Policy Name: Research Compliance Program	
Policy Owner: Research Activities and Compliance Committee	**Effective Date:** 01/30/2024
Approved By: System Performance Alignment & Innovation (SPAN)	**Last Reviewed Date:** 01/30/2024
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1.0 Scope:

1.1 Applicable Entities:
This policy applies to:

- Texas Health Resources
- Texas Health Resources (Texas Health) member hospitals
- Texas Health Physicians Group
- Affiliated Individuals doing research on a Texas Health campus
- Excludes Texas Health Urgent Care and Texas Health joint venture entities (except those listed in the Formulation and Adoption of System-Wide Policies and Procedures in Section 4.1.6 or in Section 4.1.7)

1.2 Applicable Departments:
This policy applies to all departments.

1.3 Applicable Personnel:
Texas Health research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record.

2.0 Purpose:

2.1 To establish and communicate the structure and components of the Texas Health Research Compliance Program, which is a component of the Texas Health Business Ethics and Compliance Program, under the oversight of the Texas Health Chief Compliance Officer.

3.0 Policy Statement(s):

3.1 It is the policy of Texas Health to adhere to legal and ethical standards governing the protection of human subjects, Institutional Review Board activities and other research activities.

4.0 Policy Guidance:

4.1 The Research Compliance Program includes the following components established in accordance with the Texas Health Business Ethics and Compliance Program:

4.1.1 Written Policies and Procedures - The Research Compliance Program will include written policies for the protection of human research subjects as needed for all research related activities in accordance with ethical and regulatory standards.

4.1.2 Designation of a Research Compliance Officer and the Texas Health Research Activities and Compliance Committee (RACC) - The Research Compliance Officer will be designated by the Texas Health Institutional Official and is accountable to the Texas Health Chief Compliance Officer in carrying out the Research Compliance Program. The Research Activities and Compliance Committee will provide support, assistance and feedback to the Research Compliance Officer related to research compliance risk areas and the Research Compliance Program.

4.1.3 Training and Education - Training and education will be provided to researchers, staff and others as needed to effectively communicate research standards, policies, and regulations.

4.1.4 Open Lines of Communication and Reporting - Texas Health will maintain an open-door environment including the operation of a toll-free Compliance Helpline whereby researchers, employees and others are encouraged to seek guidance, ask questions or report suspected or actual misconduct, and may do so anonymously (if desired), and without fear of retaliation or retribution for any report made in good faith. Reports involving an allegation of misconduct, violation of policies or non-compliance will be thoroughly investigated.

4.1.5 Research Compliance Internal Monitoring and Auditing - Texas Health will establish internal research compliance monitoring and auditing processes to evaluate the effectiveness of the Research Compliance Program, to validate compliance with laws and regulations, and to promote continuous improvement/best practices.

4.1.6 Remediation and Process Improvement - If an issue of non-compliance is detected, reasonable steps will be taken to respond to the issue and prevent further similar noncompliance, including making modifications to the Research Compliance Program as needed to prevent and detect future violations.

4.1.7 Enforcement of Progressive Corrective Action - Research compliance standards will be consistently enforced at all levels at Texas Health through appropriate progressive corrective action when warranted. Progressive corrective action will apply not only for individuals engaging in misconduct, but also for those who are aware of but fail to take reasonable steps to prevent and detect wrongdoing.

4.2 System-wide oversight responsibility for the Research Compliance Program rests with the Texas Health Board of Trustees and the Texas Health Audit and Compliance Committee. The Texas Health Board of Trustees has delegated direct oversight responsibility for the Research Compliance Program to the Texas Health Audit and Compliance Committee.

4.3 The Research Compliance Officer, with assistance from the RACC, has day-to-day operational responsibility for research compliance activities, including but not limited to the following:

4.3.1 Be accountable to the Texas Health Chief Compliance Officer in carrying out the Research Compliance Program.

4.3.2 Oversee implementation of research compliance policies and related activities and provide a quarterly research compliance report to the Texas Health Chief Compliance Officer and the Texas Health Institutional Official.

4.3.3 Serve as the champion for the Research Compliance Program and provide leadership on compliance initiatives.

4.3.4 Responsible for appropriate documentation and investigation regarding research compliance questions, concerns, misconduct, or allegations of wrongdoing.

