

THE
UNIVERSITY
OF RHODE ISLAND
DIVISION OF RESEARCH
AND ECONOMIC
DEVELOPMENT

Institutional Animal Care and Use Committee
Governance and Operating Policies

Table of Contents

1.0 URI IACUC..... 6

2.0 MISSION 6

3.0 APPLICABLE GUIDELINES AND REGULATIONS 6

 3.1 Office of Laboratory Animal Welfare 6

 3.1.1 Animal Welfare Assurance..... 7

 3.2 United States Department of Agriculture (USDA)..... 7

 3.2.1 Animal Welfare Act 7

4.0 GOVERNANCE 8

5.0 KEY ROLES AND RESPONSIBILITIES..... 8

 5.1 Institutional Official..... 8

 5.2 Chairperson 8

 5.3 Director of Research Integrity..... 9

 5.4 IACUC..... 9

 5.5 Investigators..... 11

 5.6 Research Study Staff 11

6.0 TRAINING IN THE HUMAN CARE AND USE OF LABORATORY ANIMALS 11

 6.1 Principal Investigators 11

 6.2 Research Study Staff 11

 6.3 Animal Care Technicians 12

7.0 IACUC MEMBERSHIP 12

 7.1 Composition 12

 7.2 Member Designations 12

 7.2.1 Veterinarian 12

 7.2.2 Chairperson..... 12

 7.2.3 Non-Affiliated Member..... 13

 7.2.4 Scientist..... 13

 7.2.5 Non-Scientist..... 13

 7.3 Recruitment and Selection of Members 13

 7.4 Periodic Review of the Membership..... 13

 7.5 Term of Appointment..... 13

 7.6 Equal Opportunity 14

| | |
|--|----|
| 7.7 Procedures for Appointment and Reappointment | 14 |
| 7.8 Resignation..... | 14 |
| 7.9 suspension or Removal of Members..... | 14 |
| 7.10 Membership Records | 14 |
| 7.11 Use of Ad hoc Consultants | 14 |
| 7.12 Member Orientation, Training and Education | 15 |
| 8.0 CONVENED MEETINGS | 15 |
| 8.1 Meetings..... | 15 |
| 8.1.1 Regular Scheduled Meetings | 15 |
| 8.1.2 Emergency Meetings | 16 |
| 8.2 Primary Reviewers | 16 |
| 8.3 Members not Assigned as a Primary Reviewer..... | 16 |
| 8.4 Quorum | 16 |
| 8.5 Attendance..... | 16 |
| 8.6 Conflict of Interest | 17 |
| 8.7 Guests..... | 17 |
| 8.8 Discussion and Vote | 17 |
| 8.9 Appeal of an IACUC Decision..... | 18 |
| 9.0 PROTOCOL REVIEW PROCEDURE | 18 |
| 9.1 Scope of Review | 18 |
| 9.2 Specific Types of Activities | 18 |
| 9.3 Exemptions..... | 19 |
| 9.4 Qualifications of the Principal Investigator..... | 19 |
| 9.5 Protocol Review Criteria..... | 20 |
| 9.6 Protocol Review Procedures | 20 |
| 9.6.1 Full Committee Review (FCR)..... | 20 |
| 9.6.2 Designated Member Review (DMR) | 21 |
| 9.6.3 Administrative Review (AR) | 21 |
| 9.6.4 Notification of Review Outcome..... | 21 |
| 9.6.5 Appeal of an IACUC Decision | 22 |
| 9.6.6 Required Principal Investigator Certifications | 22 |
| 9.7 Range of IACUC Actions..... | 23 |

9.8 Review of Modifications to Approved Protocols 23

 9.8.1 Changes Requiring IACUC Approval..... 23

 9.8.2 Administrative Changes with Attending Veterinarian Consultation..... 24

 9.8.3 Changes that can be Administratively Approved..... 24

9.9 Termination of Reviewed (Pending/Not Yet Approved) Protocols and Amendments 24

9.10 Minimization of Pain and Distress..... 25

 9.10.1 Assessing Pain and Distress..... 26

 9.10.2 Alleviation of Pain and Distress..... 26

9.11 IACUC Policies..... 26

10.0 MONITORING OF APPROVED PROTOCOLS 27

 10.1 Annual Review..... 27

 10.1.1 The Purpose of the Continuing Annual Review 27

 10.1.2 Procedures for Conducting Annual Reviews..... 27

 10.2 Three Year Renewal 28

 10.2.1 Procedures for Conducting Three Year Renewals 29

 10.3 Comparison of Protocols to Grants..... 29

 10.3.1 Verification of Protocol and Grant Consistency..... 30

 10.3.2 Timing of Verification..... 30

 10.3.3 Protocol Amendments 30

 10.3.4 Managing Grant-Protocol Inconsistencies..... 30

 10.4 Post Approval Monitoring (PAM)..... 31

11.0 SEMIANNUAL REVIEWS..... 31

 11.1 Program Review 31

 11.2 Facility Inspections 32

 11.2.1 Staffing of Facility Inspections 32

 11.2.2 Categories to be Inspected 32

 11.2.3 Performing Inspections..... 33

 11.2.4 Deficiency Correction Schedule 33

 11.2.5 Documentation 34

12.0 IACUC RECORDS 34

 12.1 Meeting Minutes..... 34

 12.2 Retention..... 35

13.0 DISCIPLINARY ACTIONS 35

14.0 NONCOMPLIANCE AND ANIMAL WELFARE CONCERNS 35

 14.1 Noncompliance with IACUC Protocol, Policies, Procedures, or Decisions..... 35

 14.2 Consequences of Noncompliance..... 35

 14.2.1 Institutional Sanctions 35

 14.2.2 Suspension of Animal Activities 36

 14.3 Principal Investigator and Research Personnel Reporting Requirements 36

 14.4 IACUC and IO Reporting Requirements 36

 14.4.1 Annual Reporting 36

 14.4.2 Internal Reporting..... 37

 14.5 Evaluation of Animal Care and Use Concerns..... 37

 14.5.1 Methods for Reporting 38

 14.5.2 Procedures for Investigating Animal Care and Use Concerns 38

15.0 MONITORING AND AUDITS..... 39

16.0 CONFIDENTIALITY..... 39

17.0 POLICIES AND PROCEDURES 40

18.0 REPORTING AND MANAGEMENT OF CONCERNS 41

1.0 URI IACUC

The University of Rhode Island (URI) Institutional Animal Care and Use Committee (IACUC) serves as the IACUC for the URI. It is the responsibility of URI to provide suitable orientation, appropriate materials, adequate resources and training to enable research faculty and staff and IACUC members to carry out their respective duties consistent with the Guide for the Care and Use of Laboratory Animals (the Guide), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and the Animal Welfare Act and Animal Welfare Regulations (AWRs).

URI is responsible for informing researchers and IACUC members of their responsibilities, providing training relative to their respective roles, and ensuring information to fulfill their duties is available.

2.0 MISSION

The use of animals is essential to the teaching, outreach, and research missions of URI. Significant benefits to the health and welfare of both animals and humans have resulted from animal use in research, and continued use is crucial to future advancements. Without the use of animals, adequate instruction of students in many programs such as agriculture, biological sciences, and veterinary science would be impossible. However, those who utilize animals in teaching and research are morally and legally obligated to care for them properly and use them humanely. Each faculty member, staff member, or student involved in the use of animals is directly responsible for promoting and protecting their welfare within the instructional, research, and outreach programs of URI. The following policy provides guidance for the proper care and humane use of animals within University programs.

The IACUC is responsible for overseeing the provisions for the care and well-being of animals used for research and educational purposes at the University and serves the public by ensuring compliance with all legal and ethical standards regarding the use of vertebrate animals in research and teaching at URI.

3.0 APPLICABLE GUIDELINES AND REGULATIONS

3.1 Office of Laboratory Animal Welfare

The Office of Laboratory Animal Welfare (OLAW) implements Public Health Service (PHS) Policy. OLAW (located with the National Institutes of Health (NIH)) is responsible for laboratory animal welfare on all PHS-supported activities involving animals. OLAW issues policy guidance, interpretation, or general notices regarding PHS Policy, and co-sponsors animal welfare workshops that are held in different locations across the country. The NIH adopted the 8th Edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*. In OLAW's judgment, the 8th Edition of the Guide empowers continued advancement in the humane care and use of vertebrate animals in research, research training, and biological testing.

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.

3.1.1 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 (Assurance). The Assurance is the cornerstone of a trust relationship between the institution and the PHS. Included in the Assurance are:

- The designation of the Institutional Official (IO) responsible for compliance;
- A commitment that the institution will comply with the PHS Policy, with the Guide, and with the Animal Welfare Act and the Animal Welfare Regulations; and
- A description of the institution's program for animal care and use.

The PHS Policy applies to the use of live vertebrate animals in any activity supported or conducted by the Public Health Service (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.

URI has an Animal Welfare Assurance on file with OLAW. The Animal Welfare Assurance number is A3690-01.

3.2 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.

URI is a registered Class R Research Facility with the USDA (customer number 268 under certificate number 15-R-0004).

3.2.1 Animal Welfare Act

The Animal Welfare Act (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 (Title 7, Chapter 54, Section 2132(g)) defines the term “animal” to mean any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal that is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes. The AWA (Title 7, Chapter 54, Section 2132(g)) excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, horses not used for research purposes, and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry, used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

4.0 GOVERNANCE

The IACUC carries out the review of Research involving animals and oversight activities on behalf of URI and reports directly to the URI Institutional Official (IO).

5.0 KEY ROLES AND RESPONSIBILITIES

5.1 Institutional Official

The URI Institutional Official (IO) is responsible for:

- Serving as the responsible institutional official for applicable government entities.
- Providing the IACUC with the necessary local resources through the institution’s annual budgeting process.
- Reporting to NIH and other relevant federal, state and local agencies, as required.
- Investigating reports of noncompliance and reports of IACUC concerns and taking corrective actions as needed.
- Holding investigators and study staff accountable for their responsibilities.
- Ensuring effective institution-wide communication and guidance on research involving animals.
- Promoting an institutional culture of ethical treatment of animals and safety when conducting research involving animals.
- Appointing IACUC members from their institution.

