Preface

Purpose and Scope of Manual

This manual establishes the University of Central Oklahoma’s Institutional Animal Care and Use Committee (IACUC) definition of animal as it relates to regulatory oversight and establishes policies related to animals approved for use in research, education, and testing.

Mission Statement

The University of Central Oklahoma (UCO) recognizes the importance of animals in research and the scientific and ethical responsibility for their humane care and use. All those involved with the use of animals are responsible for ensuring the health and well-being of the animals used in research and education at UCO. The IACUC is responsible for overseeing the provisions for the care and well-being of vertebrate animals used for research and educational purposes at UCO and serves the public by ensuring compliance with all legal and ethical standards regarding the use of vertebrate animals in research and teaching at UCO.
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1.0 References:

The requirements for the Animal Welfare Act are set forth under the Regulations and Standards in the Title 9 Code of Federal Regulations (CFR), Chapter 1, Subchapter A – Animal Welfare.

Guide for the Care and Use of Laboratory Animals (Eight Edition)
The “Guide” sets the standards for the care and use of all vertebrate animals used in biomedical research, teaching, or testing programs sponsored by UCO or conducted on UCO campuses.

Guide for the Care and Use of Agricultural Animals in Research and Teaching (Third Edition)
The “Ag Guide” sets the standards for the care and use of all vertebrate farm animals (e.g., horses, cattle, pigs, sheep, goats, poultry, etc.)

1.1 The following abbreviations will be used throughout this policy manual:

Assistant Chair – Assistant Chair of the UCO IACUC
AV – Attending Veterinarian
AWA – Animal Welfare Act
AWR – Animal Welfare Regulations
CEO – Chief Executive Officer (President)
Chair – Chair of the UCO IACUC
COI – Conflict of Interest
ESA – Endangered Species Act
Guide – Guide for the Care and Use of Laboratory Animals
IACUC – Institutional Animal Care and Use Committee
Institution/University- the University of Central Oklahoma (UCO)
IO – Institutional Official (Provost)
NIH – National Institutes of Health
OLAW – Office of Laboratory Animal Welfare
ORIC – UCO Office of Research Integrity and Compliance
PHS – Public Health Service
PI/Co-PI – Principal Investigator/Co-Principal Investigator
Staff – Staff of the UCO Office of Research Integrity and Compliance
USDA – United States Department of Agriculture
1.2 Office of Laboratory Animal Welfare (OLAW)

The Office of Laboratory Animal Welfare (OLAW) implements Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. While OLAW is located organizationally at the National Institutes of Health (NIH) in Bethesda, Maryland, OLAW’s responsibility for animal welfare extends beyond NIH to all PHS-supported activities involving animals. OLAW issues policy guidance, interpretation, or general notices regarding PHS Policy.

Specific OLAW responsibilities include:
- Implementation of the PHS Policy;
- Interpretation of the PHS Policy;
- Negotiation of Animal Welfare Assurances;
- Evaluation of compliance with the PHS Policy; and
- Education of institutions and investigators receiving PHS support.

1.2.1 Animal Welfare Assurance

Before the PHS may award a grant or contract that involves the use of animals, the recipient institution and all performance sites involving or using animals must have on file with OLAW an approved Animal Welfare Assurance (hereafter Assurance). The Assurance is the institution’s commitment of trust between the institution and the PHS. The Assurance includes the following:

- The designation of the IO responsible for compliance;
- A commitment that the institution will comply with the PHS Policy, the Guide, the AWA, and the AWR; and
- A description of the institution's program for animal care and use.

Once PHS has awarded a grant, the IO receives a request to submit an application for an Assurance.

The IACUC will work with the PI involved to submit the Assurance.