4.3.5 Identify research compliance risk areas, develop an annual Research Compliance Work Plan, and lead activities necessary to effectively carry out work plan projects.

4.3.6 Maintain employee and researcher awareness of the Research Compliance Program and answer questions regarding compliance policies and/or regulatory requirements.

4.3.7 Promptly report research compliance issues or concerns to the Texas Health Institutional Official and the Texas Health Chief Compliance Officer and work collaboratively to establish facts, reach conclusions, and implement corrective actions when needed.

4.3.8 Make periodic reports to Texas Health management regarding research compliance activities.

4.3.9 Receive feedback from the RACC regarding the research compliance activities as support in carrying out the goals and objectives of the Research Compliance Program.

4.3.10 Formulate and monitor corrective actions that may be required in response to research compliance audits or other compliance monitoring activities.

4.3.11 Other activities as may be required to carry out the Research Compliance Program effectively.

4.4 Research Compliance monitoring and auditing activities are designed to: 1) protect the safety, rights and welfare of human subjects by verifying research activities are carried out in accordance with statutes and regulations, Texas Health policies, and the approved study protocol; 2) assist researchers and the Texas Health IRB(s) of Record in maintaining research compliance; 3) work with researchers and the Texas Health IRB(s) of Record to resolve findings or deficiencies and prevent situations that may increase risks to human subjects or lead to regulatory non-compliance.

4.5 Research compliance monitoring and auditing activities are designed to identify standards of excellence as well as opportunities for improvement to enhance human research protections and research quality and may take the form of:

4.5.1 Periodic research audits; or

4.5.2 Requests from the researcher, the IRB or other party for a research audit; or

4.5.3 Other audits or monitoring activities due to complaints or allegations of non-compliance or misconduct.

4.6 Research compliance monitoring and auditing processes will include the following:

4.6.1 The Research Compliance Office will select human research studies under the oversight of the Texas Health IRB(s) of Record for audit. Studies may be selected for a routine audit, a focused audit, and/or other monitoring activities based upon various attributes, including the following:

- Studies with high enrollment
- Studies considered high risk to human subjects or with vulnerable populations
- Investigator initiated studies
- Studies which are otherwise unmonitored or with minimal monitoring
- Studies with excessive or unusual adverse event/serious events reported

- Studies with excessive or unusual protocol deviations/exceptions reported
- Complaints regarding the conduct of the research study or allegations of misconduct
- Human subject death
- Appearance of lack of investigator oversight, staff support, resources and/or high staff turnover
- Lapses in continuing IRB review or administrative closure by the IRB
- Number of study sites involved
- Funding source (federal, industry, institutional)
- Scheduled follow-up to corrective actions or routine audits
- Number of active studies overseen by a single researcher
- Abnormalities or errors in research billing

4.6.2 The Research Compliance Office will contact the researcher and/or study staff to arrange all details related to the review/audit and to obtain a current list of consented human subjects in the study selected for review/audit. In general, ten to thirty percent (10-30%) of the enrolled human subjects will be selected for review/audit. When feasible, one hundred percent (100%) of the enrolled human subjects will be reviewed if the study has four (4) or fewer subjects.

4.6.3 The researcher and study staff will be notified of the review/audit date, the study selected and the human subject records/other documents to be reviewed.

4.6.4 The researcher and study staff must provide all information requested for the review/audit such as:

- signed informed consent forms
- signed assent forms for research involving children
- clinical trial agreements, coverage analysis, and clinical study budget
- medical records or other source documentation
- IRB correspondence related to the study
- external monitoring reports
- study-related data collection forms
- study protocol, including amendments and addenda
- protocol deviation documentation
- adverse event documentation
- study related correspondence
- drug/device accountability records

- regulatory documentation
- researcher assessment of inclusion/exclusion criteria for each study subject
- research billing records and other related financial documents
- other relevant documents or information requested

4.6.5 Preliminary findings will be provided and discussed with the researcher during an exit conference. A written report noting findings will be provided to the researcher after the review/audit visit.

4.6.6 The researcher will be given an opportunity to respond to the report with clarifications and/or a correction action plan in response to any findings noted in the written report. The written report will stipulate the deadline for the researcher's response.