5.2 Chairperson

The IACUC Chairperson is a voting member of the IACUC and in collaboration with the URI Director of Research Integrity is responsible for:

- Ensuring that all IACUC members are appropriately trained.
- Presiding at convened IACUC meetings.
- Reviewing and approving Research involving animals that can be administratively reviewed.
- Overseeing investigations.
- Attending meetings with the IO.
- Participating in the development of IACUC policies and procedures.
- Performing other activities, as needed, to fulfill institutional responsibilities set forth in PHS Policy and the AWA and other federal, state, and local regulations.
- Delegating the authority to preside over a convened IACUC meeting.

- Recommend the appointment of members to the committee.

5.3 Director of Research Integrity

The Director of Research Integrity is responsible for the administrative leadership of the IACUC. The Director of Research Integrity or designee is responsible for:

- Reviewing membership of the IACUC to ensure composition meets PHS Policy (IV.A. 3. a., b) and the AWA Regulations (9 CFR, 2.31 (a) (b)).
- Assessing IACUC policies and developing new policies or changes to current policies.
- Attending IACUC meetings, preparing IACUC meeting agendas, preparing meeting minutes, and making minutes available to the public upon request.
- Notifying investigators of the results of IACUC reviews and providing guidance to ensure compliance.
- Completing annual reports to OLAW per PHS Policy.
- Communicating with the institutional biosafety committee (IBC) regarding research requiring review by multiple committees and developing processes by which appropriate projects are reviewed by the IACUC.
- Ensuring that PI has appropriate training approvals prior to protocol approvals.
- Serving as a resource to the regulated community (i.e., investigators, staff).
- Monitoring national, state and local regulatory trends and communicate regulatory changes to the IO as necessary.
- Reviewing investigations conducted by the IACUC.

5.4 IACUC

The IACUC is registered with OLAW and USDA. As the IACUC is responsible for the review and approval of all research involving animals conducted at or sponsored by URI, the IACUC will adhere to all requirements of the IACUC set forth in AWA and PHS Policy related to the composition and responsibilities of the IACUC.

On behalf of the institution, the IACUC is responsible for:

- Review at least once every six months URI'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 described in Section 11.1.
- Inspect at least once every six months all of URI's facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are described in Section 11.2.
- Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit reports to the IO. The IACUC procedures for developing reports and submitting them to the IO are described in Section 14.4.
- Review concerns involving the care and use of animals at URI. The IACUC procedures for reviewing concerns are described in Section 14.5.
- Make written recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training.
- In accord with PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals. The IACUC procedures for protocol review are described in Section 9.6.
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in PHS

Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research or educational projects are described in Section 9.8.

- Notify investigators and URI 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 as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and URI of its decisions regarding protocol review are described in Section 9.6.4.
- 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 in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are described in Section 10.0.
- Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are described in Section 14.2.2.

In the review of PHS-supported research projects:

In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with this Policy. In making this determination, the IACUC shall confirm that the research project will be conducted in accordance with the AWA insofar as it applies to the research project, and that the research project is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the research project conforms with URI's Assurance and meets the following requirements:

- Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- 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.
- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- 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 veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

5.5 Investigators

The use of animals for research and teaching is a fundamental necessity for continued progress in the biological and medical sciences. Such use of animals is a privilege to the scientific community. Therefore, each investigator and member of his or her staff is responsible to fulfill all ethical and legal requirements. URI faculty members who use animals in their research or teaching activities are accountable to federal and state regulations and policies governing animal use. All activities involving the use of animals are subject to oversight by the Institutional Animal Care and Use Committee (IACUC).

These regulations and policies cover the following:

- Preparing and submitting of protocols for the use of animals.
- Attending IACUC meetings when requested by IACUC.
- Acquisition, care and justification of the use of appropriate species and numbers of animals.
- Ensuring staff are trained, both in the appropriate methods of animal experimentation and the completion of the required CITI training modules.
- Minimizing or avoiding animal pain and distress in concert with sound scientific practices.
- Considering of alternatives to animal use.
- Conducting pre-surgical evaluation, surgical methods, and post-operative care.
- Disclosing of experimental endpoints.
- Ensuring appropriate euthanasia of animals.
- Notifying the IACUC of adverse events.

5.6 Research Study Staff

Staff, including all URI employees (faculty, staff, and students), participating in research involving animals is responsible for:

- Following all IACUC policies and procedures.
- Completing all IACUC and institutional training requirements prior to engaging in research.
- Complying with IACUC requirements associated with each protocol.
- Reporting noncompliance or incidents.

6.0 TRAINING IN THE HUMANE CARE AND USE OF LABORATORY ANIMALS

6.1 Principal Investigators

PIs conducting research involving animals are responsible to complete the CITI program's Animal Care and Use - "Working With the IACUC" module as well as any other modules pertaining to work with specific species (as applicable). Completion of this training must be accomplished every three years. Protocols from PIs without current training will not be approved by the IACUC. The IACUC may terminate approved protocols should investigators fail to maintain current training.

6.2 Research Study Staff

Research study staff is responsible to complete CITI program's Animal Care and Use - "Working With the IACUC" module as well as any other modules pertaining to work with specific species (as applicable). Protocols that list study staff without current training will not be approved by the IACUC. It is the responsibility of the PI to ensure that all research study staff is compliant with training requirements. Additionally, research study staff must also be trained by the PI on the specific procedures and policies that will be used in each protocol.

6.3 Animal Care Technicians

Animal Care Technicians are responsible to complete CITI program's Animal Care and Use - "Working With the IACUC" module as well as any other modules pertaining to work with specific species (as applicable). Completion of this training must be accomplished every three years

7.0 IACUC MEMBERSHIP

7.1 Composition

The required composition of an IACUC is described in PHS Policy (IV.A. 3. a., b.) and the AWA Regulations (9 CFR, 2.31 (a) (b)). Some IACUC members fulfill specific regulatory requirements (e.g., veterinarian with program responsibility, an individual nonaffiliated with the Institution); others have unique roles by virtue of their position (e.g., Chair, Veterinarian, etc.)

There are no specific prohibitions regarding individuals filling more than one role on the IACUC, but OLAW strongly recommends against the same person serving multiple roles, because the responsibilities and authorities vested in each of the positions are distinct and often require different skills. Appointing one individual to more than one of these roles may circumvent intended checks and balances. Also of importance is the perception of conflict of interest, which can lead to allegations of improprieties from various sources.

The IACUC is composed of regular voting members, alternate voting members, and non-voting members. The IACUC may use, as necessary, non-voting members and ad hoc consultants during review discussions.

7.2 Member Designations

Voting members shall be designated as either: (1) affiliated or unaffiliated; and (2) voting member or alternate voting member. Voting members shall be required to vote or abstain from voting on each research activity considered by the IACUC when they are present for the discussion and vote. Each voting member shall identify an alternate voting member that has similar scientific and scholarly expertise. Alternate members shall be required to vote or abstain from voting on each research activity considered by the IACUC when they are present for the discussion and vote, and the voting member for whom they are a designated alternate is not present.

Required categories of IACUC membership include:

7.2.1 Veterinarian

The PHS Policy and AWRs mandate the appointment of a veterinarian with direct or delegated program responsibility to the IACUC. The IO may appoint more than one veterinarian to the IACUC, but the veterinarian with direct or delegated program responsibility must be designated as such. The veterinarian with program responsibility, e.g., Attending Veterinarian, must have training or experience in laboratory animal science and medicine or in the care of the species being used.

7.2.2 Chairperson

The Chairperson is appointed and is a faculty member of URI with research experience.

7.2.3 Non-Affiliated Member

The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, have an affiliation with URI. "Immediate family member" is defined as spouse, domestic partner,

child, parent, or sibling. These members have equal status (e.g., voting) to every other committee member and are provided the opportunity to participate in all aspects of IACUC functions.

7.2.4 Scientist

PHS Policy requires that the IACUC include a practicing scientist experienced in research involving animals.

7.2.5 Non-Scientist

PHS Policy requires that the IACUC include a member whose primary concerns are in a nonscientific area. Examples include, but are not limited to, ethicist, lawyer, member of the clergy, librarian, etc.

7.3. Recruitment and Selection of Members

Affiliated candidates for IACUC membership shall be identified by the Director of Research Integrity and Chairperson of the IACUC through the department chairs, IO, or through current IACUC members. Unaffiliated members shall be identified through current IACUC members or various community agencies or groups. Additionally, individuals who are affiliated or unaffiliated may self-refer to the IACUC for consideration to be a new member.

New members shall be recruited as needed to ensure that the membership of the IACUC continues to include individuals with varying backgrounds and the necessary experience and scientific or scholarly expertise to review research involving animals. In addition, new members shall be recruited as needed to replace the scientific or scholarly expertise of members who resign and, when needed, to provide additional scientific or scholarly expertise to review new research programs.

Candidates for membership must be able to participate in a majority of the IACUC meetings. Appointments of new members are described in Section 7.5.

7.4. Periodic Review of the Membership

The membership of the IACUC shall be reviewed at least annually to ensure that membership includes individuals with varying backgrounds and the experience and scientific or scholarly expertise needed to review the scope of research involving animals conducted at URI. The Director of Research Integrity shall be responsible for compiling information about research protocols reviewed at convened meetings to assess the scope of research involving animals reviewed by the IACUC. The Director and Chairperson of the IACUC shall review the report, conduct the membership review and present results of the review to the IO.

7.5 Term of Appointment

Appointments to the IACUC shall be made by the IO. Members shall be appointed for terms of two (2) years; however, members may be removed by the IO for cause as described elsewhere in this document.

7.6 Equal Opportunity

The membership shall include individuals who provide a specific expertise in research involving animals. No qualified individual shall be rejected from the membership on the basis of race, gender, creed, religion, color, national origin, age, disability, or sexual orientation.