1.2.2 Public Health Service Policy

The PHS policy applies to the use of live, vertebrate animals in any activity supported or conducted by the PHS. PHS agencies include:

- Agency for Healthcare Research and Quality;
- Agency for Toxic Substances and Disease Registry;
- Centers for Disease Control and Prevention;
- Food and Drug Administration;
- Health Resources and Services Administration;
- Indian Health Service;
- National Institutes of Health;
- Office of Public Health and Safety;
- Office of the Secretary;
- Program Support Center;
- Substance Abuse and Mental Health Services Administration; and
- Office of the Assistant Secretary for Preparedness and Response

If a UCO researcher obtains funding from a PHS agency, the UCO ORIC will work in accordance with OLAW to fulfill compliance-related requirements.
1.3 **United States Department of Agriculture (USDA)**

In 1966, Congress passed the Laboratory Animal Welfare Act (PL 89-544) and the United States Department of Agriculture (USDA) was named the responsible agency for the enforcement of the Animal Welfare Act (AWA) to protect certain animals from inhumane treatment and neglect. Congress passed the AWA in 1966 and strengthened the law through amendments in 1970, 1976, 1985, and 1990. The USDA’s Animal and Plant Health Inspection Service (APHIS) administers the AWA, its standards, and its regulations.

UCO voluntarily complies with the requirements set forth by the USDA.

1.3.1 **Animal Welfare Act**

The AWA requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. Individuals who operate facilities in these categories must provide their animals with adequate care and treatment in the areas of housing, handling, sanitation, nutrition, water, veterinary care, and protection from extreme weather and temperatures. Although federal requirements establish acceptable standards, they are not ideal. Regulated businesses are encouraged to exceed the specified minimum standards.

The AWA defines an "animal" as being any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded vertebrate animal to be used for research, testing, experimentation or exhibition, or kept as a pet. Exemptions in the AWA regulations extend to birds, rats of the genus *Rattus* and mice of the genus *Mus* bred specifically for research purposes, horses not used for research, and any other farm animals, including livestock and poultry, which are used or intended for use as food or feed (AWA 7.54.2132(g)).

In order to encourage best practices for teaching and research, the UCO IACUC has extended review to include all vertebrates, including all birds, rodents, reptiles, amphibians, and fish. This is consistent with PHS Policy III.A.

1.3.2 **Exemptions**

The following are exempt from IACUC review:

- Activities involving animals that perform tasks, participate in activities, or appear in exhibits or demonstrations;
- The use of tissues, organs, or other parts of dead animals received as such.

Section 2: IACUC Authority and Responsibilities

2.0 **Authority**

As mandated by the Health Research Extension Act (HREA) of 1985 and the AWA, the Chief Executive Officer (CEO) of an organization delineates the responsibilities of the IACUC to the IO. At UCO, the CEO is the President and delineates the Provost as IO. The IO is given the administrative and operational authority to commit institutional resources to ensure compliance with regulations and other requirements. The IO will appoint the Chair of the IACUC for an indefinite period.
2.1 Committee Composition

The UCO IACUC is composed of regular voting members, and alternate voting members. Regular voting members include the chair, assistant chair, non-affiliated member, scientist, and non-scientist.

Required categories of membership include:

- Chair: The Chair is a faculty member of UCO with research experience.
- Assistant Chair: The Assistant Chair is a faculty member of UCO with research experience who can serve in the absence of the Chair.
- Nonaffiliated member(s): The nonaffiliated member(s) represent general community interest and do not have affiliation with UCO.
- Scientist: A scientist such as a faculty member experienced in research involving animals.
- Nonscientist: A nonscientist is a member whose primary concerns are in a nonscientific area (i.e. ethicist, lawyer, member of the clergy, librarian, etc.)
- Alternate member(s): Alternate members may be appointed to the IACUC as long as they can serve in a specific one-to-one designation of IACUC members.

2.2 Quorum Requirements

Certain IACUC actions require a quorum such as full committee review (FCR) of a research project per PHS Policy IV.C.2. and AWR §2.31(d)(2)), suspension of an activity (Policy IV.C.6. and AWR §2.31(d)(6)), and business related to the operations of the IACUC. The UCO IACUC defines a “quorum” as more than half of the regular IACUC voting members. If quorum is not met at the time of voting, the Committee’s action will not be approved until quorum can be met.

2.3 Confidentiality

To protect the integrity of UCO and its researchers, material provided to the IACUC or ORIC shall be privileged information and the IACUC shall assure the confidentiality of the data contained therein.

