MEMORANDUM

TO: James L. Mahon, PhD
    Interim Director. Institutional Research

FROM: Kimberly K. Hagara, CPA, CIA, CISA, CRMA
        Associate Vice President, Audit Services

DATE: November 6, 2012

SUBJECT: Animal Resource Center and Institutional Animal Care and Use
         Committee (ARC-IACUC)
         Audit Control Number 2012-036

Attached is the final audit report regarding the Animal Resource Center and the
Institutional Animal Care and Use Committee (ARC-IACUC). This audit will be
presented at the next Institutional Audit Committee meeting.

Additionally, please find attached Audit Services audit recommendation follow up
policy. Each of the recommendations is classified by type at the end of its identifying
number: Significant (S), Risk Mitigation (R), or Process Improvement (P). As you will
note in the policy, the classification of the recommendation determines the frequency of
our follow up. All follow up results are reported quarterly to the Institutional Audit
Committee.

Thank you for your cooperation and assistance during the course of this review. If you
have any questions or comments regarding the audit or the follow-up process, please
feel free to contact me at (409) 747-3277.

Attachments

c: Danny O. Jacobs, MD
    Christopher Suckow, DVM
    Ronald G. Tilton, PhD
    Cameron W. Slocum
The University of Texas Medical Branch
Audit Services

Audit Report

Animal Resource Center & Institutional Animal Care and Use Committee (IACUC-ARC)

Audit Control Number 2012-036

November 2012
Animal Resource Center & Institutional Animal Care and Use Committee  
(ARC-IACUC)  
Audit Control Number: 2012-036

Background
Laboratory animals play an essential role in biomedical research for the development of medical advancements, treatments, and cures for both humans and animals. All aspects of animal use in research are highly regulated by federal agencies such as the Office of Laboratory Animal Welfare (OLAW), the National Institutes of Health (NIH), and the Public Health Service (PHS).

The Animal Resource Center (ARC), the Institutional Animal Care and Use Committee (IACUC), and the designated Institutional Official (IO) oversee the University of Texas Medical Branch's (UTMB Health's) research animal care and use program, ensuring animal research is carried out humanely and in compliance with applicable laws.

The Animal Resource Center (ARC) provides a comprehensive program of veterinary care, animal husbandry, technical advice and assistance, and facilities to advance research on the UTMB Health campus. ARC includes approximately 108,000 square feet of assignable space staffed with 71 employees.

The IACUC is a multidisciplinary committee of 17 members and two alternate members representing both UTMB Health and the community. To fulfill its oversight responsibilities, IACUC approves research protocols, performs semi-annual protocol reviews, reviews concerns involving animal use, prepares reports and makes recommendations to the Institutional Official (IO). The IO has the authority and responsibility for the overall administration of the animal care and use program and the IACUC.

The Interim Director, Institutional Research, requested an operational review of ARC and IACUC operations after recent changes in several leadership roles within ARC.

Audit Objectives
The primary objectives of this audit are to assess ARC-IACUC operational controls and compliance with policies, procedures, and regulations.

Scope of Work and Methodology
The scope of work is current operations and the methodology includes interviews, observations, reviews of policies and procedures and related documentation, and limited testing.

The audit was conducted in accordance with the International Standards for the Professional Practice of Internal Auditing as promulgated by the Institute of Internal Auditors.

Audit Results
ARC Operational Activities
Audit Services' review of ARC operational activities included reviewing policies and procedures, facility access, oversight and monitoring activities, and animal management.

Facility Access
Ensuring a secure, protected environment for animals represents a primary ARC responsibility. Audit Services review of access procedures and practices indicated established processes are in
Animal Resource Center & Institutional Animal Care and Use Committee (ARC-IACUC)
Audit Control Number: 2012-036

place to appropriately limit access to ARC facilities. Additionally, we noted ARC facilities are equipped with adequate security and monitoring devices.

Oversight and Monitoring
Routine oversight and monitoring of ARC operations and research protocols helps ensure both the health and well-being of animals used in research as well as compliance with applicable regulations. ARC utilizes the “Watchdog” animal management tool to monitor access, temperature, humidity, lighting, and watering system functions in facility rooms. Audit Services’ observation and review of Watchdog and its reports indicates the monitoring system appears to be functioning as intended.

Audit Services reviewed 15 randomly selected medical records for evidence of ARC veterinarians and husbandry staff daily rounding and timely documentation of their observations and noted no exceptions. Medical record documentation also indicated veterinarians review specific procedures performed by Principle Investigators (PIs).

