



Texas Biomedical Device Center

Audit Report No. R2501 | *September 27, 2024*



Executive Summary

Audit Objective

To evaluate financial and accounting processes, internal controls systems, and the effectiveness and efficiency of related operations and controls within the Texas Biomedical Device Center (TxBDC).

Controls and Strengths

- TxBDC has detailed written policies and procedures and unique job descriptions.
- TxBDC consistently receives 5 out of 5-star Lab Safety Performance Evaluations.
- Human subjects and animal research protocols are kept up to date and are communicated to respective departments.

Overall Conclusion

Generally, the Texas Biomedical Device Center has good internal controls in place. Opportunities exist to enhance controls in the areas of the research participant payment process, property management, and conflicts of interest and commitment.

Observations by Risk Level

Management has reviewed the observations and has provided responses and anticipated implementation dates. Detailed information is included in the attached report. Verbal recommendations were discussed in detail with management prior to the exit conference.

Recommendation	Risk Level	Management’s Implementation Date
1. Strengthen Controls over Research Participant Payment Process	High	January 31, 2025
2. Strengthen Controls over Property Management	Medium	January 31, 2025
3. Improve Conflict of Interest and Commitment Reporting Process	Medium	January 31, 2025

For details about the audit and methodology, explanation of risk levels, and report distribution, please see Appendices A, B, and C, respectively, in the attached report.



Detailed Audit Results

The following are reportable observations and recommendations noting opportunities to enhance controls in the areas of the research participant payment process, property management, and conflicts of interest and commitment. Minor recommendations relation to operations and expenses were shared verbally with management in the TxBDC.

1. **Strengthen Controls over the Research Participant Payment Process**

High Risk: *Not segregating duties between the registration, approval, and payment to research participants can lead to an increased risk of fraud and could compromise research integrity.*

The Texas Biomedical Device Center (TxBDC) has published seven clinical trials since its founding in 2012. As part of this, research participants are typically compensated for their participation. To ensure that proper payment is made, and that policies and procedures are being followed, the TxBDC uses UTD's ClinCard system to manage research participant payments. From September 1, 2023, to May 31, 2024, payments totaling \$30,080 were made to research participants.

A lack of segregation of duties regarding the research participant payment process was noted during testing. The ClinCard system has various roles employees can be assigned. The TxBDC employees are assigned two roles:

- Site Coordinator - can register participants, assign cards, submit payments, and run reports. The only thing this role cannot do is approve payments.
- Approver - can only review and approve payments to participants.

Employees who have both roles can register a participant, submit payments, and approve the payments. TxBDC employees often submit and approve payments for participants within minutes of each task. Of the 970 payments tested, 654 (67.4%) were requested and approved by the same individual.

Recommendation: TxBDC should work with Treasury & Payment Services to ensure there is a segregation between the requestor, approver, and reconciliation roles in the research participant payment process.



Management’s Action Plan:

TxBDC will work with Treasury & Payment Services as well as the Galaxy Pay team to ensure there is segregation of duties among the requestor, approver, and reconciliation roles in the research participant payment process. Since we are in the middle of clinical trials, we will prepare to change our participant payment processes and train our staff over the next two months and implement the change over the year-end break when participant activity naturally falls. Our specific plan is to have the researcher who is working directly with the participants act as requestor, Rebecca Cedillo act as approver, and Carolyn Kudwa will be responsible for reconciliation.

Responsible Party Name and Title:

Michael Kilgard, Director

Estimated Date of Implementation:

January 2025

2. Strengthen Controls over Property Management

According to [UTDBP3066 - Property Administration](#), “each department head is responsible for the proper custody, maintenance, and safekeeping of UTD property assigned to his/her department.”

TxBDC has approximately 155 assets totaling about \$270,101. There are many tablets and cell phones used during TxBDC’s clinical trials, as well as various research equipment.

Medium Risk: Without strong controls over property, including periodic inventories, the risks are increased that can lead to the loss or misuse of assets and can result in financial losses, reputational risks, and noncompliance with State and University regulations and policies.