2.4 Functions of the IACUC

- Review at least once every year, UCO policies, procedures, and functions of the IACUC using the Guide as a basis for evaluation.
- Review at least once every six months, all of UCO’s animal facilities (including satellite facilities) using the Guide as a basis for evaluation. ([https://grants.nih.gov/grants/olaw/sampledoc/checklist.htm](https://grants.nih.gov/grants/olaw/sampledoc/checklist.htm))
- Review, approve, require modifications, or withhold approval of activities related to the care and use of animals in research. Notify appropriate individuals when needed.
- Prepare reports of the IACUC evaluations and submit as needed to IO and accrediting agencies.
- Make written recommendations to the IO regarding any aspect of UCO’s animal program, facilities, or personnel.
- Suspend an activity involving animals if a violation has occurred.
2.5 Liability

The IO is the individual held responsible on behalf of UCO for ensuring compliance. Failure to comply could result in withdrawal of funds for sponsored projects.

2.6 Conflicts of Interest

No IACUC member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest, (i.e. personal involvement in the activity) except to provide information requested by the IACUC. The member must recuse himself or herself from the portion of the meeting when the Committee will discuss the conflicting activity.

An investigator or IACUC member is said to have a conflict of interest whenever that person, his or her spouse, or dependent child falls under any of the following conditions:

- Is an investigator or sub-investigator on the protocol (IACUC members only, not applicable to PIs).
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor.
- Has an equity interest in the sponsor of $10,000 or greater or 5% or greater of the equity sponsor.
- Has received payments or other incentives from any sponsor that when aggregated for the investigator or member, spouse and dependent children, total $10,000 or greater.
- Has identified him/herself for any other reason as having a conflict of interest.

Other possible examples of conflict of interest include cases where:

- A member is involved in a potentially competing research program;
- Access to funding or intellectual information may provide an unfair competitive advantage; or
- A member’s personal biases may interfere with his or her impartial judgment.

If the investigator submitting a protocol believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded. The Chair (or in his/her absence, the Assistant Chair) will present the declared conflict and the Committee will determine whether a conflict exists. Should an IACUC member declare involvement in any way in a research protocol under review by the IACUC, or state a conflict of interest with the research protocol, then the member(s):

- May remain in the meeting room to provide information requested by the IACUC;
- Recuse themselves from the meeting room for discussion and voting; and
- Are not counted towards the vote.
2.7 Training

2.7.1 Education and Training for IACUC Members, Researchers, and Staff of ORIC

Education and training for the IACUC members, researchers, and the staff of the ORIC will be determined as needed. Throughout their tenure, attending conferences, webinars, and taking the required animal training modules will be part of the protocol for education and training. The training will be completed every three years.

2.7.2 Education and Training for IACUC members

The Chair and ORIC Administrator will schedule a meeting with new IACUC members for orientation. The meeting discussion will include responsibilities, criteria for membership, authority of the IACUC, the protocol review and monitoring processes, information about semiannual reviews, and regulatory requirements. The new member will be provided a copy of the regulatory guidance texts as well as any other pertinent information. At the time of orientation, the new member will be required to sign a Confidentiality Agreement. Members will complete the assigned animal training modules that involve general IACUC regulations.

2.7.3 Education and Training for Researchers

Researchers will complete assigned animal training that involve their research.

2.8 Meetings and Communication

The IACUC will meet once a month during each academic semester (Fall and Spring). If there is no new business, the Chair may cancel the monthly meeting at his/her discretion. The IACUC will not meet during the summer months (June, July, and August). Protocols received during this time frame will be reviewed via Designated Member Review (DMR) following the procedures outlined in Section 3.5 or held to the first meeting in the fall semester.

The ORIC staff will serve as liaison for all IACUC communication.