Additionally, the IACUC performs semi-annual inspections of animal use facilities and follow-up inspections if deficiencies are noted. The fiscal year (FY) 2012 semi-annual inspections and follow-up inspections reviewed by Audit Services appeared to be well-documented.

The IACUC’s Post Approval Monitoring Program, staffed by two Research Services Protocol Advisors and Liaisons (PALs), routinely monitors animal protocols to ensure regulatory compliance. Audit Services review of 20 randomly selected PI files indicated the PALs are consistently reviewing protocols, meeting with PIs, and performing observations on a regular basis. In anticipation of external agency regulatory inspections, the IACUC Chair requested the PALs begin reviewing all laboratories on an annual basis. During our interviews, the PALs indicated they were unable to meet this informal goal in FY 2011 and FY 2012. With approximately 160 PIs and 400 active protocols, current PALs staffing resources do not appear to be sufficient to complete annual reviews on all protocols.

Recommendation 2012-036-01-R:
The Senior Manager of Research Operations should perform an assessment of the currently protocol monitoring process to determine whether a risk based approach should be utilized or if current staffing levels should be enhanced to ensure monitoring activities provided the appropriate level of risk coverage.

Management’s Response:
This program’s intent is to educate rather than for them to be auditors. The new IACUC chair also would like to see the PALs visit every laboratory thus we will approach management to request an additional FTE. The Director will review monitoring process to ensure that we are meeting the right amount of risk based coverage.

Implementation Date: 8/31/13

Animal Management
Audit Services observed the delivery, receipt, and transport processes for both small and large animals noting overall, ARC activities comply with applicable policies, procedures, and
Animal Resource Center & Institutional Animal Care and Use Committee (ARC-IACUC)
Audit Control Number: 2012-036

regulations. However, we noted instances where research staff transport breeding room animals from the breeding room to a lab and back again. This increases the risk of exposure to rodent pathogens that can compromise the research. Additionally, external environmental sanitation issues may exist when transporting animals between buildings.

**Recommendation 2012-036-02-R:**
The ARC Interim Director should take steps to lessen the risk of animal exposure to rodent pathogens or external environmental sanitation issues during transport.

**Management's Response:**
Research staff are encouraged not to remove animals from the vivarium and take them to their laboratories. But many investigators need to do this to use specialized equipment that cannot be placed in the vivarium spaces. Progress is underway to try to separate breeding animals from experimental animals as space allows. As for transporting animals between buildings, research staff are encouraged to use ARC climate controlled trucks. We have also assessed the equipment inventory in procedure rooms, and will assess whether equipping the procedure rooms better will allow researchers to complete their studies in the vivariums instead of needing to take animals to their labs.

**Implementation Date:** 11/30/12

Audit Services review of the animal inventory and disposal processes indicated overall, appropriate census and tracking controls are established. Logs are used to record the disposal of all animals in high biocontainment areas. In July 2012, ARC implemented a similar tracking process for USDA species. Transport requests are tracked electronically.

**Training**
Individuals are required to complete mandatory training assignments before Research Services places them on a protocol; there are no exceptions. Required American Association for Laboratory Animal Science (AALAS) Learning Library courses include:

- Euthanasia of Research Animals: AVMA Guidelines,
- Pain Recognition and Alleviation in Laboratory Animals,
- Working with the IACUC: Non-VA version

The AALAS Learning Library training results automatically feed to UTMB Health's online training application and to the protocol in the InfoEd sponsored programs management system. Additionally, individuals must complete the "Proper Use of Animal Medical Records" and "IACUC: Occupational Hazard" brochure (read and acknowledgement only) via the UTMB Health online training system. ARC specific training depends upon an individual's job and interaction with different species. Auditors randomly selected 10 individuals and requested their training files for review. All of the training files were neat, organized according to the standard operating procedure, and contained the required supporting documentation.

**Per Diem Rates & Institutional Subsidy**
The ARC functions as an institutional service center, recouping some of its costs for providing animal care, housing, and other services through the charging of a per diem rate. There are 272
Animal Resource Center & Institutional Animal Care and Use Committee  
(ARC-IACUC)  
Audit Control Number: 2012-036

rates in Animal Resources Management System (ARMS), 62 rates posted on the UTMB Health intranet, and 84 on the Administrative Operations Manager’s (Manager’s) benchmarking spreadsheet. Audit Services compared per diem rates in the ARMS with per diem rates posted on the intranet and on the Manager’s spreadsheet noting inconsistencies exist. During the reporting phase of this audit, ARC management corrected the identified inconsistencies.

