

UNIVERSITY ARKANSAS, FAYETTEVILLE CAMPUS

#A3878-01

Animal Welfare Assurance for Domestic Institutions

I, Jim Coleman, as named Institutional Official for animal care and use at The University of Arkansas, Fayetteville, hereinafter referred to as "Institution", by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, and/or NSF. This Assurance covers only those facilities and components listed below.

The following are branches and components over which this Institution has legal authority:

- College of Education
- College of Engineering
- Dale Bumpers College of Agricultural, Food and Life Sciences
- J. William Fulbright College of Arts and Sciences

The following are other institution(s), or branches and components of another institution:

- None

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. 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 this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals (Guide)*.
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are provided in the Organizational Chart which is incorporated as Attachment 1.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: Kate Williams, DVM

Owner, St. Francis Animal Hospital, Springdale, AR

Degrees:

Doctor of Veterinary Medicine, Tuskegee University (1999)

Master of Science, University of Arkansas, 1993

Bachelor of Science in discipline, University of Arkansas (1991)

Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Williams has practiced veterinary medicine for 18 years in Northwest Arkansas and owns and manages a small animal veterinary hospital in Springdale, AR. She served an 8-year tenure on the Executive Board of Directors for the Arkansas Veterinary Medical Association and served as President. She has served as an IACUC veterinarian for a privately owned biological company for over 15 years and has a special interest in animal welfare and lab animal medicine. She resides in Fayetteville, AR with her husband and son.

Dr. Williams also serves in the U.S. Army as a Veterinary Corps Officer, holds the rank of Lieutenant Colonel and is the Commander of an Army Reserve Medical Detachment, Veterinary Services, in Baton Rouge, LA.

Authority:

Dr. Williams has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

Dr. Williams is a 25% employee providing a minimum of 10 hours of service a week. When Dr. Williams is not available, the Division of Agriculture's Extension Veterinarian, Dr. Jeremy Powell, Professor of Animal Science, provides emergency services for the Institution. Dr. Powell holds a B.S. in Animal Science from the University of Arkansas and a DVM from Oklahoma State University.

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. A list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations is provided in Part VIII. The Director of Research Compliance and the CLAF Manager are ex officio, non-voting members of the IACUC.

- D. The IACUC will:

- 1) Review at least once every 6 months 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 reviews are as follows:

The Program Review is conducted at a properly convened meeting (a quorum, 50% +1, of voting members present) of the IACUC. Prior to the meeting, the Veterinarian, IACUC Administrator, and Chair will review the Program Checklist. The University uses the OLAW Program Review Checklist Template, suitably amended to reflect the University's animal use program and which covers the major areas of the *Guide* and the requirements of the PHS Policy. Key aspects of the program subject to evaluation include, but are not limited to, veterinary care; disaster planning; occupational health and safety; post-approval monitoring; IACUC approval process; and animal welfare reporting. A copy of the Program Checklist is forwarded to all IACUC members prior to the convened meeting. During the properly convened meeting, all points are discussed; recommendations are recorded; and deficiencies are noted. The review will be signed by all members present.

Possible outcomes of the review of each area are:

- a) Acceptable – the area under consideration meets the guidelines of the *Guide*,
- b) Minor Deficiency – the area under consideration has a minor deficiency which must be corrected in a timely fashion, or
- c) Significant Deficiency – the area under consideration has one or more significant deficiencies which are or may represent a significant threat to animal health and/or safety. If Significant Deficiencies are found in one or more areas, the IACUC has the authority to take appropriate actions to ensure the health and well-being of the animals so threatened, including requiring that the activity cease until the deficiency has been rectified.

The results of the Program Review are reported to the Institutional Official including all deficiencies identified, reasonable recommendations for correction, and sanctions, if any, which require immediate termination of an activity to protect the health and safety of animals or personnel. (See III.D.3 below.)

- 2) Inspect at least once every 6 months all the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

A subcommittee of at least two IACUC members conducts inspections, a minimum of twice per year (six months apart). All members are invited to participate. The usual procedure is to adjourn from a properly convened meeting (i.e. a quorum of voting members is present) and divide into teams to inspect the facilities that are covered under this Assurance. The IACUC Administrator prepares a Facilities Review Checklist, which is a suitably modified version of the OLAW template and distributes it to each team. Key aspects that are evaluated include, but are not limited to, appropriate room usage; environmental controls (temperature, lighting, cleanliness, hazard controls, etc.); animal welfare; animal health; enrichment; documentation or room usage; and record-keeping. At the time of inspection, all minor deficiencies which can be corrected in the inspectors' presence will be corrected immediately. Any issues which are deemed to present an immediate threat to animal health or safety are addressed through immediate personnel action and contact with the Veterinarian. The IACUC is notified of these instances. For those deficiencies which cannot be corrected immediately, the IACUC Chair or his/her designee will contact the responsible PI to agree upon a reasonable and specific plan and schedule for correction of the deficiency. This information is documented on the checklist(s) and the subsequent report to the Institutional Official will differentiate between major and minor deficiencies and indicate that any deficiencies either have been corrected or will be addressed with a reasonable and specific plan and scheduled for correction in a timely manner. Correction of all deficiencies will be confirmed by the IACUC Chair or his/her designee.

- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

After the program and facility inspections are completed, the inspection forms (checklists) are returned to the IACUC Administrator who prepares a report which describes program and facilities deficiencies and IACUC approved departures from the *Guide* including reasons for each departure. (NOTE: All departures from the *Guide* are reported in accordance with the guidance provided by OLAW.) The report is then presented to the IACUC members for their review. At a convened meeting, with a quorum of members present, the report is approved, either as presented or with stipulated changes, and is signed by all members present. The final, signed version is then sent to the Institutional Official by the Director of Research Compliance on behalf of the IACUC.

The semi-annual report contains any minority views expressed by IACUC members or, if no minority views are expressed, the report so states. In addition, the report expressly describes any deficiencies identified during either the program or facilities inspection and a detailed description is included as to how and when these were/will be resolved. (See Attachment 2 for most recent semi-annual report.) Any deficiencies not corrected within the agreed-upon timeline are reported to OLAW as non-compliance.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The intent of the IACUC is to address all complaints as expeditiously and appropriately as possible. When indicated, infractions will also be referred for resolution under the Institution's Research and Scholarly Misconduct Policies and Procedures.

It is included in the Institution's Policy on the Use of Animals in Research, and stated in the IACUC's Policies and Procedures, that any individual, whether or not an employee of the Institution, may submit concerns or complaints about the use, care, or handling of animals to the following individuals: the IACUC Chair, the IACUC Administrator (who is also the Manager of the Central Laboratory Animal Facility [CLAF]), or the Director of the Office of Research Compliance. Further, all facilities post, in a prominent place, the policy and contact information for reporting concerns and/or complaints. All individuals that participate in projects using animals for research or teaching must complete a Collaborative Institutional Training Initiative (CITI) module which specifically reviews the Institution's Policy on the Humane Use of Animals in Research and Teaching. CLAF is a secured facility with access by admission of the CLAF supervisor or the IACUC veterinarian. Only in rare cases is a non-University affiliated individual present in CLAF. Nevertheless, all users and guests are informed of the policy.

If a charge is made, either the Chair or his/her designee will initiate an investigation of the charges via informal discussion, observation, or other reasonable means to 1) resolve minor issues to the satisfaction of all parties or, 2) determine if the complaint merits a full investigation. If a full investigation is indicated, the Chair will appoint a committee of at least three members, one of which is the IACUC Veterinarian, to conduct a full investigation of the charge. Upon completion of the investigation, the committee will prepare a written report including recommendation(s) for resolution of the situation. The Chair will submit the committee's report to the Institutional Official. If there is apparent research misconduct, the report will also be referred to the Research Integrity Officer for a potential research misconduct investigation. Upon receipt of the referral by the IACUC Chair, the Institutional Official will determine if the complaint has merit and will take appropriate action to ensure that the situation is resolved, and all animals are being used and cared for in a humane manner. Potential sanctions, as determined by the Institutional Official, include but are not limited to

letters of reprimand, restriction/suspension/removal of research privileges, and, in extreme cases, dismissal. In addition, the project may be suspended as described in Part III.D.10, below.

Any individual who submits a concern or complaint in good faith is protected from discharge, threats or otherwise being discriminated or retaliated against. These protections are described in University Policy 9.8, *Whistleblower Protection and Fraud Reporting*. The University complies also complies with University of Arkansas System Board Policy 355.1, *Whistleblower Policy*.

- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

Recommendations for improving and/or maintaining the Institution's animal use program shall be discussed at a convened meeting of the IACUC. Based on the discussion, the IACUC Chair and the Veterinarian will draft and submit written recommendations to the Institutional Official for consideration. Minority opinions will be included.

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

Protocols are submitted electronically to the IACUC Administrator no later than five (5) working days prior to a meeting. If a protocol is to be reviewed at a scheduled meeting, the protocol is distributed via email to all IACUC members at least five (5) working days prior to the meeting. There are no primary or secondary reviewers assigned. A convened meeting of the IACUC at which protocols are reviewed requires that a quorum of voting members be present for the review. A Principal Investigator may, at the request of the committee, be asked to appear before the committee to answer specific questions. At the meeting, members' concerns/questions are discussed, and any recommendations for change are noted.

Review Requirements:

In the review of a proposal, the IACUC shall determine that the components of the research project related to the care and use of animals conform to the Institution's Assurance and meet the following requirements:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly sacrificed at the end of the procedure or, if appropriate, during the procedure.
- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a facility manager, or other professional experienced in the proper care, handling, and use of the species being maintained or studied.

- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. Methods of euthanasia used will be consistent with the recommendations of the most recent edition of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified, in writing, for scientific reasons by the investigator.
- h. All apparent or potential conflicts of interest have been disclosed in accordance with UA Policy 404.0, Conflict of Interest and Conflict of Commitment, Including Outside Activity and, if required, a Conflict of Interest Management Plan has been approved.

Review Outcomes:

There are three (3) possible review outcomes.