Section 3: IACUC Review of Research

3.0 Activities that Require IACUC Review

The utilization of animals in teaching and research is valuable and worthwhile to the educational mission of UCO. The following are specific activities that fall under the purview of the IACUC:

3.0.1 Teaching

The use of live vertebrate animals in educational settings is subject to IACUC review. This includes the use of live animals in laboratory and field observations. Faculty planning to utilize vertebrate animals in coursework must submit an IACUC application for approval before instruction begins.
3.0.2 Research on Campus

The UCO IACUC has the responsibility of reviewing all research involving vertebrate animals conducted by UCO faculty, staff, and students to ensure that such research follows UCO policies and is in compliance with local, state, and federal regulations. Research involving any UCO personnel being conducted on campus, whether field studies or in laboratories must be reviewed and approved by the UCO IACUC unless it is completed under a memorandum of understanding with another PHS assured facility/university’s IACUC. It is the duty of UCO personnel to abide by UCO policy and any deviation from UCO policy must be approved in writing by a full board review of the UCO IACUC prior to UCO personnel engaging in any research. Failure to abide by UCO policies in this event shall constitute noncompliance, and shall be dealt with according to UCO policy.

3.0.3 Research at External Sites

Research involving any UCO personnel being conducted off-site and/or at multiple sites, whether field studies or in laboratories must be reviewed and approved by the UCO IACUC, unless it is completed under a memorandum of understanding with another PHS assured facility/university’s IACUC. In the event of disagreement between UCO policies and those followed at off-campus sites, it is the duty of UCO personnel to abide by policies of the primary institution (IACUC of record) overseeing the research. UCO policy must be approved in writing by a full board review of the UCO IACUC prior to UCO personnel engaging in any research.

3.0.4 Research by Affiliated Individuals

Research conducted by affiliated individuals including students, staff, adjunct faculty, and instructors at UCO are subject to UCO’s guidelines for animal use and must follow policies and procedures.

3.0.5 Research Guidelines for Specific Species

In an effort to clarify oversight of all animal care and use activities, there are guidelines on specific species (depending upon the agency). Please follow the following mandates:

Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research (2004)
American Society of Ichthyologists and Herpetologists

Guidelines to the Use of Wild Birds in Research (2010)
The Ornithological Council
https://www.aalac.org/accreditation/RefResources/SS_WildBirds.pdf

Fish Research and the Institutional Animal Care and Use Committee (2003)
Institute for Laboratory Animal Resources
http://dels.nas.edu/ilar_n/ilarjournal/44_4/v4404Borski.pdf
Guidelines for the Use of Fishes in Research (2014)
American Fisheries Society

Guidelines of the American Society of Mammologists for the Use of Wild Mammals in Research (2016)
American Society of Mammologists

3.1 Guidelines on Pain Categories and Minimizing Pain and Distress

UCO is committed to the humane and responsible treatment of animals used in research. The IACUC is given the responsibility of ensuring that research animals are treated humanely, that pain and distress is minimized as much as possible without compromising the integrity of the research, and that, where necessary, humane endpoints are observed. It is recognized that the manipulation of vertebrate animals that result in pain/distress can be an important component of an investigation. Investigators should refer to OLAW guidelines of animal welfare found at https://grants.nih.gov/grants/olaw/references/phspol.htm.

The IACUC review will be guided not only by the OLAW and USDA Guidelines, but also the search for more humane alternatives, including the replacement of animals with non-animal methods such as computer simulations, reduction of the number of animals necessary to satisfy experimental goals, and the refinement of experimental methods to minimize pain and distress.

3.2 Alternative Methodologies for Animal Research

The AWA regulations require PIs to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements (3 Rs).

**Replacement:** the study uses a non-animal model or a species deemed to be lower on the phylogenetic scale, (e.g., in vitro culture instead of an animal, or a mouse model instead of a dog).

**Refinement:** the study has minimized animal pain and distress. This includes using the least painful technique, using appropriate anesthesia and analgesia, and incorporating humane endpoints for treatment or for early intervention, potentially with removal of an animal from the study prior to the experimental endpoint.

**Reduction:** the study uses the minimum number of animals necessary to accomplish experimental objectives. Statistical tests (e.g., power analysis) should be used to confirm that the minimum number of animals is requested for the protocol.