In testing controls over property management, the following was noted:

- 15% of the assets tested (3/20) were not in the correct location.
- 20% of the assets tested (4/20) were not in use or were obsolete and should have been surplus.
- 15% of the assets tested (3/20) did not have the correct custodian noted as required by UTDBP3066.



It was also noted that in FY22 and FY23, 20% (39) of the TxBDC's assets, totaling about \$38,124, were reported missing. When an asset is listed as missing, a "Missing or Stolen Property Report for State Departments, Institutions, and Agencies" is required to be filed with the Inventory team and Police Department and approved by the Dean or Vice President. In reviewing 10 of the 39 missing asset forms from FY22 and FY23, all assets that were listed as missing in each fiscal year had the same reason for the loss documented on the form. FY22 missing assets stated, "Lab scope of work has changed and as a result, tablets were relocated/reassigned throughout the lab," and the reasoning on the FY23 forms stated "This fixed asset was distributed and installed but it is unable to be found at this time. The asset was installed in UTD facilities, and these utilized existing UTD controls for access."

Recommendation: Strengthen controls over TxBDC's property by developing internal procedures and tracking and conducting periodic inventories of the assets.

Management's Action Plan:

TxBDC will strengthen controls over TxBDC's property by updating our internal procedures for tracking and conducting periodic inventories of the assets. We will provide a specific reason for each loss that occurs and work to ensure that missing asset forms are completed yearly for missing items, rather than hoping that missing assets will "turn up".

Responsible Party Name and Title:

Michael Kilgard, Director

Estimated Date of Implementation:

January 2025



3. *Improve Conflict of Interest and Commitment Reporting Process*

UT Dallas conflict of interest (COI) and commitment policies for all employees are outlined on the Office of Institutional Compliance, Equity, and Title IX Initiatives website.¹ All UTD employees are required to disclose potential conflicts of interest and any outside activities. If any conflicts are noted, a management plan must be in place with appropriate approvals from both the School and University management.

Medium Risk: Noncompliance with conflicts of interest and commitment policies could result in misuse of university funds, noncompliance, fraud, and reputational harm.

Of the 10 employees tested in the TxBDC, three employees had potential relationships with companies that were not disclosed. One of the undisclosed companies was paid \$145,247.66 by TxBDC for professional services.

Recommendation: Remind employees and require conflicts of interest and commitments be reported in compliance with university policies and monitor the reports for completeness. Monitor for potential COI during the cost center reconciliation review and approval process.

Management's Action Plan:

The TxBDC director will remind employees about university requirements regarding conflicts of interest including prompt reporting of changes and continue to monitor for potential COI's during the cost center reconciliation review and approval process.

The TxBDC will work with the Office of Research and Innovation to resolve the appearance of conflicts caused by relationships that may appear to be financial when they are not and encourage center employees and third parties to update their websites to accurately reflect relationship status.

The Center Director has reviewed the list of possible nondisclosures identified by the audit team. All but one are due to old or erroneous information on LinkedIn, Corporationwiki, and Kendoemailapp. The director will meet with the Associate Director and Chief Technology Officer, Director of Preclinical Research, and Research Biomedical Engineer III to advise them on how to avoid the appearance of conflict by better managing their online information. The one relationship questioned by the audit team that is relevant is covered by Nate Bleker's COI management plan, which includes his relationship with Konan Medical.

¹ <https://institutional-compliance.utdallas.edu/compliance/conflicts-of-interest/>



Responsible Party Name and Title:

Michael Kilgard, Director

Estimated Date of Implementation:

January 2025

Overall Conclusion

Generally, the Texas Biomedical Device Center (TxBDC) has good internal controls in place. Opportunities exist to enhance controls in the areas of the research participant payment process, property management, and conflicts of interest and commitment.

