



TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™

INSTITUTIONAL COMPLIANCE PLAN

A handwritten signature in blue ink, appearing to read 'Tedd Mitchell'.

Approved by: **Tedd Mitchell, M.D.**
President

July 1, 2010
Revised: July 1, 2011

<u>INTRODUCTION</u>	1
<u>I. MISSION STATEMENTS</u>	2
A. TTUHSC MISSION STATEMENT	2
B. TTUHSC INSTITUTIONAL COMPLIANCE MISSION STATEMENT	2
<u>II. DEFINED TERMS</u>	2
<u>III. STANDARDS OF CONDUCT & ETHICS</u>	3
<u>IV. COMPLIANCE OVERSIGHT</u>	3
A. GOVERNING AUTHORITY	3
B. TTUHSC INSTITUTIONAL COMPLIANCE COMMITTEE	3
C. INSTITUTIONAL COMPLIANCE WORKING COMMITTEE	4
D. INSTITUTIONAL COMPLIANCE OFFICER	5
<u>V. COMPLIANCE AWARENESS, EDUCATION & TRAINING</u>	7
A. COMPLIANCE AWARENESS	7
B. COMPLIANCE EDUCATION	7
C. MANAGER AND SUPERVISOR RESPONSIBILITIES	9
D. CORRECTIVE ACTION	9
<u>VI. CRIMINAL BACKGROUND AND SANCTION CHECKS</u>	9
A. EMPLOYEES	9
B. RESIDENTS AND STUDENTS	9
C. CONTRACTORS/VENDORS	10
<u>VII. MONITORING & RISK ASSESSMENT</u>	10
A. ROUTINE MONITORING ACTIVITY	10
B. ON-GOING RISK ASSESSMENT	10
<u>VIII. REPORTING RESPONSIBILITIES & RESOURCES</u>	10
A. REPORTING RESPONSIBILITY	10
B. COMPLIANCE HOTLINE	11
C. NON-RETALIATION POLICY	11
D. CONFIDENTIAL AND ANONYMOUS	11

<u>IX. RESPONSE AND CORRECTIVE ACTION</u>	<u>11</u>
A. RESPONSE TO ALLEGATIONS	11
B. CORRECTIVE ACTION & APPEAL RIGHTS	12

INTRODUCTION

Texas Tech University Health Sciences Center (TTUHSC), with its seven (7) health professions schools, and clinical and academic centers through west Texas and parts of central Texas, is subject to many laws, rules and regulations as an academic, research and patient care center. Failure to comply with these laws, rules and regulations can adversely impact TTUHSC's ability to continue these activities. TTUHSC is therefore committed to conducting its activities in an ethical and honest manner and in compliance with applicable laws, regulations, Texas Tech University System (TTUS) Regents rules, and TTUHSC policies.

TTUHSC, through its President, adopts this Institutional Compliance Plan ("Plan") under authority of the Texas Tech University System Board of Regents to provide an institutional compliance environment supportive of existing regulatory compliance oversight efforts. It is based on the Federal Sentencing Guidelines standards for an effective compliance program, the Department of Health and Human Services Office of Inspector General's compliance guidance and corporate integrity models, as well as Texas Executive Order RP 36 (July 12, 2004), directing state agencies to focus on eliminating fraud, waste and abuse. This Plan supplements existing TTUHSC policies and procedures and is not intended to replace or diminish any other policy or program at TTUHSC that, in whole or in part, addresses compliance issues, except to the extent those are inconsistent with this Plan.

Ethical, honest and compliant behavior is an institutional and individual responsibility. Each member of the TTUHSC community, student, faculty, staff, visitor, or independent contractor, is expected to conduct his/her activities ethically, honestly and in accordance with applicable laws, regulations, and TTUHSC policies. TTUHSC management is expected to set the tone by supporting ethical, honest and compliant conduct as part of TTUHSC's daily operations. This Institutional Compliance Plan, as supported by the TTUHSC Standards of Conduct and Ethics Policy, and institutional policies, is designed to provide the TTUHSC community with resources to enhance their knowledge of applicable laws, regulations and policies, so they conduct their activities in a manner that reduces the risk of non-compliance.