- a. Disapproval - This outcome is the result of the investigator submitting a protocol that provides insufficient information for members to evaluate it, or it contains information or a description of procedures which the IACUC feels it cannot approve. A "Protocol Disapproved" notice is sent to the investigator informing him/her of the outcome of the review. The disapproval notice contains the reasons for disapproval and suggestions that might result in approval if the investigator wishes to submit a new protocol. If the investigator wishes to pursue approval of the activity, a new protocol (with new number assigned) is required.
- b. Requires modifications to secure approval - In this case the IACUC understands the rationale and objectives of the proposed research. However, either insufficient information is provided for the IACUC to make a determination or the protocol is written in an unclear manner and significant revision of the protocol is required to document compliance with regulations and policies. An "IACUC Action Notice" is sent asking the investigator to revise and resubmit the protocol. This Notice lists the protocol deficiencies which must be addressed. Depending on the degree of revision required and the seriousness of the issues (e.g., typographical errors, a change in the number of animals to be used, unacceptable method of euthanasia) the investigator is advised that the revised protocol will be reviewed at the next scheduled meeting or, if deemed appropriate by the IACUC, will undergo Designated Member Review Method as described below. The committee votes on whether the resubmitted protocol will be reviewed at the next convened meeting, or by Designated Member Review. In cases where a resubmitted protocol is selected for Designated Member Review, all IACUC members will receive copies of the protocol and have the opportunity to call for FCR. DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so.
- c. Approved - A majority of the members at the meeting vote to approve the protocol as written. The IACUC Administrator sends a written approval notice. A protocol may be approved that needs minor administrative changes, e.g., correction of typographical errors or correction of an email address or phone number. The IACUC Administrator verifies such details and withholds the written approval notice until verification is completed.

Designated Member Review

Where there are extenuating circumstances, such as an impending sponsor deadline, sponsor required changes in an existing protocol, or the required date for approval precedes the date of the next scheduled IACUC meeting, the IACUC chair or his/her designee may route the protocol for review by the Designated Member Review process. The Chair, or his/her designee, will designate an IACUC member who has the expertise to evaluate the project and the Laboratory Animal Veterinarian as reviewers. The protocol will also be distributed to all members of IACUC. Members have seven days in which to communicate questions or concerns or to call for full review at a properly convened meeting. Outcomes of a review, other than protocol disapproval, by the Designated Member Review process are the same as those for a full IACUC review, with one exception. Approval cannot be denied via the Designated Member Review process. If either reviewer feels that he/she cannot approve the protocol in question, the protocol must be reviewed at a properly convened meeting (quorum of IACUC members are present). If either reviewer finds that modifications are required to secure approval, the IACUC Administrator informs the investigator, in writing, of the required changes. Upon receipt of the revised protocol, the IACUC Administrator makes it available to both reviewers. The two reviewers must agree to approve a protocol by Designated Member Review. If the reviewers are unable to agree on approval, the protocol is referred for review by the full IACUC at a properly convened meeting. Generally only protocols that contain procedures that have been thoroughly reviewed in the past or contain procedures that subject the animals to no or very minimal stress can be reviewed by Designated Member review.

Duration of Approval

Protocols are approved for a maximum of 3 years and subjected to an Annual Review, consistent with the requirements of the Animal Welfare Act. In lieu of continuing review of a protocol for studies that are longer than 3 years, the IACUC requires that a new protocol be submitted.

Conflict of Interest

Any IACUC member who is named on a given protocol or otherwise has a personal interest in a protocol, must abstain from voting on that protocol. Members who have financial ties to an entity that is funding a protocol likewise must abstain from voting on that protocol. If abstaining leads to a failure to meet quorum, that protocol will not be reviewed at that meeting. A member abstaining from voting on a protocol may provide information requested by the rest of the IACUC, but s/he must not participate in the deliberation or voting processes.

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The Principal Investigator must submit a Request for Modification Form to the IACUC Administrator. Changes in personnel other than the Principal Investigator are not considered significant. The IACUC Administrator reviews personnel experience and training to ensure that all such personnel are appropriately identified, adequately trained and qualified, and, where indicated, enrolled in applicable occupational health and safety programs. Personnel must also meet any specific criteria required by the IACUC as a condition of protocol approval. The procedures for reviewing and approving all significant changes in ongoing research projects are the same as those for initial and continuing protocol review as described in Part III.D.6.

Examples of changes considered to be significant include, but are not limited to, changes:

- in the objectives of a study;
- from non-survival to survival surgery;
- resulting in greater discomfort or a greater degree of invasiveness;

- in the species or an increase of $\geq 10\%$ of the number of animals approved for use;
- in Principal Investigator;
- in anesthetic agent(s) or the use or withholding of analgesics;
- in the method of euthanasia;
- in the duration, frequency, or number of procedures performed on an animal;
- in housing and or use of animals in a location that has not been approved by the IACUC; and
- having an impact on personnel safety.

- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows.