If potential procedures are categorized on the protocol form as a USDA pain/distress Category D or E, the researcher is required to document that there are no less painful/distress ways to accomplish the goals of the project. If there are less painful/distressful procedures to accomplish the goals of the project, the PI must provide a scientific justification for not using the less painful approach.
3.2.1 Alternative Documentation Process

The documentation process can be accomplished with a literature search that includes at least one database search. Before you begin your search, consider the following:

- Consider other possible animal or non-animal models (e.g., tissue culture, cell culture, fish, rats, etc.).
- Consider your objectives and endpoints.
- Note any drugs or compounds used in procedures (e.g., anesthetics, analgesics, test compounds, etc.).
- Note methods and procedures using animals, paying particular attention to those procedures that may cause pain or distress to the animal.
- List any potential alternatives (all 3 Rs) of which you are aware. (e.g., alternate models, modified techniques, housing modifications, modified restraint, in vitro methods, computer simulations, etc.).
- Develop a conceptual search strategy using the keywords and concepts you noted above.
- If too many records are retrieved, additional relevant terms may make the results fewer and more useful; if too little is retrieved, fewer terms and a more conceptual approach may identify the relevant material. Use these terms and concepts as needed when searching.
- Database selection: Choose those that are appropriate for the area of study, keeping in mind the type of protocol: research, teaching, or testing protocol.

3.2.2 How to Document Alternative Searches

As per the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA/APHIS/AC) Policy 12 (Consideration of Alternatives to Painful/Distressful Procedures), when a database search is provided the narrative must, at a minimum, include:

1. the names of the databases searched;
2. the date the search was performed;
3. the period covered by the search;
4. the keywords and/or the search strategy used; and
5. the number of hits obtained from the search and describe the search results. In other words, how did the results of the search lead the PI to conclude that there is no alternative to further reduce, replace, or refine this potentially painful/distressful procedure?

The narrative should be submitted with your protocol.

3.3 Protocol Submission Procedures

It is the responsibility of investigators to access and complete the required documents for submission to the IACUC, regardless of whether a project is funded or not.

Electronic versions of each application must be submitted to the ORIC office prior to IACUC review. Electronic copy may be submitted to iacuc@uco.edu.
3.3.1 Who can be a Principal Investigator (PI)?

Faculty, staff, and students of UCO are permitted to be a PI; however, while a student can serve as PI, they must have a tenured or tenure-track faculty member serve as Co-PI.

3.3.2 Supplemental Documentation

Researchers may be required to submit supplemental documentation such as current scientific collectors’ permits (local, state, and federal) in accordance with the nature of their research projects.

3.4 Protocol Review Procedures

3.4.1 Initial Review

Upon receipt of a new application, the ORIC will log in the submission, assign it an IACUC protocol number, and open a file for that application. The ORIC staff will then complete an initial protocol review, and will contact the PI(s) with any initial edits or inquiries.

The Chair will review the application with the ORIC Administrator to make any and all determinations regarding the protocol. The ORIC staff will communicate and serve as liaison between the IACUC and researchers to receive additional information or documentation.

The ORIC staff will proceed as the Chair deems necessary by one of the following procedures:

3.4.2 Full Committee Review (FCR) – The protocol application will be reviewed by all committee members who will each complete the Reviewer Form and submit to the ORIC staff for discussion at the next IACUC meeting.

3.4.3 Designated Member Review (DMR) - The protocol application will be reviewed by all committee members. Committee members will have 72 hours (three business days) to agree or disagree with DMR review. If one member disagrees then the protocol will be reviewed at the next IACUC meeting.

3.4.4 Notification Procedures - The ORIC staff will be responsible for notifying researchers of the decision(s) made by the IACUC.

3.5 Modifications to Approved Protocols

It is recognized that circumstances may arise during the conduct of a study that may affect the progress, design, or success of the study. Any changes to an IACUC-approved study require approval prior to their implementation. The only exception is in cases where immediate action is needed in order to preserve the integrity of the study or the safety of the investigators or animals. In such cases a written report of the action taken and the justification for it in the absence of IACUC approval will be required.

