

MANUAL of STANDARD OPERATING PROCEDURES

LABORATORY ANIMAL RESOURCES (LAR)

UNIVERSITY OF OKLAHOMA, NORMAN CAMPUS (OUNC)

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I. INTRODUCTION

The Manual of Standard Operating Procedures (M-SOP) herein described applies to animal welfare program on the University of Oklahoma, Norman Campus (OUNC). These procedures are in accordance with the National Research Council "Guide for the Care and Use of Laboratory Animals" (*Guide*) and the applicable field guides for field research. The standards for laboratory animal care are in compliance with the Public Health Service (PHS) policies and U.S. Department of Agriculture (USDA) Regulations and Policies. The OUNC IACUC has responsibility for inspecting animal care and use facilities and reviewing the program as required by the Institutional Assurance of Compliance Document (IACD 2009). Animal Care Technicians will follow the procedures as outlined in IACD and described in this SOP manual. Deviations must be approved by the LAR Director and if appropriate by the IACUC (see below).

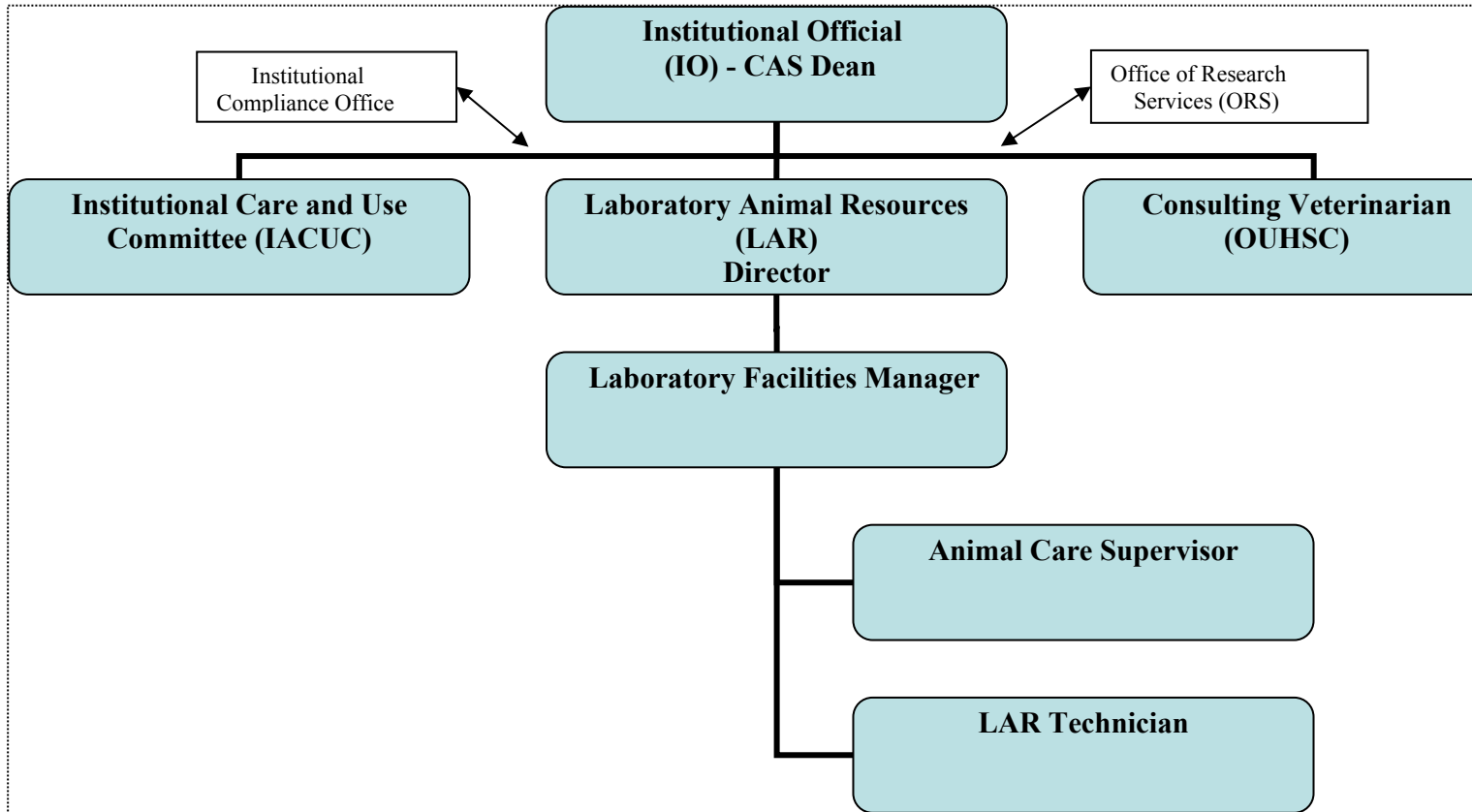
II. UNIVERSITY POLICY REGARDING USE OF ANIMALS IN RESEARCH AND TEACHING

As specified in the PHS Policy at IV.A.2, as a Category-2 Institution, all programs and facilities, including satellite facilities, that include activities using vertebrate animals, are evaluated by the Institutional Animal Care and Use Committee (IACUC) and will be reevaluated by the IACUC at least once every six months in accord with IV.B.1 & 2 of the PHS Policy, and reports will be prepared in accord with IV.B.3 of the PHS Policy. The most recent semiannual reports of the IACUC are attached (14 September 2007 and 29 February 2008 - Appendix B, Exhibit 1a & b respectively).

All IACUC semiannual reports include a description of the nature and extent of this Institution's adherence to the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations are submitted to the Institutional Official (IO), Dr. Paul Bell, Dean of the College of Arts and Sciences (CAS). Semiannual reports of IACUC evaluations are maintained by this Institution in the Office of Laboratory Animal Resources (LAR), and these records are available to the Office of Laboratory Animal Welfare (OLAW) upon request.

The Office of Laboratory Animal Resources provides care of vertebrate animals housed on campus and administratively supports the IACUC (Figure). The IACUC has responsibility for overseeing the use of vertebrate animals, whether for teaching or research, by faculty, students, and staff of the Norman Campus and by non-University persons using University facilities. The function of the Committee is to ensure that all care and use of animals follow the guidelines established by the United States Department of Agriculture, the Office of Laboratory Animal Welfare of the Public Health Service, and other applicable regulations of national, state and local agencies. All research and teaching activities that involve vertebrate animals used within the context of research or teaching and all proposals for vertebrate animal use in any capacity must be approved by the IACUC before the project is initiated. Animal Use Statement (AUS) forms for submitting proposals for review should be downloaded from the IACUC website (iacuc.ou.edu), or they may be obtained by contacting the office of the Laboratory Animal Resources (325-2609). Questions should be directed to the LAR Director. The IACUC meets monthly to review these protocols in accordance with the Animal Welfare Act issues. Oversight responsibility extends to field as well as laboratory research and teaching, and to facilities other than those belonging to the University of Oklahoma, if University personnel are involved in the work; however, oversight may be deferred to IACUC review at collaborative institutions when all operations are conducted within their purview.

UNIVERSITY OF OKLAHOMA NORMAN CAMPUS ANIMAL CARE AND USE PROGRAM



III. INSTITUTIONAL ANIMAL CARE AND USE PROGRAM/ADMINISTRATION

Both the LAR and the IACUC are administratively supported through the College of Arts and Sciences. The IACUC coordinates with the University Compliance Office, but retains its administrative support through the CAS. The operating budget for the LAR is allocated through the CAS Deans' office, Paul B. Bell, Jr., the designated Institutional Official (IO). Membership of the IACUC is in accordance with USDA Regulations and PHS Guidelines (a veterinarian, a scientist, a lay member, a non-affiliated member and one or more scientists). The IACUC reviews the Institutional Animal Care and Use Program and inspects animal holding and research facilities on a semi-annual basis according to federal guidelines. The Animal Care and Use Program operates under registration from the USDA as a research facility, and under the authority of an Institutional Assurance Compliance Document (IACD) which is reviewed and approved every four years by the Office of Laboratory Animal Welfare (OLAW) of the Public Health Service (PHS). The personnel of the LAR include a Director (0.65 FTE) who is also the IACUC Chair and a Professor in the Department of Zoology, a secretary (0.5 FTE), and three 1.0 FTE employees - an Animal Facility Manger, an Animal Care Supervisor, and a Laboratory Animal Resource Technician. For descriptions of experience and certification for staff, see the current IACD for the OUNC IACUC. Two current MOU's between LAR and the Department of Zoology clarify some space responsibilities (Appendix B, Exhibit 2a) and ensures funding for one FTE position formerly in the Zoology Department (Appendix B, Exhibit 2b), until additional funds are available to the LAR to partially, or fully support this position.

This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals. The Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training." It acknowledges and accepts responsibility for the care and use of animals involved in activities covered by the IACD. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with the Assurance as well as all other applicable laws and regulations pertaining to animal care and use. This Institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" (*Guide*). Some studies are conducted in the field and involve nontraditional, and, or native species. This Institution has established policies for reviewing field studies to assure that procedures comply with state and federal regulations and the Guide as applicable, and guidelines prepared by professional societies for using animals in field studies in accordance with "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training"

The Assurance (IACD) is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities involving live vertebrate animals supported by the Public Health Service (PHS) funding and conducted at this Institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or -supported activity.

"Institution" includes the following branches and major components of The University of Oklahoma: College of Arts and Sciences (Departments of Botany and Microbiology, Chemistry and Biochemistry, Psychology, and Zoology) College of Engineering (Bioengineering Program, Aerospace and Mechanical Engineering, Civil Engineering and Environmental Sciences), Graduate College, College of Liberal Studies, Stephenson Advanced Center for Genome Technology, Interdisciplinary Studies, Aquatic Research Facility, Sam Noble Oklahoma Museum of Natural History (SNOMNH), the Oklahoma Biological Survey (OBS), the Sutton Aviary (SA), and the University of Oklahoma Biological Station (UOBS). The SA operates as a program of the OBS and is located in Bartlesville, OK. The UOBS is a research and teaching facility on Lake Texoma, OK. All other units are located on the main campus in Norman (OUNC).

Some investigators of the Institution regularly conduct collaborative biomedical research with investigators affiliated with the Veterans Administration Medical Center, the University of Oklahoma Health Sciences Center (OUHSC), and the Oklahoma Medical Research Foundation. All of these facilities are located in Oklahoma City, OK and operate under their own Assurances and have AAALAC accreditation. Further, some investigators develop collaborative studies at other institutions. Any collaborative investigation must be approved by the IACUC of the institution where the work will be performed, and this approval will accompany the application for protocol review by the IACUC of the University of Oklahoma, Norman Campus (OUNC).

A. Institutional Animal Care and Use Program

1. Structure

The lines of authority and responsibility for administering the Laboratory Animal Resources Program (LAR) and ensuring compliance with this Policy are as follows: The University President is the Chief Executive Officer (CEO) and the Dean of the College of Arts and Sciences is the Institutional Official (IO). The Consulting Veterinarian (Appendix b, exhibit 2c) has direct lines of communication with the IO and the Director of the Laboratory Animal Resources (LAR) Program. Both the LAR Director and the Veterinarian are members of the IACUC. In addition, a representative from the Deans' office is a non-voting member of the IACUC. The LAR Director reports to the Dean (IO) relative to administering the animal care program as a whole and the LAR as a budget unit within the CAS, and he also serves as Chair of the IACUC. The LAR provides administrative support for the IACUC. The Laboratory Animal Facility Manager reports to the LAR Director. The Animal Facility Manager supervises two animal caretakers – an Animal Care Supervisor and a Technician. Neither the OUHSC nor Norman Campus (OUNC) Institutional Animal Care and Use Committees are directly administered under the Institutional Compliance Office, but communication liaison is maintained; the University Compliance Director is a non-voting member of the OUNC-IACUC. The OUHSC is located in Oklahoma City; their Animal Care Program is AAALAC accredited and maintains a separate IACUC.

2. IACUC

The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program (here Laboratory Animal Resources – LAR) and facilities. The IACUC consists of at least five members and its membership meets the composition requirements set forth in PHS Policy, Section IV.A.3.b. We currently have no set term limit for membership. Members of the IACUC are appointed by the President of the University of Oklahoma (CEO).

Membership of the IACUC includes at least 3-5 members as required by USDA regulations and PHS guidelines. The composition of the committee includes representation of at least one scientist, preferably one from each department engaged in animal research, one veterinarian, plus one alternate, one non-affiliated/non-scientist member. In addition to service on the committee, on a weekly basis, the veterinarian examines health status of animals in the housing facilities; he discusses any concerns with the facilities manager and/or investigators (Appendix B, exhibit 5f). He or other members of their staff are available on an around-the-clock basis for consultation on questions concerning animal health and care. The veterinarian:

- Maintains currency on all federal, state, and local laws and regulations that relate to the use of laboratory animals, and shares this knowledge with animal care personnel;
- Consults with research Principal Investigator (PI's) on proper anesthesia, post-operative and/or post-experimental care, and proper euthanasia of laboratory animals when requested;
- Provides workshops for investigators and animal care personnel on topics related to care and use of animals as needed and upon request;
- coordinates the animal health program with the Director of Laboratory Animal Resources;
- conducts pathology evaluations as needed.

3. Semiannual Program Review and Facilities Inspection

The OUNC Animal Care Program and Animal Holding Facilities are reviewed and inspected by the IACUC every six months according to federal regulations (NRC 1996; OLAW 2002; Silverman et al. 2000; Silverman 2002). The procedures are outlined in the current Institutional Assurance Compliance Document (ICAD) dated May 2009 for authorization of operations from July 2009-2012. PI's with drug licenses will be reminded of the requirement for a biennial physical inventory (see website announcement, December 2004) and verified in the annual review of active AUS protocols.

The IACUC will:

a. review at least once every six months all of the Institution's program for humane care and use of animals using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations include ongoing scrutiny of operations and procedures, and a more focused review in association with the semiannual inspection; a Program Review **checklist** is used to delineate areas for consideration. The **checklist** is used to guide the formulation of the description of the program evaluation for various activities that have been examined during the 6-month period covered by the report. The checklist is not a part of the formal report submitted to the IO, but is used to assure that no critical area is overlooked. A narrative report (Appendix B, exhibits 1a&b) is submitted to the IO describing the review, including any recommendations for modification to improve operations, or changes that have been instigated.

The IACUC reviews animal care procedures being performed by caretakers as outlined in the Institutional Assurance Compliance Document. Information from various animal welfare organizations is monitored, and updated procedures and recommendations are discussed with the IACUC for consideration in the program – information pertinent to investigators is included in announcements on the locally maintained website. Training is regularly discussed in the context of new PI's and new graduate students. Guidelines for degree completion relative to the animal care and use as posted on the Graduate School Website are frequently reviewed and updated (most recently May 2008).

In addition to the items listed above, the semi-annual program review also includes examination of:

- (1) IACUC membership composition and functions,
- (2) IACUC and LAR records,

- (3) Veterinary care,
- (4) Personnel qualifications and training,
- (5) Occupational Health and Safety programs,
- (6) Training Activities (OUNC website and Appendix B, exhibit 3j)
- (7) Specific issues are periodically included for review relative to the program; e.g. FAQ posted on the NIH website (<http://grants.nih.gov/grants/olaw/faqs.htm>) as bases for reviewing procedures, or recent civil disturbances by animal rights activists as a means of reviewing local practices and procedures.

b. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows: All IACUC members are invited to participate in the inspection and the review, but a quorum of members including the chair and the veterinarian must be present. The latter two lead the inspection, using a **checklist** as a means of assuring that important items are not overlooked. The checklist is not included as a part of the report to the IO, but a narrative report is provided which describes the outcome of the inspection and any necessary action to be taken. Any deficiency is classified as minor or major (significant), and a time frame is established for correction. Our animal housing facilities are dispersed across campus in nine separate locations.

c. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the IO. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows: The draft report is prepared by the chair and reviewed by all IACUC members; their suggestions are incorporated in the final report, including minority reports, if any. The report of the program review and the facilities inspection are combined into a single document. The narrative that describes the evaluation and any recommended corrective action is submitted to the IO, Dr. Paul Bell, Dean of the CAS (Appendix B, Exhibits 1a&b).

4. Animal Care Concerns

a. Review of concerns involving the care and use of animals at the Institution can be reported directly to the IACUC Chair, or any member of the IACUC, LAR staff, or the IO; all complaints will be investigated. The IACUC Chair will determine the most practicable mode of inquiry. If the incident is considered minor, the Chair will personally investigate in a timely manner, but, if it is serious, or potentially volatile, more extensive and/or immediate action may be required. Serious deviations from accepted standards, or volatile issues will be reported immediately to the IO, if he has not already been directly informed, and to the appropriate officials at PHS. If potential terrorist activity/civil disobedience is anticipated, the campus police will be notified, and the IO will be consulted relative to his role as mediator and Institutional Spokesperson in direct intervention with activists. Under these threats, the campus police have an established mechanism to provide increased monitoring of buildings where animals are housed.

b. In the case of a complaint that warrants an extensive investigation, a subcommittee composed of the Chair and two other IACUC representatives, including the veterinarian, will determine the validity of the complaint. Evaluation of a complaint will be based on standards of care and use found in the *Guide*, the IACD and MOP. If the complaint involves a field project, then evaluation will include consideration of appropriate standards for performing field research and the *Guide*. The approved Animal Use Statement for the specific project under investigation will also be consulted to determine if any deviations from approved procedures have occurred. If a non-compliance issue is validated, corrective action will be formulated by the IACUC and a time-line will be established. Neither the origin of the complaint, nor the identity of the individual making the complaint will be available to the IACUC subcommittee members, nor will it be revealed in the IACUC briefing; this information will remain confidential.

c. The substance of the incident and corrective action will be discussed with, and approved by the IACUC. A written report will be prepared by the IACUC Chair to document the details and outcome of the evaluation; this will be submitted to the IO and PHS.

d. Make recommendations to the IO regarding any aspect of the Institution's Animal Care and Use Program, facilities, or personnel training. The procedures for making recommendations for reviewing concerns area are as follows: Recommendations can be made at any time to the IO, relative to the operations of the Animal Care and Use Program. As the LAR Director is a CAS faculty member, he meets annually with the IO to discuss the year in review and to make

recommendations for needed change. Other recommendations for program improvements or changes are submitted to the IACUC Chair; these may be processed through the IACUC, and if appropriate, submitted to the IO.

5. Animal Use Statement Protocol Review

The IACUC reviews all research and teaching activities that involve vertebrate animals in accord with PHS IV.C.1-3 and articulated in the IACD (2009). PHS-supported activities are described in an Animal Use Statement Protocol (AUS). This process involves the communication of protocol information between investigators/instructors and the IACUC using the appropriate AUS forms. Effective solicitation of complete and appropriate information on which to evaluate proposed protocols is facilitated by the composition of the Institutions' AUS forms. The adequacy of this information exchange indicates whether modification to the mechanism is needed. If indicated, the revision(s) are discussed with the IACUC and these are communicated to researchers when finalized via the website; the IO is informed of any changes through written reports and via representation on the IACUC. The IACUC procedures for protocol review are as follows:

All information pertinent to protocol submittal is posted on the IACUC website (iacuc.ou.edu), including appropriate forms, step-by-step directions and training requirements. The protocol must be received at least one week prior to the scheduled IACUC meeting; meeting dates are posted on the website. Each protocol is submitted electronically for deposition in a permanent file. The draft is assigned an institutional tracking number (alpha-numeric; research or teaching, year + chronological number – e.g. R04-032). It is preliminarily reviewed by the IACUC chair for completeness, and if additional information is needed, it is requested and the protocol is accordingly revised. A hard copy of the signed cover sheet is requested. At monthly meetings, all committee members review AUS protocols for laboratory or field research projects, or teaching activities (Appendix B, exhibits 3a-h) for compliance with the care and use of animals as set forth in the PHS Policy (IV.C.2). The protocol may be approved, require modification in order to secure approval, or denied approval. A complete review will be accomplished at least once every three years. The IACUC will not extend the three-year approval by any means other than subsequent committee review and approval. When the IACUC approval expires, the AUS protocol is no longer valid. Continuation of animal activities beyond the expiration will constitute a serious and reportable violation of the PHS Policy.

