Report on Compliance with IACUC Regulations #13-119

We have completed our audit of Compliance with Institutional Animal Care and Use Committee Regulations. This audit was performed at the request of the UTHealth Audit Committee and was conducted in accordance with the International Standards for the Professional Practice of Internal Auditing.

BACKGROUND
The Institutional Animal Care and Use Committee (IACUC) is a self-regulating entity that, according to U.S. federal law, must be established at each institution using laboratory animals for research or instructional purposes to oversee and evaluate all aspects of the institution’s animal care and use program.

The ultimate responsibility of the institutional animal care and use program at UTHealth lies with the Institutional Official (IO). The IO allocates resources to ensure the overall effectiveness of the program. Working with the IO is the IACUC also known as the Animal Welfare Committee (AWC), which is responsible for assessment and oversight of the institutional program and facilities, and the Attending Veterinarian who directs the Center for Laboratory Animal Medicine and Care (CLAMC).

CLAMC is responsible for the health and well-being of all institutional animals and for providing veterinary, surgical and animal care services. Its staff includes veterinarians, veterinary technicians, and multiple animal care and support personnel. CLAMC also provides training on the care and use of animals to faculty, staff and trainees.

The Executive Vice President for Academic and Research Affairs is UTHealth’s IO for the program and appoints the chairperson of the AWC. The Attending Veterinarian is Executive Director of CLAMC and a Doctor of Veterinary Medicine who has 40 years of experience in laboratory animal medicine.

OBJECTIVES

The objective of this audit was to determine whether the Animal Research program at UTHealth is compliant with IACUC regulations.
SCOPE AND METHODOLOGY

Auditing and Advisory Services (A&AS) reviewed federal regulations and other guidance that governs an IACUC program, institutional policies and procedures applicable to UTHealth’s IACUC program and functions.

A&AS obtained copies of and reviewed UTHealth’s statement of “Assurance of Compliance with the National Institute of Health’s Public Health Service Policy (NIH PHS Policy) on Humane Care and Use of Laboratory Animals”, and the Association for Assessment and Accreditation of Laboratory Animal Care International’s (AAALAC) accreditation letter. Additionally, we reviewed approved animal research protocols, Semi-Annual Program Review and Inspection Reports from fall 2011 through 2013, the 2011 and 2012 Annual Report(s) to the Office of Laboratory Animal Welfare (OLAW), and the AWC meeting minutes from March 2013 through June 2013.

Finally, we reviewed the protocol review process, grant congruency process, training process, and Occupational Health Program as it relates to UTHealth’s IACUC. We also reviewed the procurement of laboratory animals, CLAMC’s Master Charge Sheet, cost pass-thru to investigators, and the controls surrounding the intra-institutional transportation of animals.

AUDIT RESULTS

Assurance Statement
The NIH PHS Policy requires institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities conducted or supported by the NIH. No activity involving animals may be conducted or supported by the NIH until the institution conducting the activity has provided a written Assurance statement acceptable to the NIH, setting forth compliance with their policy.

A&AS obtained and reviewed UTHealth’s “Assurance of Compliance with NIH’s PHS Policy on Humane Care and Use of Laboratory Animals” statements for 2007 and 2011 as evidence that UTHealth’s IACUC program has provided a written Assurance acceptable to the NIH. A&AS compared UTHealth’s Assurance Statement to the NIH PHS Policy and determined it contains the necessary elements. These statements describe the responsibilities and procedures of the institution regarding the care and use of laboratory animals. The Assurance of Compliance statements are renewed every four years, signed by the Institutional Official, and approved by the OLAW Senior Assurance Officer. We also obtained and reviewed copies of the approval letters from OLAW stating they reviewed and approved the renewal of UTHealth’s IACUC program. The current statement is effective from November 11, 2011 through October 31, 2015.
AAALAC Accreditation
AAALAC accreditation serves as evidence that an institution maintains high standards for animal research programs as well as having achieved the standards outlined in the Guide. In November 2011 AAALAC performed a comprehensive review of UTHHealth's IACUC standard operating procedures and found the program to be exemplary with only minor enhancements recommended.

We obtained and verified a copy of the letter from AAALAC International acknowledging they have "reviewed the report of the recent site visit to UTHHealth's CLAMC and that the program conforms to AAALAC International standards stated in the 'Guide for the Care and Use of Laboratory Animals' and will therefore continue with FULL ACCREDITATION". UTHHealth's IACUC program has been fully accredited by the AAALAC since 1978 and the next accreditation review and site visit are scheduled for 2014.

Semiannual Program Reviews and Animal Facility Inspections
The NIH PHS Policy states the IACUC shall review, at least once every six months, the institution's program for humane care and use of animals and inspect all of the institution's animal facilities using the Guide as a basis for evaluation. They should prepare reports of the evaluations conducted and submit them to the Institutional Official. It also states at least once every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW whether or not any changes have been made to the program.

To verify compliance, we obtained and reviewed copies of the Semiannual Program Review and Facility Inspection Reports from UTHHealth's IACUC office for the periods covering fall 2011, spring 2012, fall 2012, and spring 2013.

