

UT Southwestern
Medical Center

**Animal Resource Center - Controlled
Substances Audit**

Internal Audit Report 20:63

January 4, 2021

Table of Contents

I. Executive Summary	3
• Background	3
• Scope and Objectives	4
• Conclusion	5
II. Detailed Observation and Action Plans Matrix	7
III. Appendix	10
• Appendix A – Risk Classifications and Definitions	10

Executive Summary

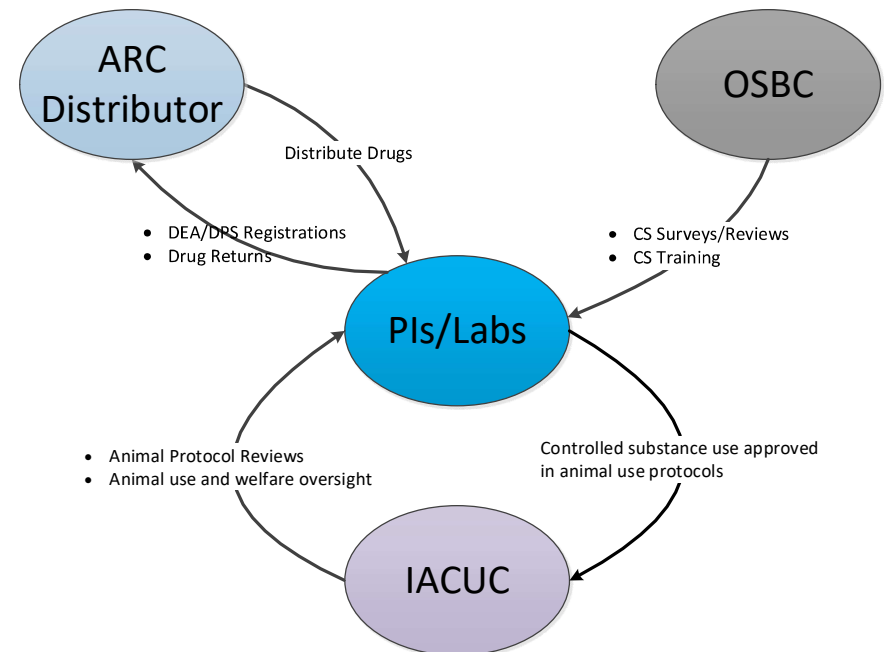
Background

The University of Texas Southwestern Medical Center's (UT Southwestern) mission promotes health and wellness that enables achievement of full human potential. The mission includes a research component that seeks better treatments, cures, and prevention with a commitment to ensuring real world application. This mission area includes conducting animal research in which controlled substances may be used. This area is governed primarily by the following three UT Southwestern organizations:

- *The Animal Resource Center (ARC)* supports the institutional animal care and use program and is responsible for:
 - Procuring all animals used in teaching, research, and testing programs.
 - Quarantining and conducting health surveillance of animals.
 - Providing veterinary care and husbandry to research animals.
 - Providing facilities and trained personnel for conducting technical procedures such as surgery, post surgical care, radiography, necropsy, collection of tissues and body fluids, etc.
 - Partnering with the Institutional Animal Care & Use Committee (IACUC) to ensure compliance with federal regulations, funding agencies' policies, state and local regulations regarding the care and use of lab animals.
 - Assisting faculty and students in planning and conducting research and teaching programs that require animals.
 - Distributing controlled and non-controlled substances to principal investigators (PIs).

- *The Office of Safety and Business Continuity (OSBC)* supports UT Southwestern staff, research laboratories, physical facilities, hospitals, and clinics to maintain a healthy, safe, and compliant work environment. OSBC completes onsite controlled substances specific lab visits with the PIs.

- *IACUC* provides oversight to ensure all animal use adheres to applicable policy requirements for such use.



Executive Summary

Principal Investigators (PI) who use and store controlled substances for animal research are required to maintain their own Drug Enforcement Administration (DEA) registration and comply with applicable requirements. The ARC Director holds a DEA Distributor license and a DEA Manufacturer license and oversees the purchase and distribution of controlled substances to registered PIs through the ARC Veterinary Drug Services (VDS) office.