Meeting material is distributed via email one week prior to the meeting. A copy of each protocol, draft minutes from the previous meeting, and any other items to be discussed are included. The agenda provides a brief description of each AUS protocol to be discussed.

a. Animal Use Protocols are classified as teaching or research; these can be field or laboratory and can involve manipulations or not. An AUS that involves an experimental manipulation, must describe the protocol in detail and must identify whether the procedure will cause pain or distress, and if it does, how these will be relieved through anesthesia or analgesia. Any procedure that does not include a means to alleviate the pain or distress, must be fully explained.

b. All AUS proposals are reviewed by each IACUC member prior to the scheduled meeting; the designated review process is not used at the OUNC. Each protocol is evaluated relative to:

- (1) Clear description of the study, including objectives.
- (2) Evidence of non-duplication based on literature search.
- (3) Explanation of the use of the particular animal model relative to alternatives.
- (4) Appropriateness of the procedures to the questions posed by the study.
- (5) Whether the manipulation will involve pain or distress to the animals, and if so, how it will be relieved or alleviated, study end points, and consideration of "Alternatives".
- (6) The anesthesia to be used, and dosage information.
- (7) Justification for the numbers of animals proposed relative to minimal number for statistical validity of results.
- (8) Appropriateness of the method of euthanasia in laboratory and/or field studies.
- (9) Use of applicable field guidelines relative to methods of collection, marking techniques, and well being during live-trapped restraint.

c. AUS Protocols are discussed at monthly IACUC meetings and they are reviewed within the month of submission, consequently no mechanism for an expedited review is made. However, consideration is given to the applicability of the NIH “just-in-time” rule if an agency deadline is imminent.

d. Action on an AUS requires a quorum of voting IACUC members to be present and a majority vote for the recommendation, but minority opinions are reported. The protocol can be approved, or approved contingent to clarification of minor issues; if edits are not extensive and the PI provides the corrected information, these minor editorial changes can be entered into the document without additional committee review. More extensive questions may require the protocol to be requests are communicated via email. Some protocols are tabled or deferred for more information. The protocol is returned to the investigator for revision. For these extensive revisions, the investigator is supplied with specific instructions concerning the questions or kinds of modifications required. The revised document from the PI is re-examined in a subsequent IACUC meeting. The AUS deliberations and action are recorded in the minutes of the IACUC. Approval can be denied if the procedures are in conflict with provisions of the PHS Policy IV.C, if the objectives of the study are not warranted relative to the issues of pain and/ or suffering of the animals, if the investigator lacks appropriate experience, or if the facilities/equipment are inadequate to successfully support the study relative to appropriate animal well being.

e. When the IACUC approves an AUS as set forth in the PHS Policy at IV.C.4, the chair prepares an approval letter. It is sent to the investigator(s), the Institutions’ Office of Research Services (ORS) and the IO (**Appendix B, exhibit 5**). The ORS notifies the extramural funding agency that the IACUC has evaluated and approved the protocol. Copies of the approved protocol and letter of approval are maintained in the LAR office, the Chairs files, and the Facilities Managers records.

6. Amendment to Protocols

Previously approved, ongoing protocols may be amended by submitting the requested change on the appropriate IACUC form (Appendix B, exhibit 4i). Deviations in either protocol or number of animals must be approved by IACUC. The amendment will be referenced to the original AUS document tracking number and identified by a suffix of the approved protocol (e.g. R04-032A). The IACUC will review, discuss and decide on the appropriate action in the same manner as for any new project.

7. Records and Monitoring

Each active AUS that is covered by PHS Policy is monitored in accordance with the PHS Policy (IV.C. 1-4). Duplicate copies of all communication with the PI relating to an AUS protocol are maintained in the office of the IACUC Chair in the LAR administrative Office. Pertinent information for each AUS, including the letter of approval, approved AUS and training credentials record are maintained in hard copy and in an electronic software program. The AUS electronic file is organized by an alpha-numeric system; the tracking system provides an abbreviated summary of active projects. Entries in this file can be sorted by the chronological alpha-numeric code, by date (approval/ expiration) or by PI. This filing system permits interrogation for critical dates, such as expiration of approval, amendments and modifications, etc. This file is automatically backed up daily by an electronic software system (Retrospect) in another building, and archived weekly on a tape. The Facilities Manager is provided a copy of all active protocols, letters of approval, training record, and any amendments

Either the facilities manager or animal technician sees all animals daily; care is described elsewhere in this document (Section VI), and records of these activities are maintained. If changes to these written guidelines are warranted, the LAR staff discuss and make appropriate adjustments. Changes will be documented and reported to the IACUC for their concurrence relative to the *Guide*. Thus, animal well being is under regular scrutiny of animal care givers, the consulting veterinarian and the researchers; any animal health-related issue is to be reported to one of the LAR staff, who in turn will report to the consulting veterinarian. The consulting veterinarian inspects the facility and its animals on a weekly basis; this activity is recorded on a summary report (Appendix B, exhibit 4f). If problems occur, the veterinarian has direct access to the IACUC Chair and/ or the IO, depending on the seriousness of the problem. The consulting veterinarian will determine the cause of the health change and recommend treatment, and he will determine if the procedures approved in the AUS are being followed. If the PI is deviating from the approved procedures, he/she will be required to justify these deviations to IACUC. If the new procedure is approved, the protocol will be amended as described above and entered in

the record. If the protocol deviations are unacceptable, and the PI persists, the project can be suspended (see Section 8).

All of these sources of information provide a tracking mechanism for monitoring operations, and as well, individual investigators have access to the IACUC and/ or the Director of Laboratory Animal Resources if needs are perceived for facility upgrades, special training of animal care personnel, or deficiencies in animal care procedures, or to discuss management of the animal care and use program. This continual monitoring of program activity feeds into the Program Review process in addition to the more formal IACUC-driven semi-annual review process.

If some needed action is identified through one of these sources, a plan is developed to address the problem. Actions to correct or rectify the problem will be made within the budgetary constraints of the Laboratory Animal Resources (LAR). For problems that involve expenditures beyond the scope of the budget, the Director of LAR will discuss with the IO. Long-term planning for facility support is presented to the IO in the LAR Director's annual administrative report from the budget unit (Appendix B, exhibit 6). The IO is directly available for issues that might require a more immediate decision.

The numbers of animals approved for use in a project are monitored by LAR through a system of records and procedures. A procedure for animal procurement (SOP-1, Nov '03, Appendix B, exhibit 4b) directs the PI to complete an Animal Order Confirmation Form (Appendix B, exhibit 4c) and submit to the LAR. The order form is processed, copied, and distributed to the PI, Animal Facilities Manager, and filed in the LAR office. As the research project progresses, the numbers of animals used can be compared to the approve number in the AUS. The information included on the form provides animal facilities personnel a time line for delivery of the specified number of animals, their type, and any instructions for special care. An inquiry can be made to the PI, if it appears that the number of animals approved might be exceeded.

Semiannual facility inspections include both animal housing and experimental space. Any deficiencies in either of these areas are noted in the inspection report and a plan for corrective action is developed; a subsequent visit will be made to verify that the problem has been corrected.

An annual update report on the anniversary of the AUS approval is requested from the PI (Annual Report and Drug Inventory form; Appendix B, exhibit 4k). It provides a mechanism to report change in personnel, interim training, general status of the project, and verifies that the biannual drug inventory has been accomplished.

At least once every 3 years a complete review of individual protocols will be conducted by IACUC according to the requirements set out in the PHS Policy IV.C. 1-4. A reminder of pending expiration is sent to the PI. If the project is to continue, a complete revision of the protocol is requested by the PI, and reviewed by the IACUC.

The LAR is subject to periodic internal audits which review all record keeping procedures, perational procedures, and financial management. The LAR, OUNC underwent an internal audit in 2004 and under went a facilities space review in 2007; various minor suggestions were provided, all of which have been accomplished or rectified.

8. Suspension of activities

The IACUC is authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. Any person who is aware of practices in any program of research or teaching which violate the principles of humane care and use of animals may bring this information to the attention of the IACUC Chair, or to any intermediary who may then convey the information to the Chair. Any suspensions must be approved by a majority of an IACUC quorum and the action to suspend a project will be reported to the IO who, in consultation with IACUC, will determine appropriate corrective action. A report of this action and a full explanation will be reported to the appropriate official in OLAW.

The IACUC procedures for suspending an ongoing activity are:

a. The IACUC Chair will investigate the matter and determine the validity and seriousness of the alleged violation, and if warranted, a committee composed of the IACUC chair, veterinarian and another member, will investigate the matter further.

b. The PI will be informed by letter if the violation is validated and is sufficiently serious. He/she will be asked to respond in writing, and an appearance before the IACUC will be scheduled. The IO will be informed of the status of the hearing procedures.

c. The PI will discuss the situation with the IACUC and report inaccuracies or falsehoods related to the accusation; if procedural or practice violations are confirmed, appropriate action will be taken. If the practice is discontinued, the decision may be to permit the project to continue without punitive action being taken. The IO will be notified of the IACUC decision.

d. The activities of the PI will be monitored for a reasonable period by IACUC representatives, including the veterinarian, facility manager. If the corrective action is discontinued and violations are repeated, the IACUC is authorized to terminate the research program; suspension requires a majority vote of the IACUC members, providing a quorum of voting members is present. The termination will be reported to the IO, the appropriate official at OLAW, and the funding agency.

9. Reporting Requirements

a. Office of Laboratory Animal Welfare

At least once every 12 months the IACUC, through the Institutional Official, will report in writing to OLAW. The currently approved reporting period for the OUNC is 1 July through 30 June (Appendix B, exhibit 9). The following issues will be included in the annual report:

Any change in the status of the Institution, any change in the description of the Institution's program for animal care and use as described in this Assurance (IACD), or any changes in IACUC membership. If there are no changes to report, this Institution will provide OLAW with written notification that there are no changes.

Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the IO.

The IACUC, through the IO, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

- Any serious or continuing noncompliance with the PHS Policy.
- Any serious deviations from the provisions of the *Guide*.
- Any suspension of an activity by the IACUC.
- Any uncorrected significant deficiencies (also reported to USDA)

Reports filed under VI.A.2 and VI.B. above shall include any minority views filed by members of the IACUC.

b. U.S. Department of Agriculture Annual Reports to USDA are due at the end of October. The primary information is the number of animals used in research and teaching according to pain categories.

c. Administrative Annual Report

As a budget unit of the CAS, the LAR submits an annual administrative report each year (Appendix B, exhibit 6) to the IO; this report reviews the units' activities and accomplishments, discusses recommendations for program or procedural modifications, and describes planned goals for the upcoming year.

B. Website

The OUNC LAR website is available at <http://iacuc.ou.edu>. It provides information on the Institutional Animal Welfare Program operations and guidance to resources and procedures. Main sections include-- IACUC, LAR, Drug License, Announcements, and Links. Current Forms are posted to facilitate protocol review of research projects and teaching activities that involve vertebrate animals. Animal Welfare resources are linked and various on-line training opportunities are accessible. The website is maintained by LAR personnel. Announcements are posted to provide updates on Animal Welfare issues and to maintain lines of communication between LAR/IACUC and animal users.

C. Forms (See website)

See the OUNC website (iacuc.ou.org) to download copies of the AUS forms, instructions for completion, and IACUC meeting dates for review and approval. The following forms have been developed to solicit the information necessary for the IACUC to evaluate compliance with the Animal Welfare Act, as articulated in USDA regulations and PHS guidelines. Field studies may require federal or state scientific permits; it is the responsibility of the PI to comply with these requirements. Similarly, for some field and/or laboratory studies, drugs that require the PI to be licensed are in the purview of the PI relative to maintaining registration, appropriate security and records of use.

1. IACUC forms

Animal Use Statement Cover form – Teaching (2002) – Identifies instructor and history of the course.

Animal Use Statement – Form I, Teaching, Field Exercise without manipulation (2002) – Description of observational objectives, e.g. visual or aural bird counts without trapping or capture.

Animal Use Statement – Form II, Teaching, Field Exercise with manipulation (2002) – Laboratory exercises where animals are captured or subject to manipulation.

Animal Use Statement – Form III, Teaching, Laboratory Exercise (2002) – Classroom exercise that includes manipulation of vertebrate animals.

Animal Use Statement Cover form – Research (2007) – Identifies PI with contact information, and funding agency, proposal title and LAR alpha-numeric tracking number.

Animal Use Statement – Form I, Field Studies with no manipulation (2002) – Research on animals in their natural habitat without capture or confinement, e.g. visual/behavioral observations.

Animal Use Statement – Form II, Field Studies with manipulation (2006) – Research on natural animal populations that include capture and manipulation.

Animal Use Statement – Form III, Laboratory Studies (2002) – Investigations under laboratory conditions that include manipulation of the vertebrate animals.

AUS Amendment form (2008) – Provides PI with mechanism to request an amendment to an approved AUS (e.g., animal number revision, change in funding source or period, protocol modification, etc.).

AUS Annual Report and Drug Inventory form (2008) – Status report of approved AUS protocol and documentation of personnel training, changes in personnel and or procedural changes that were approved by the IACUC; biannual drug inventory.

IACUC Training form (2008) – Documents occupational health and safety and on-line portion of Animal Welfare Orientation training

2. LAR forms

Animal Transfer form (2002) – Record of animal movement from housing facilities to research laboratories (< 24 h).

Animal Procurement, Use and Disposal form (2007) – Request and notification of animal order; permits animal use tracking and coordination with LAR personnel for housing preparation; SOP-1 elaborates procedure for these operations.

Daily Census form – For use of LAR personnel to maintain animal census record (not on Website).

Daily Treatment Form (2007) – Record of daily treatment such as analgesic, etc.

Veterinary Animal Health Inspection form (2007) – For veterinary use relative to weekly facility examinations.

Water/Food Deprivation form (2008) – Record of restricted feeding and watering as behavioral (> 24 h & not for pre-surgical) – form is a component of the SOP which elaborates this procedure.

D. Training

It is the responsibility of the Institution to ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities as prescribed in Animal Welfare Regulations, Section 9 CFR, Part 2, Subpart C, section 2.32(c). The development and implementation of a training program are usually performed by the IACUC, the veterinary staff, and investigators using animals. Many sources are used in training, depending on the level and orientation of the recipients; e.g. in-house training of PI's to include orientation to local procedures and resources and discussion of regulations and guidelines (Guide – NRC 1996) on specific topics (NAS 1974; Kohn 1997; Klaunberg et al. 2004). Completion of milestone training for PI's is entered into their personnel file and

an electronic record. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care and use at this institution is organized relative to experience and need. The program is structured to emphasize initial orientation to animal welfare issues and Institutional facilities and operations. In the orientation training, for investigators and new graduate students, all are fully briefed on local procedures, resources and the importance of the information solicited in the AUS protocol. Factors of stress, distress and pain are discussed, including the application of the "3 R's" (Reduction, Refinement, Replacement), and the resources that are available for considering "Alternatives". The OUNC Training Program is summarized in the outline on the website and in Appendix B, exhibit 3j.

Institutional procedures specific to thesis research are emphasized in the graduate student orientation, as the administration has some unique features. A graduate student may work on a protocol of their major professor or on one that they develop, but in the former instance, unless they were listed as key personnel during the original review, the graduate college does not know that their animal research is covered. In these instances, an amended approval letter is produced by the IACUC chair to add the student on the project; this action does not extend the usual 3-year approval period. Within the university system, several key documents verify that the student has either developed their own AUS protocol or is working on one of their major professors. The Graduate Student Handbook from the Graduate School elaborates on this requirement and several forms have check-off blocks to verify that the requirement has been accomplished. Important forms are completed and serve as reminders of this requirement: 1) Checklist for Masters Degree - thesis option, 2) Application for approval of the master's thesis topic and committee membership, 3) Report of doctoral advisory conference, and 4) Request for authority for defense of dissertation (Appendix B, Exhibits 11 & 12).

The training of IACUC members uses other resources to supplement their role (OLAW 2002; Podolsky and Lukas 1999; Silverman and Murphy 2000; Silverman 2002) and is in much greater depth relative to the IACUC responsibilities. They are provided numerous publications to guide them in performing their duties ("Survival Portfolio" – Appendix B, exhibit 10). The animal care technicians are also provided an orientation, but their ongoing training is more technical and applied (Manning and Wagner 1976; Wiesbroth et al. 1984; Flecknell 1987; Gay and Heavner 1989; Harkness and Wagner 1989; Borchard et al. 1991; Baker et al. 1997; Paddleford 1999). Further, they are engage in continuing upgrade training to progress through the AALAS certification levels. In short, our training program is modified according to the needed skills and required information. A training record portfolio is maintained in the LAR Directors' office. Completion of milestone training for PI's is entered into their personnel file.

Other Training Opportunities - The consulting veterinarians offer a workshop/training program which meets on a weekly basis for two semesters each year. Participants are taught administration of anesthetics, euthanasia procedures, administration of chemo-therapeutic agents, general diagnostic procedures, and other material which would aid them in assessing health care problems in their animal colonies.

E. OSHA/Safety Training

The occupational health and safety program for personnel who work in laboratory animal facilities follows the general provisions of the University of Oklahoma Health and Safety Policy (Appendix B, exhibit 3j). A file of pertinent information has been collated and is posted on the web; videos are available for viewing. All active researchers and technicians are directed to these resources during Orientation. When completed, a signatory file is maintained by the Facilities Manager and LAR Director.

Personnel in the LAR program participate in an annual campus-wide safety training and hazardous materials management. The following web page (<http://www.ouhsc.edu/ehso/training-norman/labchoice.html>) provides information and training to maintain compliance with the requirements of Environmental Health and Safety and Occupational Safety.



Environmental Health & Safety

On-Line Training Home Page

Where do I start?

The content of the training is dependent on the job you do. To get started, choose the area below that best describes your position:

Office /General Staff

This course is designed for employees who work in an office, in administrative or teaching duties, or general staff, and who do not have lab or patient contact responsibilities.

Laboratory Safety

The lab course is designed for employees who work in laboratories where the "laboratory use of hazardous chemicals" occurs.

Health Care

The health care course is designed for those who have **direct patient contact** such as in a clinic-type setting, including front line reception employees.

Bloodborne Pathogens

There are two bloodborne pathogen (BBP) courses available.

[Click here for the clinical/ laboratory BBP course](#)

[Click here for the general staff BBP course](#)

Additional on-line courses include the following:

[DOT Shipping and Receiving Biological Materials](#)

This course provides the mandatory training required for employees who package and ship or receive hazardous and/or biological materials including human blood/tissue samples, infectious agents, dry ice, and formaldehyde/formalin.

[Asbestos Awareness](#)

This course provides the mandatory training required for employees who may encounter asbestos-containing materials in the course of their duties, but who do not disturb, remove, or repair the material. Employees in Housekeeping and Physical Plant are examples of employees who should take this course.

F. Security

Building security is facilitated by limiting access to key personnel. Keys to the various animal holding facilities are issued as needed to PI's and lab technicians. A master list of key holders is maintained in the LAR office; university keys are of the "no-copy" type and must be returned when employment ends. Locks automatically relock and cannot be reset for subsequent non-key entry. All animal holding facilities are keyed and three areas (Dale Hall, George Lynn Cross Center and Animal House) are equipped with security alarms which are activated during non-working hours.

G. Emergency and Risk Assessment Plans

The disaster plan for the Animal Facilities of the OUNC is integrated into the University Emergency Response Plan (2008 update) and the Office of Compliance Risk Assessment Plan (2007). It includes considerations for natural disasters and human instigated civil disobedience. Severe weather damage is an ever-present in this geographic region; however, historical records counter the expectations of such a high risk to the campus and the likelihood for tornado damage to the campus is surprisingly low. The animals holding facilities on the OUNC are disjunct in seven different locations, therefore anticipation the need to relocate animals from all or most facilities is unrealistic. The capacity to maintain life support systems would be the primary effort should a weather disaster strike. An emergency electrical power supply functions in the Animal House as an automatic switchover for partial power.

Civil disobedience is an unpredictable potentiality. Animal activists are not numerous in the environs of this part of the country. However, we are aware of some PETA activities and their presence is cause for some vigilance. The management of our animal care program is of high quality and we have no high profile species, nor controversial research activities that would elicit undue attention by these protest groups. Nevertheless, our plan would be to meet any protest demonstration with response from the IO and backing of the campus security personnel. A plan is being developed with the Security Office to provide heightened oversight under threatening scenarios. Since terrorism legislation has been increasingly codified, illegal activities are more likely to be met with heightened response.

H. USDA Inspection (See USDA 2002a; USDA 2002b)

The facilities and records at OUNC are inspected by personnel from USDA at least once each year. The physical environment of housing areas, the general health of animals and the quality of the records are examined. The facility must be prepared to provide:

1. A copy of the approved AUS research protocol and summary list of active projects.
2. Animal history – Accession date and source - Order Confirmation Form and Cage Card.
3. Health record that documents any diagnoses and treatment – Record of Veterinary visits.
4. Experimental procedure history – Animal Order and Transfer forms
5. Proposed method of euthanasia – AUS
6. AUS amendments – number of animals or procedure modification

IV. LAR OFFICE PROCEDURES

A. Records

All records for the OUNC Animal Care and Use Program and the IACUC are maintained in the LAR office. The OUNC IACUC is administratively supported through the LAR. All electronic records are automatically backed up daily by a software system (Retrospect) which is remotely operated, and the records are archived weekly on tape. IACUC records include Minutes of the Meetings, Reports of Inspections of Facilities and Semiannual Program Reviews, Annual Report to the Office of Laboratory Animal Welfare of the Public Health Service (OLAW/PHS), Annual Activity Report to IO, and the Annual USDA Animal Census. In addition, the results of the annual USDA inspection are filed. Records for each University Investigator includes a research experience summary, their training file, and active AUS Protocols, letters of notification of AUS approval, annual review record, and animal order transactions. All Active projects are also maintained in an internally managed system. Projects are entered and tracked using a chronological Alpha-Numeric System (e.g. R04-025 = 25th Research AUS reviewed by the IACUC in 2004). These files can be interrogated to retrieve records according to Project Title, PI, or Expiration Date. In addition, a separate Excel-based record of active projects is

maintained as a working file. The Project filing system is the primary means of monitoring project activity and the Animal Ordering Form is a record of animals used. The following procedures ensure these functions:

AUS Review

1. AUS protocols are submitted electronically to the IACUC Chair for preliminary review and clarification as required.
2. Protocols will be reviewed by the full IACUC in the established manner, except those field or teaching activities that are strictly observational and do not interfere with the natural behavior of the animal.
3. A file will be established for each approved AUS under the PI's name, and an electronic record entry in the LAR project management system will include name of the PI, abbreviated title, the tracking number, funding agency, and date of protocol approval.
4. A letter of approval (Appendix B, exhibit 5) will be sent to PI, with copies to the Deans Office (IO), Research Services, and for Laboratory Studies to the Animal Facilities Manager. The approval letter will be filed electronically.

