

# Approved Official Policies of the Western Oregon University Institutional Animal Care & Use Committee (IACUC)

*As voted upon and approved by the Full Committee at its meetings*

## 1. Name and official abbreviation:

- 1.1. The name of the committee shall be the Western Oregon University Institutional Animal Care and Use Committee
- 1.2. This name may be abbreviated to "WOU IACUC" or "IACUC" as needed

## 2. Responsibilities and Authority of the IACUC

- 2.1. All teaching, research, and outreach activities involving the use of live, non-embryonic, vertebrate animals by members of the Western Oregon University community are under the purview of the WOU IACUC and must be approved in advance by the committee.
- 2.2. The IACUC shall review, deliberate, approve, amend, and withhold approval of animal use protocols or protocol components, involving Western Oregon University personnel or facilities.
- 2.3. The committee will investigate all reports of animal policy non-compliance, animal misuse, and animal mistreatment and compose a report of their findings for the Institutional Official (IO)
- 2.4. The committee will work with the IO to suspend and/or cancel unlawful animal use protocols or protocols that violate the policies put forth in this document
- 2.5. The committee will review WOU's animal use and care policies at least once every six months to ensure they are compliant with AWAR, the *Guide* and other relevant laws, and the mission of the University and compose a report of their findings for the IO.
- 2.6. The committee will coordinate inspection of approved animal housing facilities every six months and compose a report of their findings for the IO.
- 2.7. The committee will oversee a training program for all WOU personnel that use animals in their teaching, research, or outreach activities.
- 2.8. The committee has a duty to promulgate the WOU IACUC and WOU's policies for the use of animals.
- 2.9. The committee, with the IO, will serve as a liaison between WOU and the community regarding matters related to the use of animals by university personnel and the welfare of animals in the university's possession.

## 3. Institutional Official:

- 3.1. Appointment:
  - 3.1.1. The designated Institutional Official (IO) of the WOU IACUC will be the Dean of Research and Graduate Studies

- 3.1.2. The IO will be appointed by the university President in their role as Institutional CEO
- 3.2. Responsibilities and Powers:
  - 3.2.1. The IO acts as a representative of senior administration, bearing ultimate responsibility for the IACUC and the use of animals at WOU
  - 3.2.2. The IO is responsible for ensuring that the IACUC functions effectively and that the university provides the resources and support necessary to comply with all requirements applicable to research, teaching, etc. involving animals.
  - 3.2.3. The IO ensures alignment of IACUC goals and guidelines with the Institution's mission.
  - 3.2.4. The IO ensures the authority of the IACUC at the institution
  - 3.2.5. The IO represents the institution named in the Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare and the Registration on file with the United States Department of Agriculture or other federal offices as applicable.
  - 3.2.6. The IO appoints members of the WOU IACUC to their roles. Such appointments may be made upon the recommendation of the WOU IACUC Chair.
  - 3.2.7. In conjunction with the IACUC, the IO reviews and investigates concerns regarding animal welfare at the institution. They ensure methods for reporting and investigating animal welfare concerns are established, communicated, and maintained.
  - 3.2.8. The IO has the power to indefinitely suspend protocols in cases of concern for animal welfare, without the need to consult the IACUC.

#### **4. Composition of the IACUC**

- 4.1. The WOU IACUC will be comprised at minimum, of the following individuals, the roles of which are described in subsequent policies:
  - 4.1.1. Doctor of Veterinary Medicine (Veterinarian)
  - 4.1.2. Non-University Member (Community Member)
  - 4.1.3. Practicing Scientist Experienced in Animal Research (University member)
  - 4.1.4. Non-Scientist Member of the University (University member)
  - 4.1.5. Chairperson ("Chair"; University member)
- 4.2. Additional members may be added at the discretion of the Chairperson upon consultation with, and appointment by, the Institutional Official.
- 4.3. Not more than three members of the IACUC can be from the same "Administrative Unit" of the university

#### **5. IACUC Member Appointment**

- 5.1. Appointment on the IACUC will be for a period of three (3) academic years, with the exception of the Attending Veterinarian, who will hold an indefinitely-tenured role.
- 5.2. Vacant roles will be advertised to the university community through all-campus email, presentation at Faculty Senate, and other means as deemed necessary.

