TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 925 RESEARCH INVOLVING HEALTH AND HUMAN SERVICES

COMMISSION SERVICES

§925.1. Purpose.

The purpose of this chapter is to:

(1) describe the components and use of an institutional review board for the review of research pertaining to mental health, substance use, and intellectual or developmental disabilities within the Texas Health and Human Services Commission (HHSC);

(2) establish uniform guidelines for the review, approval, conduct, and oversight of research involving HHSC services that:

(A) ensures human subjects involved in research have established rights, privacy, and welfare protections;

(B) ensures allegations of misconduct regarding the adherence to scientific standards in research are properly investigated; and

(C) conforms with the requirements of 45 Code of Federal Regulations Part 46, Subparts A, B, C, and D.

§925.2. Application.

This chapter applies to all research involving one or more of the following:

(1) individuals receiving Texas Health and Human Services Commission (HHSC) in-patient or community-based mental health services;

(2) individuals receiving HHSC community-based substance use services;

(3) individuals receiving HHSC intellectual or developmental disabilities services;

(4) data owned or created regarding individuals receiving HHSC services; or

(5) related HHSC resources (e.g., employees, property, and non-public information).

§925.3. Definitions.

The following words and terms have the following meanings when used in this chapter.

(1) Assent--Affirmative agreement of a prospective human subject to participate in research, which is obtained when the subject does not have capacity or legal authority to consent.

(2) Authorization--The written permission given by an individual who is participating in a research study or the individual's legally authorized representative to use or disclose certain protected health information related to the research study.

(3) Children--Consistent with 45 Code of Federal Regulations 46.402(a), individuals who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(4) Code of Federal Regulations (CFR)--The codification of the general and permanent rules and regulations published in the *Federal Register* by the executive departments and agencies of the Federal Government.

(5) Designated institutional review board--The institutional review board whose purpose is to review, approve, and monitor proposed research studies as well as oversee the conduct of approved research, which includes:

(A) an external institutional review board established and operated by a non-Texas Health and Human Services Commission organization with an active Federalwide Assurance approved by the Office for Human Research Protection (OHRP); and

(B) IRB2.

(6) HHSC--Texas Health and Human Services Commission.

(7) HHSC services--Services provided by HHSC or an HHSC-contracted provider. For purposes of this chapter, HHSC services include:

(A) services delivered in state psychiatric hospitals;

(B) services delivered in state supported living centers;

(C) community-based mental health services;

(D) intellectual or developmental disabilities services;

(E) substance use prevention, intervention, and treatment services; and

(F) services delivered by other HHSC-contracted behavioral health providers required to submit data and information to HHSC.

(8) HHSC services authorized person--A person with the authority to allow research at the proposed research site where HHSC services are delivered.

(9) Human subject--Consistent with 45 CFR §46.102(e)(1), 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.

(10) Individual--A person who previously received, or is currently receiving, HHSC services.

(11) Informed consent--The knowing approval by an individual or an individual's legally authorized representative to participate in a research study, given under the individual's or legally authorized representative's ability to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

(12) Institutional review board (IRB)--A board that reviews and approves proposed research as well as oversees the conduct of approved research.

(13) Intellectual or developmental disability (IDD)--Intellectual disability consistent with Texas Health and Safety Code 591.003 or a disability that meets the criteria described in the definition of “persons with related conditions” in 42 CFR 435.1010.

(14) Investigational medication or device--Any drug, biological product, or medical device under investigation for human use that is not currently approved by the U.S. Food and Drug Administration for the indication being studied.

(15) Investigator--A principal investigator, a co-investigator, or a person who has direct and ongoing contact with human subjects participating in a research study or with prospective human subjects.

(16) IRB2--The Mental Health, Substance Use and Intellectual or Developmental Disabilities Institutional Review Board, which is established and operated by the Texas State Hospital Central Administration.