Active and Funded Projects

This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity; the inactive AUS's are retained in a separate archive file. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner. This Institution maintains records in hard copies filed in the Laboratory Animal Resources Office and in an electronic file; these are made and backed up for security as described above (III.A.9).

1. Upon notification of funding, a record will be entered in the file.
2. The LAR project management system will be reviewed monthly, and when a project approaches the anniversary of approval, an email will be sent to the PI notifying them of annual project review. A copy of the Annual review form will be attached for the PI to download, complete and return to the LAR.
3. Projects that are nearing the three-year approval limit will be flagged about 2 months before expiration, and The PI will be notified of the pending expiration date. If activity is to continue beyond expiration, the PI will be reminded that a new AUS must be filed in time for an IACUC review before the project approval expires.
4. Each Animal Order form will be processed in the LAR; the approved form will be returned to the PI and a copy will be retained in the PI's project file and in the Animal Facilities Manager's file.

Reports and Documents

1. A hard copy of the executed Institutional Assurance of Compliance Document (IACD) and any modifications thereto, as approved by PHS.
2. Hard copies and electronic files of the approved minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Original hard copies of applications, proposals, and modifications or amendments to approved protocols for the care and use of animals, as well as AUS protocols that were not approved. In addition to the hard copies of these documents, all active projects for which AUS reviews were conducted are entered in an electronic file organized by an alpha-numeric system which can be interrogated to select for PI, pertinent dates, or funding agency.
4. Original hard copies of the semiannual IACUC reports and recommendations (including minority views) as forwarded to the IO.
5. Financial records for the LAR and personnel records for PI's are maintained in the LAR Office.

B. Order and Payment Procedures

Records of the following LAR financial transactions are also maintained in the office. Financial and personnel records are managed through an internal system called People Soft. Purchases are made according to University Policies and Procedures (see OU Purchasing Web page). If the dollar amount is in excess of \$5,000 a requisition must be submitted through Purchasing, if greater than \$50,000, competitive bids are required. Purchase of less than \$5,000 can be handled directly unless services are involved.

1. Animal Facilities

Routine items are ordered by the Animal Facilities Manager (AFM). Non-routine items that are needed for the operation of the animal facilities are discussed with the LAR Director his approval. The Animal Facilities Manager (AFM) notifies the LAR office that an order is expected or when an order has been received, and the packing slip or an itemized copy of the order is brought to the LAR office. The itemized copy of the order is checked for accuracy in the office (it can be designated as "original" if necessary) and processed for payment.

The Staff Assistant receives the invoice and prepares it for the Director's approval. The Director checks the invoice and approves it for payment from one of the two LAR accounts (122-7411 or 127-9365 – per diem); the signed and dated invoice is returned to the Staff Assistant. The transaction is entered into an electronic record under various categorical expenses, then the processed invoice (original and one copy) is mailed to Financial Support Services and a file hard copy is retained. Animal orders are approved (Animal Order Form) by the LAR, but the PI is responsible for placing the order and paying for the animals.

2. LAR Office Purchases

The staff assistant orders routine supplies for the office in the same manner as above as needed with the Directors approval. Any additional needs are discussed and approved by the Director before ordering. When the invoice and product is received, the Staff Assistant prepares the invoice for authorized account sponsor signature (Director). The Director signs and dates the invoice, and the Staff Assistant submits to Financial Support Services for payment. These expenditures are reconciled at the end of each month with the Statement of Account received from Financial Support Services. A separate listing is prepared by the staff assistant to summarize and document monthly activity; the Director reviews the record and it is then filed. This document is signed by both the staff assistant and the Director. Activities on the Statement of Account(s) may also include encumbrances against the account generated by Purchase Order processing.

C. Payroll and Leave (Annual or Sick)

Annual Leave will be arranged with the appropriate supervisor and any work load redistribution will be planned with pertinent personnel.

Monthly Payroll: Monthly staff time sheets are due in the LAR office on the 10th of each month; these are processed and submitted once a month into payroll system. Leave not reported on the current month's time sheet will be entered on the following month. Additional time sheets are provided for this purpose. Leave time is reported, including holidays for monthly personnel, but no entry is necessary if no leave is taken or if there are no scheduled holidays. Once leave time is entered, it is approved by their supervisor. Monthly payroll extracts are printed after approved by the Payroll Office, then the monthly time sheets are attached to the extract report and filed.

Hourly Payroll: Personnel submit their time sheets every 2 weeks (or they may submit them weekly). However time is entered electronically into the payroll system every 2 weeks; the payroll office sends an electronic message to each unit indicating the deadline for entering time. All time worked and time taken whether paid leave or holidays are reported on each individual's time sheets and signed by their immediate supervisor. Time is then entered into the payroll system and approved by the head of the department. The payroll office notifies each department as to when the hourly extract report can be printed for filing. All time sheets, signed by the employees and their supervisors are attached to the corresponding payroll extract and filed.

D. Statement of Accounts

Financial transactions are detailed in the Statement of Account(s), which are received the first of each month. They are reviewed for accuracy by the staff assistant. All payment activities are compared to the actual invoice copies that were processed during the previous period, and a summary report is prepared for Director; this summary includes paid and outstanding invoices; the latter are those that were sent to Financial Support Services, but did not get processed that month. The outstanding invoices from this monthly activity should appear on the next statement. Financial Support Services personnel resolve any questions regarding the statements.

Funds transferred between accounts for reimbursement are similarly reviewed and processed, any discrepancies are corrected. Inter-departmental transfer of funds may include charges to credit cards or similar transactions. Payment for animal care (per diem–127-9365) is processed by transfers from PI's research accounts (see per diem billing). Funds can be transferred from 127-9465 to 122-7411, but not vice versa.

E. Budgetary Planning

The budget is periodically reviewed relative to level of expenditures. Budgetary considerations are discussed routinely during the year relative to compensation in the per diem account from our billing and expenditures from this and from our regular E&G account. In particular, a mid-year review assures that an acceptable trajectory is being followed and that consideration is given to any return of swept residual monies from the previous year. Several months prior to the end of the fiscal year (30 June), the financial status is reviewed to determine total expenditures to date and whether non-routine purchases that require Purchase Order processing can be accomplished prior to the cut-off deadlines established by the Office of Purchasing.

V. LABORATORY ANIMAL RESOURCE PROGRAM OPERATIONS

A. Animal Orders – Teaching

Procedures for ordering animals and disposing of carcasses/waste are described in a directive (SOP- 1) which is posted on the website. Procedures differ for preserved animals and live ones. Ordering live animals directly involves the LAR relative to housing and to the IACUC-approved AUS.

Preserved Specimens: Several courses taught in the Department of Zoology require the dissection of prepared specimens of various animals; these animals are representative examples from various phylogenies. These specimens are ordered from USDA-registered Biological Supply Houses. See Exhibit in Appendix B for a copy of a Purchase Order Requisition for these animals. Courses that use only prepared specimens from these sources are not required to submit AUS to the IACUC (see USDA Policy 28).

Living Specimens: Several courses in physiology taught by the Zoology Department use living specimens; these include turtles and/or frogs. These specimens are ordered from registered Biological Supply companies and are housed for brief periods until used in the laboratories (see husbandry description under animal species section). Carcass disposal is accomplished through the LAR (Appendix B, exhibit 4b). Other courses use live animals as part of the learning experience, but these animals involve field studies and are not housed or retained in LAR facilities; however some of these animals are euthanized and preserved according to accepted field practices, then retained as voucher specimens in the Sam Noble Oklahoma Museum of Natural History (SNOMNH) or in the Oklahoma Biological Survey (OBS). Coursework involving these types of field collections or manipulations must submit an AUS for IACUC review and approval. Appropriate methods of handling and euthanasia are required.

B. Animal Orders - Research

Animals used in various research programs are ordered from a registered Biological Supply facility and paid for by the PI; LAR requires that the PI notify our office of the order, including the type, source, number, date of arrival, and delivery instructions (Website – Appendix B, exhibit 4b). The PI initiates animal orders by sending the order form to the LAR office for approval and processing. One processed copy is returned to the PI, one to the Animal Facilities Manager, and one is

retained in the PI's file with the IACUC-approved AUS. The latter provides a mechanism for tracking the animals used against the number approved in the IACUC review. When the animals are received, they are housed in LAR facilities until the PI transfers them to his/her laboratory (Website– Appendix B, exhibit 4c).

C. Animal Carcass Disposal

Animal carcass disposal from research or teaching activities and from animals euthanized during LAR operations will be processed according to the SOP-1 published on the LAR website (iacuc.ou.edu). More details are described in Appendix B, exhibit 4c.

D. Animal Inventory and Per Diem Billing

A record of animals being housed is maintained and the daily population inventory is summarized monthly by the facility manager (LAR Form). This head count is delivered to the office for billing purposes. Additionally, this count is used as one data set for the USDA Annual Report. The current per diem rate based on animal species and type of housing is applied to calculate the charges levied for each funded project of PI's (Appendix B, exhibit 8 & website). Charges for animals used in teaching or by non-funded PI's (e.g. new faculty with only start-up monies) are billed to the home department. The appropriate 125-XXXX account number is verified with the PI and the Fund Transfer (University form) is sent to Financial Services for processing. These funds are transferred into the LAR per diem Account (127-9365). The college of Arts and Sciences (CAS) through the allocated budget, provides a subsidy for college investigators. The subsidized per diem is in fact a subsistence charge rather than a per diem as the PI's are not charged for housing of their research animals nor are the associated wages for the animal caretakers included; only expendable supplies such as bedding, feed and cage-washing chemicals are components of this fee. This account is managed on a break-even basis; annual review of the fund provides information relative to the adequacy of rate structure. Non-CAS investigators pay a cost-center calculated rate which includes recovery of pro-rated wages and other operating expenses.

E. Active Projects and Animal Inventory

Each Animal Use Statement (AUS) that has been reviewed by the IACUC is filed by PI and maintained for 3 years. Projects that are funded are monitored as active projects; for laboratory studies, these represent a record of the numbers of animals approved for use on the project and can be related to the animal order history and the animals housed in the holding facilities. Field projects are also maintained as active during the 3-year period, but the animals used are not monitored. PI's are requested to update active projects annually (website – Appendix B, exhibit 3k). This form provides a mechanism for progress reporting and proposed procedural modification, as well as other changes such as new personnel or funding. If modifications to the protocol are proposed, these are submitted on the AUS Protocol Amendment Form (Appendix B, exhibit 3i) for IACUC consideration. The record system used by the LAR is a MIS (Management Information System) organized by the OU School of Business for our program. Application for review of an AUS is made when a PI submits the protocol on the appropriate form (Website – Field Project or Laboratory Project, or Teaching protocol). These are assigned a chronologic Institutional Tracking number in a two-component alpha-numeric format (e.g. R04-025) and they are entered into the record system. The protocols are reviewed at the next IACUC meeting; these can be approved, denied, or tabled for future consideration after additional information is provided. Approved projects are valid for 3 years. A letter is sent to the PI indicating the action taken; a copy of the letter is sent to the Office of Research Services (ORS), the IO, and the Animal Facilities Manager. After 3 years, protocols are transferred to an archive file where they are retained for at least three years.

VI. ANIMAL CARE FACILITIES PROCEDURES

A. General Procedures and Safety and Precautions

1. Animal-care personnel should follow special care requirements specified by the research directors.
2. Animals are to be disturbed as little as possible. Loud noises within the facility are to be avoided. Only authorized personnel should enter animal housing areas.
3. Be aware of and follow safety regulations. This includes regulations for handling radioactivematerials and infected animals and their wastes.
4. Protective clothing should be worn for those tasks where such clothing is deemed appropriate. This

includes lower back support apparatus for tasks involving lifting of heavy objects. Protective shoes may be required under some circumstances. Special clothing, immunizations, etc. necessary for maintaining employee health and safety will be provided by the LAR.

5. Employees are required to obtain a tetanus immunization prior to employment and to maintain their immunization during their employment. No non-human primates are housed or pass through the OUNC Institutional facilities, so bi-annual tuberculin testing is not required. Rodents (rats, mice, chipmunks, and guinea pigs) and lagomorphs are the only mammalian species used at this Institution, consequently rabies vaccine is not required routinely.
6. The Facilities Manager will observe animal care personnel for symptoms of possible zoonoses or development of allergic responses, and if such symptoms appear, the employee will be referred to a physician. The care provided to animals that are housed in LAR facilities is described in Section VI. Water and feed is changed daily, and fresh bedding is provided regularly. Cages are washed and sterilized weekly. The LAR charges a daily subsistence fee for each animal which covers costs of supplies (Appendix B, Exhibit 8).
7. A pre-employment physical is not required, but medical history is discussed during the initial interview (see references in Appendix A - NRC 1997, Occupational Health and Safety in the Care and Use of Research Animals: 9-10, and the *Guide*:14-18). Periodic physical examination are encouraged but not required
8. Employees are trained to perform their tasks so as to minimize personal injury.
9. Employees will be trained in any special precautions necessary for working safely with infected animal models. If an infected animal study is being undertaken, the general containment procedures outlined in this Manual of Operating Procedures will be followed. Special procedures necessary for individual projects will be developed in consultation with the investigators, consulting veterinarian, facilities manager, and LAR Director. These will include proper disposal of carcasses and contaminated bedding. Employee training in these procedures will be provided. These considerations will be included in the AUS during initial IACUC review.
10. Emergency treatment for on-the-job or job-related minor injuries will ordinarily be handled by the employee's supervisor or a co-worker. First Aid kits are available in each facility. Injuries or other health emergencies requiring more than first-aid treatment will be treated at the University of Oklahoma Goddard Health Center, Norman Regional Hospital, or by the employee's personal physician.

B. Professional Conduct

Professional conduct in research and teaching activities and in the care of animals is essential in good scientific practices as well as the assurance of animal welfare. In order to maintain those standards, it is necessary that animal care personnel and animal users follow some general practices. Animals should be treated with respect, and should not be exposed to unnecessary pain nor suffering during the conduct of research and teaching. Only the number of animals necessary to obtain statistically valid results should be used and following these procedures, animals that are collected from the wild should be returned when the study is complete if they are healthy, otherwise animals that cannot be REPATRIATED, should be humanely euthanized by accepted procedures.

C. Veterinary Care

Veterinary service is provided through a Memorandum of Understanding with the OU Health Sciences Center (Appendix B, exhibit 2c). These services include a weekly inspection of animals being housed in the LAR facilities. A record of these visits is documented and any findings that require attention are noted (Website form; Appendix B, exhibit 4f). General animal health care, disease diagnosis, and treatment are provided; pathology and necropsy services are available. Charges may be levied to the PI for these services if the animals have been recently transferred into the laboratory from wild populations and have not been a part of an established population. Workshops for training in surgical techniques, anesthesia, or other specific topics can be developed and consultation for research planning is available.

D. Infectious Disease Containment and Quarantine Procedures

Animal handlers and caretakers must adhere to the following procedures:

Infectious Agent or Hazardous Material Containment: Special safety measures must be followed when handling animals or their wastes where hazardous or infectious material is involved. Animal care personnel should wear appropriate protective clothing, shoes or shoe covers and gloves. When required, face masks

must also be worn in infectious disease areas. Animal waste should be contained inside the animal room and then labeled and disposed of properly.

E. Facilities

Animal Holding facilities are located in eight locations on campus; additional space is available in another building for storage of equipment and supplies.

A central Animal House (Building 63) has an area of 7306 ft² divided in 28-30 rooms. These divisions permit separation of various species. Primary housing for research animals includes rabbits, rats, mice and fishes, as well as short-term housing for animals used in the teaching program (turtles and frogs). An aquarium fish colony is included and has a state-of-the-art closed-recirculation aquaria system. The primary cage washing and bottle washing equipment is installed in this building, and animal carcasses are held here for disposal. The three animal care technicians have offices in this building. Primary records for the animals under the LAR care are maintained in these offices as well as copies of the IACUC-approved AUS protocols. Monthly animal census information is tallied and sent to the LAR office for billing and permanent archiving. The LAR has one room (306 ft²) in the adjacent building (Building 64) for storage of feed, bedding and supplies.

Building	Space-gross (ft²) Number of Rooms	Species Housed in Unit	Approximate Average Daily Inventory (room number & bldg.)*
Animal House Building 063	7,306 28 rooms	White Mice White Mice White Rats White Rats Rabbits Guinea Pigs Centrarchids Poeciliids Poeciliids Leopard Frog, Slider Turtle	(118A AH) (121 AH) 88 (109 AH) 118 (113 AH) 1 (116 AH) 8 (120 AH) 10 (106 AH) (107/108 AH) (104 AH) 30 (122AH) 15 (122AH)
George Lynn Cross (Botany-Microbiology) Building 062	1,235** 4 rooms	White Mice,	43 (907 GLC)
Dale Hall (Psychology) Building 072	830*** 7 rooms	Least Chipmunks, Eastern Chipmunks	44 (48a-d DH) 32 (42 DH)
Physical Sciences (Biochemistry), Building 018	385 4 rooms	White Rats White Mice	5 (414A PS) 38 (414 PH)
Felgar Hall (Bioengineering) Building	360 2 rooms	White Rats	15 (133A FH)
Stephenson Genomic Center, South Campus	1 room	Zebrafish	Inactivated in 2008
Richards Hall (Zoology) Building 058	283 2 rooms	White Rats White Mice	57 (412 RH) 26 (410 RH)

*Average daily animal population; different species are housed in separate rooms; frogs and turtle are housed

< 2 weeks, until they are used in Zoology classes.

**Includes incinerator and cage washer (currently inoperable).

***Housing of chipmunks is in simulated natural open-space environment.

Animal House (Building 63) has an area of 7306 ft² divided in 28-30 rooms and is the central housing facility. These divisions permit separation of various species. Primary housing for research animals includes rabbits, rats, mice and fishes, as well as short-term housing for animals used in the teaching program (turtles and frogs). A zebrafish colony is included and has a state-of-the-art closed-recirculation aquaria system. The primary cage washing and bottle washing equipment is installed in this building, and animal carcasses are held here for disposal. The three animal care technicians have offices in this building. Primary records for the animals under the LAR care are maintained in these offices as well as copies of the IACUC-approved AUS protocols. Monthly animal census information is tallied and sent to the LAR office for billing and permanent archiving. The LAR has one room (306 ft²) in the adjacent building (Building 64) for storage of feed, bedding and supplies.

Richard Hall (Building 058) houses the Department of Zoology where two animal holding rooms provide housing for research animals for adjacent research areas of two PI's. Total floor space for the animal housing is 283 ft. The equipment includes an automatic watering system and habitat enriched cages, primarily as nurseries for white rats and white mice.

George L. Cross Hall (Building 062) houses the Department of Botany and Microbiology; it is adjacent to the above two buildings. The LAR has four rooms for a total of 1,235 ft². Two rooms house mice. The other two rooms are storage; one houses the incinerator (presently inoperative).

Physical Sciences (Building 018) contains four small rooms (total area = 385 ft²), two to house rats and mice and one for feed/bedding storage and one cleaning area. Research laboratories for PI's in the Department of Biochemistry are located nearby.

Dale Hall (Building 072) houses the Department of Psychology. Three rooms are dedicated to LAR (400 ft²); one is an animal housing room, one is a quarantine room, and the other is a cleaning room containing a cage washer. Five other rooms (430 ft²) are research space/housing for chipmunks. Most animals are housed in simulated natural areas which include sand substrate, rock piles and exercise wheels.

Felgar Hall houses various departments in engineering, including the Bioengineering Program. One room (360 ft²) functions as a surgical suite, but includes a partitioned space; the experimental white rats are housed in self-contained, air recirculating, HEPA-filter equipped unit. An adjacent laboratory is used for animal tests.

Stephenson Genomic Center (South Campus) is a new facility which was opened in 2004. It includes a zebrafish colony with a modular self-contained system.

