2018. As a courtesy, the Kuali system sends an automated notice at 30 days, 15 days, and 7 days intervals from the expiration date reminding the researcher to submit a short renewal form or final report through Kuali. However, the Principal Investigator is ultimately responsible for keeping track of continuing review deadlines and ensuring that materials are submitted promptly to maintain approval of research and avoid expiration projects. Researchers are to submit a renewal request or close request through the Kuali protocol system. Verifying enrollment numbers, any changes to procedures or consent forms, and injuries or adverse events. The applicant will be sent an automated notice of approval once approved.

Projects that were initially reviewed by the Full Board will require Full Board review of the renewal request unless they meet the following expedited review procedure criteria outlined in federal regulations:

1. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
2. where no subjects have been enrolled and no additional risks have been identified; or
3. where the remaining research activities are limited to data analysis.

Renewals of projects originally reviewed as expedited will be reviewed through the expedited review procedures unless new information increasing risks have been identified, which will be proposed for review at Full Board Review. If there are no changes to the proposal since the last IRB approval RIC HRPP staff may change the status to approved. If changes are noted or any concerns about patient safety are noted as determined by RIC the IRB chair or other voting member as a secondary reviewer(s) will be assigned as appropriate.

Only two continuations are allowed per proposal. If they are to continue past the third year (initial, Continuation 1, and Continuation 2) a new proposal will need to be submitted for review. This ensures applications are reviewed under current regulations and best practices

Approval expiration dates of continuations are determined in the same manner as the initial approval expiration date.

### 7.3 Changes to a Protocol

A person listed on a protocol can create an amendment but only the PI will be allowed by the system to submit for review. An automated notification will be sent to IRB administrators, the PI and other TXST affiliated individuals on the protocol. All modifications to the protocol must be approved by the IRB before being implemented. Otherwise, the IRB will take appropriate actions such as informing the Dean or the Head of the Department about non-compliance followed by suspending internal funds, if necessary.

### 7.4 Record Retention

**I**nvestigators are required to maintain records for at least three years after completion of the research (45 CFR 46.115(b)). Texas State law for record retention of funded research projects may be up to 7 years. ( https://www.tsl.texas.gov/slrm/rrs). FDA and OHRP requirements supersede the state requirements.

In addition, other regulations may apply and require the retention of these records for a long time. An example include FDA-regulated projects will be required to be kept until 2 years after the product has been commercialized. If NIH grant-related, it is three years after the grant has expired

Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducting research that should be maintained/retained by investigators, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent (45 CFR 46.117).

Investigators must retain records (e.g., informed consent documents signed by subjects) in some form. Such records may be preserved in hardcopy, electronic, or secure media form and must be accessible for inspection and copying by authorized representatives of HHS or Texas State ORIC at reasonable times and in a reasonable manner (45 CFR 46.115(b)). Retention of multiple copies of each record is not required. If investigators leave the institution, the investigators should identify the successor responsible for maintaining those records, either at Texas State University or wherever the records are relocated, for the time identified in the application. The Investigator should notify the IRB of the change of location.

# Section 8: Miscellaneous

### 8.1 Prisoner Studies

TXST if reviewing studies that involve prisoners as defined by 45 CFR 46.303 (d) a prisoner expert will be utilized. 45 CFR 46 Subpart C will be applied.

1. **Definition of Minimal Risk in Prisoner Subpart 45 CFR 46.303(d)(1978).**
    a. Minimal risk is the probability and magnitude of **physical or psychological** harm that is normally encountered in the daily lives or the routine medical, dental, or psychological examination of **healthy persons.**
2. **Definition of Minimal Risk in Common Rule (Subpart A, 45 CFR Part 46) 45 CFR 46.102(i) (1991)**
    a. Minimal risk means that the probability and magnitude of **harm or discomfort anticipated** in the research **are not greater** in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

### 8.2 Recruitment

All recruitment material is reviewed to ensure language is not coercive in nature.

Methods of recruitment are also reviewed to verify if private identifiable information is obtained.

### 8.3 Templates

Various templates for recruitment, letters of support, and consents are available on the IRB website.

If engaged multisite cooperative research, contact RIC HRPP staff at orsp-irb@txstate.edu for project specific guidance.

### 8.4 Consent Forms

TXST IRB reviews consent forms to verify in compliance required by 45 CR 46 or FDA 21 CFR 56.

Regulations dictate the following:

1. Essential elements
2. Waiver of elements only the IRB can approve
3. Waiver of documentation (e.g. verbal, implied)
4. Waiver of consent
5. Statement of FDA access to records
6. Statement of registering on clinicaltrials.gov

TXST consent templates contain minimal elements and additional information may need to be added per protocol to comply with regulations that apply.