- 5.3. Interested new applicants will submit a notice of interest to the Chairperson. The Chair will then consult with the current committee regarding the applications of interested individuals.
- 5.4. Upon the advice of the current committee, the Chair will then provide a recommendation of appointment to the Institutional Official.
- 5.5. At the end of their 3 year term members may apply for subsequent terms.
- 5.6. The Institutional Official will officially appoint all members of the IACUC.
- 5.7. Selection of the Chairperson:
  - 5.7.1. Solicitations for the Chairperson will be disseminated to the campus community by the IO in the final year of the current Chair's tenure. Nominations must be received in writing.
  - 5.7.2. Consideration of nominations will be conducted by the full committee, and a recommendation will be made to the IO.
  - 5.7.3. A new incoming Chair will be appointed no later than Winter term of the final year of the current chair, and the incoming chair will act as an observer for the entirety of Spring term in preparation for officially taking on the new role in July.
- 5.8. Selection of the Non-University Member (Community Member):
  - 5.8.1. The committee will solicit interest from members of the community who can adequately represent the general community interests in the proper care and treatment of animals.
  - 5.8.2. Once a list of names of individuals willing to serve in this role is obtained the committee will deliberate and decide on whom to offer this role. They will then forward that recommendation to the IO.
  - 5.8.3. The Non-University Member must not be employed by Western Oregon University and must not be an immediate family member of a person affiliated with the university.
- 5.9. Appointment of the Attending Veterinarian
  - 5.9.1. The Veterinarian will be appointed for an indefinitely-tenured period of time by the IO upon the advice of the IACUC
  - 5.9.2. The Veterinarian must possess a Doctor of Veterinary Medicine (DVM) degree and be currently licensed to practice veterinary medicine in the State of Oregon.
  - 5.9.3. The Veterinarian must be employed by Western Oregon University on a consulting basis and compensated with an appropriate hourly rate based on the time they spend on committee-related activities.
    - 5.9.3.1. Western Oregon University will create an official contract with the Veterinarian to codify this relationship.

## **6. IACUC Member Roles and Responsibilities:**

- 6.1. All members of the IACUC are expected to attend and participate in at least one full committee meeting per academic term; review protocols; be properly trained; and in general carry out the duties and responsibilities of the IACUC as described in **section 2 (Responsibilities and Authority of the IACUC)**. In addition to

these general roles and responsibilities, specific members have specific roles and responsibilities which are detailed below:

6.2. Doctor of Veterinary Medicine

6.2.1. Is a full voting member of the IACUC

6.2.2. Inspection of animal housing facilities at least once every 6 months to ensure they comply with requirements and best practices of cleanliness and animal ethics appropriate to the particular organism under care. The schedule of inspection visits should consider the number of animals, the species of animals, the type of housing for the animals, the type of work or research done on the animals, the possibility, or level, of pain or distress that may be involved, and any other conditions or factors that may affect the animal's well-being (9 CFR, Sect. 2.33(a)(1)), and will be arranged with the IACUC.

6.2.3. Provision of appropriate veterinary care to control, prevent, diagnose, and treat diseases and injuries as needed. Weekend, holiday, and emergency care must be readily available. If the veterinarian is unable to provide care directly, they may designate another veterinarian this responsibility (9 CFR, Sect. 2.33(b)(2)).

6.2.4. Provide (themselves, or through a qualified designee) adequate pre- and post-procedural care in accordance with current established veterinary medical and nursing procedures (9 CFR, Sect. 2.33(b)(5)).

6.2.5. Provide guidance to the IACUC, principal investigator, and other personnel, involved in the care and use of animals regarding housing, handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia (9 CFR, Sect. 2.33 (b)(4)).

6.2.6. Responsible for determining and carrying out review procedures for submitted protocols that include major survival surgery, euthanasia methods, death as an experimental endpoint, or procedures that cause more than minimal or momentary pain or distress without the application of anesthetics, analgesics, or tranquilizers.

6.2.7. Work with the rest of the IACUC to investigate all reports of animal policy non-compliance, animal misuse, and animal mistreatment and compose a report of their findings for the Institutional Officer.

6.2.8. Has the power to immediately and indefinitely suspend protocols in cases of concern for animal welfare, without the need to consult the rest of the IACUC.