Based on the reports provided, we obtained evidence UTHHealth’s IACUC is conducting the inspections as stipulated by the NIH PHS Policy as well as preparing and submitting the reports of activities to the IO on a bi-annual basis with a general description of the activities that were performed, a list of findings, and the investigator’s corrective action plans to address. We also verified the Annual Reports are sent to OLAW as required, with a general description of any changes to the program and membership, the dates of the program and facility evaluations, and any minority opinions.

Protocol Review Process
Federal regulations require an IACUC to determine whether proposed research projects are in accordance with NIH PHS Policy, confirm they are conducted in accordance with the Animal Welfare Act, and are consistent with the Guide. A&AS judgmentally selected 10 protocols for review and obtained their files to determine whether approved supporting documentation was present.

To corroborate and verify protocols were reviewed and approved prior to initiation, we examined the initial animal purchase dates for the protocols. Based on the dates animals were purchased, review of research support documentation, and review of AWC meeting minutes we determined the protocols were properly reviewed and approved by the AWC before initiation.

In addition to the test work noted above, we also examined one protocol conducted at another institution that is utilizing grant monies awarded to UTHHealth in order to ensure they obtained
IACUC animal protocol approval from the collaborating institution. We were able to verify the protocol appropriately obtained the collaborating institution’s IACUC approval.

Lastly, we obtained four months of AWC meeting minutes covering the period of March 2013 through June 2013 to determine whether protocols were reviewed and approved by the AWC. From the AWC meeting minutes, we noted evidence of review and approval prior to implementation of new protocols, as well as resubmissions, modifications, and change requests. We also verified a process is in place for reporting adverse events, unanticipated problems, and protocol deviations.

Grant Congruency
NIH Grants Policy Statement – Section 4.1.1.2 Verification of IACUC Approval states:

It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.

In UTHealth’s IACUC, grant congruency is the process of reconciling the animals listed on the animal research protocols to the animals listed on the grant proposals. Of the 10 protocols reviewed, only 4, based on the funding source required a congruency check. For those four protocols, we verified congruency checks were properly performed without exception.

Training
Animal welfare regulations and public health service policy require institutions to ensure all people caring for or using animals are qualified and adequately trained. Training is provided through UTHealth’s CLAMC. When a new researcher, investigator, technician, or other person having contact with animals arrives at UTHealth, they are directed by CLAMC to the animal research intranet page, which contains links to courses, descriptions, schedules and an online registration form. In addition to the introductory course, there are facility tour classes, species-specific and basic methodology courses, and surgical technique courses.

To determine whether investigators listed on the protocols have attended the introductory course or completed additional trainings, we judgmentally selected a sample of 17 individuals from the 10 protocols previously tested. We obtained evidence that each of the investigators had received at least the minimum level of training without exception.

Occupational Health Program
As stated in the Occupational Health Program policy:

Enrollment in the program is required for all individuals: 1) working within the University facilities which house animals; 2) having direct contact with animals; 3) having direct contact with non-sanitized animal cages or enclosures; 4) having direct contact with non-fixed or non-sterilized animal tissues, fluids, and/or wastes; or 5) providing service or support to animal equipment, devices, and/or facilities. Once enrolled, participation in the program is strongly encouraged; however, if an individual declines to further participate, a signed declination form is required.

Based on our review of the policy, "Enrollment" is defined as having completed a medical questionnaire with signature on file in Employee Health Services. The policy further states:

Once enrolled, an individual will participate in the medical surveillance, medical exams, vaccinations, and screening if required.

Declination is defined as the employee has declined to complete the health history form and participate in the medical surveillance; however, they must still be in compliance with all
activities required by Employee Health Services policies or AWC stipulations related to occupational health.

The above wording as stated in the institutional policy indicates that Enrollment is required; however, subsequent wording indicates Enrollment is encouraged, which is contrary to the previous wording. Additionally, it appears an individual may also decline to enroll or participate in medical surveillance. This can seem confusing to the reader as well as make it difficult to enforce compliance.

To determine whether individuals have enrolled in the Occupational Health Program we tested 19 research staff who were listed in the animal research protocols included in our testing. We determined 17 research staff enrolled in the program, 1 research staff did not enroll in the Occupational Health Program but had a signed Declination Form on file, and 1 research staff had no evidence of enrollment in the Occupational Health Program or copies of their medical records on file. Further investigation determined the researcher would not be working with animals.

**Recommendation 1:** We recommend the Occupational Health Program policy be revised so that it is clearer to participants as to whether enrollment is optional or required. The policy should also be clear regarding the requirement (if any) for the individual to participate in medical surveillance.

**Management’s Response:** The Director of Employee Health Services will be responsible for revising the latest version of the Animal Occupational Health Policy. The new version will clarify that the occupational health program is available to all employees and that while enrollment and participation is strongly encouraged, employees may decline to enroll. Each identified individual is required to complete a signed acknowledgement of the program. The new language will also clarify that the level of participation required is linked to the animal species involved. The revised policy, including language requested by Audit Services and any additional programmatic updates, was reviewed and approved at the Safety Council Meeting on January 16, 2014.

