

UT Southwestern Medical Center

The University of Texas Southwestern Medical Center Animal Controlled Substances Audit

Internal Audit Report 15:19

October 2, 2015

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Executive Summary

Background

In fulfilling its research mission, the University of Texas Southwestern Medical Center (UT Southwestern) conducts non-human research in which controlled substances may be used. This area is governed by three primary UT Southwestern organizations:

- Institutional Animal Care and Use Committee (IACUC) which assures that all animal use adheres to applicable requirements and establishes policies for such use.
- 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.
 - Partnering with IACUC to assure compliance with federal regulations, funding agencies' policies, and state and local regulations regarding the care and use of animals.
 - Assisting faculty and students in planning and conducting research and teaching programs that require animals.
- Environmental Health and Safety (EHS) supports UT Southwestern staff, research laboratories, physical facilities, hospitals, and clinics to maintain a healthy, safe, and compliant work environment.

Controlled substances, which include narcotics, stimulants, depressants, and hallucinogens, are closely controlled and regulated due to their risk of abuse. Procedures exist for the acquisition, storage, use and documentation of controlled substances for non-human research to comply with United States Drug Enforcement Administration (DEA) and Texas Department of Public Safety (TX DPS) regulations and minimize the risk of diversion, loss or theft.

Until August 2014, ARC maintained a single DEA license for non-human research operations. In accordance with DEA regulations, after August 2014, each Principal Investigator (PI) who uses and stores controlled substances was required to request his or her own registration and comply with all regulatory requirements, including DEA and TX DPS regulations. The Director of the ARC holds a DEA and TX DPS Distributor License and administers the purchase and distribution of controlled substances to registered PIs through the ARC Veterinary Drug Services (VDS) office.

As of July 2015 there were 157 PIs with active DEA registrations. For the 11 month period ending July 2015, approximately \$18,000 in controlled substances (300 specific orders) were requested by the PIs from the ARC.

See Appendix B for a diagram highlighting the roles and responsibilities for these three organizations.

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Scope and Objectives

The UT Southwestern Office of Internal Audit has completed its Animal Controlled Substances Audit. This was a compliance risk-based audit and part of the fiscal year 2015 Audit Plan.

The audit scope was from September 1, 2014 to July 31, 2015. The review included all animal research and clinical research locations that maintain inventory of controlled substances for use on animals, and included processes related to the overall handling of controlled substances.

The primary objectives of the audit were to determine whether:

- Animal Resource Center (ARC) personnel and Principal Investigators (PI) are compliant with the DEA and TX DPS registration requirements for handling controlled substances.
- Non-human controlled substances are stored and safeguarded at ARC and the labs in compliance with federal regulations and UTSW policies.
- Appropriate internal controls for the procurement, receiving, usage and inventory of controlled substances are in place and are effectively operating.
- Controlled substances transferred between ARC and the principal investigators or designee are appropriately documented and safeguarded.
- Inventory monitoring procedures are in place to identify and resolve discrepancies and ensure regulatory requirements regarding discrepancy reporting are performed on a timely basis at ARC and the labs.
- Wastage is physically safeguarded and properly destroyed or disposed.

Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, data analytics and substantive testing.

The audit was conducted according to guidelines set forth by *the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing*.

Conclusion

Overall, the procurement and handling of controlled substances is well-managed and complies with DEA and DPS regulations.

Specific strengths identified during the audit include:

- Current policies and procedures were in place for Controlled Substances for Non-Human Research
- Inventories of controlled substances were securely stored at the VDS and sampled labs.

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- Perpetual inventory records at the VDS and sampled labs were in agreement with inventory on hand.
- Effective procedures were in place to verify current license registrations and approved protocols for all distributions of controlled substances.
- Proper procedures were in place at the ARC to safely destroy or dispose of controlled substances.
- EHS has implemented an annual survey and on-site review for all locations storing controlled substances to monitor DEA and TX DPS compliance.

There are opportunities to strengthen controls to ensure animal controlled substances are effectively safeguarded and accounted for in compliance with regulatory requirements. These observations and recommendations are detailed in the next section of the report.

There were no significant (high risk) issues identified in the audit. Key improvement opportunities risk-ranked as medium are summarized below.

Included in the table below is a summary of the observations noted, along with the respective disposition of these observations within the Medical Center internal audit risk definition and classification process.

See Appendix A for Risk Rating Classifications and Definitions.

High (0)	Medium/High (0)	Medium (4)	Low (3)	Total (7)
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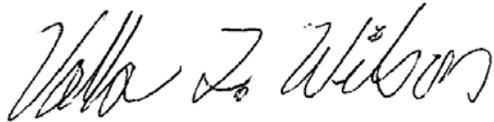
- **Improve Segregation of Duties for the VDS** - Inappropriate segregation of duties exists within the VDS office at the ARC.
- **Enhance Communication and Reporting between Responsible Parties** - There is an opportunity to enhance the governance/oversight of the use of animal controlled substances.
- **Improve Timeliness of Transfer of Expired Drugs From Inventory** - Four out of nine laboratory locations reviewed had expired drugs in inventory.
- **Review For Proper Power of Attorney** – Representatives who signed DEA 222 Forms for the purchase of C-II drugs did not always have appropriate authority via executed Power of Attorney.