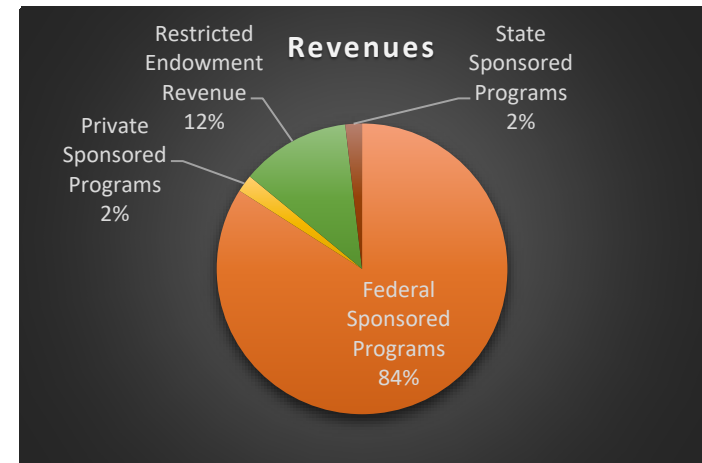
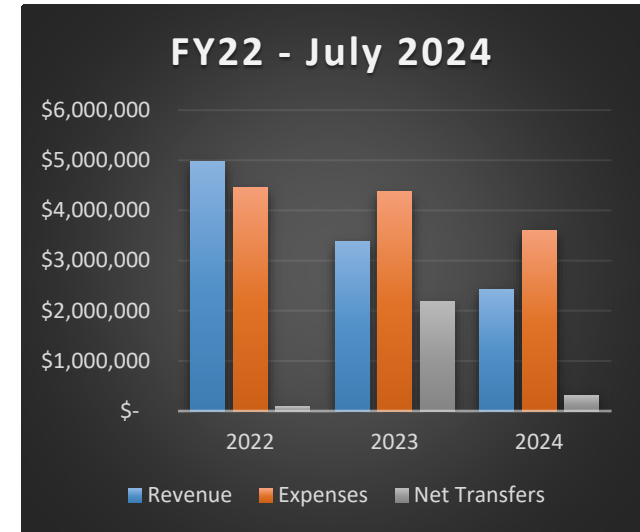


Appendix A: Information Related to the Audit

Background

The Texas Biomedical Device Center (TxBDC) “develops technologies to prevent injuries, detect impairments, and restore quality of life lost due to neurological injuries and disease.”² TxBDC was established in 2021 with donations from Texas Instruments and a private donor. Research related to phantom limb pain, chronic pain, multiple sclerosis, tinnitus, stroke, Rett syndrome, PTSD, and spinal cord injury is performed. TxBDC has many animal research protocols and recently started human subjects research with clinical trials. TxBDC is a collaborative effort engaging researchers from multiple disciplines working toward a common goal: creating new biomedical technology and therapies. This interdisciplinary program includes faculty members from the [School of Behavioral and Brain Sciences](#), the [Erik Jonsson School of Engineering and Computer Science](#), and the [School of Natural Sciences and Mathematics](#).³

In FY24 through July, TxBDC managed over \$2.4 million in revenue and \$3.5 million in expenses. Revenues consist mainly of Federally Sponsored Programs and Endowment Revenue.



² <https://txbdc.utdallas.edu/about/>

³ <https://txbdc.utdallas.edu/about/>



Objective

To evaluate financial and accounting processes, internal controls systems, and the effectiveness and efficiency of related operations and controls in the Texas Biomedical Device Center.

Scope

The scope of the audit was fiscal year 2024. Fieldwork was conducted from May 2024, and the audit concluded on September 3, 2024.

Methodology

The audit was conducted in conformance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*. Additionally, we conducted the audit in accordance with generally accepted government auditing standards (GAGAS). Both standards are required by the Texas Internal Auditing Act, and they require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. The Office of Audit and Consulting Services is independent per both standards for internal auditors.

GAGAS also requires that auditors assess internal control when it is significant to the audit objectives. We used the Committee of Sponsoring Organizations of the Treadway Commission (COSO) framework in assessing internal controls⁴.