6.3. Non-University Member

6.3.1. Is a full voting member of the IACUC

6.3.2. Provides representation for general community interests in the proper care and treatment of animals

6.4. Practicing Scientist Experienced in Non-Human Animal Research

6.4.1. Is a full voting member of the IACUC

6.4.2. Is currently employed by Western Oregon University

6.4.3. Should have demonstrated experience and expertise conducting previous scientific research on non-human animals

6.5. Non-Scientist Member of the University

- 6.5.1. Is a full voting member of the IACUC
- 6.5.2. Is a WOU faculty member whose primary professional concerns are in a nonscientific area. For the purposes and intent of this policy, "science" is referred to as a professional field within the natural or applied sciences.

6.6. Chairperson (Chair)

- 6.6.1. The scope of the responsibilities of the Chair include, but may not be limited to:
  - 6.6.1.1. The Chair shall oversee the review, deliberation, approval, disapproval, and amendment of animal use protocols involving WOU personnel or facilities
  - 6.6.1.2. The Chair will convene and chair regular Committee meetings
  - 6.6.1.3. The Chair will organize and lead regular animal holding facility inspections
  - 6.6.1.4. The Chair will help maintain compliance of the institution with federal, state, and local laws, regulations and guidelines
  - 6.6.1.5. The Chair will be the point of contact coordinating and communicating with the veterinarian, the IO, and the campus community regarding committee matters.
  - 6.6.1.6. When necessary, the chair will work in consultation with the full IACUC and the IO to correct, suspend, or remove personnel from approved protocols for which violations of animal care and use policies have occurred.
  - 6.6.1.7. The Chair, or their designee, is responsible for record retention and will maintain all animal research-related applications, protocol amendments, inspection and training records or other documents for a minimum of 3 years. Pursuant to Title 9, section 2.35 of the AWA, the chair will also retain IACUC attendance, minutes, and deliberation for a period of 3 years.
  - 6.6.1.8. The Chair will be responsible for recruiting, supervising, and meeting regularly with any student assistants or workers of the IACUC.
  - 6.6.1.9. The Chair will be responsible for other duties as described in this Policy document but not specifically listed here.

**7. IACUC Meeting Schedule**

- 7.1. The WOU IACUC will meet as a full committee a minimum of once per academic term (Fall, Winter, Spring) for a total of at least three times per year.
- 7.2. The WOU IACUC reserves the right to meet as a full or partial committee at other times of the year as is deemed necessary.

**8. Principal Investigators (PI)\***

*\*see Appendix for clarifying examples*

- 8.1. An individual is considered a Principal Investigator (PI) if they belong to one or multiple of the following three categories:
  - 8.1.1. Instructors of a class using live vertebrate animals for teaching.
  - 8.1.2. Individual (either an instructor or a student) who is conducting research on live vertebrate animals, who is primarily responsible for planning and undertaking the research.

- 8.1.2.1. Note: For students, this would usually be a student conducting an independent research study or Honors thesis, not a student enrolled in a course other than an independent study (e.g., a student enrolled in a course in which animals are being used and for which the instructor is the PI).
  - 8.1.3. Individual responsible for overseeing the housing and use of outreach animals.
- 8.2. Students enrolled in classes which might contain “mini-research” projects using animals, but whose actions in that class are being directly supervised and overseen by an instructor, would usually not be considered PIs.
- 8.3. There may be multiple PIs on a project (e.g. an Honors student and their supervising Professor).
- 8.4. PIs are responsible for supervising the actions of, and providing appropriate training (could be CITI training or not) to, any individuals (e.g., students, research assistants, volunteers, etc) working under them either formally or informally, in regards to animal welfare.
- 8.5. Any violations of IACUC policies are the sole responsibility of the PI(s).