Copies of the monthly meeting agenda (which is the vehicle by which IACUC members are informed of the results of protocols and requests for modification that are reviewed by Expedited Review), and the meeting minutes which include the protocols reviewed at the meeting and the outcome of such review are provided to the Institutional Official. Notice of approval of a protocol is made in writing to the Principal Investigator, the Laboratory Animal Veterinarian, and for Arkansas Agricultural Experiment Station projects, to the Vice President for Agriculture by the IACUC Chair. Principal Investigators whose protocols are not approved can respond to the Chair in person, by writing, or by phone, to discuss the decision. Investigators are encouraged to attend convened meetings of the IACUC to answer any questions committee members may have prior to the deliberation and voting processes.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

Approved protocols are subjected to an Annual Review consistent with the requirements of the Animal Welfare Act and PHS Policy. The Institution maintains a USDA Class R Research Facility Certification, #71-R-0001. Traditionally, no USDA covered species have been used in research activities. However, a single principal investigator is in the process of certification for hamster work and oversight by USDA and is consistent with anticipation of receiving awards for sponsored projects which require USDA oversight/approval. Investigators are required to submit annual reports which are reviewed by the full Committee. Annual reviews must be completed prior to the anniversary date of the protocol. For studies that exceed three years, the IACUC requires that a new protocol be submitted. A new protocol number is assigned, and the new protocol is reviewed in accordance with III.D.6 of this document. The protocol may be reviewed by Expedited Review or Full Committee Review. The review must be completed, and the protocol approved prior to the original protocol termination date or the study must be halted until the new protocol is approved. If the protocol cannot be approved, parties are notified in accordance with III.D.8 of this document.

The IACUC may, at its discretion, require more frequent periods of review, i.e., post-approval monitoring, for specific issues, as a condition of protocol approval. It is the responsibility of the IACUC Veterinarian and/or the IACUC Administrator to conduct the review(s) in a timely fashion and report adverse findings, if any, to the IACUC Chair for consideration by the IACUC. However, the IACUC may appoint expert consultants or other members of the IACUC to perform the continuing reviews.

Post-approval monitoring includes the following activities, performed by the Laboratory Animal Veterinarian and/or her designee:

- Scheduled and unscheduled oversight of procedures including surgery
- Review of daily procedure and surgery records
- Scheduled and unscheduled inspections
- Daily welfare checks of all animals

Any adverse findings are communicated to the Principal Investigator; the IACUC is notified of such findings at the next convened meeting. Instances posing an immediate threat to the health and welfare of animals are addressed by the Laboratory Animal Veterinarian with the staff on hand. The IACUC Chair is immediately notified of such instances by email.

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend any previously approved activity if it determines that the activity is not being conducted in accordance with an approved protocol, applicable provisions of the Animal Welfare Act, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the OLAW Institutional Animal Care and Use Committee Guidebook, the *Guide*, and/or the institution's Animal Welfare Assurance. The investigative process may include referral to the Institution's Research Integrity Officer if there is potential research misconduct.

The IACUC may suspend an activity only after review of the matter at a convened meeting during which a quorum of voting members is present, and a majority of those present vote to approve the suspension. A suspension will not occur prior to consultation with the responsible individual (that person in charge of the activity). The responsible individual will be informed of the cause for concern so that he/she has an opportunity to respond to the issue. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the PHS Office of Laboratory Animal Welfare (OLAW), the Animal and Plant Health Inspection Service (APHIS), USDA, and/or any other Federal agency funding that activity. The issue may also be referred to the Research Integrity Officer for investigation of potential research misconduct.

If the IACUC Chair and the Laboratory Animal Veterinarian determine that there is immediate and significant danger to the health and welfare of research animals or personnel, the Chair and/or the Laboratory Animal Veterinarian will issue an immediate, temporary halt and require such action as necessary to address the immediate concerns. The matter will then be referred to the full IACUC for review and resolution as described above.

- 11) Farm animals have certain needs and requirements and these needs and requirements do not necessarily change because of the objectives of the research or teaching activity. Therefore, regardless of the teaching or research objective, the FASS Ag Guide will serve as the primary reference document for the needs and requirements of agricultural animals.

- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The IACUC strives to ensure an occupational health and safety program which complies with recommendations and requirements of the *Guide* and *Occupational Health and Safety in the Care and Use of Research Animals* (National Research Council, National Academy Press,

1997) is available for all individuals with significant animal contact. It includes, but is not limited to assessment of and training for the following:

- Physical, chemical and protocol-related hazards;
- Allergens; and
- Zoonoses.

The program is based on risk assessment and hazard identification. The principal elements of the program include:

- Documentable administrative procedures in accordance with identified areas of need/concern,
- Facility design and operation,
- Exposure control methods (e.g., proper ventilation and personal protective gear),
- Equipment maintenance,
- Emergency procedures,
- Regular program evaluations, and
- Other concerns specifically identified in relation to individual protocols/activities.

Associated risks and hazard identification are routinely reviewed during daily/weekly animal checks; inspections; program reviews and any time there is a modification to an approved animal protocol. Mitigation strategies are updated as needed in response to newly identified risks and/or hazards.