### 8.5 Email Distribution List

- Available to faculty through a request from the ITAC website under requests.

- Honors students can also request a survey be distributed to a certain number of students using university e-mail as per UPPS 02.02.09

**8.6 Email Recruiting**

- Recruitment: UPPS 02.02.09
- Administrative surveys and survey fatigue: UPPS 01.03.05

**8.7 Online Surveys**

- The university-approved survey platform is Qualtrics.
- TXST Campus Qualtrics contacts are available in each college/department for assistance.
- Administrative and survey fatigue: UPPS 01.03.05

  "The university policy on Administrative Surveys (UPPS 01.03.05, http://www.txstate.edu/effective/upps/upps-01-03-05.html) prohibits students, faculty, and staff from sending survey invitations via email to the entire student body or a significant proportion of students without review and approval by the University Survey Committee. Due to a high volume of survey activity, the policy was implemented to minimize the number of survey recruitment messages received by any one individual at the same time.

**8.8 Transcription and Translation Services**

- Transcription services should be noted in the approved application. If post approval an amendment should be submitted.
- Note TXST IRB defers researchers to their departments as a contract may already be in place.
- Researchers can also contact the department of modern languages to ask for assistance if their department approves.
- Researchers not using a service must explain who translated documents and their qualifications.
- If a contract is not in place and filed with the procurement department outlining confidentiality with the transcription service, the HRPP staff as a courtesy can refer the researcher with the appropriate department that can assist.

### 8.9 Texas State Referrals for Research Risks

Counseling: (Psychologists available and refer to Student Health Services if needed)
University Health Services for counseling services at 512-245-2208. They are located on the 5th floor of the LBJ Student Center in rooms 5-4.1. Psychologists refer to Student Health services if needed.
5-4.1 LBJ Student Center
601 University Drive
San Marcos, Texas 78666
Monday-Friday, 8 a.m. - 5 p.m.
Phone: 512.245.2208
Fax: 512.245.2234
counselingcenter@txstate.edu

Student Health Services: (Psychiatrists and refer to Counseling Services in LBJ)
298 Student Center Drive
San Marcos, TX 78666
Appointments: 512.245.2161

### 8.10 Helpful Resources

1. **Office for Human Research Protections (OHRP)**
   https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

2. **International Compilation Human Research Standards (ICH)**
   http://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

1. **Texas State University Title IX:**
   https://www.txstate.edu/oei/title-IX.html

3. **Texas State University Information Security Office**
   https://infosecurity.txstate.edu/policies

4. **OHRP Educational materials:**

OHRP has created online educational materials for various interests. Only have 15 minutes? Check out their **mini-tutorials**—short primers on regulations and policies! Looking for a deeper dive? They have **Luminaries Lectures** which feature esteemed speakers with thought-provoking insights on human subjects research protections. They also have an extensive collection of **videos and webinars** covering a range of topics related to the HHS

regulations.

Visit their **Online Education webpage** to see what's available:
https://www.hhs.gov/ohrp/education-and-outreach/online-education/index.html

5. **Information on how to access and use Qualtrics:**
   https://doit.txstate.edu/services/qualtrics.html

# Section 9: Glossary of Terms

**Amendment**

An amendment to an existing approved Institutional Review Board (IRB) protocol is viewed as any change to what was previously approved during the period for which approval was given.

**Anonymized Data**

Previously identifiable data that have been de-identified and for which a code or other link no longer exists. An investigator has no means for linking anonymized data back to a specific subject.

**Anonymous Data**

Data originally collected without identifiers and were never linked to an individual. To remain anonymous a study cannot ask participants personal information that could possibly give away their identity.

**Approval Date**

The first date that research can be performed. The approval date is reflected on the Texas State IRB approval letter.

**Assent**

The affirmative agreement of a child or adolescent under the age of 18to participate in research. Mere failure to object should not be construed as assent. The child must actively show a willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.

**Assurance**

A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

**Autonomy**

Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

**Behavioral Research**

The scientific study of the interactions and activities of people in naturalistic settings. The focus of this type of research can include both the exploration of the decision processes and individual functioning.

**Biologic**

Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries. Biologics include vaccines, blood and blood products, cellular and gene therapy products, tissue and tissue products, and allergenics.

**Biomedical Research**

The study (i) to increase scientific understanding about normal or abnormal physiology, disease states, or development; and (ii) to evaluate the safety, effectiveness or usefulness of a medical product, procedure, or intervention.

