



# Animal Care

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Audit Report No. R2308 | *May 15, 2023*



## Executive Summary

### Audit Objective

To ensure compliance with federal regulations and the effectiveness of operations over animal care and the effective assignment, performance, and training of oversight committee roles of the Institutional Animal Care and Use Committee (IACUC).

### Controls and Strengths

- Implementation of the Cayuse System for animal research administration
- Strong access controls to the vivarium lab where animals are housed and cage cleaning room
- Availability of noncompliance reporting options for employees to report instances of noncompliance

### Overall Conclusion

UT Dallas has processes in place to ensure compliance with federal regulations over animal care; however, processes can be improved that will enhance the effectiveness of the risk management plan, operational processes, and the appointment process for the IACUC.

### 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.

Recommendation	Risk Level	Management’s Implementation Date
1. Improve the Risk Management Plan and the Quarterly Compliance Report	Medium	August 1, 2024
2. Revise the Appointment Process for IACUC Members	Medium	January 31, 2024
3. Improve Veterinarian Lab Inspection Process	Medium	July 1, 2023
4. Update Animal Delivery Monitoring	Low	August 1, 2024
5. Improve Record Retention Processes	Low	July 1, 2024

*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 <sup>1</sup>
<p><b>1. <i>Improve the Risk Management Plan and Quarterly Compliance Report</i></b></p>		
<p>Risk management plans are designed to document a compliance program’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.</p> <p>The Risk Management Plan (RMP) for Animal Care falls under the leadership of the Office of Research and Innovation.</p> <ul style="list-style-type: none"> <li>• Currently, three responsible persons have been identified (Assistant VP for Research Operations, IACUC Coordinator, and VP for Research and Innovation). Ideally, one party should be designated as responsible for monitoring compliance.</li> <li>• The RMP also outlines risks and corresponding controls and parties involved to mitigate the risks as well</li> </ul>	<p>Without an effective program, instances of noncompliance could result in increased risk for the safety of the animal, reputational risks for UTD, operational inefficiencies, and reduced funding or declines in research projects.</p>	<p style="text-align: center;"><b>Medium</b></p> <p>The Animal Care Risk Management Plan should be updated to reflect current processes and responsible staff.</p> <p>As part of the update, the following is recommended to further enhance the plan:</p> <ul style="list-style-type: none"> <li>• Conduct a periodic risk assessment to ensure all risks are evaluated and plans for monitoring all risks are in place.</li> <li>• 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.</li> <li>• 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.</li> <li>• A detailed list of suggestions to enhance the RMP and quarterly reporting has been provided to the animal care team.</li> </ul>

<sup>1</sup> 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 <sup>1</sup>
<p>as training and reporting procedures; however, responsible party monitoring to ensure that the controls are being performed is not included on the RMP. Ideally, a risk management plan should delineate between the <b>monitoring</b> procedures performed by the responsible party and the <b>operational/internal control</b> procedures performed by the staff.</p> <ul style="list-style-type: none"><li>• Because the Chief Compliance Officer also serves as the Associate VP for Research and Innovation, this creates both a separation of duties and a conflict of interest over the program’s oversight and compliance monitoring processes. Procedures should be put in place to outline how this issue is being managed.</li></ul> <p>The RMP is currently not up to date to reflect current risks, updated policies, and processes, including the Cayuse system processes. Several processes performed by animal care staff have changed or been updated as well as the staff who perform the processes.</p>		



Observation	Risk Level/Effect	Recommendation <sup>1</sup>
<p><b>Management’s Action Plan:</b> Revisions to Animal Care Risk Management Plan to update current processes and responsible staff and to implement audit team’s recommendations.</p> <p><b>Responsible Party Name and Title:</b> Kathan McCallister, Asst. Vice-President for Research Operations; Cynthia Tralmer, IACUC Manager; Tyler Tornblom, Research Operations Coordinator</p> <p><b>Estimated Date of Implementation:</b> August 1, 2024 (&lt;90-days)</p>		
<p><b>2. <i>Revise the Appointment Process for IACUC Members</i></b></p>		<p><b>Medium</b></p>
<p>The UT Dallas <a href="#">Institutional Animal Care and Use Committee (IACUC)</a> is a university-wide committee that is responsible for ensuring the protection of the rights and welfare of all animal utilized in research in compliance with federal, state, and university regulations and/or policies.</p> <p>Currently, the <a href="#">Committee on Committees</a>, part of the Faculty Senate, is responsible for appointing members of the IACUC. This appointment process is not in compliance with <a href="#">UTD Policy 1014 - Institutional Animal Care and Use Committee</a> and the US Department of Health and Human Services <a href="#">Public Health and Safety Policy on Humane Care and Use of Laboratory Animals</a>.</p> <p>According to both policies, the IACUC should be appointed by the President, and if the President delegates authority to appoint the IACUC, then the delegation must be specific</p>	<p>Noncompliance with UTD and PHS policies regarding the IACUC could result in safety issues for animals, reputational harm, suspension of animal research, and loss of federal funding.</p>	<p>Revise the appointment process for IACUC members to comply with UTD and PHS policies.</p>