Management has plans to address the issues identified in the report and in some cases have already implemented corrective actions. These responses, along with additional details for the key improvement opportunities listed above and other lower risk observations are listed in the Detailed Observations and Action Plans Matrix (Matrix) section of this report.

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

Sincerely,



Valla Wilson, Assistant Vice President for Internal Audit

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>1. Improve Segregation of Duties for the VDS</p> <p>The Animal Resource Center Senior Veterinarian Technician performs incompatible duties. She is assigned responsibility to place orders for controlled substances with vendors, receive orders, record inventory to perpetual logs, maintain and distribute inventory, reconcile inventory records, and handle disposals and returns of controlled substances. This presents an inappropriate segregation of duties which increases the risk of errors or misappropriation of controlled substances not being detected.</p> <p>Proper segregation of duties emphasizes the assignment of the following responsibilities to different people:</p> <ul style="list-style-type: none"> • physical control of assets • authorization • record keeping • reconciliation 	<p>1. If there are not enough employees to fully segregate all the responsibilities, at a minimum, the receipt of inventory should be verified by someone independent of the ordering of inventory, and the reconciliation of the inventory records should be segregated from the physical control of the inventory. Consider the following when updating team assignments:</p> <ul style="list-style-type: none"> • Assign the responsibility of verifying the receipt of inventory to an individual who does not order controlled substances. • Assign the responsibility of reconciling perpetual inventory records to an individual who does not have physical access to the inventory. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. Management agrees with the recommendation and will assign an independent resource to the performance of the monthly inventory reconciliation. The reconciliation procedures will include both a verification that all orders of controlled substances were received and recorded to the inventory logs, and that inventory balances agree to the stock on hand. 2. New reconciliation procedures will be documented in department Standard Operating Procedures. <p><u>Action Plan Owners:</u></p> <p>Director, Animal Resource Center</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. October 31, 2015 2. October 31, 2015

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>2. Enhance Communication and Reporting Between Responsible Parties</p> <p>There is a lack formalized reporting responsibilities, such as required alerts and communications, among the three groups (IACUC, ARC, EHS) that share oversight responsibility for use of controlled substances in the labs. These groups interact and have evidence of reporting of significant matters. However, formal reporting to ensure all groups are aware of ongoing matters has not been established.</p> <p>In addition, each PI registrant is responsible for ensuring its lab is following the requirements. However, when they are reviewed by the DEA, findings may not be reported to one of the three governing groups.</p>	<ol style="list-style-type: none"> 1. Collectively the three oversight groups should identify the events that would require alerts to the other oversight groups. Standardize the reporting that will be used to communicate reportable events. 2. Update policies and procedures to require the registrants to report the results of DEA inspections or actions taken by the DEA on the status of their registrations. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. The three oversight groups will meet and agree upon formalized communication for significant instances of non-compliance. 2. The <i>Controlled Substances for Non-Human Research Policy</i> and guidelines will be updated to require registrants to report the results of DEA inspections. <p><u>Action Plan Owners:</u></p> <p>Director, Animal Resource Center Director, Environmental Health and Safety Director, IACUC</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. October 31, 2015 2. October 31, 2015

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>3. Improve Timeliness of Transfer of Expired Drugs From Inventory</p> <p>Four out of nine laboratory locations reviewed had expired drugs in inventory. The expired drugs on hand were not marked as “do not use”. Representatives in the labs were not clear on the specific steps to take to return expired drugs.</p> <p>Expired drugs in inventory increase the risk that the drug will erroneously be administered to an animal, which could result in a non-compliance with IACUC policies and federal requirements.</p> <p>The current policy, <i>EHS-206: Controlled Substances for Non-Human Research</i>, states, “Controlled substances that are expired or no longer needed must be transferred to VDS, which will coordinate disposal with EHS, University Police, and, as needed, a reverse distributor.”</p>	<ol style="list-style-type: none"> 1. Update the policies and procedures and guidelines with detailed and clear procedure steps on how to properly label, secure, and return expired drugs to the VDS for disposal. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. The <i>Controlled Substances for Non-Human Research</i> policy and guidelines will be updated to clarify that it is acceptable to possess expired drugs as long as they are appropriately labeled and stored; and that once expired drugs are no longer needed, they can be transferred to VDS for disposal. <p><u>Action Plan Owners:</u></p> <p>Director, Environmental Health and Safety</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. October 31, 2015

