Research Participants

Audit Report No. R2303 | *November 9, 2022*

Executive Summary

Audit Objective

To ensure compliance with federal regulations and the effectiveness of operations over research participants and the effective assignment, performance, and training of oversight committee roles of the Institutional Review Board (IRB).

Controls and Strengths

- All Human Subjects Research (HSR) staff are knowledgeable about processes and elements required for a project involving research participants.
- Implementation of the online tracking and approval system for HSR Projects creates effective controls for approvals, separation of duties, and workflow tracking.

Overall Conclusion

UT Dallas has processes in place to ensure compliance with federal regulations over research participants; however, processes can be improved that will enhance the effectiveness of operations, including the IRB.

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.

Topic	Risk Level	Management's Implementation Date
1. Risk Management Program	**Medium**	August 31, 2023
2. Institutional Review Board Appointment Process	**Medium**	May 31, 2023

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

Observation	Risk Level/Effect	Recommendation[1]
1. ***Risk Management Plan***		***Medium***
Risk management plans are designed to document the responsible party's monitoring, training, and reporting procedures that help ensure instances of noncompliance are minimized. The responsible party submits quarterly compliance reports to the Office of Institutional Compliance, Equity, and Title IX Initiatives outlining the monitoring, training, and reporting performed for the compliance area during the quarter. The Human Subjects Risk Management Plan and quarterly compliance reports were reviewed and evaluated. The following was noted: a. Two parties are listed as being responsible for the compliance program: the Associate Vice President (AVP) for Research and Innovation, who also serves as the University's Chief Compliance Officer, and the Director of	The Human Subjects compliance program is considered a high-risk area at UT Dallas. Without an effective program, instances of noncompliance could result in increased risks impacting the safety of human subjects, federal funding, and UT Dallas operations and reputation.	The Human Subjects Risk Management Plan should be updated. The following is recommended to enhance the plan: • Conduct a periodic risk assessment to ensure all risks are evaluated and plans for monitoring all risks are in place. • Based on the risk assessment, update and enhance the monitoring and training procedures, including clarification of the responsibilities conducted by the first (operational) and second (monitoring) lines. • Develop alternative ways to provide oversight and monitoring over the compliance program since the Chief Compliance Officer also serves as the AVP for Research and Innovation and co-responsible party over human subject research.

[1] See Appendix B on page 12 for definitions of observation risk rankings. Minimal risk observations were communicated to management separately.

Observation	Risk Level/Effect	Recommendation[1]
Human Subjects Research (HSR). Because the Chief Compliance Officer also serves as the AVP for Research, this creates both a separation of duties and a conflict of interest over the program's oversight and compliance monitoring processes. b. The Risk Management Plan is incomplete and has not been modified in several years. The plan is unclear as to what constitutes monitoring processes performed by the second line (those that should be performed by the responsible party) and the first line (operational/internal control processes performed by the staff members)[2]. c. The Director of HSR is responsible for conducting site visits as part of the monitoring procedures. During FY21, only one site visit was performed, and no site visits		

[2] The Three Lines Model: https://www.theiia.org/globalassets/site/about-us/advocacy/three-lines-model-updated.pdf

Observation	Risk Level/Effect	Recommendation[1]
were performed during the first three quarters of FY22. d. The risk assessment process could be improved by conducting a formal risk assessment on a periodic basis. Internal Audit noted potential risk areas that should be included on the risk management plan: • payment services for research participants • appointment of the IRB Chair and IRB members • incident reporting processes • data security • sensitivity awareness training for projects, including sensitive topics e. One of the 15 projects tested for compliance with the risk management plan was approved without proper analysis. The project was a legacy project. Legacy projects are research projects that were approved before the online Cayuse system was implemented. Review		

Observation	Risk Level/Effect	Recommendation[1]
procedures for the legacy projects should be strengthened.		

Management's Action Plan:

The Office of Research and Innovation (ORI) values the Research Participant's audit observations and recommendations. ORI is committed to continuing to direct UT Dallas' Human Subject Research program to adhere to state and federal regulations, as its compliance is critical to the university's research enterprise.

In regards to the Human Subjects Risk Management Plan (RMP), please see below:

a. ORI accepts the audit's recommendation of reducing the potential conflict of interest by removing the Associate Vice President for Research and Innovation as the responsible individual for the program. The Vice President for Research will be listed as the responsible party and the Institutional Official.

b. It should be noted that the reviewed Human Subjects Risk Management Plan (RMP) is a legacy document approved in its current form. However, the Director of Human Subjects Research Office (HSR) is working closely with the Compliance Office to revise the RMP accordingly.
   - The human subjects research protocol review and post-approval monitoring process are multifaceted, requiring both first- and second-line controls. The Director of HSR clearly outline these processes in the revised RMP.

c. Post Approval Monitoring visits were difficult to coordinate in FY21, as many labs were still remote and conducting limited research activities due to COVID. Additionally, the increased volume of protocol submissions as labs resumed research activities has made it challenging to resume pre-COVID activities.
   - To address this critical issue, funding for a Quality Assurance Manager and an IRB Specialist II is allocated. It is anticipated these positions will be filled by April 2023.

d. HSR agrees potential risk should be included on the RMP:
   - The HSR Director will work with the Chief Compliance Officer to identify an appropriate monitoring plan.
   - Appointment of the IRB Chair and IRB Members: the membership of the IRB, while a significant part of the program, should not be noted in the RMP. The appointment of individuals on a committee is not an administrative function of