Aquatic Research Facility (South Campus) is an 8-acre designated outdoor research area. It includes 32 experimental ponds (4300 ft² each) supplied with well water (see below for water quality discussion). The facility currently has four 2700 ft² greenhouse laboratories. Two are dedicated to research on fishes, contains studies on aquatic invertebrate and the fourth is a teaching facility. A series of 24 outdoor artificial streams is being constructed for additional fish studies.

F Water Sources

Since the inception of the Animal Care Program at the UONC, the source of water was from deep wells on University land. Water from the same ground water source was the primary water supply for the city of Norman. The water standards are acceptable relative to microbial levels and dissolved materials, but in 2004 the acceptable arsenic level was changed. Relative to the purposes of meeting water quality for aquatic animal, the water source is also suitable (TDS-500 mg/L; total alkalinity = 300-350 mg/L; total hardness = <20 mg/L; pH = 8.5-9.0; total ammonium-nitrogen = <0.5 mg/L; dissolved oxygen is 5-8 mg/L and zero CO₂). Water quality for fishes in aquaria and/or recirculation holding systems is maintained relative to oxygen, metabolic waste accumulation, and bacterial load. These systems vary, depending on the type of life support systems, e.g. aquaria with aeration and enclosed circulation through activated charcoal systems vs. closed, recirculation systems with aeration, biofilters and UV-sterilization. We use both management systems, depending on the species. The latter system is used for intensive-housed colonies of aquarium

species, while the more extensive support systems are used for holding other species which are non-breeding populations. Frogs and turtles require only reasonably clean conditions, but not managed to maintain high water quality conditions needed by fishes.

The Federal and State standards of Arsenic level for potable water became effective in January 2006. The acceptable level changed from 50 ppb to 10 ppb; the average concentration in the University wells has been 17-35 ppb. The University changed to the City of Norman system which had a primary effect on the Animal Care Program. The City of Norman draws water from ground water as well as surface sources; consequently, the water is treated with Chloramines to control microbial organisms. Chloramines are more chemically stable than gaseous chlorine, and thus, not easily stripped by simple aeration. Therefore, to be suitable for aquatic animals, an activated charcoal system would need to be installed for each area which has many difficulties. Also because the current well-water, by the new definition, will no longer be potable, we have not been able to continue using it for animal drinking water (USDA opinion, June 2004). Consequently, because of the necessity of the required non-toxic water quality needed for aquatic organisms, we retained the well-water as our supply for these animals. The supply is labeled, as NON-POTABLE WELL WATER. Water for mammals was changed to the potable city water, but in-line renewable charcoal filters were installed if desired by PI's.

The water for the South Campus Aquatic Research Facility is supplied by five shallow wells (ca 75 ft). The water quality is similar to the well water supply to the main campus, with some important differences. This aquifer has no arsenic contamination, and while the total alkalinity is similar (ca 400 mg/L), total hardness is much higher (300-350 mg/L) and CO₂ gas is 30-40 mg/L. The carbon-dioxide gas is volatilized through aeration before being delivered to fish holding containers. Water temperature is consistent at 20-21°C and DO at about 12 mg/L. This water supply is potable with no required treatment.

G. General Maintenance Procedures

1. Hallways, Corridors and Entryways

Animal housing facilities that are under the control of the LAR personnel will be maintained under neat and clean conditions.

- a) Floors, hallways, corridors and entryways in all LAR facilities will be swept as required to maintain a litter-free condition. Once each day, the floors will be swept and wet mopped to control dust.
- b) Walls, doors, windows and other fixtures will be cleaned as required to maintain a clean and sanitary condition.

2. Feed Storage Rooms

Feed will be stored so as to retain its nutritional value and quality. Excess moisture and high temperatures should be avoided and should be protected from vermin and insect infestations.

- a) Floors will be kept free of all feed and litter. Accidental spills will be cleaned as they occur. Once each day, the feed storage area will be swept thoroughly. When new feed is delivered, the old feed will be removed, the floor swept and the new feed stacked behind the old feed so that a first in, first out rotation can be maintained.
- b) Feed and bedding will be stored off the floor on non pallets or steel shelves with the milling date face-out.
- c) Each delivery of feed will be checked for contract compliance prior to acceptance. The date of receipt, the milling date of each lot and the amounts received will be recorded as permanent records. The age of the feed is determined by the milling date, not the date of receipt.
- d) Feed and bedding stored in each animal room will be stored in covered containers and will not be interchanged between rooms. Each food bin should be labeled to identify the type of feed.

3. Cage Washing Areas

The cage washing area should be maintained in an orderly manner, free from stored equipment or objects that would interfere with maneuvering cage racks into the washer.

- a) All clean cages and equipment will be stored properly on racks or pallets off the floor.
- b) Animals refuse and trash will be placed in plastic bags and the tops closed securely prior to placing them in the dumpsters provided. No trash will remain in the cage washer rooms at the close of the working day. Re-line each trash barrel after dumping and replace lid when not in immediate use.
- c) The floors, walls, sinks and other fixtures will be washed weekly or more frequently if needed.
- d) The cage washer screens will be cleaned as needed but not less than once each month.
- e) The cage washing equipment will be maintained in good operating condition. The LAR technicians will verify the temperatures developed in the cage washers on a routine basis. Temperature monitors will be provided by LAR.
- f) Carts will be disinfected at the end of each day's work and as needed throughout the day. Spray bottles of disinfectant and sponges will be provided for each cart.
- g) Trash barrels will be sanitized weekly and feed containers will be sanitized as they are emptied.
- h) Cages and other animal care equipment will be serviced, repaired and maintained in good working order. It is the responsibility of the individual using the washers and other equipment to ensure that this is accomplished.
- i) The cage dumping room will be sanitized each week.

4. Euthanization

Animals will be euthanized according to acceptable practices (AVMA 2007; Ross and Ross 1999; Kohn et al. 1997; NIH/OACU 2004). Research animals will be euthanized by the various PI's according to approved AUS protocol approved by the OUNC IACUC and on file with the LAR. Some animals will be euthanized as operational necessity of the teaching program and LAR animal care program. One room in the Animal House is suitably equipped and sequestered to conduct these procedures with minimal visibility. Adult rats and mice are euthanized by LAR personnel by carbon dioxide application. Special treatment is given to euthanizing neonate rodents. Pups to 10 days of age will be anesthetized by hypothermia before euthanasia because of the tolerance to hypoxia (Klaunberg et al. 2004). Aquatic animals are euthanized by overdose of anesthesia, or in some instances where appropriate, anesthetized by cooling, then decapitated.

5. Animal Carcass Disposal

The proper disposal of animal carcasses and biological wastes must follow established procedures. Animal carcasses or remains from teaching exercises or from research operations must be delivered to the Animal Care Facility for disposal (Display, Appendix). Carcasses are delivered in plastic bags with appropriate information attached. Material that might be contaminated, will not be routinely included with other biological wastes. Biological Hazardous or Contaminated waste is bagged separately. Material with radioactive contamination is checked by Office of Biohazards to determine the radiation level and whether special disposal is required. The carcasses are frozen and periodically picked up by a commercial disposal company. Waste material is transferred to a commercial disposal company – Stericycle, Inc. (15 NE 47th St., Oklahoma City, OK 73105 – 405-557-0024– www.stericycle.com). The carcasses are frozen and picked up once per week. No laboratory wastes (rubber gloves, sharps, etc.) are to be included as these are to be disposed via other means; rubber gloves will be autoclaved before disposal through usual trash receptacles. When large volumes of material from teaching laboratories will be disposed of, the instructor should notify LAR personnel in advance. The following instructions outline the procedure and specifics are posted on the web as SOP-1.

- a) Animal carcasses to be incinerated will be placed in plastic bags, sealed and placed in the freezer for holding
- b) All animal carcasses (except those with radioactive contents) will be incinerated as soon as possible and no later than each Friday afternoon (See item 5 below).
- c) The incinerator room will be maintained in a clean and orderly condition. The ashes will be removed as needed and placed in metal trash cans for disposal when cool.
- d) Disposal of materials and/or carcasses contaminated with radioactive materials will be disposed of according to procedures established by the University of Oklahoma Radiation Safety Officer. A copy of these procedures is on file in the office of the Lab Animal Resources Animal Facilities Manager.
- e) A commercial operation for disposing of biomedical wastes (www.stericycle.com).

6. Animal Transport Between Holding Facilities

- a) If feasible, animals will be transferred during periods of minimal student activity and they will be transported in containers in a discrete manner and to provide protection from the elements.
- b) Any bedding or feed spills will be swept up immediately. Transport carts will be equipped with a dust pan, whisk broom and disinfectant spray bottle as needed for this purpose.
- c) The electric transport vehicle will be maintained clean and in good mechanical condition according to the recommended maintenance schedule. This vehicle will be operated in a responsible and safe manner, and only by LAR personnel. The vehicle will be stored overnight in a secure area.
- d) The Animal Transfer Form is used to monitor animal movement from the housing facilities to experimental areas (see website for form).

7. Cage Cards

The cage card is one of the most important means of communication between investigators and animal care personnel. Information on special care for the experimental animal is of particular importance. This form of record keeping is an item usually checked during the USDA inspection. Routine information on the card includes: 1) Investigator. 2) Room number – the card goes with the animal as it moves from one room to another. The new room number is added and the previous one is lined through. 3) Species. 4) Strain or Stock – Various strains of animals can express characteristic behavioral differences which may affect care. 5) Date Born/weight or Date Received – If the origin of the animal is from an internal breeding colony, birth date will be known. If the animal is obtained from a commercial source, the receipt date will apply. 6) Sex – M or F or M&F. 7) Source - Source information might facilitate communications with suppliers if needed. Numbers of Animals. 8) Experimental Procedure or Breeding Record – Special husbandry requirements can be communicated. Breeding date allows planning for parturition dates.

8. Treatment Records

Certain treatments or procedures require increased vigilance and communication between the PI and the animal caregivers. Maintenance of a record which is posted in the animal holding facility provides the coordination and the record of observations. Treatment with analgesia beyond the usual post-operative period may require monitoring for efficacy. A daily log of such treatment effects is in force (Appendix B, exhibit 4e). In addition, in the event of water or food deprivation beyond the usual 24-h pre-operative period requires special coordination and observations. A SOP was developed to cover the situations where water/food deprivation is to extend beyond this 24-h period. The procedure is attached and includes the log to record observations (Appendix B, exhibit 4d).

H. Species Considerations

1 - Rabbits

CAGING SYSTEMS

Rabbits will be housed in stainless steel cages with perforated flooring and drop pans. Space allocations will conform to the "Minimum space Recommendations for Laboratory Animals" as published in "The Guide for the Care and Use of Laboratory Animals".

HUSBANDRY PRACTICES

- a) Each morning a thorough examination of the premises and animals contained therein will be made by the responsible animal technician. The room temperature and humidity will be noted and the state of health of each individual cage of animals will be observed. Any abnormalities with the animals will be recorded and reported to the P.I. and the consulting veterinarian. Any discrepancies in the physical condition of the rooms (air conditioning, lighting, utilities, etc.) will be reported to the Manager and/or Physical Plant.
- b) The behavior of animals in cages equipped with automatic watering will be observed to determine that adequate water is available. A manual check of each water nozzle in the automatic watering system will be accomplished on a rotational basis. Check a given number of nozzles each day so that within each 3-day period, all cages have been manually examined. The technicians will assure that animals provided

with water bottles have an adequate supply of fresh, clean water. Water bottles are to be replaced with clean bottles containing fresh water once a week or more frequently as needed.

- c) Feed will be checked daily and additional fresh feed provided as needed. The feeders will be changed for clean ones when changing cages. As racks and cages are sanitized (once each week) discard old remaining feed and refill clean feeders with fresh rabbit chow.
- d) Check each rabbit's ears weekly for signs of ear mites. Oil ears once each month to prevent mite infestation. Clip rabbit nails each month as necessary. Check the teeth of incoming rabbits for malocclusion and continue to check all rabbits bi-monthly for signs of abnormal tooth growth.
- e) Excreta trays of suspended cages will be changed on Mondays, Wednesdays and Fridays with clean trays containing fresh bedding. Soiled excreta trays will be taken to the cage washing area where soiled bedding will be removed and the trays washed in the cage washer. Scale may be removed with mild acid prior to washing. Under no circumstances will soiled trays be left in the hall or cage wash room over night.
- f) Racks and cages will be washed at least once every week in the cage washer.
- g) Floors are to be swept and mopped daily with an appropriate disinfectant-detergent. Maintain clean and debris-free floor drains. In case of low census in a room, less frequent cleaning may be required. This will be determined in consultation with the Lab animal Resources Manager.
- h) Sinks are to be cleaned and clutter-free. Sinks will be cleaned not less than once a week.
- i) Animal holding rooms should be sanitized every other week, or more frequently as needed.
- j) Animal inventory sheets are to be kept current. An inventory (total animal count) will be made as necessary. Inventory information recorded on the last day of each month will be transferred to new inventory sheets on the first day of the succeeding month.
- k) Each cage is to be provided with a cage card indicating name of investigator, number of animals, sex, species, strain, date received, date of birth, weight and source.
- l) Air vents are to be inspected daily and cleaned as needed to insure proper ventilation and room pressure. Visual inspections will determine frequency of filter changes; an increase in animal inventory may require more than one filter change each month.
- m) Noise pollution will be kept to a minimum through careful handling of cages and equipment and sensitivity to voice levels. Playing of radios in animal rooms or within hearing range of the animals is generally prohibited unless specific arrangements are made with the P.I. Smoking is prohibited in all animal rooms and adjacent hallways and during any procedures involving animals.

2. Rodents (Domestic Rats and Mice, Guinea Pigs and Chipmunks)

CAGING SYSTEM

- a) White rats, mice and guinea pigs will be housed in either stainless steel solid bottom poly-carbonate or suspended cages, if required and approved by the IACUC, in accordance to space recommendations listed in "The Guide for the Care and Use of Laboratory Animals" (1996). The solid-bottom caging with bedding is preferred for rats and mice. Therefore, this type of caging will be used for all rodents (except guinea pigs) if the project protocol allows. If wire bottom cages are required for the project, it must be approved by the IACUC.
- b) Guinea pigs will be housed in stainless steel suspended cages and the mesh size of the cage bottoms will be small enough to avoid leg damage; their feet will be examined regularly to counter any irritation.
- c) Chipmunks are primarily housed in simulated natural habitat, where open enclosures with rock structures, sand substrate and other environmental enrichment structures (exercise wheels) are added. Some individuals may be housed for short periods in cages as described for other rodents, but most will be group housed in colonies depending on the study protocol. These chipmunks are captive colonies being maintained under naturalistic habitat study conditions

HUSBANDRY PRACTICES

- a) Each day a thorough examination of the premises and animals contained therein will be made by the responsible animal tech. The room temperature and humidity will be noted and the state of health of each individual cage of animals will be observed. Any abnormalities with the animals will be recorded and

- reported to the P.I. and the consulting Veterinarian. Any discrepancies with the physical condition of the rooms (air-conditioning, lighting, utilities, etc.) will be reported to the Manager and/or the Physical Plant.
- b) The behavior of animals in cages equipped with automatic watering will be observed to determine that adequate water is available. A manual check of each water nozzle in the automatic watering system will be accomplished on a rotational basis. Check a given number of nozzles each day so that within each 3-day period all cages have been manually examined. The technician will assure that animals provided with water bottles have an adequate supply of fresh clean water. Water bottles are to be replaced with clean bottles containing fresh water once a week.
 - c) Feed will be checked daily and additional fresh feed provided as needed. The feeders or wire bar lids will be changed for clean ones at a minimum of once every other week. Discard old feed at this time and supply each cage with fresh rodent chow each week.
 - d) Excreta trays of suspended cages will be changed on Mondays, Wednesdays and Fridays unless otherwise arranged. Trays containing soiled bedding will be removed and transported to the cage dump room where soiled bedding will be discarded. Clean trays will be filled with fresh bedding (Shredded Aspen and mixed hardwood shavings) in the clean room and returned to the cages.
 - e) Solid bottom cages are to be changed twice weekly at not less than 3-day intervals. Clean cages containing fresh bedding will be brought to the ward and the animals transferred from soiled to clean cages. Soiled cages will then be taken to the cage dump room where soiled bedding will be removed. The cages will be washed in the cage washer. Under no circumstances are cages to be emptied of soiled bedding either in the holding room or in the hall. Rack shelves are to be cleaned with a counter broom daily to remove waste and dust. All stainless steel rodent racks will be changed out at least once a month and run through the cage washer.
 - f) Stainless steel cages will be transported to the cage wash room at least twice every month for thorough cleaning in the cage washing machine.
 - g) Floors are to be swept each day and maintained in clean conditions; floor drains will be maintained debris-free. Floors will be mopped at least weekly.
 - h) Sinks are to be kept clean and free of clutter. Sinks will be cleaned not less than once a week.
 - i) Animal holding rooms should be sanitized every other week or more frequently as needed.
 - j) Animal inventory sheets are to be kept current. An animal inventory (total animal count) will be made as necessary or when directed. Inventory information recorded on the last day of each month will be transferred to new inventory sheets on the 1st day of the succeeding month.
 - k) Each cage is to be provided with a cage card indicating name of investigator, number of animals, sex, species, strain, date received, or date of birth, weight and source.
 - l) Air vents are to be inspected daily and cleaned as needed to ensure proper ventilation and room pressure. Visual inspection will determine frequency of filter changes; an increase in animal inventory may require more than one filter change each month.
 - m) Noise pollution will be kept to a minimum through careful handling of cages and equipment and sensitivity to voice levels. Playing radios in animal rooms or within hearing range of the animals is generally prohibited unless specific arrangements are made with the PI. Smoking is prohibited in all animal rooms and adjacent hallways and during any procedures involving animals.

3. Aquatic Animals

Turtles and Frogs - Common slider turtles and leopard frogs are obtained from licensed biological supply houses; occasionally African toad frogs are used as a substitute for leopard frogs. Most are used in teaching laboratories in exercises that have been reviewed and approved by the IACUC. These animals are housed in LAR facilities for ordered for delivery only 1-2 weeks prior to class use. During this period, the animals are housed in aquatic tanks. Turtles are fed trout fish chow pellets and the tanks are subsequently flushed daily, or as needed. Following the holding period, the tanks are scrubbed with Lysol and rinsed. The frogs are fed mealworms and the tanks are flushed after feeding. The tanks are cleaned as described for turtles when the animals have been used. The turtles are appropriately anesthetized and/or euthanized by the instructor during the laboratory exercise as approved by the IACUC.

Fishes – Aquaria range in volume from 3 to 150 L, depending on the species, size and application. Typically we keep zebrafish and other ornamental species in a battery (approximately 1,000) of 3-L aquaria which are arranged into a larger recirculation system. Care of research fishes is assumed by the PI or their designated technician. Total population levels may reach several thousand, depending on the experimental needs. Each aquarium may hold 10-15 adults and the water

turnover is about 3X/h. The water is circulated through a fluidized sand filter, a sand-bag filter, and a reverse osmosis filtration system, aeration and finally UV-chamber before returning to the bank of aquaria. Water quality is monitored regularly to maintain DO near saturation, pH near 7.0., and total ammonia-nitrogen within acceptable levels. Water temperature is maintained within close tolerance to maintain fish in spawning condition and on a 14:10 (L:D) light cycle. Fish are fed to satiation 3X/day; twice on freshly-hatched brine shrimp larvae and once on a fish flake diet. Aquaria are rotated from the system on a 1-2 week schedule; these are then treated with dilute bleach (1:6), rinsed and then passed through the automatic Cage Washing unit.

Native fishes collected from their natural habitat are used in behavioral/hormonal studies. These fishes, currently primarily centrarchids, are kept in aquaria (a total of 30); they are either 80 or 140 L in volume and with naturalized habitat structure and substrate. Unchlorinated well water is used and the water quality is maintained by internal circulation through a floss and activated charcoal filter plus air-stone aeration.

Appendix A

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Guidelines for the care and use of mammals in neuroscience and behavioral research – <http://www.nap.edu>

Methods and welfare considerations in behavioral research with animals – www.nimh.nih.gov/researchfunding/animals.pdf

Information resources on fish welfare – www.nal.usda.gov/awic/pubs/Fishwelfare/fishwelfare.htm

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Exhibit 1a

Semiannual Report of Program Review and Facilities Inspection

**Semi-Annual Inspection & Program Review
Laboratory Animal Resources
University of Oklahoma
Norman, OK 73019
William L. Shelton, Director**

**14 September 2007
Approved 25 January 2008**

PROGRAM REVIEW

The IACUC examines the program of animal care and use on a continuing basis. Issues are presented to the committee as they arise – these are discussed, resolved and action is taken as appropriate. In order to refresh the collective memories of the committee for recent issues that have arisen, a copy of the Annual Report to the IO was distributed in March 2007. This document is submitted to the IO each year to provide information on the activities of the IACUC and LAR; it reviews issues and operations relative to the Institutional Assurance Compliance Document (IACD). We began an examination of the IACD so as to update the document during 2008 in preparation for renewal submission in December 2008. Pertinent issues discussed in the reporting period included USDA re-registration, Veterinary care review, including renewal of MOU with OUHSC, AUS protocols from students, review of status of record tracking mechanism relative to AUS annual reviews and expirations, Training, Risk Assessment and Disaster Plan, and Animal Care Staff transitions. The signatory page for this program review and semi-annual inspection follows this narrative (attachment A).