The health status and safety of individuals engaged in animal research, working in laboratory animal facilities, or having frequent contact with animals is a shared responsibility with primary duties allocated to the Office of Environmental Health and Safety (EHS). Despite the current size of the Animal Care and Use Program and the limited numbers and species of animals (only purpose bred rodents from licensed suppliers) utilized, the University has in-depth, readily scalable resources and a robust campus-wide program of well trained professionals in all areas of concern to assist the IACUC with protecting the health and safety of individuals involved in the use, care and handling of research animals. EHS maintains a proactive, campus-wide health and safety program, including periodic reviews of all facilities and operating procedures and, where indicated, appropriate referral and access to one or more occupational health and safety physicians. All individuals with significant exposure to research animals will undergo a baseline medical evaluation consisting of an in-depth health history reviewed by a medical professional. Only approved individuals are given direct access to animal rooms; visitors must be accompanied by an approved user. All approved individuals are required to complete a Health Survey and the training modules required for their work. The Health Survey includes questions pertaining to medical history including immunocompromised status and pregnancy status; allergies; and immunizations. EHS and the Pat Walker Health Center (PWHC) work together to determine the appropriate health surveillance, training, protective gear, prophylactic vaccinations, and screenings required to protect the individuals and fully comply with all regulatory requirements. pre

Practices to protect individual health and safety include:

- Signage is posted on room doors.
- Facility-provided lab coats are worn over street clothes when working in all laboratory facilities. Alternatively, individuals may wear scrubs which may not be worn outside the facility.
- Disposable gloves are worn when working with animals or handling soiled caging.
- Respiratory protection and/or face shields may be worn if required by the study.
- Hands must be washed following removal of gloves and prior to leaving a room.

The PWHC is a fully accredited health care facility providing prophylactic vaccinations, health screenings, acute and chronic care, and specialized referrals for employees and students as required by state and federal regulations. PWHC also provides primary care for on-the-job injuries and work-related illness for the University Worker's Compensation

Program and is the only designated location for treatment during operating hours. All office visits are free of charge to students and laboratory, immunization, and radiologic services are provided at a nominal fee, usually covered by personal health insurance through a student insurance program or private health care insurance. Washington Regional Medical Center provides emergency care outside of PWHC operating hours.

In the event of a life-threatening injury, 911 is called immediately. The injured person is taken to the nearest emergency room for treatment. For urgent but non-life-threatening events, the University Police Department is called. Minor cuts, bites, scratches and other similar injuries are treated at the Pat Walker Health Clinic on campus.

As soon as feasible, the CLAF Manager and the individual's supervisor are notified that there has been an injury, and a report is prepared and kept on file. Information included in the report includes the following:

- Date of incident
- Description of incident
- Nature of the injury
- Diagnosis and treatment prescribed
- Prognosis as appropriate
- Restrictions on work activities during recovery

The University has various compliance committees, as described below, which are charged with ensuring the lawful and safe use of various potentially hazardous materials and agents. All protocols are referred to the appropriate committee for review and approval in addition to IACUC approval. These Committees are:

Radiation Safety Committee — Under a license from the Arkansas Department of Health, the Radiation Safety Committee oversees the use of radioisotopes and equipment which emits potentially harmful radiation, e.g., X-ray generators. The Radiation Safety Office is responsible for regular facility inspections to ensure appropriate use, monitoring, and record keeping to ensure that safe practices are followed in each laboratory authorized to use radioactive material or emitters. Use of emitters is permitted only in authorized laboratories. Employees are provided with monitoring badges and protective gear as required by the State of Arkansas Department of Health. (The State of Arkansas is an Agreement state authorized by the federal government to oversee all use of radioisotopes and equipment within the state.) The Director of Research Compliance is an ex officio, non-voting member of the Radiation Safety Committee.

Biological Safety Committee — In addition to its duties regarding the oversight and management of activities involving recombinant DNA molecules as prescribed by law and guided by the Public Health Service, Office of Biotechnology Activities, the Biological Safety Committee is responsible for reviewing and approving all campus activities which include receipt, storage, transport, use and disposal of hazardous biological agents and materials in any form including vertebrate animals, living or dead. Principal Investigators, through submission and approval of a Biological Safety protocol, are required to initiate appropriate practices for the use, handling, care, and disposal of animals which present even a potential hazard to employee, student, or public safety. Examples of the requirements include the posting of signs and warnings on all facilities and equipment; identifying precautions to be taken for vulnerable populations (e.g., pregnant women, immune compromised individuals such as transplant recipients or those taking immune suppressors); and requiring prophylactic vaccinations such as tetanus and Hepatitis B, baseline evaluations, and periodic health screenings to monitor health status as indicated by current standards of monitoring and care for those engaged in hazardous activities. The CLAF Manager and Director of Research Compliance are ex officio, non-voting members of the Biological Safety Committee.

Except for prophylactic vaccinations, the requirement for which an individual must be allowed to waive in accordance with Arkansas state law, no individual is permitted to engage in hazardous, or potentially hazardous, activities until the requirements of the Biological Safety Committee have been met.

As previously stated, the University's current animal care and use program is small. Only purpose bred rodents from licensed vendors are used. In addition, the University restricts research activities to the use of microbial agents at or below Biosafety Level 2 as defined in the publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), Centers for Disease Control, Department of Health and Human Services. The CLAF is secured and entry is controlled by the facility manager. The primary areas of concern are, therefore, allergy and animal bites. Information and training regarding these potential hazards are provided by the IACUC Veterinarian and CLAF Manager to all individuals who use or care for the animals housed in CLAF. Safe animal care and handling techniques are demonstrated by the Principal Investigator and/or the facility manager. Caretakers or research personnel are not allowed to handle animals or care for them unsupervised until they have demonstrated proficiency in the applicable skills. (The CLAF Manager is generally the only person caring for the animals housed at the CLAF. Occasionally one helper, trained personally by the CLAF Manager, is employed on a part-time basis.)