If an investigator determines that an amendment to an IACUC-approved study is necessary, the investigator shall submit the “Protocol Modification Form”. Below are the guidelines, as regulated by PHS Policy IV.C.1 that require a Modification Form.
Notice Number NOT-OD-14-126 issued August 26, 2014 by the National Institutes of Health provided guidance to PHS awardee institutions and IACUC’s on significant changes to animal activities. The guidance stated, the “The IACUC has some discretion to use IACUC-reviewed and -approved policies to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS PolicyIV.C.1. a-g. It is the IACUC’s responsibility to clearly define and communicate its policy for determining significance to investigators”.

In brief, significant changes include changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant.

Significant changes described in a.-g., below, must be approved by one of the valid IACUC approval methods described in the PHS Policy IV.C.2, that is Full Committee Review (FCR) or Designated Member Review (DMR), including changes:

- from non-survival to survival surgery;
- resulting in greater pain, distress, or degree of invasiveness;
- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- in species;
- in study objectives;
- in Principal Investigator (PI); and
- that impact personnel safety.

The specific significant changes described in a.-f., below, may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. This includes changes in:

- anesthesia, analgesia, sedation, or experimental substances;
- euthanasia to any method approved in the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals;
- duration, frequency, type, or number of procedures performed on an animal;
- extension of weaning for specific mouse strains;
- provision of genotyping on adults on case-by-case scenario; and
- case-by-case approvals for special husbandry requirements, enrichment or single housing needs, and use of alternative agents/medications either prophylactic, treatments or research use.

A significant change that may be handled administratively according to an existing IACUC-reviewed and -approved policy without additional consultation or notification is an increase in previously approved animal numbers not to exceed 10% of the original request (PHS Policy IV.D.1.a.)**.

Changes that may be handled administratively without IACUC-approved policies, consultations, or notifications include:

- correction of typographical errors;
- correction of grammar;
- contact information updates; and
- change in personnel, other than the PI. (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)

**Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.
3.6 **Annual Update**

Once an application has been approved, it is valid for a maximum of three years from the date of initial approval; however, it must be updated on an annual basis by filling out the “Annual Update Form”. Annual updates are required even if there are no changes to the project. If at the end of the three-year approval period the investigator wishes to continue the study, a new application must be submitted along with any relevant supporting documentation to the ORIC office.

If the anniversary of the approval date passes without the renewal of the study, all research activities must cease until a renewal is granted. The ORIC office will notify researchers in advance of the anniversary date that approval is set to expire, along with an inquiry as to the researchers’ intentions regarding renewal, but it is the responsibility of the researcher(s) to complete the appropriate form in a timely manner.

3.7 **Closure of Approved Protocol**

An active study may be closed at any time by the study investigator(s), or by administrative action following an investigation. A study also will close on the date of its expiration if no further action is taken to renew. The “Closure Request Form” is to be used by investigators to complete the process of closure.

3.8 **Unanticipated Problems, Adverse Events, and Deviations from Approved Protocol**

The researcher should notify the ORIC immediately if there has been an unanticipated problem or adverse event or deviation from the approved protocol while conducting animal research. The ORIC and IACUC Chair will address the issue(s) raised and determine an appropriate plan of action. If it is determined that there is an issue of non-compliance, the IACUC will follow UCO policy (SOP Section 5) regarding non-compliance.

Contact information for the Office of Research Integrity and Compliance: 405-974-5497 or 405-974-5479 or iacuc@uco.edu.

**Section 4: Semiannual Program Review and Facility Inspections**

4.0 **Semiannual Reviews Overview**

The IACUC reviews the program for humane care and use of animals at least once every six months. The IACUC also inspects all institutional animal facilities including field sites at least once every six months.

4.1 **Facility Inspections**

4.1.1 **Scheduling**

Semi-annually (April and October), the IACUC conducts facility evaluations of all areas where animals are housed or used for experiments.

4.1.2 **Categories to be inspected**

- Sanitation,
- Food and water provisions,
- Animal identification,
- Waste disposal,
- Animal health records,
- Controlled and/or expired drugs,
- Environmental control,
- Occupational health and safety concerns,
- Staff training, and
- Knowledge of applicable rules and regulations, and security.

### 4.1.3 Performing Inspections Procedures

The Chair and ORIC Manager will perform the inspections. The ORIC staff will provide notice to investigators of the dates and times of the inspections.