7.7 Procedures for Appointment and Reappointment

Prospective members shall be asked to: (1) attend a meeting of the IACUC; (2) provide a copy of their curriculum vitae or resume, and (3) complete the IACUC member orientation program. Based on the information provided and the membership requirements of the IACUC, the Director of Research Integrity and Chair shall recommend membership appointment of individuals to the membership of the IACUC. The appropriate IO shall be responsible for inviting the individual, in writing, of his/her appointment and, when applicable, the relevant Department Chair.

7.8 Resignation

Any member may resign from the IACUC by a written resignation submitted to the Director and Chairperson of the IACUC.

7.9 Suspension or Removal of Members

Any member may be asked by the IO to step down or may be replaced for failure to fulfill their responsibilities as an IACUC member.

7.10 Membership Records

The URI Office of Research Integrity shall maintain a roster of IACUC members and alternate members to include the following information:

- Name;
- Earned degrees;
- Experience and expertise, such as board certifications, licenses;
- Affiliation, if any, with URI;
- Alternate members; and
- The primary member or class of primary members for whom the alternate could substitute.

The URI Director of Research Integrity, or designee, shall be responsible for updating the membership roster and IACUC protocol information as needed when membership changes and submitting the updated information to OLAW as required. IACUC rosters shall be retained for at least seven (7) years and shall be made available upon request, when applicable. Individual membership records shall be retained by the IACUC for at least seven (7) years from date of last service.

7.11 Use of Ad hoc Consultants

The IACUC or IACUC Chairperson may invite ad hoc consultants, when needed, to supplement or provide scientific review to the IACUC. Additionally, the IACUC may vote to table action and require an expert in a scientific area or discipline to review the research and provide consultation to the IACUC. In such cases, the Chairperson or Director of Research Integrity shall be responsible for identifying the consultant and for requesting such consultation.

Ad hoc reviewers may provide reviews in writing or orally at a convened meeting. Ad hoc reviewers shall not be considered members and, as such, shall not vote on research involving animals before the IACUC; however, ad hoc consultants shall be subject to the IACUC policy on Member Conflicts of Interest. Ad hoc consultants shall be reminded that the discussions that take place at the meeting are confidential and should not be disclosed to others. Ad hoc consultants may be either affiliated or unaffiliated with URI as defined in Section 7.2.

7.12 Member Orientation, Training and Education

New IACUC member orientation consists of reviewing the following with the Director of Research Integrity: a description of the IACUC and responsibilities; AWA and Regulations; PHS Policy; criteria for membership; authority of the IACUC; protocol review process; monitoring of approved protocols, periodic review; protocol modifications; records; semiannual reviews; roles and responsibilities; and federal regulations. IACUC members shall be required to complete training in CITI Animal Care and Use - "Essentials for IACUC Members" module once every three years. Documentation of training is maintained through the use of IACUC member files.

The objectives of providing this information are the following:

- To introduce members to the role of the IACUC and its evolution;
- To provide the basic information necessary for IACUC members to discharge their responsibilities; and
- To provide a forum for response to, and discussion of, members' concerns and questions.

In addition, new IACUC members will not be asked to serve as a primary reviewer until they have attended at least one meeting.

Continuing education for IACUC members typically occurs at IACUC meeting. The objectives of providing ongoing training for IACUC members is to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It also provides a regular forum for the IACUC to discuss concerns or questions brought forth by the faculty, staff or members of the community. Information provided for these sessions will include questions and concerns brought to the attention of the IACUC, official directives, relevant publications, conference announcements, seminar proceedings, animal facility staff and/or veterinarian's observations/recommendations, issues involving facility inspections and program evaluations, and compliance issues. Additionally, IACUC members are encouraged to attend informational sessions hosted by the Director of Research Integrity throughout the year (e.g., OLAW webinars, NABR webinars).

8.0 CONVENED MEETINGS

8.1 Meetings

8.1.1 Regular Scheduled Meetings

The IACUC shall meet regularly. Meetings will occur in person or via conference call. Meetings shall be scheduled in advance and shall be posted on the IACUC internet website. The agenda shall be prepared by the Director of Research Integrity and approved by the IACUC Chairperson taking into consideration the nature and complexity of the activities on the agenda and members attending the meeting. The agenda shall be limited as needed to allow sufficient time for discussion of each research activity before the Committee. Members shall be contacted prior to the meeting to determine attendance. From among those members planning to attend the meeting, the Director of Research Integrity and Chairperson shall assign reviewer(s) to each protocol on the agenda requiring review.

When making review assignments, the Director of Research Integrity and Chairperson shall take into consideration the experience and scientific or scholarly expertise required to review the research. In general, protocols shall be scheduled for review by date of receipt by the Office of Research Integrity; the IACUC reserves the right to reschedule protocols for review based on the experience and expertise of the members planning to attend the meeting or to request the use of a consultant to supplement or provide scientific or scholarly expertise not available on the IACUC. The agenda and materials related to the

Research involving animals scheduled for review at the meeting shall typically be provided to members at least seven (7) days in advance of the meeting to allow sufficient time for review.

8.1.2 Emergency Meeting

The IACUC Chairperson or Director of Research Integrity may call an emergency meeting of the IACUC as necessary.

8.2 Primary Reviewers

The primary reviewer(s) shall perform an in-depth review of all materials provided to them relevant to the protocol that they are assigned to review. The primary reviewer(s) shall be responsible for notifying the Director of Research Integrity if s/he has a conflict of interest as defined in Section 8.6. In such cases, the Chairperson or designee shall reassign review of the research activity to another member.

8.3 Members not assigned as a Primary Reviewer

Members who are not assigned as the primary reviewer shall perform review of all materials provided to them relevant to the research involving animals in sufficient depth to vote on the research activity at the convened meeting.

8.4 Quorum

Certain official IACUC actions require a quorum: full committee review of a research project (Policy IV.C.2. and AWR §2.31(d)(2)) and suspension of an activity (Policy IV.C.6. and AWR §2.31(d)(6)). Reasonable efforts will be made to ensure that at least one unaffiliated member is present at each meeting. The presence of more than one-half plus one of the voting membership shall constitute a quorum. Alternate voting members can be counted towards a quorum when they are attending as a replacement to a voting member. A quorum shall be maintained for the discussion and vote on each research activity on the agenda. Members not present for or recused due to a conflict of interest from the discussion and vote on a research activity shall not be counted towards the quorum. The Chairperson, Director, or designee shall be responsible for ensuring that quorum is achieved before the meeting begins and is maintained throughout the meeting when each research activity on the agenda is voted upon. The Director or designee shall be responsible for recording attendance and vote on each research activity.

8.5 Attendance

Voting members are expected to attend the majority of IACUC meetings. Voting members that anticipate an absence should contact their alternate voting member to ensure that their alternate member can attend in their absence. Anticipated absences from an IACUC meeting should be communicated to the IACUC Specialist at least seven (7) days prior to the meeting.

8.6 Conflict of Interest

All members of the IACUC and ad hoc consultants shall be required to disclose financial (zero threshold) and non-financial interests with respect to the protocols to be discussed to the Director of Research Integrity and/or the Chairperson. If the Director and Chairperson or designee determines that the disclosed interest(s) would reasonably appear to affect the ability of the IACUC member to objectively review the project, and therefore constitute a "conflict of interest," the IACUC member will not be allowed, in full committee, to participate in the discussion and vote on that registration. In preparation for each meeting, the Director of Research Integrity shall remind members that they must recuse themselves from discussing and voting on protocols if they are involved in the conduct or evaluation of

the research or have financial interests (i) that would reasonably be affected by the research for which IACUC approval is sought, and/or (ii) in entities whose financial interests would reasonably appear to be affected by the research. When members recuse themselves, they shall leave the room for the discussion and vote on the research, except to provide information at the IACUC's request prior to the discussion and vote. Recusals shall be documented in the minutes of the meeting as not present for the discussion and vote.

8.7 Guests

Normally, IACUC meetings are closed to the public, although on occasion, and at the discretion of the IACUC Chairperson and Director of Research Integrity, individuals may attend IACUC meetings as guests. In such cases, guests shall be reminded that the discussions that take place at the meeting are confidential and should not be disclosed to others. Guests are not members of the IACUC by virtue of their attendance and are not eligible to vote. Guests are required to notify the Director of Research Integrity prior to the meeting of their desire to attend the meeting.

PIs (or their designees) may be asked by the Chairperson or Director of Research Integrity to attend the meeting to describe proposed research under review and answer questions. They will be asked to leave prior to the vote.

8.8 Discussion and Vote

The reviewer(s) will present their reviews. The IACUC Chairperson will open the review for discussion by the members. At the end of the discussion, any member may make a motion to approve, require modifications in the research (to secure approval), or withhold approval of the research. A vote on the motion shall be taken by show of hands or voice vote, and the number of votes for, against, and abstentions from voting shall be recorded in the minutes. All motions shall be decided by majority vote of the members present for the review.

The IACUC vote may result in one of the following:

- Approve.
- Require modifications in the protocol (to secure approval).
- Tabled.
- Withhold approval.

8.9 Appeal of an IACUC Decision

The decision of the IACUC to disapprove the research cannot be overruled by any other institutional body or individual(s); however, an investigator may appeal the decision of the IACUC in writing. The IACUC will reconsider its decision (with documentation in the minutes) based on any new information provided by the principal investigator. If requested, the investigator may appeal the decision of the IACUC in person at the convened meeting.

9.0 PROTOCOL REVIEW PROCEDURE

The IACUC is responsible for overseeing and evaluating all aspects of animal care and use, and is charged with reviewing proposals that involve animals to ensure that the criteria established in the PHS Policy and

the AWA Regulations are implemented. In its review of proposals, the IACUC's primary goal is to facilitate compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

9.1 Scope of Review

The following kinds of activities involving animals are subject to review by the IACUC prior to initiation:

- Activities conducted by University faculty, staff, or students;
- Activities performed on the premises of the University;
- Activities performed with or involving the use of facilities or equipment belonging to the University;
- Activities satisfying a requirement imposed by the University for a degree program or completion of a course of study; and/or
- Activities certified by a dean or department head to satisfy an obligation of a faculty appointment at the University, including requirements for clinical or adjunct appointments.