Observation	Risk Level/Effect	Recommendation <sup>1</sup>
<p>and in writing. There is currently no written delegation at UTD.</p>		
<p><b>Management's Action Plan:</b> Initial meeting between IO, IACUC leadership, and Faculty Senate Representative to revise appointment process to fully comply with PHS policy for IACUC Appointments.</p> <p><b>Responsible Party Name and Title:</b> Dr. Joe Pancrazio, IO and Vice-President for Research; Appointed Faculty Senate Representative; Kathan McCallister, Asst. Vice-President for Research Operations and Cynthia Tralmer, IACUC Manager</p> <p><b>Estimated Date of Implementation:</b> January 31, 2024</p>		
<p><b>3. Improve Veterinarian Lab Inspection Process</b></p>		<p><b>Medium</b></p>
<p>Veterinarians inspect the Vivarium on a weekly basis and provide regular reports to the Director of the Lab Animal Resource Center to ensure animals are healthy and research is being conducted in accordance with approved protocols. There are two types of veterinarian inspection reports used in animal care, and the following issues were noted:</p> <ul style="list-style-type: none"> <li>The weekly inspection report is not being completed consistently. We sampled 23 weeks from FY22 and 23 reports and noted that only three reports were documented.</li> </ul> <p>The reports are also kept in a public break room that can be accessed by anyone with access to the Vivarium.</p>	<p>Without appropriate, consistent documentation of lab inspections, potential health and safety hazards might not be corrected in a timely manner, research could be compromised, and the loss of federal funding and USDA and OLAW licenses could occur.</p>	<p>Lab inspections should be consistently documented and maintained in a confidential space.</p>



Observation	Risk Level/Effect	Recommendation <sup>1</sup>
<ul style="list-style-type: none"> <li>The second type of inspection report consists of a regular report, without a defined timeline, performed by the primary veterinarian. We reviewed a five-month period, and during that time there were four scheduled inspections with discussions; however, there were no reports documented on the status of the inspection or lab.</li> </ul>		
<p><b>Management’s Action Plan:</b> Further formalize Veterinary inspections and ensure completion of documentation following routine walkthroughs for both the Attending and Consulting Veterinarians. Current forms will suffice, but simply need to be utilized consistently and filed securely.</p> <p><i>*Inspection process will be revised and reflected in the RMP and QCR’s once full-time Veterinarian and Director are hired. Anticipated date of July 1, 2024.</i></p> <p><b>Responsible Party Name and Title:</b> Steven Lucas, LARC Manager; Bradly Woody, Assistant LARC Manager</p> <p><b>Estimated Date of Implementation:</b> July 1, 2023 (&lt;60-days)</p>		
<p><b>4. Update Animal Delivery Monitoring</b></p>		<p><b>Low</b></p>
<p>Principal investigators are not allowed to purchase animals without an active protocol, and all animal orders require an active IACUC number.</p> <p>The Quarterly Compliance Report procedure for animal deliveries details procedures for these deliveries. The current procedure is to track the increases in animal population through protocol amendments. This</p>	<p>Unauthorized animal shipments may require quarantine and create noncompliance issues for principal investigators ordering animals.</p>	<p>Update the animal delivery monitoring procedures to better align with the animal delivery risks.</p>