**Clinical Research**

The evaluation of biomedical or behavioral interventions related to disease processes or normal physiological functioning.

**Clinical Trials**

Research studies involving human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health–related outcomes.

**ClinicalTrials.Gov**

This is an online registry of clinical trials that are being conducted around the world. ClinicalTrials.gov is operated by the National Library of Medicine at the National Institutes of Health and can be accessed by anyone who has access to the internet.

**Coded Data**

Data separated from personal identifiers through use of a code. As long as a link exists, data are considered indirectly identifiable and not anonymous, anonymized, or de-identified.

**Coercion**

The use of express or implied threats of violence, reprisal, or other intimidating behavior to compel a person to act against their own will. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

**Cognitively Impaired**

Individuals having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

**Common Rule**

The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies. The Health and Human Services (HHS) regulations, 45 CFR Part 46, include four subparts:

- subpart A, also known as the Federal Policy or the "Common Rule";
- subpart B, additional protections for pregnant women, human fetuses, and neonates;
- subpart C, additional protections for prisoners; and
- subpart D, additional protections for children.

**Compensation**

Incentive or payment for participation in research provided to subjects as a result of being in research.

**Confidential Data**

Information collected from research participants which only the investigator(s) or individuals of the research team can identify the responses of individual subjects. Researchers must take every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

**Confidentiality:**

To ensure the protection of a participant from unauthorized access and disclosure of data, all identifying information should be recorded anonymously or coded to de-identify the data set.

**Control group -** The group of participants that receives standard treatment or a placebo. The control group may also be made up of healthy volunteers. Researchers compare results from the control group with results from the experimental group to find and learn from any differences.

**Continuing Review or Renewal**

The mechanism by which the IRB annually reviews the conduct of research. Continuing Reviews (Renewals) only apply to Expedited and Full Board protocols which extends a protocol's original expiration date.

**Data Use Agreement (DUA)**

Contractual document used for the transfer of data that has been developed by a nonprofit, government or private industry, where the data is nonpublic or is otherwise subject to some restrictions on its use.

**Deception**

Occurs as the result of investigators providing false or incomplete information to participants for misleading research subjects. The IRB accepts the need for certain types of studies to employ strategies that include deception.

**De-identified Data**

A data set in which identifying information has been removed by the original researcher and does not include any of the 18 HIPAA Privacy Rule identifiers which could be used alone or in combination with other information to identify the subject.

**Directly Identifiable Data**

Any information that includes personal identifiers.

*The following is the list of 18 identifiers under HIPPA:*

Names;

All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

- Phone numbers;
- Fax numbers;
- Electronic mail addresses;

- Social Security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).

**Education Research**

The scientific study of how humans (both adults and children) learn in various educational settings, while examining the effectiveness of educational interventions, or attempting to understand constructive teaching methods or curricula. In addition, investigating the social psychology of academic settings.

**Epidemiology Research**

A study that targets specific health outcomes, interventions, or disease states and attempts to reach conclusions about cost-effectiveness, efficacy, interventions, or delivery of services to affected populations.

**Equitable**

Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

**Ethnography Research**

The study of people in their natural environments where people live and work or in any other surrounding where people interact.

**Exempt Review**

Research can be approved as “Exempt” if it is no more than minimal risk and fits one of the 7 federally designated categories. These categories of research are not exempt from review by the Texas State IRB, state laws, or the requirements for ethical research. Typically, Research Integrity and Compliance or the IRB chairperson rather than by the entire IRB conducts an Exempt review.

**Expedited Review**

Expedited review is applicable for research activities that involve no more than minimal risk to the human participants and that can be placed in one or more of the 9 federally defined categories. Expedited review is conducted by the IRB chairperson or by one or more of the experienced IRB members designated by the chairperson or Research Integrity and Compliance to conduct the review. The IRB member conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research.

**Experimental Group**

The group of participants in a study that receive the experimental or study intervention (such as medication or psychotherapy).

**Expiration Date**

The date after the end date of the approval period. All research activities involving data collection or analysis of identifiable information must cease the day after the expiration date unless a Continuing Review (Renewal) is granted. An expiration date may not be longer than one year from the date of the original approval or Continuing Review.

**Full Board Review**

A full board review is required for research that is not eligible for exempt or expedited review. In short, research that is judged to involve more than minimal risk, or involves protected populations such as children, prisoners, or disabled individuals, must undergo a full board review. Individuals intending to conduct research that requires a full board review should allow ample time to complete the review process.