9.2 Specific Types of Activities

- Research
 - Many of the animals covered in IACUC review are used in research, including medical, biological, and behavioral research as well as agricultural research (such as the study of food and fiber production or diet manipulation). Most of these animals are acquired and housed by the URI; some may include free-ranging wildlife.
- Teaching
 - The use of animals in educational settings is subject to IACUC review. Examples include using animals to teach agricultural techniques, animal husbandry, and medical or veterinary procedures.
 - Review is required even if the activity does not seem to qualify as “true research” (e.g. when the results are not intended for publication, will not advance work in another area, or will not contribute to generalizable knowledge).
- Research Conducted by “Affiliated Faculty”
 - Research conducted by “affiliated faculty”—those who hold adjunct appointments—is subject to URI’s guidelines for animal use and must be submitted for IACUC review.
 - Any research project that is conducted by or under the direction of any employee or agent of the institution, in connection with his or her institutional responsibilities, requires IACUC approval.
- Research Projects in Which the Investigator is a Consultant
 - URI faculty or staff may serve in an advisory capacity for a research project conducted outside the URI community. IACUC review is required unless the investigator has a strict consulting relationship in which:
 - The investigator is hired on his or her own time;
 - The investigator holds no rights in the work; and
 - Neither the investigator nor URI retains any data.
 - Unless all three of these criteria are met, the IACUC must review the project. Review by another institution or facility’s IACUC is insufficient unless a cooperative arrangement between that IACUC and the Institution’s IACUC is agreed upon prior to initiating the consultant relationship.
- Research in Foreign Countries

- Research conducted by the URI's investigators in foreign countries falls under the Institution's purview and guidelines. Regardless of the setting, the standards for ethical and responsible use of animals in research will not be relaxed even if different customs prevail.
- All animal-based research conducted in foreign countries is subject to IACUC review. This includes the use of animals in foreign research institutions, and fieldwork involving either domestic or wild animals.
- Research projects must be approved by the local equivalent of an IACUC before they are initiated. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The IACUC requires documentation of this local approval, as well as documentation of any necessary permits, before granting final approval for the project.
- With regard to activities supported by PHS funds, foreign institutions that serve as performance sites must also have Assurances on file with OLAW.

9.3 Exemptions

The following are exempt from IACUC review:

- Activities involving animals that perform tasks or participate in club activities;
- Use of tissues, organs or other parts of dead animals if received as such; and
- Noninvasive observation of wild animals in their natural habitat. Field studies that involve killing, trapping, banding, darting, implantation of telemetry devices, or any other invasive manipulation require IACUC approval.

9.4 Qualifications of the Principal Investigator

All use of animals in research and/or teaching at URI must be under the direct supervision of a tenured, tenure track, or research faculty with assigned research space at URI. Faculty is considered to be sufficiently knowledgeable to supervise and/or conduct research as determined by their appointment. The IACUC, however, may, at its discretion, determine that a faculty member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience.

Research conducted by non-faculty, academic support staff, post-doctoral fellows, staff appointments, graduate students or undergraduate students must be under the direction of a faculty member, as defined above. In such cases, the faculty member shall be considered the PI. The PI may delegate the performance of any or all components of the research to non-faculty if they certify to the IACUC that the individuals are sufficiently trained to perform the functions assigned.

Individuals that do not meet any of the above criteria may, by demonstrating sufficient cause and necessary expertise, petition the Director of the Office of Research Integrity for permission to submit an application for approval of an IACUC protocol. Such agreement shall be in writing and require the individual to comply with all relevant IACUC and URI policies for the conduct of research involving animal subjects.

9.5 Protocol Review Criteria

In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with PHS Policy, AWA Regulations, and the applicable US Government Principles. Since the PHS Policy further requires that the provisions of

the Guide apply, there are many other aspects of research that an IACUC should review, such as food and water deprivation, use of noxious stimuli, and physical restraint. The Guide provides useful guidance on these and other practices.

If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal it may bring in outside expert consultants to provide information. Such consultants will not have a conflict of interest with the research activity and may not vote on any matters pertaining to the protocol. In all cases, the onus should be on the investigator to justify and explain his or her proposed experiments to the satisfaction of the IACUC.

9.6 Protocol Review Procedures

The procedural review requirements of the PHS Policy or the AWA Regulations take precedence even though they may differ from some commonly used parliamentary procedures. The URI may develop its own meeting procedures as long as the procedures do not contradict or are not inconsistent with the requirements of the PHS Policy or the AWRs.

If a proposed activity may cause more than momentary or slight pain or distress to animals, the AWA Regulations specifically require investigators to consult with the Attending Veterinarian (AV) or his or her designee during protocol development.

The PHS Policy and AWA Regulations recognize two methods of protocol review: Full Committee Review (FCR) and Designated Member Review (DMR). URI IACUC typically reviews all protocols via a FCR procedure but DMR is allowed under certain conditions (see below). The following pertains to review of initial protocols as well as to review of proposed significant changes in previously approved protocols.

9.6.1 Full Committee Review (FCR)

Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that proposals reviewed by the full committee must receive the approval vote of a majority of the quorum present in order receive approval.

At least seven (7) business days prior to a meeting, the Office of Research Integrity distributes copies of the protocols being presented or any other items of discussion to each IACUC member, including alternate and non-voting member(s). Protocols are assigned a primary reviewer, who at the meeting lead the discussion of the protocol. PI's of protocols under review are required to attend and give a brief overview of the protocol and answer committee member questions. PI's are asked to leave prior to discussion and vote. A simple majority vote of the members present is required for approval.

The IACUC has the authority to approve, require modifications in (to secure approval), disapprove, or table (defer until future meeting) any proposed activity. Committee members are given the opportunity to require that the requested modification(s) be brought before the next committee meeting. Under no circumstances will animal work be permitted to resume or begin until final approval is granted.

When modifications are required from a protocol under review by FCR, the committee may vote to allow the DMR process to review and approve the revised/amendment protocol. In order to comply with USDA and PHS Guidance, all IACUC members must sign a statement agreeing that a quorum of members at a convened meeting may decide by unanimous vote to use the DRM subsequent to FCR when modifications to a protocol are required to secure approval. However, any member may request (at any time) to see the revised protocol and/or request FCR. Annually, at the convened meeting this policy will be reviewed and acknowledged by the IACUC members.

9.6.2 Designated Member Review (DMR)

To utilize designated member review (DMR), each IACUC member will be provided with the protocol or proposed significant changes to previously approved protocols prior to the review. Each IACUC member is provided a copy of the protocol document from the Office of Research Integrity. Committee members are given a two (2)-business day member consideration period to review the protocol document and respond either allowing the DMR to review the protocol or to hold the protocol for the next FCR. Members are reminded that failure to respond within the member consideration period is considered as approval to use DMR for review. These responses are sent to the IACUC Specialist via IRBNet. The IACUC Specialist tallies the votes to ensure that more than half of the voting members respond, then at the end of the member consideration period, the IACUC Specialist sends the protocol to DMR for review. If any one member votes to hold the protocol until the next IACUC meeting, then the protocol is placed on the agenda for the next IACUC meeting. If all members vote to allow the DMR to review the protocol before the end of the member consideration period, then the IACUC Specialist sends the protocol to DMR for review.

The IACUC Chairperson (and in his/her absence, the Vice-Chair) designates one or more qualified members to review the proposal (or proposed amendment or annual renewal). These designated member(s) have authority to approve, require modifications in (to secure approval), or request full committee review. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

9.6.3 Administrative Review (AR)

While Federal regulations allow for two types of review of animal use protocols (FCR and DMR), recent guidance from the Office of Laboratory Animal Welfare (OLAW) granted authority for a small number of items to be administratively approved.

Amendment/modification applications to existing protocols that involve certain changes not considered significant (see Section 9.8.2) can be reviewed (and approved) administratively. Additionally, one a case by case basis certain modifications (e.g., small increases in animals, additional species of fish, use of animals in educational exhibits) may be administratively approved following review by the Chairperson.

9.6.4 Notification of Review Outcome

The IACUC will notify investigators 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 as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the University of its decisions regarding protocol review are as follows:

Upon completion of the review process, each Principal Investigator receives a written emailed notification of review decisions (approved, modifications required in (to secure approval), approval withheld, or tabled) and whether any special monitoring provisions will be required. Records of communication are maintained within the IACUC protocol files on IRBNet.

9.6.5 Appeal of an IACUC Decision

Investigators shall have the right to appeal a decision of the IACUC within two (2) weeks of notification by the IACUC Chairperson. A PI may appeal decisions made by the Institutional Animal Care and Use Committee (IACUC) by following the below steps:

- The appellant states in writing to the IACUC Chairperson specific points of disagreement with the Committee's action, reasons for disagreement, and the desired outcome of the appeal.
- A quorum of the IACUC membership hears the appeal from the appellant and determines an outcome.
- All decisions of the IACUC regarding an appeal request will be conveyed to the appellant in writing.
- If the person(s) appealing is not satisfied with the IACUC's decision, he or she may appeal to the IO and thereby initiate further IACUC consideration if the Official so requests. Officials of the institution, however, cannot approve an animal activity that has not been approved by the IACUC.

9.6.6 Required Principal Investigator Certifications

In order to submit a protocol to the IACUC for review, the Principal Investigator must certify the following:

- To the best of my knowledge the information provided in this protocol form is complete and accurate and that this application accurately and completely reflects the animal research described in my full grant applications (if applicable).
- I am familiar with and agree to abide by the University's policies and procedures for research involving animals, including the URI Program of Veterinarian Care and the Animal Care SOPs.
- I am familiar with and agree to abide by the Guide for the Care and Use of Laboratory Animals, The USDA Animal Welfare Act Regulations, and the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
- I certify that the activities in this protocol do not unnecessarily duplicate previous experiments.
- I understand that it is my responsibility as the Principal Investigator to ensure that all individuals listed on the protocol have read and understand the procedures described for each species and have received proper training to conduct the described procedures.
- I understand that if I wish to change any procedure or personnel as shown on this protocol, that I will request an IACUC approval by submitting the details of the change(s) as an amendment to the IACUC.
- I acknowledge that I will notify the IACUC of any adverse events (e.g., any happening not consistent with routine expected outcomes that results in any unexpected animal welfare issues or human health risks) immediately and complete an Adverse Event form within 72 hours.
- I understand that any failure to comply with guidelines and requirements of the IACUC may result in suspension of my studies and notification to the funding agency, the PHS and/or the USDA as mandated by law.