During Audit Services interviews with the Manager regarding the process for establishing per diem rates, we noted that rates are benchmarked against similar institutions and adjusted based on this information without consideration of institutional costs to provide services. Additionally, to Manager’s knowledge, no prior analysis of rates charged to costs for veterinary and veterinary technician services has been performed.

Since ARC services are essential to UTMB Health’s research mission, the Office of the Provost (Provost Office) provides an institutional subsidy to cover any budgetary shortfall. Although Audit Services was unable to identify an industry standard subsidy percentages, subsidy information obtained from eight peer institutions indicated their respective subsidies ranged from 0-50%. (what institutions were surveyed, as this information does not correlate with previous information)

Audit Services interviews with Provost Office personnel indicated the Provost’s office reviews historical subsidy amounts and targets a certain dollar range subsidy annually rather than a specific percentage. Based on financial data from the Provost’s Office, ARC’s budgeted institutional subsidy for FY 2012 equaled approximately 73%. UTMB Health’s current funding model for the ARC does not ensure adequate recovery of costs or ensure the reduction of inefficiencies.

**Recommendation 2012-036-03-P:**
The ARC Interim Director should review and expand the methodology used in determining per diem rates and miscellaneous charges to ensure the appropriate level of cost recovery is achieved.

**Management’s Response:**
The ARC Interim Director will review and expand the methodology used in determining per diem rates and miscellaneous charges to ensure the appropriate level of cost recovery is achieved. ABSL4 and ABSL3 charges have already been recalculated, and ABSL2 and ABSL1 charges are in the process of being recalculated.

**Implementation Date:** ABSL2 charges will be recalculated by 1/31/13. ABSL1 charges will be recalculated by 8/31/13.

**Recommendation 2012-036-04-P:**
The Office of the Provost, in conjunction with the ARC Interim Director, should consider developing a longer term approach to the funding model of the ARC to reduce the reliance on institutional subsidies.

**Management’s Response:**
Beginning in August, 2012, an Animal Resource Center data collection effort began with
Animal Resource Center & Institutional Animal Care and Use Committee (ARC-IACUC)
Audit Control Number: 2012-036

all such operations within the University of Texas System. Additionally, other more similar operations throughout the United States are being examined. Data being collected will include:
- annual institutional subsidy of the ARC
- per diem rates and miscellaneous charges
- number of annual animal days
- FTE’s
- number of animal facilities
- number of animal research labs

Implementation Date:
These data will be compiled and presented to the Provost Office in October-November, 2012. Through a series of meetings, subsidy and rate decisions will be made in a timely manner such that they will be incorporated into the FY14 Budget.

Leadership and Communication
Auditor Services interviewed a cross section of 19 ARC employees regarding the area’s current organizational environment and culture. Prevalent throughout the interviews were expressed concerns related to a perceived lack of leadership and communication at both the managerial and building supervisory level. As the interviews were done in the month of June, and the current ARC senior leadership has only been in place since May 10th, it appears these perceptions may be more directly related to the prior leadership’s managerial style and culture.

Recommendation 2012-036-05-P:
The ARC Interim Director should continue efforts to increase/improve communication, transparency and team cohesiveness through training and team building activities.

Management’s Response:
A monthly internal ARC newsletter was started in July to better communicate with all staff, and some employees were placed under different supervisors. During monthly ARC all staff meetings, supervisors are asked to recognize employees and how they have excelled in the previous month.

Implementation Date: Ongoing

IACUC
Committee Composition
Audit Services interviewed 12 of the 17 IACUC members regarding IACUC and ARC operations. Overall, those interviewed expressed the belief that the limited number of committee members and large workload impact the quality of reviews. Auditors contacted seven peer institutions in an attempt to benchmark IACUC committee size and workload. IACUC members for those institutions contacted ranged from 9 to 21; however, we were unable to obtain additional information such as the number of protocols overseen to provide workload comparative data.

Recommendation 2012-036-06-P:
The IACUC Chair should assess the current size and composition of the IACUC to ensure the committee size is sufficient to maintain the quality of protocol reviews.
Animal Resource Center & Institutional Animal Care and Use Committee  
(ARC-IACUC) 
Audit Control Number: 2012-036

Management's Response:
The IACUC Chair believes that the size of the committee at the time of the audit (17 members) and the number of active UTMB animal use protocols places us near the average for academic institutions within the United States. While this should not have an impact on the quality of protocol reviews, in response to discussions held during the IACUC meetings, the Chair has increased the size of the committee by 7 members to 24 for fiscal year 2012/2013. Five of these new members will be involved in protocol review (one is an alternate and one is an ex officio member).