LAR/IACUC:

IACUC Membership - The composition and complement of the IACUC continues to be in compliance with Federal guidelines.

Staff Transition – The secretary for the LAR, Kate Lovett retired in June after many years of service to the program and the university. Keith Curlee has been reassigned into the animal care-taker position vacated earlier this year. A new technician has been hired and is now in his initial 6-month trial period.

Operations – During the past 6-month period, 18 Animal Use Statement protocols were reviewed including 2 teaching, 7 laboratory and 9 field studies. The administrative mechanism for tracking animal orders, the annual review of protocols, and notification of pending expiration of protocols has been in effect for the past year; 21 annual reviews were completed during this reporting period.

Graduate Student Research - Each year, the LAR Director conducts a New Graduate Student Orientation (see training); these sessions introduce the incoming students to the Animal Care and Use Program on the Norman Campus. During this session, resources are discussed and their responsibility as investigators, PI's, and M.S. and Ph.D. candidates. All are informed that their animal-related research must be reviewed by the IACUC and that they must have a letter of approval before research begins. The only exception is that if the student work will be a component of a project already approved by their thesis chairman; in these cases, their name must appear on the approval letter as critical staff. This policy has been in effect for over a decade and was re-articulated in an announcement on the IACUC website; however, some confusion remained. We are continuing to work with the graduate college so as to clarify various forms, guidelines, and checklists relative to the requirements for graduate students who use live vertebrates in their research.

Training

New Graduate Students – The annual New Graduate Student Orientation was conducted for students from various departments; attending were 15 Zoology, 6 bioengineering, and 2 biochemistry students and 2 new laboratory technicians.

New Faculty – None of the new faculty required animal welfare training; however, as part of the campus-wide new faculty orientation, a brief introduction to the animal welfare program is scheduled for 20 November.

Space Issues

Animal care facilities are not centralized and in most cases they are located in buildings close to the laboratories of the researchers. Memoranda of Understanding are being developed to clarify space responsibilities relative to animal care areas. During the past 6-month period discussions have been initiated with the Botany/Microbiology Department for housing space in GLC Hall and with Chemistry/Biochemistry relative to the Physical Sciences Building, and the proposed construction of the new complex on South Campus. Additional holding space has been developed in the basement of Richards Hall for short-term maintenance of adult lamprey. New holding facilities were developed on the South Campus for short-term housing of song birds in support of related field studies. A MOU was earlier developed with each of department, Zoology and Psychology.

Financial Support

The LAR is a budget unit in the College of Arts and Sciences (CAS). A modest subsistence (per diem) charge is assessed animal users which covers the cost of expendable materials (food, bedding, and cleaning supplies), and more recently, the expense of disposal of biological wastes. All operational costs, including personnel salaries, are borne by the CAS. Historically, researchers who use animals have been members of the CAS; however, increasingly, scientists from the College of Engineering, bioengineering program, are being served by the LAR. While the non-CAS scientists are charged the subsistence fees, no support is received for personnel and operational costs. A meeting with the VP for research has been scheduled to discuss this problem.

New Standard Operating Procedure

A new SOP is being developed by adapting existing NIH guidelines. A draft of a policy on water and food deprivation guidelines was provided to IACUC members and is under consideration for adopting. Withholding of food for periods of less than 24 hours, or food and water prior to operative procedures are not considered 'deprivation'. The intent of the consideration is for uses in behavioral studies where the deprivation provides increased motivation to perform a particular task. Also, poikilothermic animals must be considered by different standards from homeotherms.

INSPECTION OF FACILITIES

The annual CAS Chairs and Directors retreat at the University of Oklahoma Biological Station on 16-17 May 2007 was hosted by the IO, Dean Bell. During this meeting, an independent facility and laboratory inspection was conducted. W. Shelton visited the laboratory of Dr. D. Hambright to review the procedures being used in the golden algae toxicity study. Micro-bioassays were in progress using larval fishes. The teaching and research facilities of the field campus were well kept and maintained. No long-term housing of vertebrates is accomplished.

The committee adjourned the 14 September business session to reconvene with visits to animal housing facilities and select laboratories on the main campus. Richards Hall and the Animal House were included. Only two IACUC member did not participate in the inspection – see signatory page (Attachment A). No serious deficiencies were identified during this inspection; one minor recommendation was posed by the representative from the Environmental Health and Safety Office.

The Richards Hall facility was inspected; this area provides housing for research animals used by neurophysiology scientists in Zoology. The rat room was clean, the animals were healthy, and the cages were properly labeled. The adjacent laboratories were not examined.

The main Animal Holding Facility was inspected. The aging cage and rack washer status was reiterated to the committee. The cage-washing process involves several potentially hazardous chemicals. It was noted that no eye-washing station is available; information on sources will be identified and installation of this safety feature will be accomplished. We anticipate that this issue will be rectified before the next semi-annual inspection. The turtle room was examined. The water was clean and the animals were healthy. The room for housing Guinea pigs was examined but no animals were currently in the room. Cages were in place and ready to receive the next shipment of animals. A daily record of treatment, including analgesia, is being maintained for these animals. One rabbit is

currently being maintained; it is used non-invasively in the teaching program. The aquarium room was in good order, except that a light had a cord that stretched along the floor across a door-way. The PI was notified of this potential safety hazard and he indicated it would be rectified.

The cage preparation room was examined and found to be neat and clean. The feed storage area was being managed properly - feed was being rotated and none was out-dated. The rat breeding room was clean and odor free and cage cards were properly displayed. Emergency power is available in the event of outage; however, distribution within the entire building is not well developed. Emergency lighting is available for the hallways and fire detection and supporting equipment is available.

The inspection culminated at 1245.

Exhibit 1b

**Semi-Annual Inspection & Program Review
Laboratory Animal Resources
University of Oklahoma
Norman, OK 73019
William L. Shelton, Director**

**29 February 2008
Approved 28 March 2008**

PROGRAM REVIEW

The IACUC examines the program of animal care and use on a continuing basis. Issues are presented to the committee as they arise – these are discussed, resolved and action is taken as appropriate. In order to refresh the collective memories of the committee for recent issues that have arisen, a copy of the Annual Report Draft to the IO was distributed in January 2008. This document is submitted to the IO each year to provide information on the activities of the IACUC and LAR; it reviews issues and operations relative to the Institutional Assurance Compliance Document (IACD). We continued our examination of the IACD so as to update the document during 2008 in preparation for renewal submission in December 2008. Pertinent issues discussed in the reporting period included USDA Annual Inspection, AUS protocol forms, review of status of record tracking mechanism relative to AUS annual reviews and expirations, reviews of Training, Risk Assessment and Disaster Plan, and Animal Care Staff. The signatory page for this program review and semi-annual inspection follows this narrative (attachment A).

LAR/IACUC

IACUC Membership - The composition and complement of the IACUC continues to be in compliance with Federal guidelines.
USDA Site Inspection – The USDA/APHIS site visit was accomplished on 21 June 2007 and no non-compliance issues were reported.

Staff Transition – A new LAR Animal Caretaker was hired to return the staffing to three. Micah Dearen was employed in November 2007; she began orientation animal welfare training and on-the-job training. The Animal Facility Manager, Scott Zerger, Facilities Manager, continues in his 30th year with the University; he is a well-trained and registered AALAS Certified LATG, invaluable staff member and he provides a liaison for on-the-job training and supervisor of LAR animal caretakers. The position of Zoology Animal Caretaker was transferred to LAR and Keith Curlee, LAR Animal Care Technician for the past 7 years was reassigned to this position. He currently is an AALAS certified LAT and is registered to sit for the LATG examination. Financial support within the LAR budget is still pending, but the Zoology Department will continue to fund the position until additional funds are developed for LAR to assume a portion of the salary. This transfer to be under LAR supervision (See Attachment B – Organizational chart) will greatly enhance the efficient operations of the animal care program and alleviate concerns over non-compliance of the organizational structure.

Operations – During the past 6-month period, 10 Animal Use Statement protocols were reviewed including 2 teaching, 1 laboratory, 4 field studies and two laboratory & field studies. The IACUC did not meet during November or December – no protocols were submitted. The administrative mechanism for tracking animal orders, the annual review of protocols, and notification of pending expiration of protocols has been in effect for the past year; 5 annual reviews were completed during this reporting period and 10 notifications of pending AUS expirations were sent to PI's.

Graduate Student Research - Each year, the LAR Director conducts a New Graduate Student Orientation; the next scheduled session will be August 2008. Interim training is conducted as needed. These sessions introduce the incoming students to the Animal Care and Use Program and the resources on the Norman Campus; their responsibility as investigators, PI's, and M.S. and Ph.D. candidates are discussed. All are informed that their animal-related research must be reviewed by the IACUC and that they must have a letter of approval before research begins. The only exception is that if the student work will be a component of a project already approved by their thesis chairman; in these cases, their name must appear on the approval letter as critical staff. This policy has been in effect for over a decade and was re-articulated in an announcement on the IACUC website; however, some confusion remained. We have provided all corrected information to the graduate college so as to clarify various forms, guidelines, and checklists relative to the requirements for graduate students who use live vertebrates in their research.

Training

New Students – Subsequent to the annual New Graduate Student Orientation in August 2007, two new graduate students and four undergraduates have received orientation training.

New Faculty & Post-docs – One new faculty member and one new post-doc were given orientation training to the animal welfare program and one new post-doc. As part of the campus-wide new faculty orientation, a brief introduction to the animal welfare program was presented to new faculty on 20 November 2007; however, none of these will be animal users.

Staff – All staff completed University required safety and sexual harassment training. Ongoing professional training and certification for animal caretakers as discussed above.

Space Issues

Animal care facilities are not centralized and in most cases they are located in buildings close to the laboratories of the researchers. Memoranda of Understanding have been developed to clarify space responsibilities relative to animal care areas. New holding facilities are in the planning stages new Stephenson Life Sciences complex on South Campus.

Financial Support

The LAR is a budget unit in the College of Arts and Sciences (CAS). A modest subsistence (per diem) charge is assessed animal users which covers the cost of expendable materials (food, bedding, and cleaning supplies), and more recently, the expense of disposal of biological wastes. All operational costs, including personnel salaries, are borne by the CAS. Historically, researchers who use animals have been members of the CAS; however, increasingly, scientists from the College of Engineering, bioengineering program, are being served by the LAR. While the non-CAS scientists are charged the subsistence fees, no support is received for personnel and operational costs. This situation was discussed with VP for research and Engineering Deans in 2007. Cost Centers will be developed for pertinent charges to include wage expenditures.

New Standard Operating Procedure

A new SOP was developed and approved by the IACUC for water and food deprivation guidelines. Withholding of food for periods of less than 24 hours, or food and water prior to operative procedures are not considered 'deprivation'. The intent of the consideration is application to behavioral studies where the deprivation provides increased motivation to perform a particular task. Poikilothermic animals are to be considered by different standards from homeotherms.

INSPECTION OF FACILITIES

The committee adjourned the 29 February IACUC business session to reconvene with visits to animal housing facilities and select laboratories on the main campus; Dale Hall and the Animal House were included. Three IACUC members were not present for the inspection – see signatory page (Attachment A). No serious deficiencies were identified during this inspection. The recommendation by the representative from the Environmental Health and Safety Office to install an eye-wash station in the animal house was accomplished since the previous inspection.

The main Animal Holding Facility was inspected. The cage-washing process involves several potentially hazardous chemicals. As noted above an eye-washing station has been installed. The turtle room was examined. The water was clean and the animals were healthy. The room which contains a mouse colony underwent renovation during the past few months – new wall coating and ceiling

repairs were accomplished. The room for housing Guinea pigs was examined and contained animals which appeared well cared for and in good health. A daily record of treatment, including analgesia, is being maintained for these animals. One rabbit is currently being maintained; it is used non-invasively in the teaching program. The aquarium room was in good order.

The cage preparation room was examined and found to be neat and clean. The feed storage area was being managed properly - feed is being rotated and none was out-dated. The rat breeding room was clean and odor free and cage cards were properly displayed. Emergency power is available in the event of outage; however, distribution within the entire building is not well developed. Emergency lighting is available for the hallways and fire detection and supporting equipment is available.

The animal holding space and experimental facilities in Dale Hall were examined. Chipmunks are the animal model used in this facility; studies are conducted on the food cache behavior. The housing is primarily simulation of natural habitat including rock pile structure. Some animals briefly caged have environmental enrichment in the form of exercise wheels.

The inspection culminated at 1300.

Exhibit 2a**Zoology Department Space MOU**

SUBJECT: Memorandum of Understanding between the Department of Zoology and the Laboratory Animal Resources Program of the University of Oklahoma

DATE: 16 May 2003

Introduction

The objective of this MOU is to ensure the continuation of uniform quality care for animals used for research and teaching at the University of Oklahoma and to facilitate the optimal use of shared resources and facilities.

Background

The Department of Zoology has been conducting animal research and teaching since the inception of the University. Departmental animal care was in effect long before a structured program was mandated by the Federal Government. In recent decades the Department has had continuous appointment of an Animal Caretaker. Departmental personnel were instrumental in obtaining funds to develop one of the contemporary holding facilities on campus and in pioneering much of the infrastructure used in the current Laboratory Animal Resources (LAR) Program.

When animal research was started by faculty in other departments, each developed their own holding facilities, and there was little standardization of animal care. The advent of the Animal Welfare Act (AWA - 1966) and other Federal legislation started a new era in animal care and use whereby uniform standards for care and guidelines for humane use were promulgated. These regulations mandate that each institution that uses animals in teaching and/or research must establish an animal care program and provide the necessary resources to operate it, and further, to maintain an oversight committee (Institutional Animal Care and Use Committee – IACUC) that ensures compliance.

The Laboratory Animal Resource Program of the University of Oklahoma, Norman Campus is the designated institutional animal care and use entity. The LAR is registered with the U.S. Department of Agriculture (USDA) and operates under an Animal Welfare Assurance Statement approved by Public Health Service (PHS); it reports to these agencies through the Institutional Official (IO), which on the Norman campus is the Dean of the College of Arts and Sciences. The LAR functions in accordance with AWA, PHS Guidelines and related Federal regulations. The IACUC is an independent, self-monitoring entity that has compliance oversight for the LAR in their animal care role and related institutional animal use in teaching and research. The IACUC must inspect the animal care facilities and departmental research areas each 6 months and report any deficiencies to the IO; an action plan is required to correct any problems and a time line must be defined. The operational procedures of the LAR for animal care are reviewed by the IACUC annually, including records of animals used relative to approved protocols, minutes of meetings, training, and other compliance requirements.

Substance of Agreement

The animal care and use program must operate with clear lines of authority and responsibility as described in the Institutional Assurance Statement (IAS). The attached organizational chart illustrates the approved structure for the University of Oklahoma, Norman Campus and generally depicts the current operational relationships. Animals are cared for by employees of LAR and the

Department of Zoology. In order to ensure continued compliance with the Institutional Assurance document, some relationships need clarification so as to avoid operational ambiguity. Therefore, the LAR and Department of Zoology agree on the following items:

- 1) Animals are currently housed in Dale Hall, Felgar Hall, G.L. Cross Center, Physical Sciences Building, Richards Hall and the Animal Facility; other locations may be added with the creation of new programs. Care of the animals is the responsibility of LAR, and will be accomplished by the three primary animal caretakers employed by LAR and Zoology.
Workload will be equitably shared without regard to budget units of animal users.
- 2) Animal care will be in accordance with the LAR Standard Operating Procedures and the Assurance Document; personnel will be expected to participate in any pertinent training.
- 3) Animal users with grant support will be expected to pay a fair subsistence (per per diem). Fees are posted on the LAR website. Rates are set to cover the cost of expendable supplies and the schedule is in compliance with federal guidelines as approved through research administration. Any change in fee structure will be through mutual agreement with parties involved. Compensation will be waived for PI's without extramural support and for animals used in teaching.
- 4) The LAR will purchase feed, bedding and cleaning supplies for all animals under its care, provide routine daily care and maintain veterinary service for regular health care.
- 5) Cages and other housing equipment will be maintained and supplied by LAR, except for specialized items that might be required for specific studies.

William L. Shelton
LAR Director

James N. Thompson Jr.
Zoology Chair

William J. Matthews
Zoology Chair-Designate

Exhibit 2b

Animal Technician – Zoology/LAR MOU



The University of Oklahoma

DEPARTMENT OF ZOOLOGY

MEMORANDUM OF UNDERSTANDING

5 January 2007

This document sets forth an arrangement between the Department of Zoology and the office of Laboratory Animal Resources (LAR), as discussed and agreed to during a meeting on 19 December 2006, attended by Paul B. Bell (Dean of College of Arts and Sciences), Kelly Damphousse (Associate Dean, College of Arts and Sciences), William Shelton (Director of LAR), and William Matthews (Chair of Zoology Department).

We agreed that:

There is a continuing need for laboratory animal care on the University campus, which falls under the immediate supervision of LAR. This need was formerly met, in part, by availability of an Animal Caretaker staff line salaried full time in the Zoology Department. The individual in that line has recently retired.

A new position of Animal Caretaker (Zoology Animal Care Supervisor) will be established within LAR. The position will be advertised by, and the selected individual will report to, the Director of LAR; all administrative support will be provided by the LAR. The person will not be a staff member in the Zoology Department.

Funds for the position will be provided by the Zoology Department by annual transfer of funds to LAR so long as this arrangement is in force, but the funds will remain permanently in the existing line within the Zoology budget.

All requisite labor for animal care in Zoology will be provided by LAR, with appropriate per diem charged per established rates.

The principles outlined above will remain in force unless modified by agreement among the Dean of CAS, the Director of LAR, and the Chair of the Zoology Department.

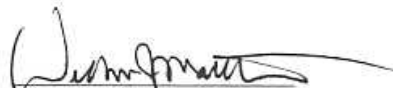
Agreed to as signed below:


Paul B. Bell, Dean, CAS

Date: 1/16/07


William Shelton, Director, LAR

Date: 5 Jan 2007


William Matthews, Chair,
Department of Zoology

Date: 5 Jan 2007

**MEMORANDUM OF UNDERSTANDING (MOU)
FOR PROFESSIONAL AND TECHNICAL SERVICES**

OUHSC Principal Investigator: Stanley Kosanke, DVM, Ph.D.

This Memorandum of Understanding ("MOU") is entered into by and between the University of Oklahoma, Health Sciences Center on behalf the Animal Resources Division ("OUHSC"), and the University of Oklahoma, College of Arts and Sciences, Norman, Oklahoma ("OU Norman").

A. OUHSC agrees to provide OU-NORMAN with both veterinary clinical and pathology professional consulting services.

B. The term of this MOU shall be from July 01, 2008 through June 30, 2011. This MOU may be terminated by either party without penalty or prejudice with thirty (30) days prior written notice to the other party. Either party may terminate this MOU immediately upon written notice to the other party in the event of material breach of this MOU.

C. OUHSC will provide the following services to OU-NORMAN:

Clinical Services:

1. Clinical consultation, both by phone and on location at OU-NORMAN regarding animal health and management related problems
2. Interpretation of results of clinical problems
3. Evaluation of the health and maintenance of the experimental animals

Pathology Services:

1. Necropsy and histopathologic evaluation of experimental animals that become clinically ill or die unexpectedly
2. Written report of the clinical and histological findings

Other Services:

1. Assistance with manuscript preparation, grant applications and renewals
2. Site visits requiring veterinary consultation
3. Provision of a veterinarian to attend OU-NORMAN Animal Care and Usage Committee meetings and to evaluate pending Project Reviews that require animal usage

D. OU-NORMAN shall pay OUHSC \$1,030.00 per month for professional services described above. Total cost for services are \$12,360.00 per year.

E. OUHSC will invoice OU-NORMAN monthly for the professional and technical services. OU-NORMAN will pay OUHSC no later than forty-five (45) days following receipt of the invoice. OUHSC will also invoice OU-NORMAN separately for the cost of technical services such as clinical laboratory tests, slide preparation, technician time and

transfer of supplies. OUHSC will invoice separately for laboratory services. Charges may be transferred to an Investigator when and/or if animals have not been part of an established animal population.

F. Upon request of OUHSC, OU-NORMAN shall permit any representative of the State, University, or other authorized agency with jurisdiction over the University to conduct a site visit and inspect and audit the books and records of OU-NORMAN related to the services, items, or responsibilities provided or to be provided hereunder.