I. MISSION STATEMENTS

A. TTUHSC MISSION STATEMENT

The mission of Texas Tech University Health Sciences Center is to improve the health of people by providing educational opportunities for students and health care professionals, advancing knowledge through scholarship and research, and providing patient care and service.

B. TTUHSC INSTITUTIONAL COMPLIANCE MISSION STATEMENT

The mission of the TTUHSC Institutional Compliance Office is to advance an institutional culture of ethics, integrity and compliance with laws, regulations and policies, governing institutions of higher education through awareness programs, monitoring and responding to non-compliance.

II. DEFINED TERMS

These terms are defined for purposes of this Plan as follows:

TTUHSC employees include full and part-time faculty, residents, staff and others employed by TTUHSC who receive salary compensation that is included in IRS W-2 wage and tax statement forms.

TTUHSC community or Members of TTUHSC community include, but are not limited to TTUHSC students, residents, faculty, staff, independent contractors, vendors and volunteers.

Regulatory Oversight Committees/Areas refers to existing and/or future Committees and/or Departments that have responsibility for certain regulatory areas, including, but not limited to, Institutional Review Board, Institutional Animal Care and Use Committee, Institutional Biosafety Committee, Billing Compliance, HIPAA Committee, Conflict of Interest Committee, Radiation Safety, Human Resources.

Fraud, Waste and Abuse, whether used collectively or separately, have the following meanings:

- *Fraud* has the same meaning as contained in TTUS Regents' Rule 07.03.
- *Waste* means over-utilization of services or misuse of resources;
- *Abuse* means actions inconsistent with acceptable business or medical practice.

Violation of Law means failure or refusal to follow any applicable state or federal law such that criminal and/or civil penalties may be imposed.

Non-compliance means failure or refusal to follow applicable state or federal laws or institutional policies whether or not such conduct results in financial risk to TTUHSC. It can include acts that constitute fraud and/or violations of law or institutional ethical standards.

III. STANDARDS OF CONDUCT & ETHICS

Members of the TTUHSC community are expected to comply with all applicable laws, regulations and policies. In support of this Institutional Compliance Plan, HSC OP 52.06, Standards of Conduct and Ethics Guide, provides a non-exclusive summary of ethical and legal principles for members of the TTUHSC community based on laws, regulations applicable to TTUHSC's activities. Except as otherwise stated, it does not replace any existing Regents Rules or TTUHSC policies or TTUHSC faculty or student handbooks.

IV. COMPLIANCE OVERSIGHT

Pursuant to HSC OP 52.01, Institutional Compliance Plan, TTUHSC has appointed an Institutional Compliance Officer (ICO) and designated the Compliance Committees identified below to assist in the development and oversight of the TTUHSC Institutional Compliance Plan (Plan). The ICO, working with these Committees is responsible for implementing and monitoring a continuous, collaborative and proactive culture of compliance at TTUHSC.

A. GOVERNING AUTHORITY

The TTUS Board of Regents ("Regents"), appointed by the governor and confirmed by the legislature, is vested with the governance, control, jurisdiction and management of TTUS, which includes TTUHSC as one of its three component institutions. The Chancellor is appointed by the Regents and is responsible for the management and operation of the TTUS administration and component institutions, under the direction of the Regents. The President of TTUHSC, has general authority and responsibility for administration of TTUHSC and reports to the Chancellor and Regents. By Resolution dated August 10, 2007, the Regents approved the establishment of an institutional compliance program at TTUHSC.

B. TTUHSC INSTITUTIONAL COMPLIANCE COMMITTEE

1. **Membership.** The TTUHSC President's Executive Council (PEC) is designated as the Institutional Compliance Committee (ICC). **The PEC, when separately convened as the ICC (and any subcommittees established by the ICC), shall each be considered a "medical committee" as defined under Texas Health & Safety Code §161.031(a), and/or other applicable state and federal laws. All documents generated by the ICC, submitted to the ICC or created for the purposes of fulfilling ICC's duties are confidential and privileged**

and shall be identified as a “Confidential – Medical Committee Document”.