<u>The following categories of research require full IRB approval:</u>

- Projects for which the level of risk is determined by the IRB Chair to be greater than minimal
- Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants
- Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals)
- Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

**Generalizable Knowledge**

Information intended to be shared, published, presented, and is intended to have an impact (theoretical or practical) on others within one's discipline. Activities that are disseminated with the intent to influence behavior, practice, theory, or future research designs are contributing to generalizable knowledge.

**Healthy Volunteer**

In a clinical study, a person who does not have the disorder or disease being studied. Results from healthy controls are compared to results from the group being studied.

**HIPAA**

The Health Insurance Portability and Accountability Act of 1996. Also known as "The Privacy Rule," HIPPA regulations are intended to protect patients from inappropriate disclosures of their protected health information (PHI) that could cause harm to their insurability, employability and/or their privacy.

HIPAA is the "Health Insurance Portability and Accountability Act of 1996", Public Law 104-191. HIPAA contains three parts relevant to healthcare information, which include requirements related to the:

1. Privacy of individually identifiable health information;
2. Security of electronic health information; and
3. Standardization of transaction and code sets.

**Human Subject**

There are two definitions depending on the federal agency overseeing the research

1. Food and Drug Administrations (FDA) definition is an individual who is or becomes a participant in research, either as:
    a. a recipient of a test article (investigational drug, biologic or device)
    b. as a control and may be either a healthy human or a patient. The definition also includes an individual on whose specimen a device is used.
2. Department of Health and Human Services regulations define human subjects as a living individual about whom an investigator (whether professional or student) conducting research:
    a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**Identifiable Biospecimen**

Means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**Identifiable Data**

Investigators can readily ascertain or associate the information with the individuals' identities.

**Identifiable Private Data**

Information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**Inclusion/exclusion criteria** - are the factors that allow someone to participate in a clinical trial. Exclusion criteria are the factors that prevent someone from participating in the trial. These factors may include a person's illness, health history, past treatment, age, sex, or where he or she lives.

**Indirectly Identifiable Data**

Data that do not include personal identifiers, but link the identifying information to the data through use of a code. These data are still considered identifiable by the Common Rule.

**Informed Consent**

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. The information that is given to the subject shall be in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

**Institution**

Means any public or private entity, department, or agency (including federal, state, and other agencies).

**Institutional Review Board (IRB)**

A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

**IRB Approval**

The determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.

**Interaction**

Includes communication or interpersonal contact between investigator and subjects, "i.e. The interaction may be remote or an anonymous, online survey".

**Intervention**

A manipulation of research participants' environment for modifying one or more health-related or behavioral processes or endpoints.

**Investigational Drug**

This is also known as an experimental drug and is being studied to see if a disease or medical condition improves while taking it. Scientists are trying to prove in clinical trials:

- If the drug is safe and effective.
- How the drug might be used in that disease.
- How much of the drug is needed.
- Information about the potential benefits and risks of taking the drug.

**Journalism**

The production and distribution of reports on the interaction of events, facts, ideas, and people that are the "news of the day" and that informs society to at least some degree of accuracy.

**Key Personnel**

Those involved in the design, conduct, or reporting of the research. Key personnel can include students.

**Legally authorized representative**

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research. If there is no applicable law addressing this issue, a legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

**Limited Data Set**

As defined by HIPAA, limited data sets are data sets stripped of certain direct identifiers that are specified in the Privacy Rule. They are not de-identified information under the Privacy Rule.

A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (1) names; (2) postal address information, other than town or city, State, and zip code; (3) telephone numbers; (4) fax numbers; (5) e-mail addresses; (6) social security numbers; (7) medical record numbers; (8) health plan beneficiary numbers; (9) account numbers; (10) certificate/license plate numbers; (11) vehicle

identifiers and serial numbers; (12) device identifiers and serial numbers; (13) web URLs; (14) Internet Protocol (IP) address numbers; (15) biometric identifiers, including fingerprints and voiceprints; and (16) full-face photographic images and any comparable images.

Importantly, unlike de-identified data, protected health information in limited data sets may include the following: city, state and zipcodes; all elements of dates (such as admission and discharge dates); and unique codes or identifiers not listed as direct identifiers.

Recognizing that institutions, IRBs and investigators are frequently faced with applying both the Common Rule and the HIPAA Privacy Rule, OHRP does not consider a Limited Data Set (as defined under HIPAA) to constitute individually identifiable information under 45 CFR 46.102(f)(2).

**Medical Device**

Any health care product that does not achieve its primary intended purposes by chemical or by being metabolized. A Medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins.