Laboratory and animal care employees must complete two basic safety courses provided by the Office of Environmental Health and Safety. They are: a) Occupational Safety Training – a course designed to provide information about and to promote awareness of potential hazards in the work environment as well as provide information regarding faulty or unsafe work practices; and b) Campus Safety Training – a course which addresses such topics as ergonomics, fall prevention, forklift safety, personal protective equipment, sound surveys and noise abatement, heat stress prevention, defensive driving, power tool safety, electric safety, air quality, confined space entry, safety audits, and OSHA training.

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the Section X. Facility and Species Inventory table.

It is University of Arkansas policy that all research (and teaching) projects using live warm-blooded vertebrate animals, except those studies which involve food and fiber research and require domestic farm species to be housed in an agricultural setting, will be housed in the Central Laboratory Animal Facility (CLAF). In cases where there are legitimate circumstances under which experiments using animals must be conducted in areas other than the CLAF, the location and rationale for use must be approved by the IACUC prior to beginning such activities. Currently there are approved, satellite animal housing areas in addition to the CLAF. One facility, of approximately 170 sq. ft., plus 90 sq. ft. of support space for cage washing, supplies, etc., has an average population of 100 mice when studies are being conducted. This facility is located within the Engineering Research Center and is supervised by the CLAF Manager, in conjunction with the Facility Manager. Another approved facility, with 250 sq. ft. for animal housing and a dedicated surgical suite of 108 sq. ft., is located within the Poultry Science Building. It is used exclusively for housing poultry that, because of the need for frequent observation, biological status, surgical manipulation, etc., cannot be housed in the farm facilities. When a study is in progress, the average daily population is approximately 6 birds. The facility is supervised by the principal investigator. SCEN 703/714 is being prepared for housing an avian breeding colony, as it was determined that less stress would be placed on the colony if it were isolated and collocated with the research program. SCEN 402/403, CHMP 224, SCEN 503, and FERR 281 house snakes and/or frogs.

The CLAF (9295 sq. ft.) contains 13 animal holding rooms. There are three large and eight smaller rooms of the same design, a room with four cubicles, and a quarantine room which is of the same design as the regular animal rooms, but on a smaller scale. All animal

holding rooms allow for individual control of temperature and lighting cycles and provide the recommended ventilation rates. There is also procedure and laboratory space, an area for aseptic surgery, and support areas for these functions. Specialized support areas that allow for the proper sanitization of animal caging and for the storage of clean equipment, animal feed and bedding are also included within the facility. Mice and rats are the only species that have been housed in the facility since 2009).

- G. The training or instruction available to scientists, animal technicians, IACUC members, and other personnel involved in animal care, treatment, or use is as follows:

The training, instruction, and qualifications of scientists and students are assessed in the review of protocols by the IACUC. Vitae detailing the experience and qualifications for all individuals with significant involvement in the care and/or use of animals in approved protocols are maintained by the IACUC Administrator.

Scientists, animal technicians, and other personnel using animals are trained by the personnel in charge of the animal facility they are using. Students (graduate and undergraduate) are instructed and supervised in proper techniques, handling and use by the Principal Investigator in charge of the project. New techniques and procedures with which a Principal Investigator is unfamiliar are taught by other scientists with expertise in the area or by a qualified veterinarian. All faculty, staff, and students who use live, vertebrate animals for teaching or research purposes are required to complete mandatory IACUC Training. This training, provided by CITI, is available through web access. LATA was phased out of our training process in May 2017, and all individuals involved with animal research are expected to complete CITI modules by February 28, 2018.

Upon logging into CITI, a person must select and complete the module(s) appropriate to his/her level of interaction:

- "Working with the IACUC" for Researchers, Animal Technicians, Research Administration/Staff and Students working with animals.
- "Working with the IACUC Members, Staff and Community Members"
- "Essentials for IACUC Members" for IACUC Members and Staff
- "Essentials for IACUC Members" for IACUC Community Members
- IACUC Community Member
- Institutional Officials
- IACUC Chair
- Post-Approval Monitoring (PAM)
- Minimizing Pain and Distress
- The Humane Care and Use of Laboratory Animals
- University of Arkansas Policy and Procedures for the Care and Use of Laboratory Animals

Additional modules are selected based on a set of questions that identify species-specific electives:

- I work with Mice. Family: Muridae Cricetidae
- I work with Rats. Genus: Rattus
- I work with Hamsters: Family: Muridae
- I work with Gerbils
- I work with Guinea Pigs
- Working with Ferrets in Research Settings
- I work with Rabbits. Family: Leporidae
- I work with Horses
- I work with Sheep and Goats
- I work with Fish
- I work with Zebrafish

- I work with Swine

Completion of these additional modules is voluntary unless explicitly required as a condition of IACUC protocol approval. There is no charge to the individuals completing either mandatory or voluntary training via the website. New protocols are not reviewed until all research personnel have completed the mandatory training.

