

MEMORANDUM

TO: Randall J. Urban, MD
Vice President and Chief Research Officer

FROM: Desolyn Foy, CPA, CIA, MHA
Vice President, Audit Services

DATE: September 14, 2022

SUBJECT: Research Operations and Compliance Audit
Engagement Number 2021-013

Attached is the final audit report regarding the audit of Research Operations and Compliance. This audit will be presented at the next Institutional Audit Committee meeting.

Thank you for your cooperation and assistance during the course of this review. If you have any questions or comments regarding the audit or the follow-up process, please feel free to contact me at (409) 747-3277.

Attachment

c: Charles Mouton, MD, MS, MDA
Claudia Delgado
Sharon Comvalius-Goddard



The University of Texas Medical Branch
Audit Services

Audit Report

Research Operations and Compliance Audit

Engagement Number 2021-013

September 2022

The University of Texas Medical Branch
Audit Services
301 University Boulevard, Suite 4.100
Galveston, Texas 77555-0150

Research Operations & Compliance Engagement

Engagement Number: 2021-013

Background

The University of Texas Medical Branch's (UTMB Health) Office of Research Administration is responsible for policy formation and oversight. This office also provides research specific resources to assist principal investigators in finding and securing funding opportunities, initiating, building, and submitting proposals, training, regulatory reviews, project setup, and award management through project completion. The Office of Research Administration is supported by the Office of Institutional Compliance and the newly formed (fiscal year 2021) Research Regulatory & Compliance Office of Research Integrity and Regulatory Affairs which functions as a research quality assurance and monitoring program.

The Research Integrity and Regulatory Affairs Office offers a variety of support services such as, allowing for centralized monitoring of investigator-initiated clinical trials and providing monitors with proper expertise to ensure each study is conducted according to clinical practice guidelines and other regulations.

Objective, Scope and Methodology

The objective of this audit was to determine whether adequate internal controls are in place related to Research Administration and Compliance Operations. The scope of the audit included a review of Research Administration, Office of Institutional Compliance, and Research Regulatory and Compliance processes. Our methodology included interviews with key personnel, a review of policies and procedures, financial and operational activities, oversight, monitoring, and reporting. Specifically, we performed the following procedures to achieve our objective:

- Analyzed adequate segregation, reporting responsibilities and compliance monitoring related to research within the Research Administration, Office of Institutional Compliance, and the Research Regulations and Compliance Office.
- Reviewed UTMB Health's respective daily operations and regulatory compliance function's organizational structure to determine alignment with other UT System Institutions.
- Evaluated the communication and reporting provided to the research teams regarding new and emerging issues, policies, and risks, as well as a report research misconduct or policy violations.
- Evaluated the management reports for sufficiency, adequacy and timeliness distribution to support overall operational and financial decisions.

Results Summary

The UTMB Health Research Administration Office performed a series of initiatives by reorganizing the

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operations in Research Administration and adding a Research Regulatory and Compliance core office to monitor compliance with federal, state, and local laws and regulations as well as institutional policies independent of day-to-day research operations.

Overall, policies, procedures and internal controls are adequate to provide UTMB leadership information to make informed decisions regarding operational and financial decisions. Communication and reporting of emerging issues, policies, and risks to determine misconduct or policy violations occurs through regular staff and committee meetings; however, there are opportunities to improve oversight, and monitoring of research activities.

Detailed Results

Oversight and Monitoring

The Research Regulatory and Compliance Department established a Research Integrity and Regulatory Affairs Office in Fiscal Year 2021, which functions as the research quality assurance and monitoring program. However, due to limited staffing resources cause by difficulty in recruiting, an assessment of risk and compliance monitoring has not been fully developed.

Recommendation 2021-013-001-Medium:

Research Regulations & Compliance Office should fully define, formally document, and develop an assessment of risk to ensure an effective monitoring program in order to identify instances of non-compliance.

Management's Response: Since the time of engagement, staff has been hired in the office of Research Integrity and Regulatory Affairs. They have since begun creating the framework, i.e., the policy and procedures which include risk assessment, remedies, key review elements and frequency, around the monitoring process for clinical trials. They expect to begin study monitoring by December 31, 2022. Future activities outside of monitoring include creating a Responsible Conduct of Research Program for faculty and a Foreign Influence program.

Responsible Party: Associate Vice President of Research Regulations & Compliance Office

Implementation Date: December 31, 2022

Conclusion

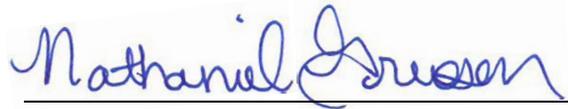
Overall, the internal controls and processes related to research operations and compliance appear to be adequate and in compliance with applicable policies and procedures. We appreciate the assistance provided by the Office of Institutional Compliance, Research Administration, Research Regulatory & Compliance Office staff.

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The engagement was conducted in accordance with the International Standards for the Professional Practice of Internal Auditing as promulgated by the Institute of Internal Auditors.

A handwritten signature in black ink that reads "Desolyn Foy".

Desolyn Foy, CPA, CIA, MHA
Vice President and Chief Audit Executive,
Audit Services

A handwritten signature in blue ink that reads "Nathaniel Gruesen".

Nathaniel Gruesen, MBA, CIA, CISA, CFE
Interim Director, Audit Services