**Minimal Risk**

The probability and the magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Minors**

Individuals under the age of full legal responsibility, regardless of the jurisdiction in which the research is performed.

**Noninvasive**

A medical procedure that does not enter or penetrate the body (e.g., ultrasound, collection of sweat, hair or nail clippings).

"Off Label Use" - also called unapproved use of an approved product, is when your healthcare provider uses an FDA-approved medical product for a use that has not been studied yet.

**Personal Identifiable Information**

Information about an individual including but not limited to, education, financial transactions, medical history and criminal or employment history, and information that can be used to distinguish or trace an individual’s identify, such as: name, Social Security number, address, phone number, date, place of birth, mother’s maiden name, biometric data, and/ or any other personal information that is linked or linkable to a specific individual.

**Pilot Study**

A small, preliminary study designed to evaluate procedures and measurements in preparation for a subsequent, more detailed research project. Although pilot studies are conducted to reveal information about the viability of a proposed project and to implement necessary modifications, they may also provide useful initial data on the topic of study and suggest avenues or offer implications for future research.

**Principal Investigator (PI)**

The PI is the person who is ultimately responsible for the conduct of the study. For student-initiated research, the student's faculty advisor serves as the PI and is ultimately responsible for the conduct of the study.

**Private information**

Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

**Privacy:** Data privacy is the protection of personal data from those who should not have access to it and the ability of a person to determine for themselves when, how, and to what extent personal information about them is shared with or communicated to others.

**Prospectively Assign**

A pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

**Protected Health Information (PHI)**

Any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis, treatment, or payment.

**Protocol/study**

The formal design or plan of an experiment or research activity or, specifically, the plan submitted to an IRB for review and to an agency for the support of the research. The protocol/study includes a description of the research design and methods to be employed, the eligibility requirements for subjects and controls, the treatment regimen(s), evaluation of expected or unexpected problems, risks, and discomforts to study subjects, and the methods of analysis to be performed on the collected data.

**Public Behavior**

Anything that is in a setting or location accessible to anyone in the general public without the need for any special permissions or privileges. Individuals being observed have no reasonable expectation of privacy.

**Public health authority**

An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, a foreign government, or a person or public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

**Publicly Available Data**

Information in the public domain that can be freely used, reused, and/or redistributed by anyone with no existing local, national or international legal restrictions on access or usage.

Randomization/random assignment - This is the process in which researchers evenly assign study participants into a group receiving the experimental treatment being studied, and others into a group receiving standard or no treatment. Participants are assigned to a group based on chance, not choice. You have the same chance to be placed in any of the test groups.

**Repository Research**

The examination of stored data (retrospective or prospective data, various outcome measures or artifacts, photographs and recordings) or materials (cells, tissues, fluids, and body parts) from individually identifiable living persons.

**Research**

A systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Research that does not require IRB review.

**Risk**

The discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. The probability, magnitude, duration, and reversibility of the risks should be described in the application. Consider physical, psychological, social, legal, and economic risks?

**Scholarly and journalistic activities**

The collection and use of information, that focus directly on the specific individuals about whom the information is collected.

Examples include the following:

- oral history
- journalism
- biography
- literary criticism
- legal research
- historical scholarship

**Social Research**

The scientific study of how people and groups interact. This research may explore social behavior and mental processes but with an emphasis on how humans think about each other and how they relate to each other.

**Sponsors** - Clinical trials are sponsored or funded by various organizations or individuals, including physicians, foundations, medical institutions, voluntary groups, and pharmaceutical companies, as well as Federal agencies such as NIH, FDA, the Department of Defense, and the Department of Veterans Affairs.

**Surveys**

Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, email, social media, or similar procedures.

**Systematic Investigation**

Predetermined method for studying a specific topic, answering question(s), testing a specific hypothesis, or developing theory. A scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective and a set of procedures intended to reach the objective. Examples of systematic investigations include (but are not limited to):

- surveys and questionnaires
- interviews and focus groups
- public or private observations
- evaluations of social or educational programs
- cognitive and perceptual experiments
- medical chart or student record review studies

**Undue influence**

Occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit,

then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

**Voluntary**

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

**Vulnerable Populations**

Special classes of subjects who may be vulnerable in terms of their research participation. Subjects are considered vulnerable when they are not respected as autonomous agents and/or their voluntariness is compromised.

*There are two important types of vulnerability:*

> *Decisional impairment, whereby potential subjects lack the capacity to make autonomous decisions in their own interest, perhaps due to undue influence/inducement.*
>
> *Situational/positional vulnerability*, whereby potential participants may be subjected to coercion.