Our audit methodology included interviews, observations of processes, reviews of documentation, and testing. The following table outlines our audit procedures and overall controls assessment for each of the audit area objectives performed.

Audit Area	Methodology	Observations Related to the Audit Area
Gaining an Understanding of TxBDC Operations	<ul style="list-style-type: none"> Gained an understanding of operations by conducting interviews with TxBDC personnel. 	None

⁴ <http://www.coso.org>



Audit Area	Methodology	Observations Related to the Audit Area
	<ul style="list-style-type: none">Performed a risk assessment to identify areas of high risk within operations, and focused audit procedures on those risks.Conducted a physical walkthrough of the TxBDC to observe strengths and weaknesses which assisted in the risk assessment process.	
Expense Testing	Tested controls over expenses for authorization, accuracy, operational effectiveness, and compliance with applicable policies and procedures.	None
Self-Sufficiency Analysis	Performed a five-year analysis of TxBDC expenses and revenues to determine if they are working towards becoming self-sufficient.	None
Property Management	Tested assets for proper internal controls and compliance with university policies and procedures.	Observation #2
Conflict of Interest Review	Determined if the proper COI and COC disclosures were in place for selected employees.	Observation #3
Access Control Assessment	Tested individuals for appropriate access based on their responsibilities.	None
Lab Safety and Protocol Review	Reviewed the Lab Safety, Human Subjects Research, and Animal Research Protocols to determine if TxBDC is complying with safety and research standards.	None
Research Participant Payment Testing	Gained an understanding and tested the participant payment process for adequacy of internal controls.	Observation #1
License Agreement and IP Review	Gained an understanding of TxBDC's intellectual property and licensing agreements. Reviewed a selection of license agreements to ensure approval and no unusual contract terms were noted based on the purpose of the contract.	None



Follow-up Procedures

Though management is responsible for implementing the course of action outlined in the response, we will follow up on the status of implementation subsequent to the anticipated implementation dates. Requests for extension to the implementation dates may require approval from the UT Dallas Audit Committee. This process will help enhance accountability and ensure that timely action is taken to address the observations.



Appendix B: Observation Risk Rankings

Audit observations are ranked according to the following definitions, consistent with UT System Audit Office guidance.


Risk Level	Definition
Priority	If not addressed immediately, a priority observation has a significant probability to directly impact the achievement of a strategic or important operational objective of UT Dallas or the UT System as a whole. These observations are reported to and tracked by the UT System Audit, Compliance, and Risk Management Committee (ACRMC).
High	High-risk observations are considered to be substantially undesirable and pose a high probability of adverse effects to UT Dallas either as a whole or to a division/school/department level.
Medium	Medium-risk observations are considered to have a moderate probability of adverse effects to UT Dallas either as a whole or to a division/school/department level.
Low	Low-risk observations are considered to have a low probability of adverse effects to UT Dallas either as a whole or to a division/school/department level.
Minimal	Some recommendations made during an audit are considered of minimal risk, and the observations are verbally shared with management during the audit or at the concluding meeting.



Appendix C: Report Submission and Distribution

We thank the Texas Biomedical Device Center management and staff for their support, courtesy, and cooperation provided throughout this audit.

Respectfully Submitted,

DocuSigned by:

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Toni Stephens, CPA, CIA, CRMA, Chief Audit Executive

Distribution List

Members and ex-officio members of the UT Dallas Institutional Audit Committee

Responsible Vice President

Dr. Inga Musselman, Provost and Vice President for Academic Affairs

Persons Responsible for Implementing Recommendations:

Dr. Michael Kilgard, Director of the Texas Biomedical Device Center

Other Interested Parties

Ms. Heather Burge, Associate Provost

External Parties

- The University of Texas System Audit Office
- Legislative Budget Board
- Governor's Office
- State Auditor's Office

Engagement Team

Project Leader: Mr. Rob Hopkins, CFE, Audit Manager

Staff: Ms. Caitlin Cummins, Internal Auditor III