OUHSC

OU NORMAN

Lisa C. Asch 8-5-08
Lisa C. Asch, MS, MPH, CRA Date
Associate Director
Office of Research Administration
1000 Stanton L. Young Blvd., Lib 121
Oklahoma City, OK 73117

Paul Bell, Jr. 8/11/08
Paul Bell, Jr., Ph.D. Date
Dean, College of Arts and Sciences

Read and Acknowledged:

Stanley D. Kosanke 08/10/08
Stanley Kosanke, DVM, PhD Date

Exhibit 3a

**IACUC Forms – Compressed Display
Teaching AUS – Cover Sheet**

Project number: T

TEACHING COVER SHEET
ANIMAL USE STATEMENT

Course Number & Title:
 Period of Approval (3 years): Course Frequency Enrollment cap.
 Instructor(s) Name: Signature: Date:
 Experience with this Course:
 Campus Address:
 Telephone: E-Mail:
 Class exercises include the following Animal Use categories:
 Field study involving no manipulation or significant disturbance of animals (see Teaching Form I)
 Field study involving manipulation or disturbance of animals (see Teaching Form II)*
 Laboratory study (see Teaching Form III)
Mail material to: Or deliver to:
 Laboratory Animal Resources William L. Shelton
 Zoology Department LAR Office
 Richards Hall Sutton Hall 308c
 FAX: 325-7031 Telephone: 325-2609

* It is assumed by the IACUC that instructors have the appropriate Scientific Collectors Permits

IACUC Action: Approve _____ Deny _____ Defer _____
 IACUC Agent Signature: _____
 DATE: _____

Revised 10/02

Exhibit 3b

**Teaching AUS Form I – Field Exercise w/o manipulation
AUS TEACHING FORM I**

CLASS FIELD EXERCISES THAT INVOLVE NO MANIPULATION OF ANIMAL SUBJECTS

COURSE:

INSTRUCTOR(S):
 NARRATIVE DESCRIPTION OF ANIMAL USE
 Briefly describe the use of animals in the class, to include:
 (1) Kinds of observations to be made.
 (2) How observations are to be made.
 (3) The degree and type of observer/animal interactions.

Exhibit 3c

Teaching AUS Form II– Field Exercise with Manipulation
AUS TEACHING FORM II

FIELD EXERCISES INVOLVING MANIPULATION OR SIGNIFICANT DISTURBANCE OF ANIMALS

A. CLASS NAME AND EXERCISE(S)

B. EXERCISE DESCRIPTION(S)

Describe each different procedure in which animals are used. You may provide a copy of the exercise description given to the student; some additional information may be needed. If not included, describe for each experiment as appropriate, species, capture methods, and whether experimental procedure will cause the animals' pain or distress. How long will captured animals be held until processed? Will animals be released, marked, and recaptured? If the animals are killed, what is the method of euthanizing. If animals are retained alive for a subsequent laboratory study, see Teaching Form III.

C. JUSTIFICATION FOR THE NUMBER OF ANIMALS

List the maximum numbers of various species to be used in each exercise; consider whether the procedure(s) will be a group activity, or if each student processes their own samples? Multiple sections?

¹ Revised 10/02

Exhibit 3d

Teaching AUS Form III – Laboratory Exercise
AUS TEACHING FORM III
LABORATORY EXERCISE INVOLVING LIVE ANIMALS

A. CLASS NAME AND EXERCISE(S)

B. EXERCISE DESCRIPTION(S)

Describe each different procedure in which animals are used. You may provide a copy of the exercise description given to the student; some additional information may be needed. If not included, describe for each experiment as appropriate, species, capture methods, and whether experimental procedure will cause the animals' pain or distress. How long will captured animals be held until processed? Will animals be released, marked, and recaptured? If the animals are killed, what is the method of euthanizing. If animals are retained alive for a subsequent laboratory study, see Teaching Form III.

C. JUSTIFICATION FOR THE NUMBER OF ANIMALS

List the maximum numbers of various species to be used in each exercise; consider whether the procedure(s) will be a group activity, or if each student processes their own samples? Multiple sections?

¹ Revised 10/02

Exhibit 3e

Research AUS - Cover Sheet

PROJECT NUMBER: R

**RESEARCH COVER SHEET¹
ANIMAL USE STATEMENT**

(TO BE ATTACHED TO THE FRONT OF EACH ANIMAL USE STATEMENT)

DATE: _____ **PROPOSED PERIOD OF INVESTIGATION:** _____

TITLE OF PROJECT: _____

SPONSORING AGENCY: _____ **DEADLINE:** _____

PRINCIPAL INVESTIGATOR: _____ **SIGNATURE:** _____

KEY PERSONNEL: _____

CAMPUS ADDRESS: _____ **TELEPHONE:** _____ **E-MAIL:** _____

Check ONE of the following Animal Use categories:

_____ **Field Study involving no manipulation of animal subjects
(Complete FORM I only)**

_____ **Field Study involving manipulation of animal subjects
(Complete FORM II only) ***

_____ **Laboratory Study**
(Complete FORM III only)**

_____ **Combined Field and Laboratory Study ***
(Complete FORMS II and III)**

Mail forms to: (wshelton@ou.edu)
Laboratory Animal Resources
Zoology Department
Richards Hall
FAX: 325-7031

Or Deliver to:
William L. Shelton
LAR Office
Sutton Hall 308c
Telephone: 325-2609

* It is assumed by the IACUC that investigators have acquired all appropriate Scientific Collectors Permits.

** PI's must meet appropriate drug license requirements when controlled substances are involved.

*** Animals collected from the field for study in the laboratory must be covered by appropriate state licenses and should be quarantined until health inspection is completed; copies of health forms will be provided to LAR.

IACUC Action: Approve _____ **Deny** _____ **Defer** _____

IACUC Agent Signature: _____ **Dat** _____
Exhibit 3f

Research AUS Form I

¹ Amended 2007

Field Experiment w/o Manipulation

DATE:

TITLE OF PROJECT:

PRINCIPAL INVESTIGATOR:

PERSON RESPONSIBLE FOR PROJECT OVERSIGHT:
(IF OTHER THAN THE PRINCIPAL INVESTIGATOR)

NARRATIVE DESCRIPTION OF THE PROJECT
Briefly describe your study in lay terms. Include:

- 1) The scientific purpose of the study.
- 2) A description of the kinds of observations to be made, how they are made, and the manner and degree of interaction of the observer with the animal subjects.

Revised 10/02

Exhibit 3g

**AUS RESEARCH FORM II
FIELD STUDIES INVOLVING
MANIPULATION OF ANIMAL SUBJECTS**

TITLE OF PROJECT:

PLEASE CHECK ONE OF THE FOLLOWING:

- STUDY INVOLVES NO SIGNIFICANT PAIN OR DISTRESS TO ANIMALS.**
(Greater than that experienced through administration of an anesthetic, analgesic or tranquilizer by simple injection, or as experienced through mild electric shock. **Significant distress** would cause a change in normal food and water uptake, movement, or other obvious behavioral characteristics.)
- STUDY INVOLVES THE USE OF APPROPRIATE ANESTHESIA, ANALGESIC OR TRANQUILIZER TO AVOID PAIN OR DISTRESS.**
- STUDY INVOLVES PAIN OR DISTRESS WITHOUT ADMINISTRATION OF APPROPRIATE ANESTHETIC, ANALGESIC OR TRANQUILIZER (MUST BE JUSTIFIED IN NARRATIVE)**

A. NARRATIVE DESCRIPTION OF THE STUDY

Briefly describe the study in lay language, but it must include the following:

- 1) The scientific purpose of the project.
- 2) Describe the role of animals in the project.
- 3) Describe procedures which may cause pain and/or distress to the animals and justify.
- 4) Describe the types of animals in the study (SIZE, HABITAT, BEHAVIOR, ETC.)

Revised March 08

B. ANIMALS PROPOSED FOR THE STUDY

- 1) List the species and estimated number of animals to be used in the project.
Be sure to include animals required to train personnel in your total. Give common and scientific names of the animals if applicable.

SPECIES

ESTIMATED NUMBER

- a)
b)

2) JUSTIFICATION FOR NUMBER OF ANIMALS USED

This is a very important part of the Animal Use Statement. One objective of protocol review is to optimize the number of animals used in research. The estimate of the total number of animals required for a project **should be explained** in sufficient detail that the IACUC can understand how the number was obtained (**HOW MANY ANIMALS PER SITE X NUMBER OF COLLECTIONS**). If based on statistical analysis, you should indicate which tests were employed, the power value assigned, the numbers of animals in the control and test groups, respectively, and the number of replications proposed. In population censuses, statistical analysis may not be appropriate. If animals are collected through trapping, you should identify and justify an upper number of animals of each type that will be collected. This can be based on your previous experience, review of the pertinent literature, etc. If animals are batch collected, as in seining or mist netting, an upper number of collection events (i.e., seining, netting the experimental sites) should be identified and justified. As above, personal experience, literature review, etc. can serve as a basis for these estimates.

C. EVIDENCE OF NON-DUPLICATION

Use Science Citation Index, National Agricultural Library, etc. or other literature search engines to verify that research does not involve duplication and that 3 R's were considered if necessary; provide indices searched and key words or phrases.

D. FIELD STUDY PROTOCOL

- 1) Are the animal subjects of this study captured in any way?

_____ yes _____ no

- 2) If captured, how?

_____ Live Trapped (live traps include mist nets, gill nets, pitfalls, etc.)
 _____ Hand captured
 _____ Killed
 _____ Seined

- 3) Describe the trapping mechanism, including the mechanism by which kill traps cause death.

- 4) If the animals are live trapped:

a) How often will the traps be checked?

b) Are trapped animals protected from predation?

_____ yes _____ no

c) If they are not protected from predation, justify why not.

d) Will food be provided while the animals are confined in the traps?

_____ yes _____ no

e) Will water be provided while the animals are confined in the traps?

_____ yes _____ no

f) If food and/or water are not provided, justify why not.

g) Will shade be provided?

_____ yes _____ no

h) If shade is not provided, explain why not.

- 5) Will the captured animals be euthanized rather than released?

_____ yes _____ no

- 6) If yes, describe the method.

(NOTE: If the ability of animals to survive in the wild has been significantly compromised by physical damage through taking tissue samples or by extended

holding in the laboratory environment, euthanasia may be a more humane treatment than to release into the wild.)

7) If released, will they be marked for future identification?

_____ yes _____ no

8) If they are marked for future identification, describe the marking procedure.

9) Will tissues, blood samples, etc. be taken from the animals?

_____ yes _____ no

10) If tissues, blood, etc. are collected, describe the procedure.

11) Will captured animals be transported alive to the laboratory for study?

_____ yes _____ no

(If yes, complete FORM III - Laboratory Study)

Exhibit 3h

AUS RESEARCH FORM III
LABORATORY STUDIES OF ANIMALS

TITLE OF PROJECT:

PLEASE CHECK ONE OF THE FOLLOWING:

_____ STUDY INVOLVES NO SIGNIFICANT PAIN OR DISTRESS TO ANIMALS.

(Greater than that experienced through administration of an anesthetic, analgesic or tranquilizer by simple injection, or as experienced through mild electric shock. **Significant distress** would cause a change in normal food and water uptake, movement, or other obvious behavioral characteristics.)

_____ STUDY INVOLVES THE USE OF APPROPRIATE ANESTHESIA, ANALGESIC OR TRANQUILIZER TO AVOID PAIN OR DISTRESS.

_____ STUDY INVOLVES PAIN OR DISTRESS WITHOUT ADMINISTRATION OF APPROPRIATE ANESTHETIC, ANALGESIC OR TRANQUILIZER (MUST BE JUSTIFIED IN NARRATIVE).

A. NARRATIVE DESCRIPTION OF THE PROJECT

Briefly describe the study in lay language, but it must include the following:

- 1) The scientific purpose of the project.
- 2) Describe role of animals in the project.
- 3) Describe the procedures that may cause pain and/or distress to the animals and justify.

B. ANIMALS PROPOSED FOR THE STUDY

- 1) List the species and estimated number of animals to be used in this project. Be sure to include animals required to train personnel in your total. Give common and scientific names of the animals if applicable.

SPECIES

ESTIMATED NUMBER SOURCE

a)

b)

Revised March '08

2) JUSTIFICATION FOR THE NUMBER OF ANIMALS TO BE USED

This is a very important part of the Animal Use Statement. One objective of protocol review is to optimize the number of animals used in research. Justification may be based on a calculation of animals required to provide sufficient tissue for enzyme preparation, or the minimum required to give statistically valid results. Base calculations on your personal experience in similar studies, or from initial studies outlined in this Animal Use Statement. Include references, types of statistical tests, the power analysis, if appropriate, considering the expected variance, mean difference and degree of reliability (power analysis information is available upon request).

C. EVIDENCE OF NON-DUPLICATION

Use Science Citation Index, National Agricultural Library, etc. or other literature searches to verify that research does not involve duplication and that the 3-R's were considered where required; provide search indexes and key words.

D. PROTOCOL

1) Housing

a) Where will the animals be housed?

Building: _____

Room Number: _____

b) Will the animals be individually _____ or group _____ housed?

c) Describe the caging and other housing conditions if different from the standard housing provided by LAR.

d) Describe any special requirements for animal care (i.e., special diet, light-dark cycle, bedding change schedule, etc.).

2. Invasive Procedures (injections, incisions, invasion of body cavities such as insertion of gastric tubes, rectal thermometers, etc.)

a) Describe any invasive procedures.

b) Are anesthetics, analgesics and/or tranquilizers used to alleviate pain and/or distress arising from the invasive procedures?

_____ yes _____ no

If yes, list the drugs and dosages used, and describe the method of administration.

If no, justify why such drugs are not utilized.

c) Describe any anesthetizing procedure other than routine administration of drugs or inhalants that you may use to alleviate pain and/or distress (e.g., cooling the animal, etc.).

d) If anesthetics, analgesics and/or tranquilizers are used, how did you determine the appropriate drug(s), etc., dosage (i.e., literature review, consultation with veterinarian, personal experience with the system, etc.)?

(NOTE: LAR has a contractual agreement with the veterinary staff at the Health Sciences Center to provide veterinary services and consultation.)

e) Will the invasive procedures be performed under aseptic conditions?

_____ yes _____ no

If no, explain why aseptic conditions are not followed.

f) If the animals are anesthetized during the invasive procedure, will they be allowed to recover from the anesthetic effects?

_____ yes _____ no

If yes, describe measures taken to alleviate post-procedural pain and distress.

If measures will not be taken to alleviate post-procedural pain and/or distress, explain why not.

3. FINAL DISPOSITION OF ANIMALS

a) At the conclusion of the study, will the animals be:

Euthanized
 Returned to Housing

b) If euthanized, describe the method of euthanasia.

Exhibit 3i

REQUEST TO AMEND AN ANIMAL USE PROTOCOL

1. ORIGINAL TITLE OF PROJECT and PROJECT NUMBER

2. ORIGINAL INVESTIGATOR

Principal Investigator

Department

Phone

email

3. PROPOSED AMENDMENTS TO THE EXISTING PROTOCOL

The Principal Investigator proposes to amend IACUC AUS project because of:

A. Project Extension (Only if AUS was approved for less than three years)

B. Add personnel working on this project

C. **Procedural** change: New Additional

D. **Funding:** New or Additional

E. Number of animals to be used is changed:

Species: # originally approved: additional # requested:

Signature of Principal Investigator

Date

Approval Signature of IACUC Chair

Date

**TRAINING PROGRAM – UNIVERSITY OF
OKLAHOMA IACUC**

“It is the responsibility of the institution to ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities.” The development and implementation of a training program are usually performed by the IACUC, the veterinary staff, and investigators using animals.

Orientation

1. Principal Investigators new to the Institution
 - a. Personal meeting with LAR Director to discuss Animal Care Program, including facilities, IACUC operations, Regulations, Policies and Guidelines for animal care and use to include pain and 3R's.
 - b. Establish personnel file that documents credentials and experience.
 - c. Complete on-line tutorial - PHS Policy on Humane Care & Use of Lab. Animals. (<http://grants.nih.gov/grants/olaw/tutorial/index.htm>)
 - d. Discuss website and procedures for filing Institutional AUS.
2. New Graduate Students – Orientation for incoming students (August of each year)
 - a. Introduction to animal regulations and Institutional Animal Care and Use Program and filing of AUS.
 - b. Introduce on-line tutorial - PHS Policy on Humane Care & Use Lab. Animal.– see above
 - b. More detailed follow-up in Professional Aspects (required course for all graduate students in Zoology, which includes professional ethics, proposal writing, etc.).
3. New IACUC members
 - a. Survival Manual – SOP, OU Assurance Statement, IACUC Handbook (CRC), Guide (NRC), Code-Title 9 (USDA), IACUC Committee Guidebook (OLAW), field guides [fish, Birds, mammals and herptiles, and discussion of links (www.aalas.org)].
 - b. Encourage completion of VA on-line tutorial –Essentials for IACUC Members (www.researchtraining.org) - Access code/on-line testing.
 - c. NIH Introduction to Animal Care & Use Committees (www.researchtraining.org).
4. LAR Personnel
 - a. AALAS certification (www.aalas.org).
 - b. On-the-job training, including familiarization with IACUC operations, regulations and guidelines, and Occupational Health and Safety issues.
5. Lab Technicians & Undergraduate Students – Student research
Assistants and Technicians receive training on animal care and welfare issues and specific training from PI on experimental protocols; Occupational Health and Safety and health hazards are included. SEE FORM BELOW.

Ongoing Training

All receive annual training in appropriate safety areas (e.g. radiation, chemical, etc.) through the Institutional Environmental Health and Safety Office (<http://www.ou.edu.ehos>) and LAR Occupational Health Information for research investigators, technicians and students, relative to the animal types in their respective activities (see forms on LAR website under Training (iacuc.ou.edu)).

1. IACUC Members
 - a. Periodic refresher training on regulations and AUS review procedures
 - b. Semiannual Program Review and facilities inspection provide review of regulations and guidelines.
 - c. Review of AUS provide continuous review of issues for animal welfare relative to care and use.
2. PI's
 - a. Encouraged to access NIH Refresher Course Series, Refresher Course for PI's
 - b. Specific training workshops – Technique/species oriented
3. LAR Staff
 - a. Annual meetings of AALAS – one staff each year
 - b. OLAW IACUC 101 shortcourses – as available.
4. Technicians, graduate students
 - a. Laboratory animal care training on handling and safety, etc.
SEE FORM BELOW
 - b. Appropriate on-line tutorials
 - c. Review AUS of PI relative to thesis research or job responsibilities.

Amended May 2008

University of Oklahoma Institutional Animal Care and Use Committee (IACUC)

This form must be completed by all Staff and Students (undergraduate and graduate) prior to their involvement in vertebrate animal research. A separate form is required for each individual and The form must be cosigned by the Faculty Advisor and a representative of the Laboratory Animal Resources Program.

Faculty Investigator: _____

Training Areas (Please check off when completed):

I have:

____ Familiarized myself with the contents of the Tutorial on the “Public Service Policy on Humane Care and use of Laboratory Animals”

<http://grants.nih.gov/grants/olaw/tutorial/index.htm>

Read the following Chemical Safety Publications and the Occupational Health Fact Sheets:

- ____ Proper Handling & Utilization of Chemicals in a Lab Animal Care Facility .
- ____ Personal Hygiene
- ____ Human Allergies to Animals
- ____ Immunosuppression and Working with Animals
- ____ Animal Bites and Scratches
- ____ Rat Bite Fever
- ____ Salmonellosis

Signature: PI. _____ LAR: _____

Exhibit 4b

University of Oklahoma, Norman Campus
Animal Procurement, Use, and Disposal Procedures¹

All Investigators must follow the appropriate procedures of the University of Oklahoma, Norman Campus LAR for procurement, use, and disposal of laboratory animals.

Ordering

- a. Complete the animal order form (see Web) and send to LAR.
- b. Receive confirmation from LAR to proceed with order.
- c. Call in order as described.
- d. Be available to receive the animals at delivery location.

Receiving

- a. Receive animals and place in the appropriate cages.
- b. Investigators will be responsible for the welfare of animals until they are delivered to the Animal Facilities.

Housing

- a. Housing location will be determined by the Office of Lab Animal Resources, with the Investigator's concurrence.
- b. Location of the research and well-being of the animals will be primary concerns.

Disposal

- a. Deliver to the freezer in the Animal House for disposal.
- b. Carcasses will be placed in plastic bags; no laboratory or surgical trash should be included.
- c. Identify contents on a label, include investigator's name, and whether contents have biohazards, infectious, or radioactive materials.

¹ SOP-1, Nov 2003

Exhibit 4c

Animal Order Confirmation Form

Complete this form and send it to:

Director, Laboratory Animal Resource, Dept. of Zoology, Richards Hall, Room 314.
Project Name & Animal Use Statement Number (R0X-XXX)

Project Number or Course Number: _____
Principal Investigator/ Instructor: _____ Phone Number: _____
Housing of Animals: Building: _____ Room#: _____
Single : _____ Group: _____ Number of Animals Per Cage: _____
NOTE: Animals will be segregated by sex unless otherwise directed.