It is implicit upon submission of the protocol that the Principal Investigator has read and agrees to abide by the above obligations.

9.7 Range of IACUC Actions

- Upon review of protocols, the IACUC may take one of several different actions depending upon the findings of the committee: approval, modifications required (to secure approval), and withhold approval. An IACUC may also defer or table review of a protocol. The PHS Policy and AWRs require the IACUC to notify investigators and the institution in writing of its decision to approve or withhold approval, or require modifications (to secure approval) of a protocol. If

approval is withheld the IACUC must provide the reasons for its decision and give the investigator an opportunity to respond.

- Approval
 - When the IACUC has determined that all review criteria, based on the PHS Policy and AWRs, have been adequately addressed by the investigator, the IACUC may approve the project, thus granting the investigator permission to perform the experiments or procedures as described.
 - The IACUC-approved proposal may be subject to further appropriate review and approval by institutional officials due to financial, policy, facility, or other institutional or administrative considerations. Those officials, however, may not approve an activity if it has not been approved by the IACUC.
- Modifications required (to secure approval)
 - The IACUC may require modifications to the protocol before granting approval. If the IACUC determines that a protocol is approvable contingent upon receipt of a very specific modification (e.g., receipt of assurance that the procedure will be conducted in a biosafety cabinet), or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details that any member, such as the Chair, could verify prior to granting approval.
 - If the protocol is missing substantive information necessary for the IACUC to make a judgment, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be revised and resubmitted. If the IACUC wishes to shift to the designated member reviewer mode for the approval of the modified protocol, that shift should be explicitly noted in the meeting minutes and the requirements for designated review must be met.
- Withhold approval
 - When the IACUC determines that a proposal has not adequately addressed all of the requirements of the PHS Policy and AWRs, as applicable, or the described activities represent inappropriate or unethical use of animals, the Committee may withhold approval. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.
 - As indicated above, a higher institutional authority may not administratively overrule an IACUC decision to withhold approval of a proposal.
- Defer or table review
 - If the protocol is missing substantive information, requires extensive or multiple modifications, or requires significant clarification in order for the IACUC to make a judgment, then the IACUC can require that the protocol be revised and resubmitted. Similarly, if committee members with certain expertise are not present, the IACUC wishes to seek external consultation, or any of a number of other reasons prevent the IACUC from conducting its review, then the IACUC may wish to defer or table review until a future FCR.

9.8 Review of Modifications to Approved Protocols

9.8.1 Changes Requiring IACUC Approval

A number of changes to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur (PHS Policy IV.C.1., and AWA Regulations §2.31[d][1]). The Institution interprets changes requiring IACUC approval to mean those that have the potential to impact substantially and directly on the health and well-being of the experimental animals. The determination of the significance of a change

is made on a case-by-case basis by a consensus of the IACUC Chairperson, the Director of Research Integrity, and the IACUC Specialist.

Examples of changes requiring IACUC approval include, but are not limited to, 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);
- that impact personnel safety.

Proposed significant changes require IACUC review (and approval) prior to initiation.

9.8.2 Administrative Changes with Attending Veterinarian Consultation

The specific significant changes described below, may be handled administratively in consultation with the attending veterinarian (AV), the IACUC chair and/or the Director of Research Integrity. Consultation with the veterinarian must be documented. The veterinarian, Chair, and/or Director of Research Integrity may refer any request to the IACUC for review for any reason. This includes changes in:

- anesthesia, analgesia, sedation, or experimental substances;
- euthanasia to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#);
- duration, frequency, type, or number of procedures performed on an animal.

9.8.3 Changes that can be Administratively Approved

Several significant and non-significant changes can be administratively approved.

A significant change that may be handled administratively is an increase in previously approved animal numbers (PHS Policy [IV.D.1.a.](#)). A change in animal numbers requires the review and approval by either the Chair and/or the Director of Research Integrity.

The University interprets non-significant changes to mean those that do not have the potential to impact substantially and directly on the health and well-being of the experimental animals. Examples of non-significant changes include, but are not limited to, changes to:

- Funding source;
- Personnel (other than the PI); and
- Correction of grammar
- Contact information updates

Proposed non-significant changes require administrative review (and approval) by the IACUC Specialist prior to initiation.

9.9 Termination of Reviewed (Pending/Not Yet Approved) Protocols and Amendments

The IACUC has the responsibility to require modification(s) to requests for animal use prior to approving a protocol or amendment to an existing protocol. To prevent the development of a collection of pending/not yet approved protocols or pending/not yet approved amendments, that results in slower service to all researchers, complicates the oversight process, and interferes with support of active research, the IACUC has established a process for protocol and amendment review and approval. The goal of the IACUC and Office of Research Integrity is to rapidly process protocols in an effort to provide faculty with the maximum amount of time possible to address IACUC concerns and clarifications. This policy specifically addresses the duration of time at which point the IACUC will administratively inactivate an application for failure to respond for further clarification and queries.

The process for PI notification of IACUC administrative actions is as follows (counting from the day of FCR as day 0):

- Day 0-5 (Week 1): IACUC Specialist will provide IACUC communication to PI detailing the modifications required (to secure approval), including specific IACUC clarifications, required training, etc.
- Day 10-15 (Week 3): If no response from the PI is received by this milestone, then the IACUC Specialist will send a second correspondence to the PI requesting a response to the IACUC's previous correspondence. Email is the preferred method of communication. If there is no email address, then a facsimile or hard copy mailed letter may be used.
- Day 20-25 (Week 5): If no response from the PI is received by this milestone, then the IACUC Specialist will send a third correspondence to the PI requesting a response to the IACUC's previous correspondence.
- Day 30-35 (Week 7): If no response from the PI is received by this milestone, then the IACUC Specialist will place a phone call to the PI, and if the PI is not available, a message will be left on the voice messaging system.
- Day 40 (Week 8): If no response by the PI is received by this milestone, then the IACUC Specialist will send an email to the PI advising them of the termination action and advising them that a new protocol / amendment must be submitted to the IACUC if they wish to pursue this proposed activity.

9.10 Minimization of Pain and Distress

In design of the research, training or educational activities, it is the responsibility of the PI to consider and include procedures that minimize animal pain or distress.

As required by the PHS Policy and the AWA Regulations, and reiterated in the Guide, the IACUC is mandated to critically evaluate research protocols to ensure that pain and distress are minimized in laboratory animals and assure that appropriate steps will be taken to enhance animal well-being. The AWRs stipulate that the IACUC determine that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources used to determine that alternatives were not available. The Guide states that the IACUC should ensure the protocol addresses:

- Appropriate sedation, analgesia, and anesthesia;
- Criteria for timely intervention, removal of animals from study, or euthanasia if painful or stressful outcomes are anticipated; and
- Details of post-procedural care.

The protocol must provide adequate information for the IACUC to assess the potential animal pain and/or distress resulting from the study and the effectiveness of the pain and distress relieving agents proposed for use. Criteria for re-dosing the animal should also be established. The AV must be consulted for any procedure that has the potential to cause more than momentary pain or distress.

Examples of procedures which the Guide suggests may have the potential to cause pain or distress, include:

- physical restraint,
- survival surgeries,
- food or water restriction,
- death as an endpoint,
- noxious stimuli,
- skin or corneal irritancy testing,
- tumor burdens,
- intra-cardiac or orbital sinus blood sampling, and
- abnormal environmental conditions.

9.10.1 Assessing Pain and Distress

Numerous references indicate that both laboratory animals and humans receive and process noxious stimuli using similar mechanisms. An animal's response to pain is often adaptive to reduce movement to minimize re-injury and aid recuperation. This response, however, may lead to physiological and behavioral changes which impact negatively on both the animal's well-being and the research results.

Fundamental to the relief of pain is the ability to recognize its clinical signs in various species of animals. Due to the inability of animals to verbalize, it is essential that animal care staff and researchers receive adequate training on how to recognize clinical signs of pain and distress. It is often useful to start with a general set of observations for assessing pain and distress such as change in body weight, physical appearance/posture or changes in unprovoked and provoked behavior. The assessment system should then be modified on a case-by-case basis using specific changes that may be anticipated in a particular study.

9.10.2 Alleviation of Pain and Distress

Accepted best practices for dealing with the possibility of unrelieved pain and distress should be considered and incorporated into protocols unless there is a sound scientific rationale for deviation from those practices. The investigator must also provide an assurance that unrelieved pain will continue for only the minimum period of time necessary to attain the study objectives.

Protocol methodology should be considered that decreases the potential for pain or distress. In addition to thorough searches of the literature, this can be done through the careful use of pilot studies to determine earlier endpoints or less invasive alternatives.

Pharmacologic treatment of pain or distress should be given as consistent with the type of pain/distress and the needs of the research question. The veterinarian must be consulted for all such protocols and should provide guidance to investigators and the IACUC. Non-pharmacologic treatments should also be employed. This may include special housing considerations, dietary and other environmental enrichments, adjustments and careful supportive care.

It is the responsibility of the investigator to show s/he has considered all the options for minimizing pain and distress that do not compromise the scientific validity of the experiment. The IACUC's deliberations regarding the management of potential pain and distress in a protocol will be documented. Personnel should be trained in pain and distress management. The IACUC should ensure that there is a mechanism in place for prompt reporting of sick animals to the veterinary staff.