Observation	Risk Level/Effect	Recommendation[1]
the HSR office. These are faculty appointments made by members of the faculty senate, and the monitoring and reporting of this item will be a subjective process. • Incident Reporting Process: reporting adverse events or deviations to IRB approved protocols is routinely reported. The HSR office agrees this should be noted on the RMP. • Data security: data management and security are part of the protocol review process. The IRB does not approve protocols without appropriate data security and management in place. However, the HSR agrees the risk related to potential security reaches beyond the IRB process institutionally. The HSR Director will work with the Chief Compliance Officer to identify an appropriate monitoring plan. • Sensitivity awareness training: the RMP will be revised to expand human subjects training from CITI and include additional topics and modules on a case-by-case basis per IRB recommendation. e. One of the 15 projects tested for compliance with the RMP was approved without proper analysis. The project was a legacy project. A review of Legacy projects approved before the online Cayuse system should be strengthened. • HSR office requests the IRB number and title of the project that was approved without proper analysis. Understanding how it determined was determined to not be properly analyzed would be beneficial in preventing future occurrences. • The HSR will conduct a congruency check of its 200 Legacy projects no later than August 31, 2023. **Responsible Party Name and Title:** Amanda Boone, Director of Human Subjects Research **Estimated Date of Implementation:** RMP revisions will be completed by October 31, 2022. Additional staff positions will be filled by April 30, 2023. The review of Legacy projects will be completed by August 31, 2023.		
2. ***Institutional Review Board Appointment Process***		***Medium***
The UT Dallas Institutional Review Board (IRB) is a university-wide committee that reviews and monitors research involving human subjects and is governed by both	Human subject research projects can be negatively impacted without effective and efficient appointment and approval processes.	Consider revising the IRB appointment process to align with best practices from other research universities that involve appointment approvals by research.

Observation	Risk Level/Effect	Recommendation[1]
federal regulations (45 CFR 46) and by the UT Dallas policy UTDPP1035 Committee on Research Involving Human Subjects (Institutional Review Board). The current election process for the IRB is through the Committee on Committees; however, this process is not stated in the policy. The current process is for the Committee on Committees to appoint the members, and the President has delegated membership approval to the Provost. This process can take a significant amount and time which impacts human subject research projects. Internal Audit requested information from other research universities regarding their IRB appointment processes and noted the following best practices for UT Dallas to consider: • A vice president or assistant vice president for research typically approves the IRB Committee appointment. • Alternate members of the IRB are specified and documented. • Standard operating procedures are well documented for project		

Observation	Risk Level/Effect	Recommendation[1]
review processes and other HSR related processes. • Some universities have two IRB committees to include additional members for specialized topics.		
Management's Action Plan: The HSR Office values the audit's observations and recommendations regarding this IRB Committee selection procedure. Please keep in mind that this is outside ORI and HSR office; however, noting the membership as a potential risk will support our interest. The Director of HSR has begun discussions with UT Dallas' Chief Compliance Officer to address this issue as a compliance risk to the institution's federal funding. We plan to update the process to comply with both federal regulations (45 CFR 46) and by UT Dallas policy UTDPP1035 Committee on Research Involving Human Subjects (Institutional Review Board). **Responsible Party Name and Title:** Amanda Boone, Director of Human Subjects Research **Estimated Date of Implementation:** May 31, 2023		

Overall Conclusion

UT Dallas has processes in place to ensure compliance with federal regulations over research participants; however, processes can be improved that will enhance the effectiveness of operations, including the IRB.

Appendix A: Information Related to the Audit

Background

Research Participants are individuals who volunteer or get paid to participate in research projects. The Human Subjects Research (HSR) Office "facilitates and promotes the ethical involvement of human subjects in research by providing administrative support to the Institutional Review Board and consultative services to investigators and their research staff."[3] HSR staff manage over 1,000 research projects that must adhere to federal and state regulations as well as UT System and UT Dallas policies and procedures.

The FY22 Human Subjects Risk Management Plan lists the following as risks of noncompliance for human subject research:

- *Non-compliance with federal regulations regarding the use of human subjects or human subject data in research*
- *Inadequate or no review by Institutional Review Board (IRB)*
- *Lack of required elements in consent forms*
- *Non-compliance with Health Insurance Portability and Accountability Act (HIPAA), required for studies approved at UTSW*
- *Inadequate protection of vulnerable populations and lack of oversight with confidentiality of participants and/or data*
- *Loss of federal funding*
- *Confidentiality breach of participants*
- *Possible physical harm*

Objective

To ensure compliance with federal regulations and the effectiveness of operations over research participants and the effective assignment, performance, and training of oversight committee roles of the Institutional Review Board (IRB).

Scope

The scope of the audit was fiscal year 2022. Fieldwork was conducted from June 29, 2022, and the audit concluded on September 7, 2022.

[3] https://research.utdallas.edu/researchers/human-subjects-research

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 controls[4].

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
Human Subjects Research/Research Participants	• Gained an understanding of the compliance program by reviewing federal regulations and the related UT Dallas policies. • Interviewed various responsible parties within the Office of Research.	N/A
Risk Management Plan	Reviewed and evaluated the Risk Management Plan to ensure that a plan exists that will ensure compliance with federal regulations over research participants.	Observation #1

[4] www.coso.org

Audit Area	Methodology	Observations Related to the Audit Area
Quarterly Compliance Report	Reviewed the quarterly compliance report to ensure the monitoring procedures, training procedures and reporting procedures were performed as outlined in the risk management plan.	N/A
Institutional Review Boards	Reached out to other research universities for benchmarking related to Institutional Review Boards.	Observation #2

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 Office Research management and staff for their support, courtesy, and cooperation provided throughout this audit.

Respectfully Submitted,

Toni Stephens Digitally signed by Toni Stephens
Date: 2022.11.09 11:57:57 -06'00'

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

Distribution List

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

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Ms. Amanda Boone, Director of Human Subjects Research

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

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