New IACUC members are required to complete the module "Working with the IACUC." This module, also required of all researchers, animal technicians, staff and students who work with animals, provides guidance on numerous topics, including reducing the number of animals on a study to that necessary to obtain valid results, as well as reducing pain and distress in those animals.

Every member is provided with access to electronic copies of the PHS Policy; The Guide; the IACUC Guidebook; the Animal Welfare Act and Animal Welfare Regulations (USDA, "The Bluebook"); the Guide for the Care and Use of Agricultural Animals in Research and Teaching; and the University's Animal Welfare Assurance. Experienced members, under the guidance of the Chair and the IACUC veterinarian, teach new members how to conduct facility and program reviews. In addition, new members are provided access to the ORI/PHS training, <http://ori.hhs.gov/education/products/IACUC/home.html>, "An IACUC Member's Guide to Animal Facility Inspections."

IV. Institutional Program Evaluation and Accreditation

All this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and 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's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category 2 — not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached (Attachment 2).

V. Recordkeeping Requirements

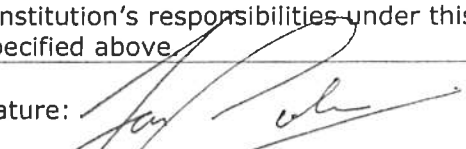
- A. This Institution will maintain for at least 3 years:
 1. A copy of this Assurance and any modifications made to it, as approved by the PHS.
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld.
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Jim Coleman, Ph.D.
 5. Records of accrediting body determinations.


- B. 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 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked).
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance.
 - 3. Any change in the IACUC membership.
 - 4. 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 Institutional Official, Jim Coleman, Ph.D.
 - 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy.
 - 2. Any serious deviations from the provisions of the *Guide*.
 - 3. Any suspension of an activity by the IACUC.
- C. Reports filed under VI.A. and VI.B., above, will include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Jim Coleman	
Title: Provost and Executive Vice Chancellor for Academic Affairs	
Name of Institution: University of Arkansas	
Address: (street, city, state, country, postal code) 1125 N. Maple Avenue 422 Administration Bldg. 1 University of Arkansas Fayetteville, AR 72701	
Phone: (479) 575-5459	Fax: (479) 575-3846
E-mail: jscolema@uark.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 2.8.2018

B. PHS Approving Official (to be completed by OLAW)	
Doreen H. Bartlett Senior Assurance Officer, Division of Assurances Office of Laboratory Animal Welfare (OLAW) NIH/OD/OER 6705 Rockledge Drive RKL 1, Suite 360-MSC 7982 Bethesda, Maryland 20892-7982 bartletd@mail.nih.gov	
Signature: 	Date: 2/12/18
Assurance Number: D16-00506 (A3878-01)	
Effective Date: 2/8/18	Expiration Date: 2/28/22

VIII. Membership of the IACUC

Date: 1/1/2018			
Name of Institution: University of Arkansas			
Assurance Number: A-3878-01			
IACUC Chairperson			
Name*: Craig N. Coon			
Title: Professor	Degree/Credentials: •Ph.D., Biochemistry and Biophysics, Texas A&M University, 1973 •M.S., Plant Physiology and Biochemistry, Texas A&M University, 1970 •B.S., Animal Science, Texas A&M University, 1966		
Address: (street, city, state, zip code) Center of Excellence for Poultry Science 211 Poultry Science 1 - University of Arkansas Fayetteville, AR 72701			
E-mail: ccoon@uark.edu			
Phone: (479) 575-4134		Fax: (479) 575-877	
IACUC Roster			
Name of Member	Degree/ Credentials	Position Title	PHS Policy Membership Requirements
Kate Williams	D.V.M.	Animal Welfare Veterinarian	Veterinarian
Jason Apple	Ph.D./Animal Science	Professor	Scientist
Michele King	M.S. Library Science	Assoc. Librarian	Non-Scientist
Arlo Juarez	B.A. Political Science	Community Representative – Cabinet Maker	Non-affiliated member
J.D. Willson	Ph.D./Biological Science	Assistant Professor	Scientist
Jeff Wolchok	Ph.D./Biomedical Engineering	Associate Professor	Scientist
David McNabb	Ph.D./Biological Science	Professor	Scientist
Larry Kamees	Ph.D./Graduate Student	Student Representative	Scientist
Billy Hargis	D.V.M./Ph.D. Poultry Science	Professor	Scientist
Nic Greene	Ph.D./Exercise Science	Assistant Professor	Scientist
Tina Poseno	B.A./LVT, CLAF manager, IACUC administrator	Ex-officio, non-voting	
Jason G. Ramage	B.S. Zoology/M.S. Biology, MBA	Ex-officio, non-voting	