9.11 IACUC Policies

From time to time, the IACUC will issue new policies to URI's animal research community. These policies will be included in this document as attachments. These policies are written to assist faculty, staff, and students in performing vertebrate animal procedures in a humane manner and complying with pertinent regulatory requirements. Under some circumstances deviations from these procedures may be indicated but such variances must be approved in advance by the IACUC.

10.0 MONITORING OF APPROVED PROTOCOLS

10.1 Annual Review

AWA Regulations require an annual review of protocols. PHS Policy requires the IACUC to 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 in accordance with the PHS Policy IV.C.1-4 at least once every three years.

At URI, regardless of the species used, the IACUC requires an annual report on the status of each protocol. In doing so, the Investigator verifies that completed activities were conducted in accordance with the approved protocol, describes any proposed departures from the approved protocols, and solicits information about activities projected for the upcoming year. In addition, the number of animals used over the course of the previous protocol year needs to be provided.

When Annual Continuing Review Forms are submitted to the IACUC via IRBNet prior to the protocol's expiration date, the protocol is considered active and experiments can be conducted while the annual renewal is under review.

10.1.1 *The Purpose of the Continuing Annual Review*

The purpose of continuing review is primarily threefold:

- To inform the IACUC of the current status of the project;
- To ensure continued compliance with PHS, USDA and institutional requirements; and
- To provide for re-evaluation of the animal activities at appropriate intervals.

Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IACUC's conduct appropriate and meaningful reviews of ongoing animal protocols in the same responsible manner that initial reviews are done. This means that the IACUC will not "rubber stamp" a previously approved protocol during continuing review just because it has undergone a thorough initial review. In a society where use of animals in research, testing and teaching is viewed with increasing concern, high standards of oversight must be maintained. Within the framework of federal regulations and policies, however, there is need for institutions to develop review procedures that are reasonable, meaningful and efficient, and that do not burden the IACUC or investigators with unnecessary requirements that do not contribute directly to the welfare of the animals or provide significant information relevant to the role of the IACUC.

10.1.2 Procedures for Conducting Annual Reviews

Starting at sixty (60) days before the first and second anniversary of the protocol approval, the PI is sent a notification requesting the status of the protocol (active or inactive), requesting any proposed modifications to the protocol, and asking for the number of animals the PI has used in the previous 12 months. The PI must complete the Annual Continuing Review Form and submit it to the IACUC via IRBNet by the first and second anniversary of the protocol approval. When the PI has successfully submitted the Annual Continuing Review Form, animal work may continue. If a PI submits an Annual Continuing Review Form that requires modifications, the IACUC Specialist will follow the PI notification of IACUC administrative actions described in Section 9.9.

If a PI fails to submit an Annual Continuing Review Form by the first and second anniversary of the protocol approval, the following action is taken:

- If the protocol covers species not regulated by the USDA:
 - The IACUC Specialist will notify the PI and the AV. The AV, in consultation with the Director of Research Integrity and IACUC Chairperson (or in his/her absence, the Vice-Chair), will determine if any threat to animal well-being is posed and if so will take the appropriate action. If the Annual Continuing Review Form is not submitted within 7 days of the anniversary date, all work under the animal protocol must cease until further notice.
 - If the PI fails to submit the Annual Continuing Review Form within 30 days of the protocol anniversary date, the protocol will be considered to be permanently expired and the PI will be required to resubmit a new protocol in order to restart work. Additionally, the IACUC may consider suspending (as described in Section 14.2.2) or terminating that PI's animal use privileges.

- If the protocol includes species that are regulated by the USDA:
 - The IACUC Specialist will notify the PI, the AV, and the Director of the Office of Sponsored Projects (if the project is externally funded), that all work under the animal protocol must cease until further notice. The AV, in consultation with the IACUC Chairperson (or in his/her absence, the Vice-Chair), will determine if any threat to animal well-being is posed and if so will take the appropriate action.
 - The PI must promptly provide, in writing, a statement that he or she will not use any animals under the protocol for teaching or research until the IACUC has reviewed and approved the annual review. If the PI fails to promptly provide such a verification statement and continues animal work, then URI may report such incident to the USDA.
 - If the PI fails to submit the Annual Continuing Review Form within 30 days of the protocol anniversary date, the protocol will be considered to be permanently expired and the PI will be required to resubmit a new protocol in order to restart work. Additionally, the IACUC may consider suspending (as described in Section 14.2.2) or terminating that PI's animal use privileges.

If a protocol is allowed to lapse while the associated vertebrate animals are still being housed on campus, they must be turned over to the custody of the AV (an IACUC-approved holding protocol is present to cover such situations). The AV will make a determination (after possible consultation with the IACUC Chair, the relevant Dean, and/or the IO) on whether the animals can be safely and humanely maintained temporarily by the AV, or if they should instead be transferred to another study, placed with an outside agency, or euthanized.

If the animals have been used primarily for teaching or demonstration and were originally privately-held animals that were not purchased with university funds, they may be able to be returned back to the original owners or another experienced individual. Requests for such transfers can be made to the AV.

10.2 Three Year Renewal

The PHS Policy requires that a complete IACUC review of PHS-supported protocols be conducted at least once every three years. This triennial review is interpreted by OLAW as a requirement for de novo review, meaning that the criteria and procedures for review specified in IV.C. of the PHS Policy must be applied not less than once every three years.

The three-year period begins on the actual date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. Since protocol approval period cannot be extended, investigators must be cognizant of the protocol approval period. To aid investigators, the Office of Research Integrity shall attempt to provide adequate warning of pending protocol expiration. It is the responsibility of the investigator to submit the three-year renewal by the appropriate deadline date for a scheduled FCR prior to protocol expiration. The IACUC requires a Three Year Renewal be submitted as a new proposal, using the most recent version of the application.

10.2.1 Procedures for Conducting Three Year Renewals

Starting at sixty (60) days prior to the three-year anniversary of the animal protocol approval date, the PI is sent a notification requesting a renewal of the protocol. The PI must resubmit the entire protocol to the ORS. A *de novo* review of the three-year resubmission is conducted as described in Section 9.0. The three-year renewal must be approved by the IACUC before the expiration date of the original protocol. If a PI fails to submit a three-year resubmission and receive approval by the expiration date of the protocol, the following action is taken:

On the third anniversary of the protocol approval, the IACUC Specialist will notify the PI, the PI's dean (and/or department chair), the IACUC Chairperson, the AV, and the Director of the Office of Sponsored Projects (if the project is externally funded), that the animal protocol has expired. The PI will be notified in writing that all activities under the protocol must cease and any ongoing work under the expired protocol is a serious and reportable violation of PHS Policy.

The AV will be notified of the expired protocol and any remaining animals under that protocol will be transferred to a holding protocol. In the event that animal care charges are being charged to a sponsored project, an alternate account must be identified for such charges.

When the PI has successfully obtained approval of the protocol, animals will be transferred from the holding protocol to the new approved protocol.

If the PI fails to successfully renew the protocol, the IACUC may consider suspension or recommending to the IO that the PI's animal use privileges should be terminated.

10.3 Comparison of Protocols to Grants

Public Health Service (PHS) agencies will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance and have provided verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy. Additionally, PHS agencies will not make an award for research involving live

vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with the Policy and has filed the necessary assurance with OLAW.

Regardless of when the review occurs, the investigator should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IACUC. A copy of the funded or unfunded grant proposal application is requested by the IACUC and reviewed by designated member(s) to confirm that all research outlined in the grant is included in the approved IACUC protocol.

10.3.1 Verification of Protocol and Grant Consistency

The extents of the verification of consistency between grant proposals and IACUC protocols will be a confirmation that the species and procedures relating to use of animals described in the proposal are included in the protocol. This will be a unidirectional comparison of the procedures described in the grants. In conducting the verification, the IACUC focuses on the following two (2) questions:

- Are the species used in the grant proposal included in the IACUC protocol?
- Are animal care and use procedures described in the grant proposal included in the IACUC protocol?

Verification of grant and protocol consistency concentrates on animal care and use and will not include a judgment of scientific merit.

10.3.2 Timing of Verification

The IACUC will compare the grant to the protocol during the review of the protocol. In addition, the IACUC will compare the grant to the protocol when a new funding source for a protocol is proposed, or when the Office of Sponsored Projects requests verification.

10.3.3 Protocol Amendments

There are two types of amendments to animal research protocols that have specific relevance to this policy—(1) a change in funding source and (2) a change in animal use procedures. Submission of an administrative amendment requesting a change in funding source will include a verification of consistency between the new grant and the current protocol to which it is being linked. The verification will include a confirmation that the species and procedures relating to use of animals described in the proposal are included in the protocol.

The IACUC understands that research projects evolve over time and therefore the specific direction of a protocol may change from the original description of animal use procedures. These changes should be submitted as a significant amendment to the protocol and should be consistent with the objectives, purpose, or aims stated in the original protocol. It is the Principal Investigator's responsibility to explain how the changes relate to the original protocol. Because the determination of consistency between the grant and original protocol has already been established, there will generally be no need to "re-verify" grant-to-protocol consistency for amendments.

For PHS-supported grants (e.g., NIH, CDC, etc.) it is the responsibility of the PI to indicate any significant changes in the use of vertebrate animals in the Progress Report Summary section of their Non-Competing Continuation Progress Report (PHS 2590).

10.3.4 Managing Grant-Protocol Inconsistencies

The Director of Research Integrity or designee usually conducts the grant to protocol comparison. The PI, through the IACUC, will be consulted regarding any apparent inconsistency. As noted above, significant changes require that the PI notify the extramural Program Official. Verification of this request and subsequent approval must be shared with the IACUC.

10.4 Post Approval Monitoring (PAM)

Periodically, the IACUC will identify certain protocols or procedures that the IACUC determines that the laboratory could benefit from close veterinary oversight. The requirement of specific monitoring can be a provision of protocol approval and is communicated to the PI. Once a protocol action (e.g., new protocol, revision, etc.) is approved with a proviso for PAM, a specific notice to that effect will be sent to the PI. The notice will be sent separately rather than being combined with any other correspondence (such as approval notices or review queries). The animal care staff is notified of the need for monitoring and provided with the pertinent details. The animal care staff coordinates this monitoring and periodically, and as necessary, provides updates to the IACUC.