(17) Legally authorized representative (LAR)--Consistent with 45 CFR 46.102(i), 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 procedure or procedures involved in the research. If there is no applicable law addressing this issue, LAR 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 or procedures involved in the research.

(18) Limited data set--Consistent with 45 CFR 164.514(e), protected health information of an individual or of relatives, employers, or household members of an individual that excludes the following direct identifiers:

(A) names;

(B) postal address information, other than town or city, state, and zip code;

(C) telephone numbers;

(D) fax numbers;

(E) electronic mail addresses;

(F) social security numbers;

(G) medical record numbers;

(H) health plan beneficiary numbers;

(I) account numbers;

(J) certificate or license numbers;

(K) vehicle identifiers and serial numbers;

(L) device identifiers and serial numbers;

(M) Web universal resource locators (URLs);

(N) Internet protocol (IP) address numbers;

(O) biometric identifiers, including finger and voice prints; and

(P) full face photographic images and comparable images.

(19) Minimal risk--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 examination or tests.

(20) Misconduct in science--The fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

(21) Notice of privacy practices--A written notice describing:

(A) the uses and disclosures of protected health information that may be made; and

(B) the individuals' rights and the legal duties of the HHSC service with respect to protected health information.

(22) Office for Human Research Protection (OHRP)--The office that provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services.

(23) Principal investigator--The person identified as responsible for conducting a research study.

(24) Privacy coordinator--An HHSC staff member who is responsible for working with the Texas Health and Human Services Privacy Division to implement the policies and procedures relating to state and federal privacy laws.

(25) Protected health information (PHI)--

(A) Any information that identifies or could be used to identify an individual, whether oral or recorded in any form, that relates to:

(i) the past, present, or future physical or mental health or condition of the individual;

(ii) the provision of health care to the individual; or

(iii) the payment for the provision of health care to the individual.

(B) The term includes:

(i) an individual's name, address, date of birth, or Social Security number;

(ii) an individual's medical record or case number;

(iii) a photograph or recording of an individual;

(iv) statements made by an individual, either orally or in writing, while seeking or receiving HHSC services;

(v) any acknowledgment that an individual is seeking or receiving or has sought or received HHSC services;

(vi) direct identifiers of relatives, employers, or household members of the individual; and

(vii) any information by which the identity of an individual can be determined either directly or by reference to other publicly available information.

(C) The term does not include:

(i) health information that has been de-identified in accordance with 45 CFR §164.514(b); and

(ii) employment records.

(26) Research--Consistent with 45 CFR §46.102(l), 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 chapter, 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. For purposes of this chapter, the following activities are not deemed as research.

(A) 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.

(B) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in 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).

(C) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(D) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(27) Rights officer--An employee appointed by an agency authority who oversees the research site to protect and advocate for the rights of individuals receiving HHSC services.

(28) State Hospital Central Administration--The HHSC office that is responsible for the management and oversight of the state hospital system.

(29) Texas Health and Human Services (HHS) Privacy Division--The HHS workforce responsible for creating and maintaining privacy policies and procedures and investigating potential unauthorized disclosures of protected health information, personally identifiable information, and sensitive personal information. The Privacy Division is responsible for declaring whether an incident is a breach of information and notifying or recommending notification to affected individuals. The Privacy Division acts as a resource and subject matter experts to HHSC.

§925.4. General Principles.

(a) Participation in research that can advance scientific knowledge of mental disorders, substance use disorders, and intellectual or developmental disability is integral to the mission of the Texas Health and Human Services Commission (HHSC).

