
Date: December 13, 2023

To: Dr. Robert Hromas, Dean,
Long School of Medicine

From: John Lazarine, Chief Audit Executive
Internal Audit & Consulting

Subject: Body Donation Program Audit

As part of our FY 2023 Audit Plan, we recently completed an audit of the Body Donation Program. Attached is the report detailing the results of this review.

We appreciate the cooperation and assistance we received from the Long School of Medicine Department of Cell Systems and Anatomy throughout the review.

Respectfully,



John Lazarine, CIA, CISA, CRISC
Chief Audit Executive
Internal Audit & Consulting Services

Distribution:

cc: Dr. William Henrich, President
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Executive Summary

Background

The Body Donation Program at UT Health San Antonio (UTHSA) is managed by the Department of Cell Systems and Anatomy within the Long School of Medicine. The program provides anatomical material that is essential for the furtherance of medical knowledge. Most of the specimen donations¹ that come through the program are used in the teaching of anatomy to medical and dental students or students of the allied health sciences. Specimens are also used by resident physicians and dentists and/or by biomedical scientists in research aimed at the solution of specific health problems or the development of new medical or surgical procedures or devices. Specimens can also be transferred to other accredited in-state institutions for educational purposes by request, or necessity should a student of UTHSA be related to the donor.

Faculty and staff of the Body Donation Program are responsible for the in-processing, identification, embalming, storage, and cremation of the specimen donations. The cremains are returned to the family or are buried in the University's well attended community cemetery located on campus. The Body Donation Program is regulated by the Anatomical Board of the State of Texas (SAB). The SAB is responsible for developing guidelines regarding the procurement, distribution, and use of human specimens in support of medical education in conformance with Texas Administrative Code (TAC)² and Texas Health Code (THC)³.

Objective & Scope

As part of our approved annual audit plan, we conducted an audit of the Body Donation Program. The objective of this audit was to evaluate the Institution's procedures and methods for receiving, storing, using, and transporting anatomical specimens and disposing of remains as required by TAC and THC requirements. The scope of this audit was focused on the processes and internal controls related to the receipt, transfer, use and cremation of anatomical specimen donations for the period of September 2019 through November 2023 in accordance with State requirements.

We conducted our audit in accordance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing and Government Auditing Standards*. The audit also meets State regulations requiring that an audit⁴ of the program be conducted every five years prior to the regularly scheduled SAB inspections.

Conclusion

Our assessment concluded that the Body Donation Program was compliant with the regulatory requirements for receiving, storing, using, and transporting anatomical specimens, and disposing of remains.

We would like to thank the staff of the Body Donation program for the support and assistance provided during this audit.

¹ Specimen donations can be stored for a period of 1-5 years depending on the type and state of the human tissue specimen (i.e. whole bodies and/or body parts). This review included inspections of all types of specimen donations.

² Texas Administrative Code, Title 25 Health Services, Part 4: Anatomical Board of the State of Texas, Chapters 477, 479 and 485

³ Texas Health Code, Title 8. Death and Disposition of the Body, Subtitle B. Disposition of the Body, Chapter 691 and 692A.

⁴ The last UTHSA Internal Audit report published regarding the Body Donation Program was issued on July 11, 2018 (project # 18-20).

Summary of Results

Audit Objective

The objective of this audit was to evaluate the institution's procedures and methods for receiving, storing, using, and transporting anatomical specimens and disposing of remains as required by Texas Administrative Code (TAC)⁵ and Texas Health Code (THC)⁶ requirements.

Criteria

The Body Donation Program is regulated by the Anatomical Board of the State of Texas (SAB). The SAB is responsible for developing guidelines regarding the procurement, distribution, and use of human specimens in support of medical education in conformance with TAC and THC requirements.

Testing Methodology

All pertinent procedures related to the Body Donation Program were reviewed and compared to the corresponding SAB requirement and summarized in the table listed on pages 3 - 5. Most of the specimen donations⁷ that come through the program are used for teaching anatomy and are used, and in some cases stored in individual cadaver specific tanks within the lab/classrooms. Internal Audit (IA) performed physical inspections of the facilities and equipment utilized by the Body Donation Program to complete our assessment of conformance to SAB requirements. All testwork was conducted by IA on a sample basis, except for the air exchange testing which was deferred to the Institution's facilities management team due to their expertise and equipment.