In addition, the Director of Research Integrity in coordination with the animal care staff conducts random visits to high-use areas, including satellite facilities. The Director of Research Integrity has the philosophy that maintaining a friendly and collaborative presence in the research lab areas is a proactive way to ensure that minor issues are identified rapidly for quick and cordial correction, and that major issues are prevented.

11.0 Semiannual Review

The PHS Policy and AWA Regulations stipulate that the IACUC must review the program for humane care and use of animals at least once every six months, using the Guide as the basis for evaluation. Federal requirements also state that the IACUC must inspect all institutional animal facilities at least once every six months

11.1 Program Review

The animal care and use program review includes an evaluation of institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC record keeping and reporting procedures. It also includes a review of the adequacy and appropriateness of the veterinary medical care program, the training program for personnel, Standard Operating Procedures (SOP) for the animal facilities, and the occupational health and safety program.

The IACUC will review at least once every six months URI's program for humane care and use of animals, using the 8th Edition of the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

During the regular convened meetings of the IACUC, typically in April and October of each year, the IACUC reviews URI's animal care and use program using OLAW's Semiannual Program Review Checklist. The checklist is designed to evaluate the animal care and use program, disaster planning and emergency preparedness, the IACUC, special considerations of protocol review, IACUC membership and function, training for IACUC members, research staff, and animal care staff, IACUC records and reporting requirements, veterinarian care, personal qualifications and training, occupational health and safety, personal security, and investigations and reports of animal welfare concerns. Each area of evaluation is evaluated and any deficiencies are categorized as minor or significant. No member is involuntarily excluded from participating in any portion of the program review.

Findings from the Program Review, including a deficiency correction schedule, are compiled and prepared for IACUC review and discussion at a regular, convened IACUC meeting following the Program Review, usually in May and November. The IACUC Specialist requests additional comments and minority views from all members present.

11.2 Facility Inspections

The facility inspections are a physical inspection of all buildings, rooms, areas, enclosures and vehicles (including satellite facilities in which animals are housed for more than 24 hours) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. The AWA Regulations apply to animal study areas where animals are maintained for more than 12 hours (applicable only to USDA-covered species).

Laboratories in which routine procedures, such as immunization, dosing, and weighing, are conducted may be evaluated by other means such as random inspections. The institution, however, through the IACUC, is responsible for all animal-related activities regardless of where animals are maintained or the duration of the housing. The IACUC must have reasonable access to these areas for the purpose of verifying that activities involving animals are being conducted in accordance with the proposal approved by the IACUC.

The IACUC inspects, at least once every six months, all of the University's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

Every six (6) months the IACUC Specialist organizes the inspection schedule of the animal facilities located on campus and any satellite facilities. These inspections are conducted using the Guide as a basis for evaluation (OLAW's Semiannual Facility Inspection Checklist). Inspections are typically conducted in April and October. Deficiencies are categorized as minor or significant. All IACUC members are invited, and encouraged, to attend the facility inspections. At a minimum, two (2) members are present for each inspection. No member is involuntarily excluded from participating in any portion of the facility inspections.

A responsible party (e.g., PI, facility manager) is notified, in writing, of any minor or significant deficiency identified in their laboratory, facility or designated space. Responsible parties are required to promptly provide a response to the deficiency notification with a description of how the deficiency has been corrected or to submit a written plan with a timeline outlining how the deficiency will be corrected.

Findings from the Facility Inspections, including a deficiency correction schedule, are compiled by the IACUC Program Coordinator and prepared for IACUC review and discussion at a regular, convened IACUC meeting following the inspections, usually in May and November. The IACUC Program Coordinator requests additional comments and minority views from all members present.

11.2.1 Staffing of Facility Inspections

Inspections are conducted by at least two IACUC members. No IACUC member should be excluded should she or he wish to participate in an inspection. Ad hoc consultants may be used although the IACUC remains responsible for the evaluations and reports. The inspection team should have a working knowledge of the Guide and AWA Regulations in order to fully evaluate the facilities that are being inspected.

11.2.2 Categories to be Inspected

Inspections are conducted using OLAW's Semiannual Inspection Checklist. Categories for review include:

- 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,
- Knowledge of applicable rules and regulations, and security.

The IACUC may determine whether the supervisory personnel of various facilities should be notified of the date and time of an inspection. Advance notification allows individuals to be available to answer questions; an unexpected visit may show the facility during usual operations but also may result in a visit having to be rescheduled if key individuals are not available. Although advance notification is not required, the IACUC usually provides reasonable notice to investigators of the dates, times, and locations of inspections.

11.2.3 Performing Inspections

Adherence to the following recommendations will assist the IACUC in performing inspections:

- An updated list of all facilities to be inspected should be maintained by the IACUC.
- All proposals submitted to the IACUC should specify locations where animal procedures will be performed.
- It is helpful to maintain a list of all facilities including room number, function of the room, species and deficiencies identified during the previous inspection.
- For satellite areas, a contact person is useful.
- For facilities with multiple rooms, a floor plan can assist the inspectors.
- If a subcommittee is performing the inspection, a blend of Committee members who last inspected the area with members who did not participate in the last review, can improve the process.
- Apparent deficiencies should be discussed with the person in charge of the facility to ensure that the team's perception of the situation is accurate. In some cases an apparent deviation will be due to the experiment in progress, e.g., withholding of food prior to surgery.
- Use of a checklist provides consistency and helps document that all categories were assessed.

11.2.4 Deficiency Correction Schedule

All deficiencies identified during the Facility Inspection and/or Program Review are designated by the IACUC as minor or significant. A significant deficiency is defined as a situation that is or may be a threat to animal health or safety. The IACUC, through the IO, is obligated to promptly report to OLAW any serious or continuing noncompliance with the PHS Policy or any serious deviation from the provisions of the Guide (See Section 14.0).

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. If the institution is unable to meet the plan, the IACUC, through the IO,

will inform Animal and Plant Health Inspection Service (APHIS) officials within fifteen business days of the lapsed deadline (AWA Regulations). Federally funded projects will have their relevant funding agency informed.

11.2.5 Documentation

A written report of the semiannual program review and facility inspection is prepared. The AWA Regulations require the report to be signed by a majority of the IACUC members at a convened meeting. The report describes the institution's adherence to the AWA Regulations, PHS Policy, the Guide, and identifies specifically any deviations from these documents.

The report will indicate whether or not any minority views were filed, and minority views will be included in the final document. A copy of the report is sent to the IO and is kept on file for a minimum of three years in the Office of Research Integrity. URI notifies OLAW of the dates of the semiannual program evaluations and facility inspections in the annual report to OLAW.

12.0 IACUC RECORDS

The IACUC records include:

- IACUC meeting minutes.
- IACUC protocols and attachments thereto.
- IACUC membership.
- IACUC policies and procedures.
- IACUC documentation related to unanticipated problems, including reports of noncompliance of PHS Policy and/or AWA Regulations.

12.1 Meeting Minutes

The minutes shall include the following:

- Voting members present;
- Presence of unaffiliated member(s);
- Staff and guests, including consultants present for each protocol reviewed at the meeting;
- Action voted on by the IACUC;
- Number of votes for, against, and the number of abstentions from voting (documentation of quorum);
- Members attending the meeting but not present for the discussion and vote;
- Recusals of voting members due to conflicts of interest;
- When applicable, summary of information presented by IACUC member(s), ad hoc consultants, or guest(s);
- Summary of the discussion of issues and their resolution, if any;
- Modifications required and/or additional information requested by the IACUC; and
- Basis for requiring changes or disapproving the research.

Minutes shall be made available to the IACUC members for review and approval and shall not be altered once approved. Minutes shall be retained by the IACUC Office for at least seven (7) years and shall be maintained in a secure area within the IACUC Office or secure shared filed area on the URI network.

12.2 Retention

The IACUC shall retain the following records for at least seven (7) years after the completion of the research activity:

- IACUC meeting minutes.
- IACUC protocols and attachments thereto.
- IACUC membership.
- IACUC policies and procedures.
- IACUC documentation related to unanticipated problems, including reports of noncompliance of PHS Policy and/or AWA Regulations.

13.0 DISCIPLINARY ACTIONS

The IACUC can launch investigations, and suspend or rescind protocols based on noncompliance and/or unacceptable risk. In addition, the IO may place limitations or conditions on an investigator's or research study staff's privilege to conduct research involving animals upon recommendation of the IACUC, where such actions are required to maintain the compliance with federal, state, local, and/or institutional requirements.

14.0 NONCOMPLIANCE AND ANIMAL WELFARE CONCERNS

14.1 Noncompliance with IACUC Protocol, Policies, Procedures, or Decisions

Protocol noncompliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include performing unauthorized surgery or unauthorized persons participating in a research project that the IACUC has not approved. When faced with protocol noncompliance, the IACUC's first step, if possible, should be to find a way to bring the protocol into compliance.

If allegations of protocol noncompliance are verified, the IACUC can apply sanctions. If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. A clearly minor and unintentional misinterpretation of an IACUC policy that has created no problem for an animal is an example of where a verified allegation of protocol non-compliance might lead to an explanation, not a sanction.

14.2 Consequences of Noncompliance

Subsequent actions of the IACUC may include:

- Implementing measures to prevent recurrence;
- Notifying the IO and the AV of its actions;
- Notifying funding or regulatory agencies, as required; and/or

14.2.1 Institutional Sanctions

Examples of institutional sanctions that have been devised include:

- Counseling;
- Issuing letters of reprimand;
- Mandating specific training aimed at preventing future incidents;
- Monitoring by the IACUC or IACUC-appointed individuals of research, testing, or training that involves animals;
- Revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;

- Recommending to the IO that institutional (e.g., reassignment, termination of employment) sanctions be imposed.