(b) HHSC's guiding principle for all research involving human subjects is the protection of the personal rights, safety, well-being, privacy, and dignity of the subjects to:

(1) ensure the protection of human subjects involved in research HHSC promulgates this chapter and adopts by reference 45 Code of Federal Regulation (CFR) Part 46, Subparts A, B, C, and D;

(2) ensure ethical principles are maintained when research involving human subjects is conducted, HHSC adopts by reference "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research" (April 18, 1979);

(3) ensure all research undertaken is conducted with a fundamental commitment to high ethical standards regarding the conduct of scientific research, HHSC adopts by reference 42 CFR Part 50, Subpart A; and

(4) protect the privacy of human subjects involved in research, HHSC adopts by reference the Federal Standards for Privacy of Individually Identifiable Health Information, 45 CFR Part 160 and Part 164, Subparts A and E, promulgated by the U.S. Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996.

(c) HHSC is committed to research conducted in a manner that is consistent with the best interests and protection of personal rights and the welfare of human subjects involved in the research.

(1) An investigator may not approach an individual to participate in a research study if the research conflicts with the individual’s treatment goals.

(2) No research involving human subjects may be conducted unless the risks to human subjects are minimized and are reasonable in relation to the anticipated benefits.

(3) No undue inducement or coercion may be used to influence human subjects to participate in a research study.

(4) Unless scientifically justified, individuals may not be excluded from participating in research based on personal characteristics, such as race, color, ethnicity, national origin, religion, gender, age, ability, sexual orientation, or political affiliation.

(5) Human subject participation in research studies must be equitable with measures taken to ensure the research sample is representative of the population of interest. Within the population of interest, subject selection procedures must offer equitable opportunity for access to participation in research and access to potential benefits of participation.

(6) An investigator may not approach individuals receiving HHSC services under an order of protective custody pursuant to the Texas Health and Safety Code Chapter 574 about participation in a research study involving an investigational medication or device prior to the entry of an order for temporary or extended mental health services.

(7) Research may not be conducted with human subjects who are involuntarily committed if the research involves:

(A) placebos as the primary medication therapy;

(B) medication or doses of medication as the primary medication therapy which are known to be ineffective for the targeted disorder or condition; or

(C) an investigational medication or device that is proposed to be undertaken when previous research on the medication or device with 100 human subjects or fewer has provided minimal or no documentation of the efficacy and safety of the medication or device for the population with the targeted disorder or condition.

(8) Research may not be conducted if the protocol:

(A) extends the use of a placebo or washout period beyond what has been approved by the institutional review board (IRB);

(B) deprives the human subject of reasonable relief; or

(C) extends a human subject's use of placebos as the primary medication therapy after the subject is discharged.

(9) Unless otherwise provided for in this chapter, research involving human subjects may not be conducted unless:

(A) the designated IRB reviews and approves the research in accordance with §925.7 of this chapter (relating to Review and Approval of Proposed Research);

(B) the HHSC services authorized person agrees to the research being conducted; and

(C) the necessary assurance and certification has been submitted to the appropriate federal agency, (e.g., Health and Human Services, Food and Drug Administration) if required, and the agency has indicated its approval.

(10) Research conducted may not hinder the ability of the research site or program to accomplish its primary purpose.

(d) Right to file a complaint.

(1) An individual involved in research or the individual’s legally authorized representative (LAR) is entitled to file a complaint about alleged mistreatment or other concerns relating to the research with an HHSC rights officer or with any other applicable complaint mechanism in place.

(2) An individual or the individual’s LAR is entitled to file a complaint about violations of the Federal Standards for Privacy of Individually Identifiable Health Information as provided by 45 CFR Part 160 and Part 164, Subparts A and E with the Office for Civil Rights at the U.S. Department of Health and Human Services or refer to the [HHSC Health Insurance Portability and Accountability Act (HIPAA) policy](https://hhs.texas.gov/laws-regulations/legal-information/hipaa-privacy-laws), which can be found at https://hhs.texas.gov/laws-regulations/legal-information/hipaa-privacy-laws, as set forth in the Notice of Privacy Practices.

§925.5. Designated Institutional Review Board.

(a) Each research project conducted involving HHSC services must have a designated institutional review board (IRB). The designated IRB is responsible for reviewing, approving, and monitoring all research conducted.