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>4. Review For Proper Power of Attorney</p> <p>In one of two laboratories reviewed that had purchases of Schedule II Controlled Substances (C-II), the DEA 222 Purchase Forms were signed by a representative of the DEA License Registrant; however, the representative did not have proper authority via an executed Power of Attorney, which is a violation of DEA requirements.</p> <p>The VDS does not confirm that signors of the DEA 222 purchase form have an executed Power of Attorney for C-II purchases.</p> <p>Confirmation of this DEA requirement should be performed to ensure all transfers of C-II drugs are performed only under proper authority.</p>	<p>1. When the DEA 222 Purchase Form is signed by a representative of the registrant, require the appropriate Power of Attorney document be presented to the VDS in order to pick up the C-II drug.</p>	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. Management agrees with the recommendation and will incorporate this requirement into the <i>Controlled Substances for Non-Human Research</i> policy and guidelines. 2. The requirement to check for proper Power of Attorney will also be incorporated into the VDS standard operating procedures. <p><u>Action Plan Owners:</u></p> <p>Director, Environmental Health and Safety Director, Animal Resource Center</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. October 31, 2015

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: : Low ●</p> <p>5. Strengthen Inventory Record Keeping Procedures</p> <p>Laboratory testing of nine labs identified random instances of non-compliance with policy <i>EHS-206: Controlled Substances for Non-Human Research</i> for proper record keeping of controlled substances inventory transactions. It is important to maintain all controlled substances documentation in appropriate order in order to be prepared for any unannounced inspection by the DEA.</p> <p>Specific examples of non-compliance included:</p> <ul style="list-style-type: none"> • Perpetual inventory logs with documentation of expired drugs removed from inventory, even though the drugs had not been transferred from the lab. • Manual perpetual inventory logs that recorded separate units of drugs on separate log pages. • Documentation supporting the transfer of controlled substances that was not maintained on file. • Inventory reconciliations not performed within at least 6 months. • Laboratory personnel who were terminated or transferred, but not removed from the VDS list of individuals authorized to pick up controlled substances. 	<ol style="list-style-type: none"> 1. Communicate and re-train lab personnel on the updated detailed procedures for controlled substances inventory recordkeeping. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. A communiqué will be sent to registrants of controlled substances for non-human use reminding them of the proper inventory procedures and documentation. 2. An online training module will be submitted to the Human Resources' Office of Development and Training. The training will be for use by registrants and authorized personnel in Taleo, covering all aspects of the controlled substances for non-human use. <p><u>Action Plan Owners:</u></p> <p>Director, Animal Resource Center Director, Environmental Health and Safety</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. October 31, 2015 2. December 31, 2015

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Low ●</p> <p>6. Strengthen Security Over Access to Controlled Substances at the ARC Surgical Support Room</p> <p>Security of controlled substances may not be adequate to prevent loss or theft of controlled substances at the ARC Surgical Support room.</p> <p>Controlled substances are maintained in the Surgical Support room within a lockbox and locked refrigerator. While access to the room is controlled by assigned door keys, the keys to the lockbox and refrigerator were kept unsecured and accessible to anyone with access to the room.</p>	<p>1. Secure the keys to the lockbox and refrigerator to ensure only individuals authorized to handle controlled substances have access to the inventory.</p>	<p><u>Management Action Plans:</u></p> <p>1. Management relocated the keys for the lockbox and refrigerator to a secure area, accessible only to individuals with authority to handle controlled substances.</p> <p><u>Action Plan Owners:</u></p> <p>Assistant Director, Animal Resource Center</p> <p><u>Target Completion Dates:</u></p> <p>1. Complete</p>

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Low ●</p> <p>7. Update ARC Standard Operating Procedures</p> <p>ARC Standard Operational Procedures (SOPs) for the procurement of veterinary drugs were linked at the ARC website but were not current.</p> <p>The following SOPs were not yet updated for the 2014 process changes:</p> <ul style="list-style-type: none"> • Veterinary Drug Acquisition for Principal Investigators and Users SOP #340 • Maintenance and QA of Veterinary CS SOP #341 • Ordering Receiving, Storage and Distribution of Veterinary Drugs SOP #342. <p>Posting of outdated SOPs at the website may cause confusion for customers of the VDS. SOPs should accurately reflect current procedures in order to ensure procedures will be consistently applied.</p>	<ol style="list-style-type: none"> 1. Remove department SOPs from the ARC website. 2. Update the ARC SOPs to reflect current procedures. 	<p><u>Management Action Plans:</u></p> <ol style="list-style-type: none"> 1. Outdated SOPs were removed from the link at the ARC website. 2. The ARC <i>Standard Operational Procedure for Maintenance and Quality Assurance of Veterinary Controlled Substances</i> has been redrafted and approved by management. <p><u>Action Plan Owners:</u></p> <p>Director, Animal Resource Center</p> <p><u>Target Completion Dates:</u></p> <ol style="list-style-type: none"> 1. Complete 2. Complete

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	
	High	The degree of risk is unacceptable and either does or could pose a significant level of exposure to the organization. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.
	Medium/High	The degree of risk is substantially undesirable and either does or could pose a moderate to significant level of exposure to the organization. As such, prompt action by management is essential in order to address the noted concern and reduce risks to the organization.
	Medium	The degree of risk is undesirable and either does or could pose a moderate level of exposure to the organization. As such, action is needed by management in order to address the noted concern and reduce risks to a more desirable level.
	Low	The degree of risk appears reasonable; however, opportunities exist to further reduce risks through improvement of existing policies, procedures, and/or operations. 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.

Appendix B – Animal Controlled Substances Interdepartmental Coordination