Implementation Date: Completed September 1, 2012

ARC Infrastructure
Some IACUC members commented that the ARC facility infrastructure overall is antiquated with a need for improvements and modernization. An example provided included that the southwest side of one building is open and exposed to the elements resulting in exterior rodents accessing the building, transported into ARC via caging item, and then, contaminating the area inside ARC.

Recommendation 2012-036-07-R:
The Interim Director, Institutional Research, should continue his engagement with UTMB Health leadership on the current and future facility and funding needs for the ACR in support of the institution's planned research growth.

Management's Response:
The Interim Director with the support of the Director, Research Laboratory Operations & Support will continue to engage leadership for their support of the ARC facility. The Interim Director continues to have a pulse on the research needs and is fully supportive of the growth.

Implementation Date: Ongoing

IACUC Involvement in ARC Operations
Additionally, several members indicated their perception that the IACUC is too involved with ARC's day-to-day operations rather than focusing on its primary function of monitoring and oversight. Examples cited by IACUC members included lack of empowerment of veterinarians in addressing and implementing corrective actions when adverse events occur; IACUC's mandate for veterinarian review of every protocol prior to IACUC submission; and, IACUC's intervention or influence over personnel matters within ARC.

Recommendation 2012-036-08-P:
The ARC Interim Director, in coordination with the IACUC Chair and IACUC members, should assess the necessity for and extent of IACUC's involvement in day-to-day ARC operations.
Animal Resource Center & Institutional Animal Care and Use Committee (ARC-IACUC)
Audit Control Number: 2012-036

Management’s Response:
The ARC Interim Director, in coordination with the IACUC Chair and IACUC members, will assess the necessity for and extent of IACUC’s involvement in day-to-day ARC operations and take steps as needed to ensure appropriate alignment and understanding of responsibilities between ARC and IACUC.

Implementation Date: 11/1/12

Appeals Process for IACUC “Withhold Approval” Decisions
Audit Services interviews with ARC leadership indicated there is a process in place to appeal IACUC protocol “withhold approval” decisions; however, this process is not documented outside the communication letter to the individual principal investigator. Audit Services compared the Committee’s appeals process with the documented processes used by six peer institutions and noted the IACUC “withhold approval” appeals process appears consistent with industry standards. Although IACUC leadership feels this process is adequately documented within the “withhold approval” letter and OLAW Assurance, documenting this process in a written standard operating procedure would be seen as a best practice based on both industry guidance and actions of other comparable institutions.

Reporting Adverse Events
IACUC’s Reporting Adverse Events (AE) in Research Animal Care and Use Policy Number 27 states, “It is the responsibility of all animal users on an IACUC protocol to self-report AEs to the ARC veterinary staff within 24 hours of the event. Primary means of communication should be through phone or in person to ensure timely reporting of the event.” Interviews with ARC personnel indicated there is no mechanism in place to ensure events reported through phone or in person are formally recorded on an ARC Reportable Event form.

Recommendation 2012-036-9-R:
The IACUC Chair, in conjunction with IACUC, should establish an appropriate tracking methodology to ensure adverse events are reported and tracked in accordance with Policy Number 27.

Management’s Response:
This has been discussed in detail by the IACUC, and such methodology already is in place. In response to ARC husbandry/vet tech/supervisory staff or PI staff, an AE is reported to the veterinarian on duty in a vivarium, that vet fills out an Incidence Report which is immediately sent to the ARC Director. The ARC Director contacts the IACUC Chair and IACUC office manager via email with the Incidence Report attached. The IACUC Office Manager will investigate the incident to gather more information and make a preliminary determination of a potential compliance issue. He reports to the IACUC Chair when the investigation is complete, and the IACUC chair, in consultation with the Office Manager and possibly the ARC Director, will decide whether it is an AE or a compliance issue. The latter would be sent to the compliance subcommittee. The former would be reported to the full IACUC at the next convened quorum, of the AE. All AE are thoroughly documented, via emails, ARC forms, IACUC minutes, etc, and are kept on file in the IACUC and ARC offices.
Animal Resource Center & Institutional Animal Care and Use Committee
(ARC-IACUC)
Audit Control Number: 2012-036

Implementation Date: Ongoing

Conclusion
Overall, ARC appears compliant with policies, procedures, and regulations. Additionally, appropriate operational controls exist over animal populations. Audit Services identified opportunities for improvement in ARC operations and within the IACUC.

We greatly appreciate the assistance provided by ARC staff and IACUC members and hope that the information presented in our report is beneficial.

Kimberly K. Hagara, CPA, CIA, CISA,
CRMA
Associate Vice President, Audit Services

Barbara L. Winburn, CIA, CRMA, RHIA
Audit Services Senior Manager