Observation	Risk Level/Effect	Recommendation <sup>1</sup>
<p>procedure does not appear to satisfy the actual risk of not having an active protocol when purchasing animals.</p>		
<p><b>Management’s Action Plan:</b> Update RMP to clarify animal delivery monitoring process is tied directly to IACUC approval, and that procedures upon arrival are tied directly to animal health surveillance.</p> <p><b>Responsible Party Name and Title:</b> Tyler Tornblom, Research Operations Coordinator</p> <p><b>Estimated Date of Implementation:</b> August 1, 2024 (&lt;90-days)</p>		
<p><b>5. Improve Record Retention Processes</b></p>		<b>Low</b>
<p>Many of the Animal Care records are kept on paper in filing cabinets and are rarely disposed of or deleted. According to the current <a href="#">UT Dallas Records Retention Schedule (RRS)</a>, IACUC Records which include: “meeting minutes, records of attendance, activities of the Committee, Committee deliberations, records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether IACUC approval was given or withheld, and semiannual IACUC reports and recommendations” should be disposed of three years after the completion of the activity.</p>	<p>Without proper record management, the risks of inefficient workflow, inability to find documents timely, and noncompliance with policies is increased.</p>	<p>Consult with the Office of Legal Affairs regarding records retention requirements for animal care documents to ensure that federal, state, and university requirements align with the current records retention schedule. Put procedures in place to ensure animal care and IACUC records are destroyed in accordance with the schedule and consider moving the animal care records to an electronic format that is periodically backed up.</p>
<p><b>Management’s Action Plan:</b> Consultation with the Office of Legal Affairs regarding record retention requirements to improve record storage and/or record disposal is carried out in accordance with federal, state, and institutional requirements. Implementation of recommendations will immediately follow completion of consultation.</p>		



Observation	Risk Level/Effect	Recommendation <sup>1</sup>
<p><b>Responsible Party Name and Title:</b> Steve Lucas, LARC Manager; Bradly Woody, Asst. LARC Manger; Tyler Tornblom, Research Operations Coordinator</p> <p><b>Estimated Date of Implementation:</b> July 1, 2024 (&lt;60-days)</p>		

### Overall Conclusion

UT Dallas has processes in place to ensure compliance with federal regulations over animal care; however, processes can be improved that will enhance the effectiveness of the risk management plan, operational processes, and the appointment process for the IACUC.



## Appendix A: Information Related to the Audit

### Background

Any research that involves the use of animals falls under the Institute of Animal Care and Use Committee (IACUC). The IACUC mission “is to ensure the protection of the rights and welfare of all animals utilized in research as conducted by university faculty, staff, and students.”<sup>2</sup> Animal Care staff manage over 70 research projects as well as the Lab Animal Resource Center that must adhere to federal and state regulations as well as UT System and UT Dallas policies and procedures.

The FY22 Animal Care Risk Management Plan lists the following risks of noncompliance for animal research, and controls to mitigate these risks are included in the plan:

- *Research involving vertebrates does not have IACUC approval; protocols are not current*
- *Unapproved access to the vivarium*
- *Research is not conducted according to the approved protocol*
- *Inappropriate use of animals in research*

### Objective

To ensure compliance with federal regulations and the effectiveness of operations over animal care and the effective assignment, performance, and training of oversight committee roles of the Institutional Animal Care and Use Committee (IACUC).

### Scope

The scope of the audit was FY2022 and FY2023. Fieldwork was conducted from December 2022 through April 2023, and the audit concluded on April 27, 2023.

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<sup>2</sup> <https://research.utdallas.edu/researchers/iacuc>

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## 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 in 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<sup>3</sup>.

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
Animal Care Research	<ul style="list-style-type: none"><li>Gained an understanding of the compliance program by reviewing federal regulations and the related UT Dallas policies.</li><li>Interviewed various responsible parties within the Office of Research and Innovation.</li></ul>	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 animal care.	Observation #1

<sup>3</sup> <http://www.coso.org>



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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.	Observation #1, 3 and 4
Institutional Animal Care and Use Committee	Determined IACUC appointment processes for other universities with animal research.	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
<b>Priority</b>	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).
<b>High</b>	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.
<b>Medium</b>	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.
<b>Low</b>	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.
<b>Minimal</b>	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 of Research and Innovation management and staff for their support, courtesy, and cooperation provided throughout this audit.

Respectfully Submitted,

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

### Distribution List

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

#### *Responsible Vice President*

Dr. Joseph Pancrazio, VP for Research and Innovation

#### *Persons Responsible for Implementing Recommendations:*

Mr. Kathan McCallister, Assistant VP of Research Operations

Cynthia Tralmer, IACUC Manager

Tyler Tornblom, Research Operations Coordinator

Steve Lucas, LARC Manager

Bradly Woody, Asst. LARC Manger

#### *Other Interested Parties*

Ms. Sanaz Okhovat, Chief Compliance Officer and Associate VP for Research and Innovation

#### *External Parties*

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

#### *Engagement Team*

Project Leader: Ms. Caitlin Cummins, Staff Auditor III; Staff: Ms. Dora Vasquez, CFE, Staff Auditor III