### 4.1.4 Deficiency Correction Schedule

All deficiencies identified during the inspection and/or program review are designated by the ORIC staff and IACUC Chair as minor or significant. A significant deficiency is defined as a situation that is or may be a threat to animal health or safety.

For both categories of deficiencies, a reasonable and specific plan and schedule with dates for correction must be included in the final report. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic.

## Section 5: Animal Welfare Concerns and Issues of Non-Compliance

To help ensure that vertebrate animals receive humane care, use or treatment in accordance with the highest ethical standards, laws, regulations, and policies governing animal research, the IACUC must review and, if warranted, address any animal-related concerns raised by the public or institutional employees. Procedures are established to ensure that concerns are communicated to the IACUC. The Committee will review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions.

### 5.0 Methods for Reporting

There are options available for reporting concerns about animal care and use at UCO. The staff in the ORIC is readily available to be of assistance with these concerns. Contact information for the ORIC: 405-974-5497 or 405-974-5479 or iacuc@uco.edu. The names and phone numbers of contact persons are available on the ORIC website as well (http://www.uco.edu/academic-affairs/research-compliance/).

### 5.1 Procedures for Addressing Non-Compliance

#### 5.1.1 Initial Evaluation, Action Assigned, and Complaint Assessment

When an alleged non-compliance issue is raised, the ORIC staff will notify the Chair of the IACUC. After the ORIC staff and Chair discuss the allegation(s), the Chair will determine whether the concern(s) requires:

- Further investigation and immediate action,
- Further investigation but no immediate action, or
- No action.

Once this decision has been made, the ORIC staff will notify the appropriate individuals.
5.1.2 Investigation

The nature of the information investigated will vary depending upon the circumstances, but often involves:

- Speaking with complainants (if known), any persons against whom allegations were directed, and pertinent individuals;
- Observing or viewing the animals and their environment; and
- Reviewing any pertinent records (applications, animal records, or other miscellaneous documents).

5.1.3 Outcomes and Final Actions

The Chair and ORIC staff will provide a report to the members of the Committee, which summarizes:

- The concern(s),
- The results of discussion(s),
- The condition of animals and their environment, and
- The results of records and other document reviews.

5.1.4 Consequences of Non-Compliance

Subsequent actions of the IACUC may include:

- Implementing measures to prevent recurrence.
- Notifying the complainant and any persons against whom allegations were directed.
- Notifying the IO and any relevant UCO staff such as Dean(s) and Department Chair(s).
- Notifying the funding or regulatory agencies, as required.

Notification will be written by the Chair and disseminated by the ORIC staff to those deemed necessary to receive communication.

5.1.5 Reporting Requirements

Failure by research personnel to follow Federal and/or UCO regulations, guidelines, policies, and/or procedures may require reporting to the appropriate institutional, local, state, and/or Federal agencies. Violations may include, but are not limited to:

- Serious or continuing non-compliance with regulations,
- Serious deviations from the Guide for the Care and Use of Laboratory Animals, and
- IACUC suspensions.

Self-reporting of non-compliance should be in writing and emailed to iacuc@uco.edu or mailed to the ORIC.
Section 6: Office of Compliance Recordkeeping Procedures

6.0 Maintaining IACUC Records

The ORIC is responsible for maintaining:

- Minutes of IACUC meetings;
- Records of IACUC activities and deliberations;
- Documentation of protocols reviewed by the IACUC, and proposed significant changes to protocols; and
- IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction.

All records are to be kept for a minimum of three years, with the exception of records that relate directly to protocols, which must be kept for the duration of the activity and for an additional three years after completion of the activity.

6.0.1 Protocols

The regulations require that IACUC applications and proposed significant changes be retained for the duration of the animal research activity and for an additional three years after the end of the activity. Applications submitted to the IACUC must be kept for three years even if approval was not granted. The records must show whether or not IACUC approval was given.

6.0.2 Committee Records

Both the PHS Policy and the AWRs require that UCO retain the Semiannual Program Review and Facility Inspections Report and any recommendations of the IACUC. All these records must be kept for at least three years; and must be accessible to OLAW, USDA/APHIS, and funding agencies for inspection or copying.