**Responsible Party:** Susan Parnell, Director, Employee Health Services  
**Due Date:** May 1, 2014

**Procurement of Laboratory Animals**  
Per HOOP 78 – Purchase of Animals:

- **All requests sent to the CLAMC to purchase animals must be accompanied by an approved AWC protocol number.**

To determine whether institutional rules for research animal purchases were followed, we used the 10 protocols previously tested as our sample. Of the 10 protocols selected, 4 had purchased animals. We found institutional rules for these purchases were appropriately followed.

**CLAMC’s Per Diem and Fee Schedule**  
The Office of Management and Budget (OMB) Circular A-21 Cost Principles for Educational Institutions establishes principles for determining the costs applicable to grants, contracts, and other agreements with educational institutions, and requires they provide adequate documentation to support costs charged to sponsored agreements.
A&AS analyzed CLAMC’s Per Diem and Fee Schedule to determine how CLAMC identifies their costs and whether they can be justified. The Per Diem and Fee Schedule contains a list of rates for the care of all animal species, room charges, import/export fees, and other additional service charges. Based on our analysis and interviews we determined rates are based on cost factor information CLAMC collects over the course of a year using an enhanced cost accounting program developed specifically for them to formulate the costs and respective fees.

CLAMC tracks the “board days” or census of all animals the lab has housed categorized by animal species. In general, the total number of “board days” is calculated on a per cage basis for small animals, and a per animal basis for large animals. Other expenses that are tracked and included in the formulation are salaries, expenses for supplies and materials (i.e. equipment, food, and bedding), and administrative costs. These costs are entered into the enhanced cost accounting program, which allocates the costs based on time and effort spent, salaries of the individuals performing the tasks and use of supplies and materials.

Based on our review of the enhanced cost accounting program, expenses, salaries, and time and effort, we determined the formulations for the Per Diem and Fee Schedule are adequate and can be reasonably justified.

Costs Properly Passed on to Investigators
OMB Circular A-21 requires the costs of services provided by specialized facilities operated by an institution must be charged directly to applicable awards based on actual usage of the services on the basis of a schedule of rates or an established methodology.

Based on our interviews and observations, all animal care charges such as per diems, purchases, surgery, transportation, import/export fees, indirect costs, and serology are combined into a monthly project bill and sent with accompanying support to the appropriate departments and investigators. The department administrator verifies the bill with each affected principal investigator (PI) in their respective department. Once the availability of funds is verified, the PI in collaboration with department administration determines which projects/protocols to charge. Based on a review of three monthly bills, we verified the bills were appropriately sent to the respective departments and the investigators who incurred them.

Intra-Institutional Transportation of Animals
Institutional policy requires CLAMC to be contacted and coordinate the move of research animals to ensure compliance with federal regulations and the safety of our personnel and lab animals. Based on our interviews, the biggest concern is in the transfer of primates. CLAMC labs generally do not have capacity for all of the people involved in research. Therefore, primates are often transferred to the investigator’s lab where there is greater room capacity for behavioral studies.

Based on our interviews and a review of training and research guidance, we obtained reasonable assurance procedures are in place and followed to safeguard the animal and general public when transporting animals within the institution.
CONCLUSION

In our opinion, UTHealth's IACUC program policies and procedures comply with accreditation standards as well as federal law. Our audit included review of several areas spanning most all program activities. No exceptions were noted in any of these areas.

In addition to our audit, IACUC has been subject to site visits by outside agencies and found exemplary and given "FULL ACCREDITATION" standing. By maintaining high standards in its animal research programs, IACUC has retained its fully accredited status since 1978. IACUC has also received approval of program renewal from the NIH until October 2015.

One recommendation was made to revise a portion of the Occupational Health Program policy in order to better define the requirements for enrollment and participation in medical surveillance of the research staff. Implementation of this recommendation will clarify the participants' understanding of their required responsibilities as well as facilitate compliance with standards and retain good standing with accrediting agencies. This recommendation can be implemented by management at no cost to the institution.

We would like to thank the staff members of the Institutional Animal Care and Use Committee and the Center for Laboratory Animal Medicine and Care who assisted us during our review.

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Assistant Vice President

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Attachment
Appendix I

Glossary of Acronyms

AAALAC................................. Association for Assessment and Accreditation of Laboratory Animal Care
AWC............................................ Animal Welfare Committee
CLAMC................................. Center for Laboratory Animal Medicine and Care
GUIDE................................. Guide for the Care and Use of Laboratory Animals, 8th Ed.
IACUC........................................ Institutional Animal Care and Use Committee
IO............................................. Institutional Official
NIH............................................. National Institute of Health
NIH PHS Policy.......................... National Institute of Health Public Health Service Policy
OLAW........................................ Office of Laboratory Animal Welfare
OMB........................................ Office of Management and Budget
PI............................................. Principal Investigator