Rating Legend Table

Results Rating Symbol of Compliance to State Requirements	
✓	Non-compliance exception noted
✓	Non-compliance exception was noted, item resolved
✓	No non-compliance exceptions noted

Conclusion

Our assessment concluded that the Body Donation Program was compliant with the regulatory requirements for receiving, storing, using, and transporting anatomical specimens, and disposing of remains. The Body Donation Program's tracking system was adequate and enabled staff to identify the locations of all specimens to include proper disposal (cremation) in accordance with state requirements and donor or their designee's wishes.



⁵ Texas Administrative Code, Title 25 Health Services, Part 4: Anatomical Board of the State of Texas, Chapters 477, 479 and 485

⁶ Texas Health Code, Title 8. Death and Disposition of the Body, Subtitle B. Disposition of the Body, Chapter 691 and 692A.

⁷ Specimen donations can be stored for a period of 1-5 years depending on the type and state of the human tissue specimen (i.e. whole bodies and/or body parts). This review included inspections of all types of specimen donations.

Texas Administrative Code:
Title 25: Health Services
Part 4: Anatomical Board of the State of Texas
Chapters: 477, 479, & 485

#	TAC Chapter and Rule	Sub-Section Categories	Rating
A. Chapter 477: Distribution of Bodies			
A.1	Rule §477.1: Definition and Jurisdiction of the Board		n/a ⁸
A.2	Rule §477.2: Institutional Requirements	<ul style="list-style-type: none"> • Institutional Accreditation • Approved Facilities • Identified Individual 	<p style="text-align: center;">√</p> <p style="text-align: center;">√</p> <p style="text-align: center;">√</p>
A.3	Rule §477.3: Distribution Priorities		n/a
A.4	Rule §477.4: Transport, Importation and Exportation of Bodies	<ul style="list-style-type: none"> • Transport of Bodies • Importation of bodies from out-of-state • Exportation of bodies to another state 	<p style="text-align: center;">√</p> <p style="text-align: center;">n/a</p> <p style="text-align: center;">n/a</p>
A.5	Rule §477.5: Transfer of Bodies	<ul style="list-style-type: none"> • Application of Transfer • Approval of Transfer • Disposal of Transferred Bodies 	<p style="text-align: center;">√</p> <p style="text-align: center;">√</p> <p style="text-align: center;">√</p>
A.6	Rule §477.6: Fees	<ul style="list-style-type: none"> • Fees Received for Bodies Received Directly or by Transfer 	<p style="text-align: center;">√</p>
A.7	Rule §477.7: Board Forms	<ul style="list-style-type: none"> • SAB Form Completed for each Body Received • SAB Forms submitted to the SAB • Yearly cadaver procurement and use report 	<p style="text-align: center;">√</p> <p style="text-align: center;">√⁹</p> <p style="text-align: center;">√</p>
A.8	Rule §477.8: Forms for Recording of Willed and Donated Bodies		n/a
B. Chapter 479: Facilities – Standards & Inspections			
B.1	Rule §479.1: Institutions Authorized to Receive and Hold Bodies		n/a
B.2	Rule §479.2: Application and Inspection of Facilities		n/a

⁸ Items not tested will be represented as “n/a” in the “Rating” column. Items may not have been tested due to the criteria specified being informational in nature, or the action to be tested did not occur for IA to observe and assess.

⁹ SAB forms were completed but not forwarded to the SAB due to technical issues with a new records management system implemented by the SAB in 2021. Information from all specimen forms have since been submitted to the SAB electronically for the period between January 2021 to current, thereby resolving the issue to the State’s satisfaction prior to the completion of this audit.