2. Meetings. The ICC shall meet at least twice each year (or more often as necessary) before or after regularly scheduled PEC meetings. The TTUHSC ICO shall serve as the Chair while the PEC sits as the ICC.
3. Role and Responsibilities. The ICC’s responsibilities include:
 - a) Review and give final approval of the TTUHSC Compliance Plan, Standards of Conduct and Ethics Guide, and policies and procedures, and any amendments thereto, related to institutional compliance.
 - b) Furnish adequate resources for and support of the TTUHSC Institutional Compliance Plan.
 - c) Review and evaluate risk assessments prepared by the Institutional Compliance Working Committee (ICWC) and approve compliance monitoring plans.
 - d) Review confidential final investigative compliance reports presented by the ICO to verify that findings of non-compliance are addressed through appropriate corrective action plans and/or disciplinary action to assist in reducing the risk of similar non-compliance in the future.
 - e) Enforce consistent application of compliance standards, including fair, equitable and consistent disciplinary action of individual(s) identified as responsible for confirmed non-compliance.
 - f) Review the annual compliance report presented by the ICO to confirm effective compliance oversight.
 - g) Provide guidance to the ICO on the operation of the compliance program to prevent and/or detect non-compliance with applicable laws, regulations and policies.

C. INSTITUTIONAL COMPLIANCE WORKING COMMITTEE

1. Membership. The ICC shall, based on recommendations for membership, appoint members to serve on the TTUHSC Institutional Compliance Working Committee (ICWC). Each Executive Vice President, Senior Vice President, Vice President, Dean, and the Assistant Vice President for Human Resources shall each recommend one member to serve on the ICWC. The Faculty Senate shall recommend a representative to serve on the ICWC. The ICO shall serve as the Chair with voting rights. The ICO may recommend additional members for the ICWC. The Office of Audit Services and Office of General Counsel shall each recommend a representative to serve on the ICWC as ex-officio members without vote. **The ICWC, and any subcommittees established by the ICWC, shall each be considered a “medical committee” as defined under Texas Health & Safety Code §161.031(a), and/or other applicable state and federal laws. All documents generated by the ICWC, submitted to the**

ICWC or created for the purposes of fulfilling ICWC's duties under TTUHSC's Compliance Plan are confidential and privileged and shall be identified as a "Confidential – Medical Committee Document".

2. Meetings. The ICWC shall meet at least quarterly or more often as necessary to meet its responsibilities under TTUHSC's Institutional Compliance Plan.
3. Role & Responsibilities. The ICWC is responsible for identifying compliance risks and providing guidance for TTUHSC to conduct its activities in compliance with applicable laws, regulations and policies. The ICWC shall:
 - a) Identify emerging risk areas and high risk activities within the various compliance oversight areas of TTUHSC's operations and prepares risk assessments and compliance monitoring plans for review and approval by the ICC.
 - b) Provide guidance to the ICO in the development of compliance policies and procedures related to institutional compliance oversight.
 - c) Identify and share with the TTUHSC Community best practices related to compliance in an academic health care setting.
 - d) Assess TTUHSC regulatory compliance needs and opportunities for the ICO to present to the ICC.
 - e) Confirm that appropriate education and training is provided by Regulatory Oversight Committees/Areas within TTUHSC.
 - f) Assess compliance needs and make recommendations to the ICO and ICC.
 - g) Identify TTUHSC areas with regulatory oversight responsibilities and update as necessary to provide appropriate oversight of those identified areas.
 - h) Review and approve the annual compliance report prepared by the ICO prior to submission to the ICC.
 - i) Review and analyze data related to compliance activities and make recommendations to the Institutional Compliance Officer and ICC on the functioning of the Compliance program in identifying, avoiding, and/or minimizing non-compliance with applicable laws, regulations and policies.

D. INSTITUTIONAL COMPLIANCE OFFICER

1. The Institutional Compliance Officer. The Institutional Compliance Officer (ICO) reports to the TTUHSC President and has overall responsibility for the implementation and effectiveness of the TTUHSC Institutional Compliance Plan. The ICO shall be given adequate resources and authority to carry out such responsibility and shall report on the

implementation and effectiveness of the Compliance Plan directly to the ICWC and ICC.