(b) The IRB2 must approve the designated IRB from the following options:

(1) an external IRB; or

(2) the IRB2.

(c) The membership of the designated IRB must comply with the requirements in 45 CFR §46.107 and this subsection. The IRB2 membership must include at least three members who are familiar with the mental disorders or conditions, intellectual or developmental disability (IDD), and concerns of the populations of individuals HHSC serves, including:

(1) at least one of the three members must be a professional in the field of mental health, IDD, or substance use; and

(2) at least two of the three members described in this paragraph must be:

(A) an individual with a serious mental illness, severe emotional disturbance, substance use disorder, or a person with IDD who is or has received HHSC services;

(B) a family member of a person described in subparagraph (A) of this paragraph; or

(C) an advocate for an individual described in subparagraph (A) of this paragraph.

(d) Each designated IRB must have written policies and procedures that are consistent with this chapter and HHSC's rules governing the care and protection of individuals as described in Texas Administration Code Title 25, Chapter 404, Subchapter E (relating to Rights of Persons Receiving Mental Health Services) and 40 TAC Chapter 4, Subchapter C (relating to Rights of Individuals with an Intellectual Disability) and that address:

(1) the review or screening process to determine whether proposed research is exempt from the requirements of federal regulations made in accordance with 45 CFR §46.104, including required documentation and any necessary approvals;

(2) the process for ensuring that each IRB member and investigator involved in an approved research study receives documented training in applicable ethics, laws, and regulations governing research involving human subjects; and

(3) the process for disclosing and considering potential conflicts of interest, financial or otherwise, by IRB members and investigators.

§925.6. Designated Institutional Review Board Functions and Operations.

(a) Each designated institutional review board (IRB) shall:

(1) follow its written policies and procedures as described in §925.5(d) of this chapter (relating to Designated Institutional Review Board);

(2) function in accordance with 45 Code of Federal Regulations (CFR) §46.108;

(3) ensure proposed research is reviewed and approved in accordance with §925.7 of this chapter (relating to Review and Approval of Proposed Research);

(4) except when an expedited review is used as described in 45 CFR §46.110, ensure proposed research is reviewed and approved only at meetings in which at least one of each of the following members are present, participating, and voting:

(A) a member who satisfies the requirements of §925.5(c) of this chapter, as appropriate to the IRB; and

(B) a member who satisfies the requirements of §925.5 of this chapter, as appropriate to the IRB, and in the case of the IRB2, as appropriate to the facility or facilities for which the research is proposed;

(5) exercise appropriate oversight to ensure:

(A) its policies and procedures designed for protecting the rights, privacy, and welfare of human subjects are being applied; and

(B) research is being conducted in accordance with the approved protocol;

(6) maintain records of its operations in accordance with 45 CFR §46.115;

(7) maintain documentation of its continuing review of all approved and active research protocols; and

(8) maintain documentation of any unanticipated serious problems or events involving risks to the human subjects or others.

(b) Each designated IRB has the authority to suspend or terminate research that is not being conducted in accordance with the IRB's requirements or that has been associated with significant unexpected harm to human subjects. If an IRB suspends or terminates research, the IRB must promptly notify the following in writing of the suspension or termination and include a statement of the reasons for the IRB's action:

(1) the principal investigator;

(2) the appropriate HHSC services authorized person; and

(3) the IRB2.

(c) When IRB2 is not assigned as the designated IRB for a research protocol, a reliance agreement will be signed by the IRB2 chair outlining all oversight responsibilities and obligations in order to ensure the protection of human subjects.

§925.7. Review and Approval of Proposed Research.

(a) Proposed research must be submitted to the designated institutional review board (IRB) and contain written information for the IRB to determine whether the requirements described in 45 Code of Federal Regulations (CFR) §46.111 are satisfied.

(b) Each designated IRB shall review all proposed research in accordance with 45 CFR §46.109.