As of October 2020, 95 UT Southwestern PIs have active DEA registrations. For fiscal year 2020 and fiscal year 2021 through October approximately 300 orders were dispensed to PIs by VDS for animal research medications and supplies totaling \$67,000. The PIs place controlled substances orders via the Jaggaer Procurement Portal and orders are reviewed and consolidated for ordering by VDS. Each month, VDS processes billing to the individual PI labs via the Topaz system to Peoplesoft where expenses are posted to the applicable research protocols. The Topaz system is a web-based animal management software package that consolidates animal protocols, census, and billing into one program for animal research tracking, monitoring and reporting.

Scope and Objectives

The Office of Internal Audit has completed its Animal Controlled Substances audit. This was a risk based audit and part of the fiscal year (FY) 2020 Audit Plan. The audit scope period included controlled substances and non controlled substances procurement, storage and inventory management and disposal processes from September 2019 to October 2020. The review included assessing the adequacy and effectiveness of processes and internal controls to ensure:

- Animal Resource Center (ARC) personnel and Principal Investigators (PIs) comply with DEA registration requirements described in Title 21 Code of Federal Regulations Part 1301 “Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances”.
- ARC and PI labs are properly securing and storing controlled substance in compliance with DEA regulations described in Title 21 Code of Federal Regulations, Part 1304 — Records and Reports of Registrants Inventory Requirements, Part 1304.11 Inventory requirements, Part 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors and UT Southwestern policies.
- Appropriate internal controls are in place at the ARC and in principal investigator labs for the procurement, transfer, receiving, and inventory movement and management for controlled substances used in animal research.
- Physical security and disposal of wastage.

Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, substantive testing and data analytics. We conducted our examination according to guidelines set forth by The Institute of Internal Auditors’ *International Standards for the Professional Practice of Internal Auditing*.

Executive Summary

Conclusion

Overall, processes and controls for controlled substance procurement, storage and inventory management are operating as intended. Opportunities exist in the individual PI labs to improve drug inventory tracking and monitoring to protect against the risk of theft or significant loss of non-controlled and controlled substances. Enhanced training performed by the Office of Safety and Business Continuity would allow for the PIs and their teams to share common recommendations and corrective actions identified during on-site lab reviews to assist in strengthening practices across PI labs.

Included in the table below is a summary of the observations along with their respective disposition within the UT Southwestern internal audit risk definition and classification process. See Appendix A for Risk Rating Classifications and Definitions. There were no priority or high rated issues identified in the audit.

Priority (0)	High (0)	Medium (2)	Low (0)	Total (2)
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Key improvement opportunities risk-ranked as Medium are listed below.

- **#1 Improve Drug Inventory Tracking Procedures** - Lab inventory tracking requirements for controlled and non-controlled substances are not consistently followed increasing the risk of theft or significant loss and noncompliance with institutional policies and federal regulations.
- **#2 Reemphasize Principal Investigator Training** - The on-site lab inspection results are not communicated to the ARC or to the Drug Services team so that common issues and recommendations for remediation can be communicated across all labs. Lack of training increases the risk of noncompliance with institutional policies and federal regulations.

We would like to thank the individuals included in this audit for the courtesies extended to us and for their cooperation during our review.

Sincerely,

Valla F. Wilson, Vice President for Office of Internal Audit and Chief Audit Executive

Executive Summary

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Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>1. Improve Drug Inventory Tracking Procedures</p> <p>Inventory tracking requirements for controlled and non-controlled substances used in animal research are not consistently followed at the PI labs increasing the risk of theft or significant loss and noncompliance with UT Southwestern policies and federal regulations.</p> <p>One recurring observation from the OSBC on site lab reviews is registrants or their authorized users did not reconcile controlled substance inventory records with the on-hand quantity as required by UT Southwestern policies and federal regulations.</p> <p>During on-site lab visits we identified the following control opportunities:</p> <ul style="list-style-type: none"> Inventory variances are not consistently identified and resolved in a timely manner. A controlled substance inventory variance was not identified until the onsite audit inspection was performed. The recorded inventory total was in excess of the actual inventory on hand. The previous physical inventory count performed by the lab personnel did not identify the variance. 	<ol style="list-style-type: none"> Investigate and resolve the controlled substance inventory variance and update records to properly document inventory on hand. Provide refresher training to the PIs to remind them of the procedures to be followed. Develop monitoring controls such as routine confirmation procedures whereby PIs would confirm expired controlled and non-controlled substances are returned in a timely manner to the VDS for proper disposal. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> The PI investigated and resolved the inventory variance. The inventory has been accounted for. As part of the lab visits, the OSBC team will provide refresher training to the PIs to return expired Controlled Substances to the VDS team. Refresher training will also be provided to remind PIs of the proper procedures to be followed for non-controlled substances. The OSBC team will use the onsite PI lab visits to confirm if expired medications are still being stored and will remind PIs and lab team members to return expired medications to VDS for proper disposal. <p><u>Action Plan Owners:</u></p> <ol style="list-style-type: none"> Associate Director, Animal Resources Center Director Biological & Chemical Safety, Safety & Business Continuity Director Biological & Chemical Safety, Safety & Business Continuity