2. Responsibilities of the ICO. The ICO shall:

- a) Oversee and monitor implementation of the TTUHSC Compliance Plan.
- b) Develop, and periodically review and update the Institutional Compliance Plan, Standards of Conduct and Ethics Guide, and related policies consistent with the elements of an effective compliance program.
- c) Develop, coordinate and implement a compliance training program that addresses general compliance training for all employees and other training as necessary to promote compliance awareness.
- d) Serve as an institutional resource and support for regulatory oversight areas within TTUHSC.
- e) Monitor compliance activities and high risk areas as identified and outlined in the annual monitoring plan approved by ICC.
- f) Publicize the TTUS Compliance Hotline and other TTUHSC reporting resources and coordinate investigation of alleged non-compliance, working collaboratively with General Counsel, Office of Audit Services, and other individuals with primary responsibility for specific areas of regulatory compliance oversight.
- g) Work collaboratively with Office of Audit Services, with input from ICC and ICWC to identify high risk areas.
- h) Maintain current knowledge of laws and regulations that may affect TTUHSC's policies, procedures and processes, sharing best practices and communicating that information through TTUHSC compliance channels.
- i) Identify new areas of compliance oversight as they arise and make recommendations to ICC and ICWC to verify proper oversight.
- j) Management oversight of clinical billing and HIPAA privacy compliance activities.
- k) Prepare and submit an annual compliance report outlining compliance with this Plan to the ICC.
- l) Serve as primary contact for any external government audits related to institutional, billing or HIPAA privacy compliance concerns and assist other regulatory oversight areas, as requested, in addressing government audits of their areas.

V. COMPLIANCE AWARENESS, EDUCATION & TRAINING

A. COMPLIANCE AWARENESS

All TTUHSC employees will receive a copy and acknowledge receipt of the Standards of Conduct and Ethics Guide. TTUHSC contracts shall, where appropriate, reference the TTUHSC Institutional Compliance Plan, Standards of Conduct and Ethics Guide and related policies.

The ICO shall post this Plan and the Standards of Conduct and Ethics Guide on the TTUHSC website. The ICO shall periodically publish information in various resources regarding the TTUHSC Institutional Compliance Plan, Standards of Conduct and Ethics Guide, and related policies to raise awareness regarding general and specific compliance issues.

B. COMPLIANCE EDUCATION

Compliance education is a critical element of an effective compliance program. TTUHSC is committed to providing general and specific compliance education so that TTUHSC employees understand their obligations and responsibilities in accordance with applicable laws, regulations, and policies.

1. Introduction

TTUHSC employees shall complete initial and on-going general compliance education in addition to any initial and on-going specific training required for their position. Other individuals, such as students and contractors, may be required to complete general and/or specific compliance education before providing services on behalf of TTUHSC. As new developments or concerns arise, TTUHSC may require additional training for some or all TTUHSC employees, students and/or contractors.

Employees are expected to complete required compliance education within the time frames and frequencies established by the department or committee requiring and/or providing the compliance education. Notification of compliance education requirements will be communicated through various means, including, but not limited to supervisors, written memorandum, internet/intranet and/or e-mail.

General and Specific Compliance Education programs and related information shall be periodically reviewed and updated to address current risk areas and improvement opportunities. A variety of educational methods, materials, and tools, will be utilized to present General and Specific Compliance Education programs.

2. General Compliance Education Content and Delivery.

The ICO shall be responsible for developing the content for and delivery of general compliance education for TTUHSC. The content of the general compliance education will include, but is not limited to, overview of pertinent laws and regulations, the TTUHSC Compliance Plan, TTUHSC risk areas, roles & responsibilities and other information necessary to maintain an effective general compliance education program. General compliance education requirements shall be published on the Institutional Compliance website and advertised through other resources as necessary to communicate the information.

