

<b>Policy Name: Structures, Monitoring and Audits</b>	
<b>Originating Officer:</b> Research Activities and Compliance Committee (RACC)	<b>Effective Date:</b> 7/15/13
<b>Approved By:</b> System Performance Council	<b>Last Reviewed Date:</b> 7/11/13
<b>Page 1 of 7</b>	

### 1.0 Scope:

#### 1.1 Applicable Entities:

This policy applies to the Texas Health Resources (Texas Health) member hospitals and excludes the Texas Health joint venture entities that do not request oversight by the Texas Health Institutional Review Board (IRB).

### 2.0 Purpose:

2.1 To establish and communicate the structure and components of the Texas Health Resources (Texas Health) Research Compliance Program, which is a component of the overall 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.

<b>Policy Name: Structures, Monitoring and Audits</b>
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<b>Page 2 of 7</b>
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- 4.1.3 Training and Education – Training and education will be provided to IRB members, 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 Hotline 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 (process review) and auditing processes to evaluate the effectiveness of the Research Compliance Program, validate compliance with laws and regulations and to promote continuous improvement/best practices. These activities are further described in Section 7 of this policy.
- 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 wrong doing.
- 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.

<b>Policy Name: Structures, Monitoring and Audits</b>
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<b>Page 3 of 7</b>
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- 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 wrong doing.
  - 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 process reviews, 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 in maintaining research compliance; 3) work with researchers and the Texas Health IRB to resolve findings or deficiencies and prevent

**Policy Name: Structures, Monitoring and Audits****Page 4 of 7**

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:
- Periodic process reviews;
  - Requests from the researcher, the IRB or other party for a process review; or
  - 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 active human research studies and sites under the oversight of the Texas Health IRB for audit. Studies may be selected for a process review, for a focused audit and/or other monitoring activities based upon various attributes such as the following:
- 4.6.1.1 Studies with high enrollment
  - 4.6.1.2 Studies considered high risk to human subjects or with vulnerable populations
  - 4.6.1.3 Investigator initiated studies
  - 4.6.1.4 Studies which are otherwise unmonitored or with minimal monitoring
  - 4.6.1.5 Studies with excessive or unusual adverse event/serious events reported
  - 4.6.1.6 Studies with excessive or unusual protocol deviations/exceptions reported
  - 4.6.1.7 Complaints regarding the conduct of the research study or allegations of misconduct
  - 4.6.1.8 Human subject death
  - 4.6.1.9 Appearance of lack of staff support, resources and/or high staff turnover
  - 4.6.1.10 Lapses in continuing IRB review or administrative closure by the IRB
  - 4.6.1.11 Number of study sites involved
  - 4.6.1.12 Funding source (e.g. federal, industry, institutional)
  - 4.6.1.13 Scheduled follow-up to corrective actions or routine audits
  - 4.6.1.14 Number of active studies overseen by a single researcher
- 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. As a general rule, ten to thirty percent (10-30%) of the

<b>Policy Name: Structures, Monitoring and Audits</b>
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<b>Page 5 of 7</b>
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enrolled human subjects will be selected for review/audit. 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
  - medical records or other source documentation
  - IRB correspondence related to the study
  - external monitoring reports, if any
  - study-related data collection forms
  - study protocol, amendments and protocol deviations
  - adverse event documentation
  - study related correspondence
  - drug/device accountability records
  - regulatory documentation
  - researcher assessment of inclusion/exclusion criteria for each study subject
  - other 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 subsequent to 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 to determine if the final report needs to be provided to the IRB Chairperson. When warranted, the written report and researcher's response, if response available or if response needed, will be submitted to the Texas Health IRB Chairperson for reporting to the Texas Health IRB. A copy of the report will also be provided to the Texas Health Institutional Official and the Texas Health Chief Compliance Officer.

<b>Policy Name: Structures, Monitoring and Audits</b>
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<b>Page 6 of 7</b>
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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 authorized by the Texas Health Board of Trustees 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

<b>Policy Name: Structures, Monitoring and Audits</b>
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<b>Page 7 of 7</b>
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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 Senior Vice President Chief Compliance Officer
  - 6.1.1 Senior Vice President and Chief Compliance Officer – Responsible for oversight of the THR-wide Business Ethics and Compliance Program that includes human subject research compliance as one sub-component.
- 6.2 Director of Research Compliance
  - 6.2.1 Oversees compliance of the human subject protection program which includes the implementation of policy, procedures and personnel.

#### **7.0 References:**

- 7.1 Texas Health Corporate Policy for Protection of Human Research Subjects
- 7.2 Texas Health Corporate Policy for Conflicts of Interest in Research Involving Human Subjects
- 7.3 Texas Health Corporate Policy on Research Privacy under HIPAA
- 7.4 U.S. Federal Sentencing Guidelines
- 7.5 Texas Health Code of Business Ethics
- 7.6 Texas Health Business Ethics and Compliance Program policy
- 7.7 Texas Health Non-Retaliation – Good Faith Reports of Suspected Misconduct policy
- 7.8 Texas Health Internal Reporting and Investigation Policy
- 7.9 Texas Health Business Ethics and Compliance Program Auditing and Monitoring policy
- 7.10 Texas Health Business Ethics and Compliance Education and Training policy
- 7.11 Texas Health Cooperation with Search Warrants, Subpoenas and Governmental Investigations policy

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.