(c) Each designated IRB has the authority to approve, require modifications to, or disapprove any proposed research. Approval of proposed research shall be based on:

(1) consideration of the information described in 45 CFR 46.111;

(2) the IRB's verification that the requirements in 45 CFR §46.111, §925.4 of this chapter (relating to General Principles), and §925.8 of this chapter (relating to Informed Consent) are met; and

(3) the IRB's verification that procedures for obtaining and documenting authorization to use or disclose protected health information (PHI) meet the requirements in 45 CFR §164.508, unless:

(A) the IRB approves a waiver or alteration of the authorization requirement as permitted in §925.9(b) of this chapter (relating to Using and Disclosing Protected Health Information in Research); or

(B) the IRB determines and documents that:

(i) the data needed for the research is contained in a limited data set and the investigator will comply with the requirements in 45 CFR §164.514(e), including the execution of a data use agreement; or

(ii) the data needed for the research is limited to decedents' PHI and documentation submitted by the investigator meets the requirements in 45 CFR §164.512(i)(1).

(d) The Designated IRB may take into consideration deliberations and reviews from another IRB that has approved the protocol for a specific research proposal, but the designated IRB is ultimately responsible for approval of the proposed research.

(e) Research review and documentation process.

(1) External IRB as the designated IRB. The research review and documentation process for research using an external IRB is generally as follows.

(A) The IRB2 screens the research proposal and, if determined appropriate for implementation, the investigator submits the research proposal to the external IRB for review.

(B) The external IRB reviews the research proposal.

(C) The investigator informs the IRB2 of the external IRB’s approval or disapproval. The IRB2 informs the Texas Health and Human Services Commission (HHSC) services authorized person of the external IRB's approval or disapproval and recommendations, if any.

(D) If the research proposal is approved by the external IRB, the IRB2 considers the external IRB's recommendations, if any, and determines if additional review is required.

(2) IRB2 as the designated IRB. The research review and documentation process for research involving HHSC services using the IRB2 is generally as follows.

(A) The principal investigator submits the proposal to the IRB2.

(B) The IRB2 reviews the research proposal.

(C) The IRB2 informs the HHSC services authorized person of the IRB2's approval or disapproval and recommendations, if any.

(D) If the research proposal is approved by the IRB2, the HHSC services authorized person considers the IRB2's recommendations, if any, and either approves or disapproves the research proposal for implementation.

(f) In addition to approval by the designated IRB and HHSC services authorized person, review and approval by the chief medical officer or chief medical director of the state hospitals, state supported living centers, or other entity primarily responsible for the health and safety of the research subjects, as applicable, is required for any research proposal involving:

(1) a placebo as the primary medication therapy;

(2) medication or doses of medication as the primary medication therapy which are known to be ineffective for the targeted disorder or condition; or

(3) an investigational medication or device.

(g) The review process for proposed research may require additional steps as necessary, (e.g., in the event a proposal is initially rejected).

(h) The HHSC services authorized person is responsible for ensuring that all investigators are qualified to perform any clinical duties assigned to them and are knowledgeable of HHSC's rules governing the care and protection of individuals as described in Texas Administrative Code Title 25 Chapter 404, Subchapter E (relating to Rights of Persons Receiving Mental Health Services) and 40 TAC Chapter 4, subchapter C (relating to Rights of Individuals with an Intellectual Disability).

§925.8. Informed Consent.