Ordering Information:
Vendor: _____ Phone Number: _____
Name of Person Placing the Order: _____
Species: _____ Sex: _____ Strain/Stock _____
Weight/Age: _____
Date Ordered: _____ Expected Deliver Date: _____
Deliver Animals to: _____
Special Requirements:

Order Form Received in LAR office: _____ by: _____

Processed Form will be sent to P.I. and Facilities Manager

Exhibit 4d

Water/food deprivation SOP & Form

Approved October 2007

GUIDELINES FOR DIET CONTROL IN BEHAVIORAL STUDIES* (does not apply to pre-surgical *per os* restriction)

Behavioral research often requires that an animal perform a task for which it receives a food or fluid reward (Toth and Gardiner 2000). This situation resembles conditions in the wild, in which animals must forage, travel extended distances, solve problems, or otherwise work to obtain their food and water. In the professional judgment of many investigators, veterinarians, and animal behaviorists, performing a task for rewards is behaviorally enriching for laboratory animals. As noted in the Guide, “the least restriction that will achieve the scientific objective should be used” (NRC 1996). The policy articulated in this document is developed for application to homeothermic vertebrates but it does not apply for pre-surgical restriction of *per os* sustenance or for short-duration periods (< 24 hours) In the development of protocols utilizing food or water regulation, investigators must address three fundamental issues: a) the necessary level of regulation; b) the potentially adverse consequences of regulation; and c) the methods for assessing the health and well-being of their animals. Consideration of these three issues can facilitate the establishment of interventional endpoints to maintain the health and well-being of the animals under study (NRC 2003). The ICUC must evaluate the pain-distress categorization of animals that are on restricted diets in accordance with USDA Animal and Plant Health Inspection Service, Animal Care Policy #11 (<http://www.aphis.usda.gov/ac/policy/policy11.pdf>). It is recommended that experimental animals on food or fluid regulation be weighed once to several times a week (NIH 2002).

Young, developing animals have additional dietary requirements for maintaining their normal rate of growth. Investigators working with young animals should specifically address, in their animal study proposal, their expectation for any retardation of growth rate and adult size. Comparisons with litter mates or other similar control animals may prove useful when assessing growth in young, developing animals. In many situations, when caloric or fluid restriction has been justified in developing animals, animals may never reach their projected adult size, but will in all other respects develop into normal adults. In all situations, young, developing animals on restricted food or fluid regimens should be carefully monitored by investigative, veterinary and husbandry personnel.

In all situations, professional judgment must be used to ensure the well-being of the animals

throughout the period of study. Consideration must be given for the species, strain, body condition, and/or hydration status of each animal. The purpose of this document is to provide investigators with guidelines for the proper use of diet control in behavioral studies in which food or fluid consumption is not the independent variable in the research design.

Food

Whenever an animal obtains any portion of its diet through food reward, the investigator must ensure that the sum of the nutritional value of the food earned through reward and of the food provided "free" (without the necessity of earning it) is sufficient to maintain the animal in a healthy state. Whenever possible, the food reward should be a substance that is sufficiently rewarding and motivating (e.g., raisins, peanuts) such that dietary restriction is minimized or unnecessary. However, dietary control is often required to provide motivation for performing a task, depending on the species, the behavioral task, and the requirements of the research design. In such cases, some food should be provided every day, unless a specific exception to this policy has been obtained in an approved animal study proposal. Experience has demonstrated that short periods, generally forty-eight hours or less, of markedly reduced food intake or fasting may be required during the initial phases of diet control, or after periods of increased food intake (e.g., ad libitum food availability). To date, experience has demonstrated no adverse consequences to a short period without food intake in normal healthy animals. However, if any period of markedly reduced food intake or fasting is required, the principal investigator should provide a clear justification for the reduced food intake, as well as the extent and duration of food reduction in the animal study proposal.

When caloric control is an experimental requirement, other aspects of the animals' diet should remain balanced (e.g., vitamins, minerals, etc.). Weight records must be kept for all animals on dietary control, a minimum of once each week, and should be available for examination by the veterinary staff and the institute Animal Care and Use Committee. An animal's weight must be measured and recorded at no less than weekly intervals. If an animal shows a loss in body weight of more than 15% during the period of study, when compared to the highest recorded weight of the animal, the animal must be evaluated by a veterinarian and, if required, its food increased appropriately. One exception to the above rule is an obese animal that is placed on caloric restriction. When evaluating an animal with a 15% weight loss that was previously obese, the veterinarian may determine that the current weight of the animal is closer to the "ideal" weight for the animal. In such situations, the veterinarian must clearly indicate in the animal's permanent medical record that the animal's current weight is used rather than their highest recorded weight for future 15% weight loss assessments. Exceptions to this policy are allowed only if the attending or facility veterinarian determines that the weight loss does not endanger the animal's health. Many investigators have maintained normal healthy animals with a 15% weight loss or more. Therefore, there appears to be a low risk to the animal's health in using the 15% weight reduction limit. However animals with a 15% weight loss under dietary control maybe more susceptible to the deleterious effects of a short-term fast and may require closer monitoring than other animals. Animals on diet control should be allowed a short-term unrestricted feeding period prior to any surgical procedure to avoid the development of hypoglycemia during the recovery period.

It is recommended that animals be gradually reduced to a target weight and acclimated to the feeding schedule to mitigate the stress response. Ideally, the diet restriction should be limited so that the body weight is reduced not more than 10% per week.

Special attention should be given to ensure that the diet fed meets the animal's nutritional needs. In general, the total caloric intake of a food-regulated animal is 50-70% of that associated with ad libitum feeding. With the exception of short term fasts, it is recommended that animals should be fed a daily ration containing at least 30% of their minimum caloric requirements. Physical evaluation of the animal by a veterinarian, changes in palpable muscle mass and evaluation

of serum chemistry can be helpful for assessing clinical health in animals under dietary control. In addition, it may at times be helpful to monitor an animal for signs of ketosis or metabolic acidosis.

It may be advisable in some long-term research designs (often termed chronic preparations) to intermittently allow animals a sufficient period of ad libitum feeding to establish a new plateau of unrestricted body weight after a period of diet control. This may be necessary if the attending or facility veterinarian determines that the animal's current weight endangers its health. When transitioning an animal from a controlled food access paradigm to ad libitum access, careful monitoring of the animal's dietary intake is recommended to aid in the prevention of deleterious gastrointestinal complications.

Fluid

As with food intake, whenever an animal obtains any portion of its fluid requirements through fluid rewards in behavioral testing, the investigator must ensure that the sum of the fluid earned through reward and the supplemental fluid provided outside of the experiment is sufficient to maintain the animal in a healthy state. Experience has demonstrated that the transition of an animal to a controlled water access paradigm is best accomplished through a gradual, systematic limitation of fluid intake over a several-day period (Toth and Gardiner 2000). Whenever possible, concurrent with the systematic limitation of available free-choice water, animals should be provided with an opportunity to work for additional water until satiated. In many cases, the restriction often may be relaxed or reduced after the animal becomes proficient at a given task. It is recommended that at the start of a new research protocol the amount of fluid consumed, body weight and hydration assessment be recorded daily for each animal. Some animals on controlled fluid paradigms are provided with "vacations". A "vacation" is a period of time, ranging from a day to a few weeks in duration, when the animal is provided a markedly increased fluid allocation, commonly >1.5-3 times their routine daily consumption. When an animal is not required to perform their learned task for prolonged periods of time, several weeks duration or longer, gradually increasing the animal's consumption to ad libitum access is recommended. In addition, it is recommended that animals be provided with free access to fluid for some period on days when research procedures are not scheduled, unless scientifically justifiable reasons preclude such fluid supplementation. When transitioning an animal from a controlled water paradigm to ad libitum fluid access, careful monitoring of the animal's dietary intake is recommended to aid in the prevention of deleterious gastrointestinal complications.

Experience has demonstrated that short periods without or with markedly reduced fluid intake may be required during the initial phases of a research design requiring water control. The duration of the period will vary with the species and hydration status of the animal. Many, larger species of nonhuman primates do well with markedly reduced or no fluid intake for periods up to thirty-six hours, but smaller species, especially some New World species, may be more susceptible to the effects of marked fluid restriction. Similarly, following a "vacation" period, an animal may require a period without fluid intake to regain the motivation to perform their learned task. To date, experience has demonstrated no adverse consequences of short periods without fluid intake in normal, healthy animals. However, if any period without or with markedly reduced fluid intake is required, the principal investigator should provide a clear justification for the reduced fluid intake, as well as the extent and duration of fluid reduction in his or her animal study proposal.

Because the difficulty of a given behavioral task can, in part, determine the degree of water control required, whenever possible animals should be acclimated to easy task(s) prior to their systematic and gradual progression to more difficult tasks. Once a baseline fluid intake has been established on a given task, each animal should be allowed to earn fluids to satiety or its fluid intake should be appropriately supplemented on a daily basis. In cases in which supplements are required, the minimum amount of fluids to be provided each day should be equivalent to the amount typically consumed by the animal when it is permitted to earn fluids to satiety. It is recognized, however, that to ensure the animal's welfare and experimental

integrity, daily adjustments in fluid intake are often required during the course of the research. Once an animal has learned a behavior, the daily amount of fluid provided should be increased to the maximum level that will ensure adequate performance of the task.

Assessment of Adequacy of Fluid Intake

Even though animals typically learn to work in a manner that earns their entire daily fluid requirement during the testing session, a number of precautions must be taken to avoid the detrimental effects of fluid control. The nature (e.g., water, fruit juice) and, if applicable, concentration of the fluid reward should be specified in the animal study proposal. Daily records of fluid intake must be maintained and be available for review by the veterinary staff and the institutional ACUC. The daily record should indicate the fluid earned during the recording session and any supplemental fluid and/or fruit provided to the animal. Each animal under fluid control must be observed daily for its health status by the animal care staff. Normal physiological responses to fluid control routinely result in changes in the animal's clinical pathological status. For example, fluid control will often result in elevated blood parameters (e.g., Hematocrit, Serum Total Protein, etc.), while physical and behavioral assessment of the animal indicates that the animal is healthy and adapting normally to the controlled access paradigm. If at any time the attending veterinarian determines that an animal is not adapting sufficiently to the controlled fluid paradigm, the veterinarian will consult with the investigator to develop a plan to maintain the health of the animal.

Some animals on a controlled fluid access paradigm may decrease their total caloric intake in response to changes in their access to water. Because food intake is correlated to the amount of fluid consumed, monitoring food consumption can also be a valuable tool. In most cases, the decreased caloric intake is minor and does not result in a body weight loss greater than fifteen percent (>15%). However, in the case of obese animals or those experiencing chronic fluid deficiency, loss of body weight in excess of 15% has been observed. This weight loss does not pose a problem in the case of obese individuals, but can lead to severe complications in the case of a chronic fluid deficiency. Therefore, as a precaution against chronic fluid deficiency, the animal's weight must be measured and recorded at no less than weekly intervals. If an animal shows a loss in body weight of more than 15% during the period of study, when compared to the highest recorded weight of the animal, the animal must be evaluated by a veterinarian and, if required, its fluids increased appropriately. One exception to the above rule is an obese animal which is placed on fluid restriction. When evaluating an animal with a 15% weight loss which was previously obese, the veterinarian may determine that the current weight of the animal is closer to the "ideal" weight for the animal. In such situations, the veterinarian must clearly indicate in the animal's permanent medical record that the animal's current weight be used rather than their highest recorded weight for future 15% weight loss assessments. Exceptions to this policy are only allowed only if the attending or facility veterinarian determines that an animal is adequately hydrated and that the weight loss does not endanger the animal's health.

Summary

It is imperative that investigators, animal care staff and veterinarians working with animals on food or water controlled access paradigms know the species-typical signs of distress for the animals with which they are working. Animals routinely adapt well to the research design and display no signs of distress.¹ Animals must be carefully monitored on a daily basis to ensure that they are healthy, adapting normally, and consume sufficient food and/or water to maintain good health. Close monitoring is particularly important when an animal is initially acclimated to food or water control, during transition back to an ad lib state or when increasing the difficulty of the behavioral task. In all situations, the details of the training paradigm used and accountability of the individuals involved must be clearly outlined in the approved animal study proposal. Experience has demonstrated that diligent record keeping on the daily food or fluid volume consumed, hydration status,

appearance, general affect, experimental performance, and routine weighing are reliable for the identification of changes in behavior patterns. Records should be reviewed regularly and kept accessible to veterinary staff and others who have a need to evaluate them. The daily records should indicate the food or fluid earned during the recording session and any supplemental food or fluid provided to the animal. In addition, a plan of action, complete with endpoints for therapeutic intervention, should be considered when the experimental animal proposal is developed.

References

NIH (2002). *Methods and Welfare Considerations in Behavioral Research with Animals*. Washington, DC: U.S. Government Printing Office [http://www.nimh.nih.gov/researchfunding/animals.pdf]

NRC (1996). *Guide for the Care and Use of Laboratory Animals*. Washington, DC: National Academy Press [http://www.nap.edu/readingroom/books/labrats/]

NRC (2003). *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research*. Washington, DC: National Academy Press [http://oacu.od.nih.gov/GdeMammNeuro.pdf]

Toth, L. A., and T. Gardiner (2000). Food and Water Restriction Protocols: Physiological and Behavioral Considerations. *Contemporary Topics in Laboratory Animal Science* 39: 9-17

*(adapted from <http://oacu.od.nih.gov/ARAC/dietctrl.pdf>)

Attachment A - Daily Log

****NOTE: Post in the animal room for the entire food/fluid restriction****

Daily Log Sheet for Food/Fluid Restriction for Individual Research Animals

Animals that are approved by the IACUC to undergo food or fluid restriction in excess of 24 hours must be monitored on a daily basis by research personnel, including weekends and holidays; this procedure does not apply to routine presurgical *per os* restrictions. This log sheet must be posted in the housing facility for the entire period of food or fluid restriction. Once the period of restriction has ended, the log sheet should be removed from the animal room and retained with the investigator's animal records. For more information, refer to the IACUC policy for food or fluid restriction posted on: (iacuc.ou.edu - Announcement – September 2007)

Animal Identification: _____

Type of Restriction: Food Water Both Protocol #: R0X-XXX

Length of Restriction Period: _____ Lab Contact: _____

Food/Water Restriction Start Date: _____ Work Ph. #: _____

End Date: _____ After Hrs. #: _____

Date	Animal Body Weight (must be measured once per week)	Status Notes	Observer

copy of lab Record - Sep Aus

Protocol

Animal Resources Facility
INDIVIDUAL ANIMAL RECORD

Animal # <u>GP06-2-8</u>	Species <u>Guinea Pig</u>	Date Received <u>11/27/06</u>
Vendor <u>Chavels River</u>	Investigator <u>Dr. Gan</u>	Date Assigned <u>11/28/06</u>

DESCRIPTION

Weight <u>210</u>	Sex <u>F</u>	Color <u>white</u>	Breed	Age
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DAILY LOG

Date	Weight(lb/kg)	Information
<u>11/28/06</u>	<u>210</u>	<u>check in</u>
<u>12/4/06</u>	<u>270</u>	<u>ear checks</u>
<u>12/7/06</u>	<u>280</u>	<u>ear check, 10 B.K., TVM, INO.</u>
<u>12/8/06</u>	<u>282</u>	<u>Bur</u>
<u>12/9/06</u>	<u>288</u>	<u>Bur. } analgesic</u>
<u>12/10/06</u>	<u>291</u>	<u>Bur</u>
<u>12/11/06</u>	<u>292</u>	<u>Bur.</u>
<u>12/12/06</u>	<u>294</u>	<u>Bur.</u>
<u>12/13/06</u>	<u>300</u>	<u>Bur</u>
<u>12/14/06</u>	<u>305</u>	<u>ear check, Bur.</u>
<u>12/22/06</u>	<u>325</u>	<u>ZOP.</u>

? status of analgesic treatment?
Does new student (Li) know about?

Guinea Pigs Strain: _____

Investigator Dr. Gan

Room No. of investigator _____

Born _____ Sex _____

Date Acquired 11/27/06

Source _____

Number of animals in cage 1 GP06-2-8

Treatment:

12/8/06 10 B.K. 12/22/06 ZOP

Exhibit 4f

Veterinarian Animal Health Inspection Form
Record of Weekly Visits

Date:

Veterinarian:

Animal House () Comments:

Richards Hall () Room 410C, Comments: () Room 412, Comments:

G.L. Cross Ctr. () Rooms 906/07, Comments:

Physical Sciences () Rooms 414A/H, Comments:

Felgar Hall () Room 130A, Comments:

Dale Hall () Room 42, 46-48, Comments:

Exhibit 5

Letter to PI for IACUC review of AUS

16 May 2008

Dr. X
Department of Zoology
Richards Hall 314

Dear Dr. X:

The following AUS protocol relative to an application for NSF funding was reviewed by the IACUC and approved with no modifications:

Title of Application: **Mechanisms for termination a neonatal sensitive period (R08-008)**

This protocol approval is granted for three years, ending 16 May 2011. If at the end of this period, the project is still ongoing, a new protocol must be submitted to this office for review by the IACUC. Please reference the protocol title and **R08-008** when corresponding with our office concerning this protocol. If modifications to the protocol are required, notify the LAR on the appropriate form (iacuc.ou.edu – Animal Use Protocol Amendment) for IACUC approval. The University of Oklahoma has an Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (A3240-01) effective through June 2009, and is registered with USDA as a research facility (Certificate number 73-R-0100) through March 2010.

Sincerely yours,

William Shelton, Chair
IACUC

cc: Research Support
Paul Bell, IO
Facilities Manager

Exhibit 6

Annual Administrative Report to IO

Laboratory Animal Resources
William L. Shelton, Director
Activities Report for Calendar Year 2007

25 February 2008

My reappointment as Director of Laboratory Animal Resources was effective on 1 July 2006; my academic appointment in Zoology continued and pertinent information from the Departmental Service Report is attached for documentation. This report will summarize the activities and accomplishments for the LAR and IACUC during the past calendar year. The Laboratory Animal Resources program provides animal care to researchers and instructors from four departments within the College of Arts and Sciences and for the bioengineering program. The Laboratory Animal Care program of the University is regulated under the Animal Welfare Act (AWA) plus amendments, and the Health Research Extension Act (Public Health Service Act) as administered through the Office of Laboratory Animal Welfare (OLAW) of NIH and through USDA, Animal Plant Health Inspection Service (APHIS). The authorization for operation on the Norman campus is based on (1) an Institutional Assurance of Compliance Document (IACD) which is approved by PHS/OLAW through 1 July 2009, and (2) a USDA registration as a research facility which was renewed in 2007(Attachment A) and is effective through March 2010. The 1985 amendment of the PHS Research Extension Act provides legislative authority for enforcing PHS policy, and directs the organization and operation of an IACUC as a self-regulating entity to oversee animal care and use; oversight is exercised by the IACUC through semi-annual inspections of facilities and examination of programmatic issues (copies on file).

LAR

Operations

We continue to report activities to OLAW/PHS on a FY-year basis (1 July through 30 June) as approved in 2005. The IACD that was activated in May 2005, and continues in effect through June 2009. A renewal request of the IACD is expected in December 2008. An on-site visit is made annually by one of the Federal Agencies (USDA/APHIS) to verify compliance as described in the IACD.

Accomplishments: No non-compliance issues were found during the 21 June 2007 USDA inspection (Attachment B).

Space

Animal holding facilities are located in the vicinity of animal users research space; current locations are in six buildings, one of which is dedicated to LAR activities.

Accomplishments: LAR space allocations were clarified during 2007 for all animal holding space in Dale Hall, Felgar Hall, George L. Cross Center and Physical Sciences Building; the Animal House is the only area solely under LAR control. Animal holding space in the Stephenson Center is limited to fish, but development of facilities were discussed for the proposed Stephenson Life Sciences Building. Space allocations and use were reported in the 2007 University Space Survey.

Goals: Finalize plans for animal facilities in Stephenson Life Sciences Building.

Finances

The operational expenses of animal care includes fixed direct and variable costs. Variable costs for expendable supplies in animal care are being recovered through charges levied to funded animal users and this continues to be adequate compensation for expendables, but does not generate funds for personnel expenses. Essentially this is a subsistence charge rather than per diem, since wages, salaries and other expenses are provided in the allocated M&O budget through the CAS. The lack of any monetary contribution from Engineering relative to fixed direct costs continues to be an unresolved issue. A mechanism for monetary contribution from engineering entities would provide supplementation to compensate for additional personnel costs accrued through care of non-CAS animals.

Accomplishments: Meetings were held with Engineering Deans during 2007 to discuss options; they were supportive but desired further input from VPR and CAS. A mechanism was proposed in a subsequent meeting with the Engineering deans,

CAS representatives and personnel from the Office of the VPR. The recommendation was that personnel expenses should be documented through developing Costs Centers for pertinent categories, and then to establish a per diem rate that incorporates this increment. The full rate would be charged to non-CAS PI's. Investigators in CAS would have a subsidy equivalent to the appropriate animal caretakers salaries and wages. The oversight of all animal care has now come under the supervision of the LAR.

Goals: The arrangements related to animal users in engineering research will continue to be explored so as to accommodate the increasing expenses that are being incurred for animal care in this program, and too coordinate with the Office of Research Support to finalize an acceptable per diem rate. The PI's would be notified prior to implementing the new rate. The increased rates would not take effect on established projects.