3. Specific Compliance Education Content and Delivery

It will be the responsibility of the individual, department or committee having regulatory compliance oversight to develop the content and deliver specific compliance education related its area of regulatory oversight responsibility. The content of these educational programs shall include those areas mandated by law, regulation and/or policy and may include a review of relevant laws and regulations applicable to that regulatory compliance area, identified or potential risk areas, responsibilities, and methods to improve compliance. Specific compliance education includes, but is not limited to education for the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Radiation Safety, Safety, Human Resources, Billing Compliance, Privacy, and other education as may be required by law, regulation and/or TTUHSC policy. Specific compliance training requirements shall be communicated by the department or committee responsible for the content and delivery of the Specific Compliance Education.

4. Education Reporting and Maintenance of Compliance Education Materials

Records of completion of compliance education shall be maintained by the department or Committee responsible for delivery of the education in accordance with institutional/regulatory guidelines. Summary reports of compliance with mandatory compliance education requirements shall be compiled by the department responsible for the education at least annually or more often as necessary and submitted to the ICO for review by the ICWC and/or ICC.

Copies of all general and specific compliance education materials (electronic and/or hard copy) shall be retained in accordance with HSC OP 10.09, Records Retention, and/or legal and regulatory requirements, whichever is more stringent.

C. MANAGER AND SUPERVISOR RESPONSIBILITIES

The promotion of and adherence to the Institutional Compliance Plan by all managers and supervisors is considered an integral part of their job performance. *Persons serving in management or supervisory positions at TTUHSC (to include faculty, etc...) shall receive notice of those who need to complete compliance training and are ultimately responsible to make sure that each TTUHSC employee reporting to them has completed the required compliance training applicable to that person.* Completion of required compliance training will be monitored and documented. Specifically, managers and supervisors shall:

- Complete all required compliance training for their own respective position.
- Inform employees of required compliance training specifically related to their job function and appropriately monitor employees to verify that employees complete all mandatory compliance training.

D. CORRECTIVE ACTION

Compliance training is required of all employees and is a condition of employment with TTUHSC. It is the responsibility of the manager or supervisor to take appropriate action, including disciplinary action, for employees who fail to timely complete TTUHSC mandatory training.

VI. CRIMINAL BACKGROUND AND SANCTION CHECKS

A. EMPLOYEES

All new TTUHSC employees undergo a criminal background and sanction checks pursuant to HSC OP 70.20, Employment Background Screening Policy and HSC OP 52.11, Sanction Check Process. TTUHSC may prohibit the employment of any person listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in federal or state funded programs to maintain compliance with federal and/or state laws.

B. RESIDENTS and STUDENTS

In accordance with HSC OP 10.20, Criminal Background Checks for Students, Trainees and Residents, students and residents participating in patient interactions or clinical training will be required to undergo initial criminal background and sanction checks. Residents will not be placed on the payroll or assigned clinical duties until cleared based on criminal background and sanction check results. Once employed, Residents will be subject to routine sanction checks in accordance with HSC OP 52.11, Sanction Check Process. Any resident listed by a federal or state agency as debarred, excluded, or

otherwise ineligible for participation in federal or state funded programs shall not be enrolled in the TTUHSC residency program.

C. CONTRACTORS/VENDORS

In accordance with HSC OP 52.11, Sanction Check Process, TTUHSC Purchasing and Contracting Offices shall conduct appropriate searches of vendors and contractors against federal and state sanction lists as part of the review process. TTUHSC shall not contract with any individual or entity which is listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in federal or state funded programs.

VII. MONITORING & RISK ASSESSMENT

A. ROUTINE MONITORING ACTIVITY

Regulatory Oversight Committees/Areas conduct routine monitoring in accordance with identified risks. The ICO shall be responsible for conducting routine monitoring of TTUHSC compliance policies and activities, including activities of Regulatory Oversight Committees/Areas based upon risks identified as part of the on-going risk assessment or as otherwise directed by the ICC or ICWC.

B. ON-GOING RISK ASSESSMENT

The ICO shall conduct on-going risk assessments of TTUHSC activities to identify potential risk areas. This information shall be shared with the TTUS Office of Audit Services as part of its annual risk assessment activities.

