Human Subject Research

Dell Medical School

November 2019

The University of Texas at Austin
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November 27, 2019

President Gregory L. Fenves
The University of Texas at Austin
Office of the President
P.O. Box T
Austin, Texas 78713

Dear President Fenves,

We have completed our audit of human subject research at Dell Medical School (Dell Med). This audit was part of our fiscal year 2019 Audit Plan. The objectives of the audit were to determine whether Principal Investigators (PIs) were obtaining key elements of the consent form from human subjects and whether PIs completed required training prior to receiving approval to perform research.

The report is attached for your review.

Overall, Dell Med researchers working in human subject research are obtaining consent from participants, and researchers completed their University of Texas at Austin (UT Austin) required training.

Please let me know if you have questions or comments regarding this audit.

Sincerely,

Sandy Jansen, CIA, CCSA, CRMA
Chief Audit Executive

cc: Dr. S. Claiborne Johnston, VP for Medical Affairs and Dean of the Dell Medical School
Ms. Rosemaria Martinelli, Chief of Staff, Office of the Executive VP and Provost
Mr. Carlos Martinez, Chief of Staff, Office of the President
Dr. Maurie McInnis, Executive VP and Provost

Executive Summary

Human Subject Research

Dell Medical School
Project Number: 19.019

Audit Objectives

The objectives of this audit were to:

- Determine whether Principal Investigators (PIs) were obtaining consent form key elements from human subjects
- Determine whether PIs listed on human subject research protocols[1] completed required training prior to receiving approval to perform research

Conclusion

Overall, Dell Medical School (Dell Med) researchers are obtaining consent from participants, and researchers completed their University of Texas at Austin (UT Austin) required training.

Audit Observations

No recommendations were provided.

Engagement Team

Ms. Angela McCarter, CIA, CRMA, Assistant Director
Mr. Robert Castillo, CGAP, Auditor III
Mr. Ramiro Munoz, Auditor I

[1] According to bizfluent.com/facts-5916663-define-research-protocol.html: "A research protocol clearly and plainly provides an overview of a proposed study in order to satisfy an organization's guidelines for protecting the safety of human subjects who might be impacted by the work. Research protocols are typically submitted to Institutional Review Boards (IRBs) within universities and research centers".

Audit Results

Dell Med researchers are obtaining consent from participants, and researchers completed their UT Austin required training.

The results of the human research studies reviewed are as follows:

- The enrolled participants were within allowed limits as established by the Institutional Review Board (IRB).
- Consent forms aligned with IRB standards.
- The subject, legal guardian, and/or third-party surrogate signed consent forms.
- The IRB application listed each researcher collecting consent forms, and researchers completed applicable training.
- Responses from PIs and staff members demonstrated adherence to policies and procedures for managing human subject research studies.

In addition to the results above, we found that the IRB management tool requires multiple integrated systems working together to manage documentation (e.g., evidence of training and protocol approvals). The systems are difficult to navigate. UT Austin is implementing a new system in summer 2020. The new system is expected to enhance management of documentation. We agree with this system improvement.

No recommendations were provided.

Background

"Research is a major pillar of Dell Medical School's work to revolutionize how people get and stay healthy."[2] One area of research conducted by Dell Med is Human Subject Research.

Dell Med defines human subject research as a "living individual about whom an investigator:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

The IRB is responsible for approving research conducted at Dell Med. The nature of the study and level of interaction with human subjects determines the level of risk for a human subject research protocol. The classification of the risk assigned to the human subject research protocol varies from exempt to full board.

[2] Conducting Research: https://dellmed.utexas.edu/research/support-services/conducting-research

Scope, Objectives, Methodology, and Criteria

The scope of this review included human subject research protocols from September 1, 2017, to July 1, 2019. The human subject research protocols originated in the following departments: LiveStrong Cancer Institute, Surgery and Perioperative Care, Pediatrics, Psychiatry, and Neurology.

Specific audit objectives were to:

- Determine whether PIs are obtaining consent form key elements from human subjects
- Determine whether PIs listed on applicable human subject research protocols completed required training prior to receiving approval to perform research

To achieve these objectives, Internal Audits:

- Reviewed IRB applications and signed informed consent forms
- Reviewed and verified that required training was completed
- Interviewed PIs and related staff concerning policies and procedures specific to sick and acutely ill participants

Internal Audits randomly selected a sample of eight human subject research studies from a listing of greater than minimal risk human subject research protocols provided by the Office of Research Support. Six human subject research protocols originated from UT Austin and two transferred from Seton Medical Center.

The governing policies used as the criteria for this audit are as follows:

- Section 7-1320 of UT Austin's *Handbook of Operating Procedures: Human Subjects Used In Research*[3]
- *IRB Policies and Procedures Manual, Pre January 21, 2019, Changes*[4]
- *Office of Research Support and Compliance Policies and Procedures Manual Post January 21, 2019*[5]
- UT Austin overview of revised Common Rule changes applying to research supported by Department of Health and Human Services and other federal agencies[6]

[3] (https://policies.utexas.edu/policies/human-subjects-used-research)
[4] (https://research.utexas.edu/ors/human-subjects/policies-and-procedures/)
[5] (https://research.utexas.edu/ors/human-subjects/policies-and-procedures/)
[6] (https://research.utexas.edu/ors/human-subjects/common-rule-and-other-regulatory-changes/)

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