14.2.2 Suspension of Animal Activities

The IACUC is empowered to suspend a project if it finds violations of URI policy, PHS Policy, the Guide, Assurance, or Animal Welfare Act Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and a vote for suspension by a majority of the quorum present. Further, the IACUC must consult with the Institutional Official regarding the reasons for the suspension. The Institutional Official is required to take appropriate corrective action, and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly.

14.3 Principal Investigator and Research Personnel Reporting Requirements

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

- Serious or continuing noncompliance with the PHS Policy;
- Serious deviations from the Guide for the Care and Use of Laboratory Animals; and
- IACUC suspensions.

The PI and protocol personnel must report any serious or continuing noncompliance with an IACUC protocol, policy, procedure, decisions, or deviation from the Guide. The report should be on University/departmental letterhead, addressed to the IACUC Chairperson, and emailed (preferred) to researchintegrity@ds.uri.edu or mailed to the Office of Research Integrity. The self-report of noncompliance should include the following information:

- Relevant grant or contract number(s);
- Full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal care staff, student, veterinarian, etc.);
- Description of actions taken by PI to address the situation; and
- Description of short- or long-term corrective plans and implementation schedule(s).

14.4 IACUC and IO Reporting Requirements

14.4.1 Annual Reporting

The IACUC, through the IO, will submit an annual report to OLAW and USDA.

Annual Reports to OLAW are due by January 31 of each year. URI's reporting period is January 1 – December 31. The report will include:

- Any change in the description of URI's program for animal care and use as described in the Assurance, or any change in the IACUC membership. If there are no changes to report, the University will provide written notification that there are no changes.
- Notification of the dates that the IACUC conducted its semiannual evaluations of the University's program and facilities (including satellite facilities) and submitted the evaluations to the IO.

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

- Any serious or continuing non-compliance with PHS Policy.
- Any serious deviations from the provisions of the Guide.
- Any suspension of an activity by the IACUC.

The USDA Annual Report of Research Facilities is due prior to December 1 of each year. The report will include:

- A census of USDA covered species used by or under control of URI
- A summary of any IACUC-approved exceptions to the regulations or standards must be submitted in hard copy to USDA as part of the Annual Report. At a minimum, this summary should include the following:
 - Identify IACUC-approved exception(s) to the regulations or standards, including exemptions to the dog exercise plan and/or the nonhuman primate plan for environmental enhancement.
 - Describe the IACUC-approved exception(s).
 - Identify the species and number of animals affected.

14.4.2 Internal Reporting

All investigations by the Office of Research Integrity and/or the IACUC will be reported internally at the completion of the investigation to the following individuals, as appropriate:

- Principal Investigator (PI),
- PI's Department Chair,
- PI's School Director and/or College Dean,
- Chair, IACUC,
- Director, Office of Research Integrity,
- Director, Office of Sponsored Projects (if project is externally funded),
- Office of General Counsel,
- Vice President for Research and Economic Development.

14.5 Evaluation of Animal Care and Use Concerns

To help ensure that laboratory 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 must be established to ensure that concerns are communicated to the IACUC. The IACUC must review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions.

14.5.1 Methods for Reporting

To facilitate communication, there are a number of options available to communicate concerns about animal care and use at URI, or to report instances of suspected non-compliance with laws, rules, regulations and policies. The names and phone numbers of contact persons including the Attending Veterinarian, the Director of Research Integrity, and IO are posted in or near the entrance to animal

facilities and are listed on the Office of Research Integrity website, readily available to institutional employees. Additionally, concerns can be reported anonymously via the URI Ethics Hotline (855-236-1845 and www.uriethicsline.com).

Although written concerns are more convenient to handle, complainants may not be willing to submit them in this manner. In such cases, the individuals who receive concerns should document them fully to ensure that the issues are clear and to prevent misunderstandings.

Requests for anonymity should be honored to the extent possible. This includes protecting the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The State of Rhode Island Whistleblower Protection Act prohibits unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

14.5.2 Procedures for Investigating Animal Care and Use Concerns

Concerns may include situations or activities ranging from those in which animals are reported to be in immediate, actual or perceived jeopardy to those in which violations of the AWA Regulations or institutional Animal Welfare Assurance are alleged to be occurring but animals are not in apparent danger. They may focus on allegations of past policy and procedure violations or protocol non-compliance.

The course of action taken by the IACUC should be driven by the potential significance of the alleged situation. For example, conditions that reportedly jeopardize the health or well-being of animals should be evaluated immediately. To cope promptly with such situations, the Attending Veterinarian is authorized to halt procedures which they believe do not comply with institutional policies until the IACUC can be convened and consider the matter formally. Similarly, situations that may involve potential criminal activity or human safety should be reported promptly to the institution's law enforcement or occupational health and safety officials. Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be deferred merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

Upon receipt of a concern, the IACUC Chair should convene a meeting of the Complaint Assessment Subcommittee (CAS) comprised of IACUC members designated by the Chair. The CAS can either meet in person, or via email discussion. After initial review of the complaint, the CAS will determine whether it requires further investigation and immediate action, further investigation but no immediate action, or no action. Once this decision has been made, the CAS should determine which individuals or other institutional or non-institutional offices may require notification at this time.

If immediate action appears warranted because animal or human welfare may be compromised, the IACUC should notify the IO and proceed accordingly. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately to protect animal or human welfare. In accordance with the AWA Regulations, if an activity is suspended, the IO shall report that action to APHIS and any federal agency funding that activity. If the PHS supports the activity in any way, the IACUC, through the IO, must promptly notify OLAW.

Should the IACUC determine that further investigation is required, the CAS should conduct the investigation and report back to the IACUC. It is important to avoid actual or perceived conflicts of interest in this process.

The IACUC should charge the designated person or group with its requirements for information gathering and impose a completion date. The assigned completion date will depend on the IACUC's determination of whether immediate remedial action may be required. The nature of the information required will vary depending on the circumstances, but often involves:

- Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
- Observing the animals and their environment; and
- Reviewing any pertinent records, (e.g., animal health records, protocol, and other documents).

The CAS should provide a report to the IACUC, which summarizes:

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

The report should also contain:

- Any supporting documentation such as correspondence, reports, and animal records,
- Conclusions regarding the substance of the concerns vis-à-vis requirements of the AWRs, the PHS Policy, the Guide, and institutional policies and procedures, and
- Recommended actions, if appropriate.

Upon receipt and evaluation of the report, the IACUC may request further information or find that:

- There was no evidence to support the concern or complaint,
- The concern or complaint was not sustained, but
- Related aspects of the animal care and use program requires further review, or
- Other institutional programs may require review, or
- The concern or complaint was valid.

15.0 MONITORING AND AUDITS

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal, state, and local statutes, regulations and institutional requirements may conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

16.0 CONFIDENTIALITY

To protect the integrity of URI and its researchers, IACUC members must not:

- Disclose confidential or proprietary information (protocol or investigator specific) to any non-IACUC member or,
- Discuss, or disclose any details of IACUC business (e.g., protocol reviews, non-compliance discussion, subcommittee investigations or reviews, etc.) to third parties without the consent of the IACUC Chair (or in his/her absence the Director of Research Integrity).

Material provided to the IACUC for review shall be considered confidential information and the members must, therefore, assure the confidentiality of the data contained therein. All IACUC protocols and other sensitive review materials must be either filed in a secure location or otherwise disposed of in an appropriate manner, e.g., shredding.

Under the AWA (§2157), IACUC members who violate confidentiality regarding “trade secrets” or other proprietary information may be subject to significant fines. However, this provision of the AWA is not intended to discourage participation on the IACUC, but rather to protect institutions. It should be noted that the USDA AWA Regulations (which implement the Animal Welfare Act itself) state that reports of violations to regulatory agencies by IACUC members are NOT violations of confidentiality requirements.

The IACUC views the sharing of information for educational purposes in faculty and staff meetings an important benefit of departmental representation and is considered a vital part of the member’s experience. This information may include such items as IACUC concepts, policies, regulations, and educational issues, providing no specific personal, confidential, or proprietary information is divulged.

If, following a Full Committee Review, the IACUC agrees that consultation or discussions with individuals outside of the IACUC are necessary; a person designated by the IACUC will first obtain permission from the PI. If the PI does not grant such permission, this may preclude final approval by the IACUC if questions concerning the protocol cannot be resolved.

17.0 POLICIES AND PROCEDURES

The IACUC shall adopt such Policies and Procedures and develop such guidance as may be necessary for the review of research involving animals in compliance with federal, state, and local laws and regulations. Policies concerning IACUC operations shall be developed by the Director of Research Integrity and IACUC Chairperson and reviewed by the IO. Policies intersecting with or affecting other institutional offices or processes may be developed in consultation and coordination with those offices or institutional research leadership and are generally approved by the IO. The IACUC Policies and Procedures, including IACUC guidance documents and significant policy-related communications to the research community, shall be made available on the URI Office of Research Integrity website and shall be maintained by the URI Office of Research Integrity for at least seven (7) years from the date of their adoption/distribution and shall be made available upon request to authorized representatives of the sponsor and, when applicable, authorized representatives of NIH, USDA and other federal agencies.

18.0 REPORTING AND MANAGEMENT OF CONCERNS

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the IACUC may be reported orally or in writing. Employees are permitted to report concerns and may do so on an anonymous basis. Concerns may be reported to the IACUC Chair, IO, Research Integrity, or URI’s Ethics Hotline (1-855-236-1845 or www.uriethicsline.com).

The IACUC is responsible for investigating allegations and findings of non-compliance and taking corrective actions as needed. The IO is responsible for investigating reports of IACUC non-compliance and taking corrective actions as needed.

Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the IO.

Contact information for the Institutional Official is as follows:

Gerald Sonnenfeld, Ph.D., Vice President for Research and Economic Development
Division of Research and Economic Development
Carlotti Administration Building, Suite 209
75 Lower College Road
Kingston, RI 02881
401 874-4576

Contact information for the Director of Research Integrity is as follows:

Theodore A. Myatt, Sc.D.
Division of Research and Economic Development
70 Lower College Road
Kingston, RI 02881
401 874-2636