Disposal of biological wastes continues through a commercial contractor. This cost has being adequately covered by the current subsistence income. However, large volumes of biowaste are produced from the teaching of Comparative Anatomy in the Department of Zoology, and from some research activities in Bioengineering; these entities were previously charged separately for disposal of these specific materials. However, the transport of this biomass to the Animal House also has presented major logistic problems.

Accomplishments: Zoology and the individual Bioengineering PI have developed separate contracts with the biowaste disposal company which provides pick-up at the specific buildings. Disposal of other animal-related biowastes from research/teaching activities in Zoology/bioengineering continues to be managed by LAR.

LAR Administration

Effective administration of the LAR and efficient record keeping associated with the IACUC operations are important compliance issues. Modifications continue to be made in the LAR office operations as appropriate.

Accomplishments:

- 1) The LAR Records Management System continues to provide a means of maintaining AUS protocols. It permits the tracking of active projects, annual progress reports, notification of pending expirations, protocol modifications and/or personnel changes.
- 2) Animal ordering procedures have been codified to provide a mechanism to link AUS-approved animal numbers with animals used in projects.
- 3) Veterinarians weekly animal health inspections are being documented to verify continued monitoring.
- 4) The LAR website (iacuc.ou.edu) continues to provide a convenient means of transferring information to animal users. The announcements page is used to update PI's on pertinent developments relative to animal welfare, and to communicate important procedural issues.
- 5) Met twice during 2007 with Graduate School Personnel (Dr. J. Paul) and the Zoology Department Graduate Liaison (Dr. R. Knapp). Discussed discrepancies and inaccuracies on IACUC responsibilities in the graduate school website information, including forms and documents. Corrections are being made.

Goals: Continue to improve the integration of operational records for LAR and IACUC: animal tracking relative to AUS approval; expense records relative to care; query PI's for status report on anniversary of AUS approval; PI notification of pending AUS expiration. Monitor Graduate College Website to verify corrections to these documents.

LAR Personnel

Some changes in the LAR personnel occurred in 2007.

Accomplishments: Susan Lovett has been hired to replace Kate Lovett who resigned after 25 years of University service. The Animal Facility Manager, Scott Zerger, Facilities Manager, continues in his 30th year with the university; he is a well-trained, invaluable staff member and he provides a liaison for on-the-job training and supervisor of LAR animal caretakers. The position of Zoology Animal Caretaker was transferred to LAR and Keith Curlee, LAR Animal Care Technician was reassigned to this position. Financial support within the LAR budget is still pending, but the Zoology Department will continue to fund the position until additional funds are developed for LAR to assume a portion of the salary. This transfer to be under LAR supervision will greatly enhance the efficient operations of the animal care program and alleviate concerns

over non-compliance of the organizational structure. Another animal care-taker has been hired into a temporary part-time position.

Goals: Continue efficient care of animals in compliance with the animal welfare Guidelines.

University Office of Compliance

The University of Oklahoma Office of Compliance (CO) was organized in 2002. The Animal Resources Programs and the IACUC's for the two campuses (OUHSC and Norman) continue to be operated under their respective Institutional Officials and with the existing compliance agreements (AAALAC accreditation at OUHSC vs. IACD on the Norman campus). Each Unit has very different financial structures and they have widely divergent research orientations (laboratory only vs. a mix of laboratory and field studies, respectively). Liaison with the CO and IO continues through IACUC representation from both offices. In addition, the Office of Health and Safety is represented on the Norman Campus IACUC.

Accomplishments: Details of the Risk Assessment Plan were finalized with this office and integrated with the University Emergency Disaster Plan.

Goals: Rectify deficiencies in resources needed for Emergency Disaster Plan.

IACUC

The LAR continues to provide administrative support for the Institutional Animal Care and Use Committee (IACUC).

Accomplishments:

- 1) The IACUC membership continues in full compliance with federal (PHS & USDA) guidelines.
- 2) The website (<http://iacuc.ou.edu>) continues to facilitate communications with PI's and other animal users; "Contribute2"

software supports the site. The website offers:

- IACUC forms;
- Meeting schedules and application deadlines;
- Subsistence rates;
- IACUC membership;
- Training Outline;
- Links for on-line testing/web-based courses and tutorials;
- Links to field guidelines for animal research;
- Links to Animal Welfare Organizations & resources;
- SOP for animal purchase and disposal;
- Announcements pertinent to animal welfare;
- Drug registration information.

- 3) During the past year, the IACUC reviewed 23 AUS research proposals, and 4 teaching protocols. The research proposals included 14 field and 7 laboratory studies, plus 2 combined field/laboratory studies.
- 4) Two semi-annual inspections of animal-holding facilities and program reviews were accomplished (9 March 2006; 14 September 2007); only minor issue were identified, and these have been corrected.
- 4) The OLAW/NIH-approved Institutional Assurance Compliance Document (IACD) expires in June 2009; revision has been started so as to meet the anticipated request for draft submittal in December 2008.
- 5) Manual of Operating Procedures continues to evolve. The University Emergency Response Plan and Risk Assessment Plan of the Office of Compliance have been integrated.

7) USDA reviewed the OU, NC program on 21 June 2007; no non-compliance issues were found.

8) Personnel Training and Outreach Activities:

The Director:

- (a) Conducted New Graduate Student Orientation, 14 August 2007 – Introduction to LAR and Federal Regulations. Fourteen new Zoology students, four from Bioengineering and three from Biochemistry attended.
- (b) Offered orientation training throughout 2007 for new animal user PI's, Post-docs, and Lab. Technicians.
- (c) Discussed Animal Care Program with 30 new faculty through the University Instructional Development Program.
- (d) Completed University training on Laboratory Safety and Space Inventory and Functional Usage Reporting
- (e) Participated in A&S Chairs and Directors retreat at UOBS.
- (f) Participated in Zoology Department Retreat at UOBS.
- (g) Attended two National scientific meetings, contributed presentations in two student workshops.

LAR Staff:

Animal Care Technician, K. Curlee and Animal Facilities Manager, S. Zerger completed the OLAW-sponsored animal welfare training course – 'IACUC 101'.

Goals: Maintain appropriate and effective IACUC membership according to Federal guidelines. Effectively review Animal Use Statement (AUS) proposals from animal users so as to meet PHS guidelines for animal studies. Provide appropriate training for animal users, and continue training for animal care staff. Continue to act as information source for proper animal care and use. Improve tracking system for active AUS so as to monitor animal use, perform annual review update, and develop system for alerting PI's of pending AUS expiration.

SUMMARY OF LAR/IACUC ACCOMPLISHMENTS

- 1) Institutional Assurance Compliance Document (IACD) and Manual of Operating Procedures being updated internally in preparation for renewal submittal in December 2008.
- 2) Integrated Disaster Plan of LAR with University plan and Risk Assessment Plan.
- 3) USDA registration as Animal Research Facility continues through March 2010.
- 4) Improved monitoring of active research activity through annual review.
- 5) Expansion of training activities plus more effective tracking.
- 6) Website improvements.
- 7) Maintained IACUC membership in compliance.

SUMMARY OF LAR GOALS

- 1) Complete financial support arrangement relative to proposed Per Diem rates.
 - 2) Develop partial salary support for animal caretaker position formerly in Zoology.
 - 3) Develop financial support for increasing labor demands relative to bioengineering activities; finalize Per Diem modification.
 - 4) Continue to improve tracking records that relate numbers of animals proposed in AUS with numbers actually used.
 - 5) Continue to develop annual reporting by PI relative to Federal guidelines, including training of new personnel.
 - 6) Continue to upgrade OSHA and Disaster guidelines and training and Risk Assessment Plan.
 - 7) Monitor Graduate School Website to verify that corrections are made for the errors/inconsistencies relative to animal welfare compliance.
-

Exhibit 7

Syllabus for Undergraduate Senior Capstone Course taught by LAR Director

Animals in Science and Modern Society
Zoology 4983, Section 902, 3 credit hours, Spring 2006
Th 6:30-9:30 P.M., Sutton Hall 312
W.L. Shelton

Objectives: Overall the capstone courses should be interdisciplinary, focusing on contemporary social, ethical and economic issues, where ideas are synthesized from major fields of Zoology. This section will examine the role of animals in science relative to their use in biomedical, basic and applied research and the variety of other interactions which involve animals and contemporary society. Interactive discussions will address animal welfare issues from several perspectives, such as: a regulatory perspective relative to ethical considerations; genetic manipulations relative to a balance between societal attitudes and pragmatic applications; evolution of husbandry and the science of food production; historic environmental alteration and impact on wildlife conservation and endangered species.

A number of literature sources will be provided to serve as a basis for discussion of the various topics. One paperback book will supplement these readings.

General Outline:

I. Background

- A. Ethics – Professional, biological, environmental
- B. Animal Welfare vs. Animal Rights
- C. Legislation – Laws, regulations, guidelines
- D. Physiological bases – Sentience, pain, stress, distress

II. Animals in Research and Testing

- A. Laboratory Studies – Lab animals vs. farm animals vs. wild animals;
biomedical vs. agricultural vs. wildlife management
- B. Field Studies – Collecting techniques, manipulations and biomonitoring
- C. Agricultural - Biomedical vs. production

III. Animals in Society

- A. Ecological relations and societal values
- B. Animal husbandry & aquaculture (GMO, Cloning, etc.)
- C. Wildlife/Fisheries (Harvest and non-consumptive uses)
- D. Conservation (Protection and restoration of endangered species; zoos)
- E. Animal utility in biomedical support roles (Companions, Seeing-Eye, Pets, etc.)
- F. Animal Sports – Racing, blood sports

Required book: Singer, P. (ed). "In Defense of Animals"
Other resources will be provided

Guidelines for class conduct:

We will explore various animal welfare topics using contemporary literature as source material. All members will read the assignments each week to provide a basis for interactive discussion; a brief quiz will be given each week. A panel consisting of three members will be assigned each week, two will lead and facilitate the discussion and one will be a rapporteur. The discussion of most topics can be approached from an advocacy vs. oppositional perspective; the position of each facilitator will be assigned by the flip of a coin for the panels' first topic, thereafter, their role will alternate. Non-panel members will enter the discussion at the behest of the moderators. The rapporteur will document the discussion and provide the instructor with a written synopsis for each week. It should provide a short statement of the topic(s) under discussion, objectives and the general position of the panel (pro/con) and a summarization of pertinent contributions from the discussion. During the first class period, you will examine the scheduled list of discussion topics, and sign up for three sessions (you must be a rapporteur once). Each week the non-panel class members will prepare a synopsis of the material discussed; panel members will not be required to do a narrative for the weeks of their presentation. Some sessions will be led by the instructor.

Details of each are:

1. Each individual, during the semester, will have the opportunity to serve as one of two panel-member facilitators on two occasions and rapporteur once when their panel is leading the discussion for the week. The duty of the rapporteur is to provide a written summary of the discussions, as well as interpretations of background materials that may pertain to the discussion. It is the job of the rapporteur to capture the essence of the topic and articulate the panel's discussion and class input; this narrative will be graded on the quality of writing and its effectiveness in capturing the discussion. This is a large, "one-time" effort and has twice the weighting of that of the facilitators.
 2. Each group will have three opportunities for making weekly presentations and therefore to be a facilitator twice, once as a panel member discussing from a supportive position and the other taking the position of an opponent. You will be evaluated relative to your articulation of the topic and effectiveness in soliciting group discussion.
 3. Each week a quiz will be given that is related to the reading material for the week's focus. Obviously attendance is required.
 4. A synopsis of the material from the previous week will be turned in each week. You will be graded on your written material and the effectiveness in summarizing the material discussed. If you were absent, a synopsis may be accepted based on the assigned reading, but this must be arranged with the instructor.
-



The University of Oklahoma

LABORATORY ANIMAL RESOURCES

MEMORANDUM

TO: Non-CAS (College of Arts & Sciences) Animal Users
FROM: W. L. Shelton, LAR Director
SUBJECT: Animal Per-Diem Rate Change
DATE: 28 April 2008

This memorandum is to notify you of significant change in the rate structure for animal care. We have not modified rates for animal care since 2002, but because of significant increases in costs of expendables (feed, bedding, and cleaning supplies), we must add an increment to the daily rate structure in order to maintain our cost recovery (Table 1). Further, we must now begin to recover an increment of operational and fixed costs not previously covered by non-CAS animal users. The CAS supports the animal care program by providing a budget which includes personnel costs, veterinary services, and other operational expenses. Your administrative units have declined to provide any comparable financial support to subsidize these expenses, consequentially, you will be required to build this new structure into your future proposal budgets (Table 2); it will take effect in August 2008. The increase is substantial, but represents the actual Per-Diem costs for the care of the research animals; these rates are comparable to those of the OUHSC and less than permitted by the NIH/NCRR Cost Analysis and Rate setting (2008).

Table 1. Daily Animal Care Per-Diem Rates – PI’s Subsidized by CAS

Table with 3 columns: Animal Type, Group Housed (daily \$ per animal), and Individually Housed. Rows include Mice, Rats, Rabbits, Guinea Pigs, and Chipmunks.

Table 2. Non-Subsidized Animal Care Per-Diem Rates – Non-CAS Investigators

Table with 3 columns: Animal Type, Group Housed (daily \$ per animal), and Individually Housed. Rows include Mice, Rats, Rabbits, and Guinea Pigs.



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

July 16, 2007

Reference: Receipt of the Annual Report
For Animal Welfare Assurance# A3240-01
For the reporting period of July 1, 2006 through
June 30, 2007

William L. Shelton, Ph.D.
IACUC Chairperson
Professor, Zoology
University of Oklahoma
Zoology Department
730 Van Vleet Oval
Norman, OK 73019

Dear Dr. Shelton:

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) received and reviewed your institutions above referenced report that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals as revised in August 2002.

The Annual Report to OLAW is a key document in a continuing relationship with the PHS. It contains pertinent information regarding the policies and procedures in place to provide for the appropriate care and use of laboratory animals.

We look forward to receiving your next report, for the period July 1, 2007 through June 30, 2008 within 30 days of the end of the reporting period.

Thank you for your attention to these matters.

Sincerely,

Jonique F. Taylor, BTAED
Program Assistant (Contractor)
Office of Laboratory Animal Welfare (OLAW)

Exhibit 10

SURVIVAL PORTFOLIO -- 10 November 2006 (Update)
Plus tutorial and website info – no PC
Provided to new IACUC members – started Fall 2002

- 1) OLAW “IACUC Guidebook – 2nd edition, 2002 – also on Web
<http://grants.nih.gov/grants/olaw/GuideBook.pdf> or
<ftp://ftp.grants.nih.gov/IACUC/GuideBook.pdf>
- 2) NRC (1996) “Guide for the Care and Use of Laboratory Animals”
also OLAW web.
- 3) Silverman et al., editors. (2000). The IACUC Handbook. CRC Press.
- 4) Tutorial – PHS Policy on Humane Care and Use of Laboratory Animals.
(see above OLAW site +
- 5) USDA, Part 9 - (www.nal.usda.gov/awic/pubs/IACUC/usdareg.htm)
- 6) Field Guidelines –FIELD RESEARCH GUIDELINES – WEB SITE ACCESS

Field Research Guidelines. 1988. SCAW public - \$10.00, not posted on web
(<http://www.scaw.com>)

Mammals – (<http://www.mammalsociety.org/pubsociety/index.html>)
see 98 iacuc guidelines

Birds – (<http://www.nmnh.si.edu/BIRDNET>)

Fish – (<http://www.asih.org/pubs/fishguide.html>)

Reptiles/Amphibians – (<http://www.asih.org/pubs/herpcoll.html>)
- 7) Animal Welfare Act – AWIC web site
- 8) Links to KSU/OSU/ OUHSC web sites.
- 9) OLAW/ARENA “Institutional Animal Care and Use Committee Guidebook, 2nd Ed
Reviewed in OU IACUC workshop, March 2003.
- 10) University of Oklahoma, Norman Campus Institutional Compliance Assurance
Document & Manual of Operating Procedures (OUNC)

✓ Checklist for Master's Degree Thesis Option

First Semester (prior to or during)

- Consult the graduate liaison of your academic unit for an advisor. Plan your program of study. Check the master's degree requirements for your academic unit and review the Graduate College Bulletin for enrollment standards.

Preparing for Thesis Work

- No later than the semester in which you plan to start work on your thesis, select a thesis topic and the members of your thesis committee in conjunction with your advisor.
- **RESEARCH SUBJECTS:** For any research that includes human or vertebrate animal subject involvement of any kind, approval must be obtained from the appropriate office prior to beginning any research. This includes the administration of all surveys and the use of existing data collected on any human or animal subjects. For information about human subject involvement, the IRB web site can be accessed at <http://research.ou.edu/irb/default.asp>. For information about vertebrate animal subject involvement, the IACUC web site can be accessed at <http://iacuc.ou.edu/>. A copy of the approval letter should be submitted to the Graduate College along with the *Application for Approval of Master's Thesis Topic and Committee Membership* during the semester before you intend to graduate.

UNIVERSITY OF OKLAHOMA - GRADUATE COLLEGE Application For Approval Of The Master's Thesis Topic And Committee Membership

The following is to be completed and signed by student and verified by the major professor

1. Does this thesis contain any research that involves human and/or other vertebrate animal subjects in any way? Yes No

If "Yes", please move on to question 2. If "No", please skip to question 4.

2. Does the research in this thesis involve the use of human subjects and has been or will be submitted for approval by the Institutional Review Board (IRB)? Yes No

- A. **Approved** – (Attach a copy of the approval.)
B. **Pending** – (submitted _____ (date) to IRB, approval will be secured **prior to any data collection**)
C. **To be submitted** - (will be submitted later to IRB for approval **but prior to any data collection**)

3. Does the research in this thesis involve the use of vertebrate animal subjects and has been or will be submitted for approval by the Institutional Animal Care and Use Committee (IACUC)? Yes No

- A. **Approved** – (Attach a copy of the approval.)
B. **Pending** – (submitted _____ (date) to IACUC, approval will be secured **prior to any data collection**)
C. **To be submitted** - (will be submitted later to IACUC for approval **but prior to any data collection**)

REPORT OF ADVISORY CONFERENCE

ENDORSEMENTS

I, the undersigned, agree to the above mentioned program of study. I have read and understand the policies, regulations, and procedures relative to graduate study at the University of Oklahoma as published in the Graduate College Bulletin. In addition, I am aware that research involving human subjects or vertebrate animals must be reviewed and approved by the Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC), respectively, before the research can begin.

STUDENT SIGNATURE _____ DATE _____

The Dissertation

- Maintain continuous enrollment of at least 2 hours of Dissertation Research Hours (5000) each semester (excluding summer sessions) until the doctoral degree is completed. Enrollment in the Summer Session is required only if (1) the degree is conferred in the summer session, or (2) work is being done on the dissertation.
- **RESEARCH SUBJECTS:** For any research that includes human or vertebrate animal subject involvement of any kind, approval must be obtained from the appropriate office prior to beginning any research. This includes the administration of all surveys and the use of existing data collected on any human or animal subjects. For information about human subject involvement, the IRB web site can be accessed at <http://research.ou.edu/irb/default.asp>. For information about vertebrate animal subject involvement, the IACUC web site can be accessed at <http://iacuc.ou.edu/>. A copy of the approval letter should be submitted to the Graduate College along with the Application for Approval of Master's Thesis Topic and Committee Membership during the semester before you intend to graduate.
- **PATENTABLE MATERIAL:** If the dissertation research contains inventions/discoveries owned by the University as defined by the University Patent Policy, a reading copy of the dissertation must be submitted to the Office of Technology Development (OTD) for review and evaluation.

The University of Oklahoma
GRADUATE COLLEGE

REQUEST FOR AUTHORITY FOR DEFENSE OF DISSERTATION

(FINAL EXAMINATION)

Part 3. To be completed and signed by student and verified by the major professor.

YES	NO	
<input type="radio"/>	<input type="radio"/>	This dissertation contains research that involves human and/or other vertebrate animal subjects.
<input type="radio"/>	<input type="radio"/>	The research in this dissertation involves the use of human subjects and has been approved by the Institutional Review Board (IRB). If the answer is yes, attach a copy of the approval from IRB.
<input type="radio"/>	<input type="radio"/>	The research in this dissertation involves the use of vertebrate animal subjects and has been approved by the Institutional Animal Care and Use Committee (IACUC). If the answer is yes, attach a copy of the approval from IACUC.
<input type="radio"/>	<input type="radio"/>	The research in this dissertation includes intellectual property that potentially can be patented. If the answer is yes, you must give the Graduate College a copy of the letter that indicates the Office of Technology Development has received a reading copy of the dissertation and is reviewing it.
<input type="radio"/>	<input type="radio"/>	A research contract has been signed, therefore, the final copies and electronic submission must be held in confidence until OTD notifies the Graduate College and Library to release for publishing and public viewing. If the answer is yes, you must give the Graduate College a copy of the letter that indicates the Office of Technology Development has received a reading copy of the dissertation and is reviewing it.

 Signature of Student

 Signature of Major Professor