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

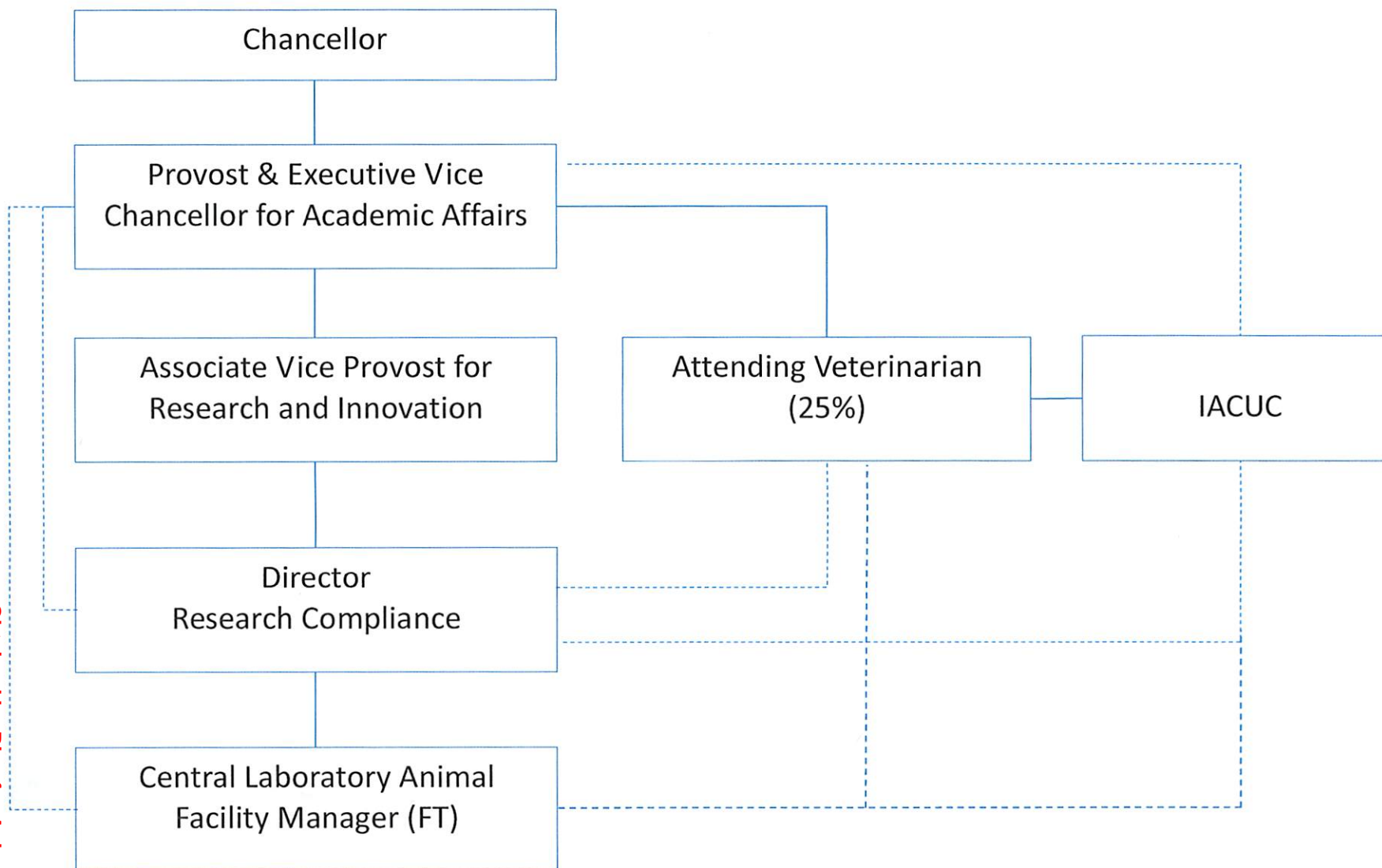
Contact #1	
Name: Jason G. Ramage	
Title: Director, Research Compliance	
Phone: (479) 575-2105	E-mail: ramage@uark.edu

X. Facility and Species Inventory

Date: November 21, 2017			
Name of Institution: University of Arkansas			
Assurance Number: A3878-01			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
Central Laboratory Facility	9295	Rat, mouse	50 Rats 400 Mice
Engineering Research Center	360	Mouse	100
Poultry Science	358	Chicken	6
CHMP 224	200	Frogs	50
FERR 218	400	Frogs, snakes	100 Frogs 10 Snakes
SCEN 503	220	Fish	50

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

Attachments



Memorandum to: Jim Coleman

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date: 6/15/17

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)), Section [IV.B.1.-3.](#), the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)), and the Animal Welfare Act ([AWA](#)) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy [IV.A.1.a.-i.](#)): [optional]

I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA

Departures from the PHS Policy, the *Guide*, and the AWA.

Select A or B:

☒ A. There were no departures during this reporting period.

☐ B. The following departures have been reviewed and approved by the IACUC:

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s):

Select A or B:

☒ A. There were no deficiencies in the program during this reporting period.

☐ B. The following deficiencies have been identified:

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s):

Select A or B:

☐ A. There were no deficiencies in the animal facility during this reporting period.

[x] B. The following deficiencies have been identified:

See Attached Table.

IV. Minority Views

Select A or B:

☒ A. No minority views were submitted or expressed.

[] B. The following minority views were expressed:

V. Status of AAALAC Accreditation

VI. Signatures

Names of IACUC Members

Signatures

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