Requirements for approval of proposed research. Investigators shall ensure:

(1) procedures for obtaining and documenting informed consent meet the requirements in 45 Code of Federal Regulations (CFR) §46.116 and 45 CFR §46.117 and address:

(A) any extension of the subject's length of stay because of participation in the research;

(B) the subject's ability to receive the medication or device after the research has concluded if the research involves an investigational medication or device;

(C) whether the research involves the use of a placebo and the likelihood of assignment to the placebo condition;

(D) whether the research involves medication or doses of medication which are known to be ineffective for the targeted disorder or condition and the likelihood of assignment to such medication or doses of medication; and

(E) any risk of deterioration in the subject's condition and the potential consequences of such deterioration (e.g., an extension in the length of stay, or the use of interventions, such as restraint, seclusion, or emergency medications);

(2) there are procedures to ensure prospective human subjects are assessed for capacity to consent for research protocols that present greater than minimal risk, and:

(A) provide for a qualified professional, who is independent of the research study, to assess prospective human subjects for capacity to consent;

(B) identify and document who will conduct the assessments; and

(C) describe the nature of the assessment and justification if less formal procedures to assess capacity will be used;

(3) the requirements in 45 CFR §46.408 are met if children are the proposed human subjects;

(4) there are procedures that:

(A) each prospective human subject or the subject's legally authorized representative (LAR) understands the information provided before obtaining consent to research participation; and

(B) if consent is obtained from the subject's LAR, attempts are made, to the extent possible given the prospective subject's capacity, to obtain the human subject's assent to participation;

(5) there are adequate safeguards to minimize the possibility of coercion or undue influence. For example, the possible advantages of the subject's participation in the research may not be so valuable as to impair the subject's ability to weigh the risks of the research against those advantages. Possible advantages within the limited choice environment may include enhancement of general living conditions, medical care, quality of food, or amenities; opportunity for earnings; or a change in commitment status;

(6) there are procedures for ensuring a prospective human subject's objection to enrollment in research or a human subject's objection to continued participation in a research protocol is heeded in all circumstances, regardless of whether the subject or the subject's LAR has given consent. Objection may be conveyed verbally, in writing, behaviorally, or by other indications or means; and

(7) procedures to ensure, throughout the course of the research study, human subjects' comprehension and capacity are assessed and enhanced since informed consent is an ongoing process.

§925.9. Using and Disclosing Protected Health Information in Research.

(a) Except as provided by this section, to use or disclose protected health information (PHI), an authorization is required that:

(1) conforms with the requirements of 45 Code of Federal Regulations (CFR) §164.508 and, if applicable 42 CFR Part 2; and

(2) includes a statement that the subject's right to access their PHI created or obtained during research may be temporarily suspended while the research is in progress, and will be reinstated upon completion of the research, if the research includes treatment.

(b) During the review of proposed research, the designated institutional review board (IRB) has the authority to approve a waiver or alteration of the authorization requirement in accordance with 45 CFR §164.512(i).

(c) The designated IRB has the authority to approve the use or disclosure of PHI for purposes preparatory to research if the IRB obtains from the investigator adequate representations as required by 45 CFR §164.512(i)(1)(ii).

§925.10. Investigation of Allegations of Misconduct in Science.

(a) Investigation of misconduct in science is the formal examination and evaluation of all relevant facts to determine if misconduct in science has occurred.

(b) All research involving Texas Health and Human Services Commission (HHSC) services shall be conducted with a fundamental commitment to high ethical standards regarding the conduct of scientific research.

(c) Reports of alleged misconduct in science are made to the IRB2, which must ensure:

(1) each allegation is reviewed and investigated by an appropriate entity in accordance with 42 Code of Federal Regulations (CFR) Part 50, Subpart F;

(2) the investigating entity submits to the IRB2 information documenting the disposition of each allegation; and

(3) the following are notified of confirmed incidents of misconduct in science:

(A) the institutional review board (IRB) that approved the research protocol; and

(B) the agency funding the research.

§925.11. Responsibilities of the Institutional Review Board 2.

Other responsibilities of IRB2 include:

(1) reviewing and developing Texas Health and Human Services Commission (HHSC) rules and policies governing the conduct of research; and

(2) providing technical assistance and interpretation of policies, procedures, HHSC rules, and regulations concerning the conduct of research involving human subjects.