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<ul style="list-style-type: none"> An expired non controlled substance medication was included in the active medication inventory. In addition, the expired drugs on hand were not marked as “do not use”. Expired drugs in inventory increase the risk that the drug will erroneously be administered to an animal, which could impact research outcome and result in a non-compliance with institutional policies. <p>Although, these were limited incidents, monitoring controls would help to ensure practices are being followed as intended.</p>		<p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> Completed February 28, 2021 Completed and ongoing

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>2. Reemphasize Principal Investigator Training</p> <p>The OSBC performs on site lab inspections which includes review of DEA requirements for the handling of controlled substances for animal use. The OSBC team works with each PI on corrective actions to ensure compliance with requirements as needed. However, the results of these inspections are not communicated to the ARC and the Drug Services team, so that common issues can be communicated to all PIs to reduce the risk of noncompliance with institutional policies and federal regulations for inventory and records requirements.</p> <p>Top issues identified during the completed lab inspections are:</p> <ul style="list-style-type: none"> • The PI's Biennial Inventory Form which is required to be used for recording controlled substances was not completed and/or made available. • All controlled substance quantities coming into PI labs were not properly recorded in the PI's manual ledger as required by policies and federal regulations. • Quantity on hand', 'total quantity received and on hand' and 'returned to VDS' were not properly recorded in the PIs manual ledger. 	<ol style="list-style-type: none"> 1. Provide routine updates for the commonly recurring issues across all PIs to ARC leadership and the VDS team. 2. Collaborate to provide training to PIs to improve compliance with policies and regulatory requirements for animal controlled substances. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. OSBC will add ARC leadership to each PI lab report that is issued and will host routine meetings with ARC leadership to discuss results of completed lab reviews. 2. OSBC is updating Taleo training for PI lab members to include recurring issues identified in lab reviews. As issues are identified, the PI lab members will be directed to the Taleo training for education. Additionally, during onsite visits, the OSBC team will provide refresher training for regulatory requirements. <p><u>Action Plan Owners:</u></p> <p>Director Biological & Chemical Safety, Safety & Business Continuity</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. February 28, 2021 2. February 28, 2021 – Review, evaluate and modify current Taleo training with management <p>March 31, 2021 – Finalize, relaunch and resubmit modified Taleo training</p>

Appendix A – Risk Classifications and Definitions

As you review each observation within the Detailed Observations and Action Plans Matrix of this report, please note that we have included a color-coded depiction as to the perceived degree of risk represented by each of the observations identified during our review. The following chart is intended to provide information with respect to the applicable definitions and terms utilized as part of our risk ranking process:

Risk Definition- The degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management.	Degree of Risk and Priority of Action	
	Priority	An issue identified by Internal Audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.
	High	A finding identified by Internal Audit that is considered to have a high probability of adverse effects to the UT institution either as a whole or to a significant college/school/unit level. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.
	Medium	A finding identified by Internal Audit that is considered to have a medium probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action is needed by management in order to address the noted concern and reduce the risk to a more desirable level.
	Low	A finding identified by Internal Audit that is considered to have minimal probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action should be taken by management to address the noted concern and reduce risks to the organization.

It is important to note that considerable professional judgment is required in determining the overall ratings presented on the subsequent pages of this report. Accordingly, others could evaluate the results differently and draw different conclusions. It is also important to note that this report provides management with information about the condition of risks and internal controls at one point in time. Future changes in environmental factors and actions by personnel may significantly and adversely impact these risks and controls in ways that this report did not and cannot anticipate.