VIII. REPORTING RESPONSIBILITIES & RESOURCES

A. REPORTING RESPONSIBILITY

Reporting suspected fraud, violations of law or non-compliance is essential to the effectiveness of the TTUHSC Institutional Compliance Plan. TTUHSC employees and students shall report suspected violations of, or non-compliance with, federal or state laws, and/or TTUHSC policies. There are various methods and resources available to report suspected fraud, violations of law or non-compliance. Any member of the TTUHSC community who has a reasonable basis for believing fraud, violation of law or other non-compliance has occurred has a responsibility to promptly notify his/her supervisor, TTUS Office of Audit Services, Texas Tech Police Department, Human Resources (as applicable), the TTUHSC Institutional Compliance Officer, or use the external confidential Hotline (See Section B below).

It is a violation of TTUHSC policy to intentionally make or submit false reports of fraud, violations of law or non-compliance. Those found to have made or submitted false

reports will be subject to disciplinary action, up to and including termination of employment or association with TTUHSC.

B. COMPLIANCE HOTLINE

Members of the TTUHSC community are encouraged to attempt resolution of concerns through established channels whenever possible. However, in those situations where that is not possible, TTUS has contracted with an outside company, EthicsPoint, to provide a confidential and anonymous mechanism to report suspected fraud, waste and abuse, or other illegal or unethical conduct of employees, students, vendors or independent contractors of any of the component institutions, including TTUHSC.

TTUS COMPLIANCE HOTLINE

1-866-294-9352 (also available in Spanish)

or

www.ethicspoint.com

Reports may be submitted by telephone or through the secure website address noted above. See also HSC OP 52.03, Compliance Hotline.

C. NON-RETALIATION POLICY

Those making or submitting good faith reports of violations of law and/or TTUHSC policies or non-compliance are protected from retaliation under federal and state laws, including the federal and Texas Whistleblower Acts.. Pursuant to HSC OP 52.04, Reporting Violations, Non-Retaliation Policy, TTUHSC shall not intimidate, threaten, coerce, terminate, discriminate against or take any retaliatory action against any person who, in good faith, reports suspected non-compliance or violations of law or TTUHSC policies.

D. CONFIDENTIAL AND ANONYMOUS

Reports will be handled and investigated in a confidential and anonymous manner subject to existing policies (including faculty or student handbooks) and to the extent allowed by law.

IX. *RESPONSE AND CORRECTIVE ACTION*

A. RESPONSE TO ALLEGATIONS

All reports of suspected fraud, violation of law and/or non-compliance shall be tracked and investigated. If the report concerns an allegation of suspected fraud, the matter shall

be reported to the Office of Internal Audit pursuant to Regents Rule 07.03, which may conduct the investigation or collaborate with others to conduct the investigation. Allegations of suspected violations of law or non-compliance shall be reviewed and investigated, if warranted, by the responsible Regulatory Oversight Committee/Area, with assistance from the ICO. Advice from the Office of General Counsel regarding any investigation may be obtained whenever necessary. A written report of each investigation by the ICO shall be prepared, to include findings and recommendations and marked confidential in accordance with this Plan. A summary report of all ICO compliance investigations shall be provided to the ICC. The ICC has the authority to require action in addition to those recommended by the investigating entity/individual.

TTUHSC students, faculty and staff shall cooperate during any compliance investigation and shall not alter or destroy any documentation during the course of the investigation.

B. CORRECTIVE ACTION & APPEAL RIGHTS

Failure or refusal to comply with this Plan, applicable laws, regulations and/or TTUHSC policies will result in corrective action. An employee's supervisor, Chair, or Dean may also be subject to corrective action when he/she (i) directs or approves the employee's improper actions; (ii) is aware of the improper actions and fails to correct them, or (iii) otherwise fails to exercise appropriate supervision. Corrective action may also be imposed where an employee should have detected, but failed to detect fraud, a violation of law or non-compliance. Correction may include, but is not limited to, any of the following actions

- Mandatory training
- Counseling
- Increased monitoring/auditing
- Reclassification or reassignment of duties
- Suspension of billing privileges for health care providers,
- Termination of employment or contractual relationship

Corrective action and any appeal rights, will be addressed in accordance with existing policies, including, but not limited to each School's Faculty Handbook and Student Handbook, the Student Affairs Handbook, HSC OP 70.31, Employee Conduct, Discipline and Separation of Employees and Regents Rule 04.03.