B.3.1	Rule §479.3: Institutional Requirements	<p><i>Health Standards</i></p> <ul style="list-style-type: none"> • <u>Dissection facilities.</u> Dissection areas must be clean, well ventilated, and well lighted. • <u>Storage Facilities.</u> Storage facilities must have adequate space to hold one years' worth of cadavers. • <u>Preparation area.</u> The preparation area must be clean, well ventilated, and well lit. It must be fully equipped with a table and drain and the equipment necessary for satisfactory embalming. • <u>Embalming.</u> The embalming formula shall be appropriate to the long-term preservation of cadavers and will not present a health hazard to persons dissecting. 	<p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>
B.3.2	Rule §479.3: Institutional Requirements	<p><i>Technical Support</i></p> <ul style="list-style-type: none"> • Member institutions who directly accept Willed Body Program donations must employ or contract with a State of Texas Licensed Funeral Director to supervise transport of cadavers and anatomical specimens. • Member institutions who directly accept Willed Body Program donations must employ or contract with a State of Texas Licensed Embalmer to perform embalming procedures. 	<p>✓</p> <p>✓</p>
B.3.3	Rule §479.3: Institutional Requirements	<p><i>Safety Standards:</i></p> <ul style="list-style-type: none"> • <u>Air Exchange.</u> All dissecting and preparation areas must have sufficient air-handling machinery to provide for not less than seven full changes of air per hour. • Storage of hazardous chemicals. • Dangerous fumes. 	<p>✓</p> <p>✓</p> <p>✓</p>
B.3.4	Rule §479.3: Institutional Requirements	<p><i>Public Welfare:</i></p> <ul style="list-style-type: none"> • <u>Visibility.</u> All areas where human bodies are handled must not be visible from the outside of the building or so located that the public has ready visibility of transport, preparation, or dissection in progress. • <u>Accessibility.</u> All areas used for receipt and preparation, storage, or dissection of human bodies must be inaccessible and inadmissible to the general public and all unauthorized personnel. 	<p>✓</p> <p>✓</p>
B.4	Rule §479.4: Final Disposition of the Body and Disposition of the Remains	<ul style="list-style-type: none"> • <u>Final Disposition of the Body (informational).</u> Final disposition of the body occurs upon completion of the donation or bequest by acceptance of the body by the board-member institution. • <u>Manner of Disposition of the Remains.</u> Intact remains shall be disposed of by cremation. The residual remains of these processes shall be disposed of in a manner 	<p>n/a</p> <p>✓</p>

		<p>appropriate to the disposal of human remains or returned to family members. An institution is obligated to return residual remains to the donor's family if at the time of the donation or bequest (documentation required).</p> <ul style="list-style-type: none"> • <u>Cremation</u>. Cremation shall occur at a professional crematorium or at its own crematory. • <u>Return of Residual Remains</u>. If residual remains are to be returned to family members, the chamber must be completely cleaned before subsequent use, and the body must not be commingled. 	<p>✓</p> <p>(n/a)¹⁰</p>
B.5	Rule §479.5: Abuse of a Corpse	<p>Abuse of a Corpse¹¹:</p> <ul style="list-style-type: none"> • Procurement of Bodies • Distribution of Bodies • Handling of Bodies 	<p>✓</p> <p>✓</p> <p>✓</p>
C. Chapter 481: Willed Body Program			
C.1	Rule §481.1: Willed Body Program	<p>Statement of the Program:</p> <p>Each authorized institution or organization that conducts a willed body program should provide the secretary-treasurer of the board with a statement of its program.</p>	<p>✓</p>
C.2	Rule §481.2: Willed Body Program	<p>Requirement for Self-Sufficiency:</p> <p>Schools and other major users of cadavers should establish a willed body program with the goal of becoming self-sufficient in obtaining cadavers for its own use within four years of instituting the program.</p>	<p>✓</p>
D. Chapter 485: Audit Procedures			
D.1	Rule §485.1: Audit Procedures	<p>Audit Procedures:</p> <p>Each member institution shall conduct an audit of its procedures and methods for receiving, storing, using, and transporting bodies or anatomical specimens and disposing of remains. This audit must be conducted at an interval of 5 years, coincidental with regularly scheduled Board inspections. The audit shall be performed by the institution's audit department according to an audit template prescribed by the Board. The results of the audit shall be filed with the secretary-treasurer within 30 days of its completion.</p>	<p>✓</p>


¹⁰ Documentation was reviewed to determine if residual remains were properly returned to the donor's family. IA could not determine if the crematorium was adequately cleaned between cremations since there were no remains to cremate at the time of the audit in which to observe this process, therefore, our opinion on the testing results schedule is listed as n/a. Faculty and staff appear to take the program very seriously and informed IA that they ensure that the chamber is cleaned between cremations to ensure the appropriate remains are given to the donor's family.

¹¹ Abuse of a Corpse defined in Texas Penal Code §42.10 states that dissection in an authorized institution by authorized persons is specifically exempted from this provision and not considered as abuse of a corpse. The SAB has determined dissection of human cadaveric materials in health science, and related, education and research, and activities found by the SAB to be related to dissection are a special privilege and are legally authorized for members and students of the health, and related, professions for the purpose of the advancement of knowledge in these fields. Therefore, due diligence and security is required within the Body Donation Program to ensure the cadavers are utilized and handled appropriately.

AUDIT TEAM

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APPROVED FOR RELEASE

A rectangular box containing a handwritten signature in blue ink. The signature appears to be "John Lazarine".

John Lazarine, Chief Audit Executive, Internal Audit & Consulting Services

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