4.6.7 The report and the researcher's response, if response available or if response needed, will be provided to the RACC. When warranted, the written report and researcher's response (if response available or if response needed) will be submitted to the IRB Chairperson for reporting to the Texas Health IRB of Record. A copy of the report will also be provided to the Texas Health Institutional Official and the Texas Health Chief Compliance Officer.

4.6.8 Follow-up review will be scheduled to validate implementation of corrective actions, when deemed appropriate by the Research Compliance Officer and/or at the IRB's request.

5.0 Definitions:

5.1 Institutional Official - The person designated by the Texas Health Board to oversee research activities and the protection of human subjects.

5.2 Institutional Review Board (IRB) - The Committee or Committee(s) authorized to serve as the IRB(s) of Record for Texas Health Resources and to review and monitor research involving human subjects in accordance with ethical standards, laws, and regulations.

5.3 Research Activities and Compliance Committee (RACC) - The Committee authorized by the Texas Health Board of Trustees to assist the Texas Health Institutional Official and the Research Compliance Officer in on-going evaluation of research activities, processes, and controls to maintain compliance with laws and regulations.

5.4 Research Compliance Officer - The Texas Health employee designated by the Texas Health Institutional Official to be responsible for the day-to-day operation of the Research Compliance Program with direct accountability to the Texas Health Chief Compliance Officer for research compliance activities.

5.5 Texas Health Audit and Compliance Committee - The Texas Health committee designated with oversight responsibilities for Texas Health internal and external audit activities, the Texas Health Business Ethics and Compliance Program.

5.6 Texas Health Business Ethics and Compliance Program (the Program) - A comprehensive strategy including policies, personnel and resources designed to assist employees in adherence to the Texas Health Code of Business Ethics, compliance policies, laws, and regulations. The Program includes the essential elements necessary for an effective compliance program and builds upon the practices of checks and balances, ethics, common sense, trust, and best practices. The Research Compliance Program is a component of the overall Texas Health Business Ethics and Compliance Program.

5.7 Texas Health Chief Compliance Officer - The Texas Health employee delegated authority by the Texas Health Board of Trustees for the day-to-day operation of the Texas Health Business Ethics and Compliance Program. The Chief Compliance Officer is charged with responsibility for implementing and operating the Program in an independent and objective manner and is accountable to the Texas Health Chief Executive Officer and the Texas Health Audit and Compliance Committee.

6.0 Responsible Parties:

6.1 Chief Compliance Officer

6.1.1 Responsible for oversight of the THR-wide Business Ethics and Compliance Program that includes human subject research compliance as one sub-component.

6.2 Research Compliance Officer

6.2.1 Oversees compliance of the human subject protection program which includes the implementation of policy, procedures, and personnel.

6.3 Texas Health Research Activities and Compliance Committee (RACC)

6.3.1 Has responsibility for the oversight and implementation of this policy.

7.0 External References:

7.1 U.S. Federal Sentencing Guidelines

Applicability of external clinical practice/procedure guidelines and other clinical resources may be dependent upon resources available at the hospital or a health care professional's licensure and/or certification.

8.0 **Related Documentation and/or Attachments:**

8.1 Human Research Protection Program - THR System Policy

8.2 Texas Health Corporate Policy for Conflicts of Interest in Research Involving Human Subjects

8.3 Corporate Policy on Research Privacy under HIPAA - THR System Policy

8.4 Texas Health Code of Business Ethics

8.5 Business Ethics and Compliance Program - THR System Policy

8.6 Non-Retaliation - Good Faith Reports of Suspected Misconduct - THR System Policy

8.7 Internal Reporting and Investigation - THR System Policy

8.8 Business Ethics and Compliance Program Auditing and Monitoring - THR System Policy

8.9 Business Ethics and Compliance Education and Training - THR System Policy

8.10 Cooperation with Search Warrants, Subpoenas and Governmental Investigations - THR System Policy

9.0 **Required Statements:**

9.1 This policy represents the collaborative effort of the Texas Health system entities to determine and direct the recommended practice for the care anticipated under this policy and includes the input of clinical subject matter specialists.

As no policy or published procedure can anticipate every clinical and/or medical presentation, this policy is a guideline and is not intended as a substitute for the clinician's clinical judgment and/or experience.

9.2 Physicians on the medical staff of a Texas Health hospital practice independently and are not employees or agents of the hospital. Physicians in training in Graduate Medical Education programs are employees of the hospital/institution that hosts or sponsors their training program.