## **9. Mandatory Training**

- 9.1. With the exception of animal use falling into Review Category 1B, PIs are responsible for taking both the basic (“Working with the IACUC”) and taxon-specific CITI Program training modules listed below for any live vertebrate animals being used in their research / class, and providing copies of certificates of completion to the IACUC.
  - 9.1.1. Required for all PIs, except for Review Category 1B:
    - 9.1.1.1. Working with the IACUC
    - 9.1.1.2. Taxon-Specific training (e.g., “Working with Fish in a Research Setting” if the project involves fish, etc.)
  - 9.1.2. Required for PIs working with Wildlife:
    - 9.1.2.1. Wildlife Research
- 9.2. CITI Training will be considered valid for 3 years.
- 9.3. PIs must complete the following CITI Program refresher course and submit certificates to the IACUC before CITI certificates of completion training expires:
  - 9.3.1. Working with the IACUC - Refresher
- 9.4. PIs (including those covered under Review Category 1B proposals) are responsible for providing appropriate training (could be CITI training or not) to any individuals (e.g., students, research assistants, volunteers, etc.) working under them either formally or informally, in regards to animal welfare.
- 9.5. Co-PIs from institutions other than Western Oregon University that are collaborating on projects with a WOU PI may provide alternative evidence of training which may include, but is not limited to, training certificates from an alternative training program; and/or approved IACUC proposals from a different

institution's IACUC where the same procedures are used as are proposed in the application behind currently reviewed by the WOU IACUC.

## **10. Approved Animal Housing Facilities**

### 10.1. Definition:

10.1.1. An "Animal Housing Facility" is a facility where animals are held for over 24 hours, either on-campus or off-campus, for the primary purpose of teaching or research.

### 10.2. On-Campus Housing

10.2.1. The IACUC will designate specific buildings and rooms on the Western Oregon University campus as approved on-campus housing for animals. Only these approved animal housing facilities will be permitted to house animals under the purview of the IACUC. The IACUC will publish a list of approved on-campus housing facilities.

10.2.2. Approved on-campus housing must maintain the following conditions:

10.2.2.1. Have a dedicated secure (locked) entrance that is not accessible to members of the public or the campus at large.

10.2.2.2. Have a mechanism in place for the regulation of temperature, lighting, and humidity to allow animals to be housed under natural circadian rhythms and at temperatures and humidities appropriate to their biology, and in general follow those housing requirements as outlined in *The Guide*.

10.2.3. Individuals may apply to the WOU IACUC for designation of an on-campus approved housing facility by writing to the Chair. The IACUC will inspect such a facility prior to the full committee voting upon approval.

10.2.4. Future development of animal housing facilities at WOU must take place in consultation with, and receive approval by, the WOU IACUC.

### 10.3. Off-Campus Housing

10.3.1. If animals will be housed for more than 24 hours off-campus and the hosting institution has an IACUC in place, protocol approval must be sought from the hosting institution and a copy of the approved protocol be submitted to the WOU IACUC.

10.3.2. If animals will be housed off-campus for more than 24 hours and the hosting institution does not have an IACUC in place, protocol approval must be sought through the WOU IACUC.

10.3.2.1. The IACUC must inspect these housing facilities prior to animals being present.

10.3.2.1.1. Exceptions apply for field work where animals are being held for more than 24 hours in transit to an approved facility. In this case, this action must be approved in advance by the IACUC through a regular IACUC protocol.

10.3.2.2. The PI is solely responsible for the care of animals in off-campus facilities.

10.3.2.3. Off-campus facilities must maintain the same appropriate conditions for the proper housing and maintenance of animals as those described for on-campus facilities.

10.3.2.4. Off-campus facilities are subject to inspection by the IACUC.

## **11. Mandatory Inspection of Animal Housing Facilities**

- 11.1. As per federal requirements, the WOU IACUC will perform a mandatory inspection of all approved animal housing facilities once every 6 months. Inspections will occur in Fall and Spring terms, to coincide with the full committee meetings in those terms.
- 11.2. The WOU IACUC reserves the right to perform inspections of approved animal housing facilities at other times as deemed necessary in addition to the 6-month mandatory inspection.
- 11.3. Principal Investigators (PIs) will be notified of any inspections of housing facilities.

## 12. Categories of Review

- 12.1. Review category levels are not the same as pain category levels (see Appendix 2); review category levels split up the pain categories listed in Appendix 2 based on what level of review is necessary for the application.

### 12.1.1. Category 1A:

- 12.1.1.1. *Description:* Observational Study only, with manipulations designed to have no or minimal stress; and/or use of outreach animals
- 12.1.1.2. *Reviewed by:* IACUC Chair or their designee
- 12.1.1.3. *Decision:* made by IACUC Chair on an ongoing basis (no full committee review mandatory)
- 12.1.1.4. *Review Schedule:* upon receipt of application

### 12.1.2. Category 1B:

- 12.1.2.1. *Description:* On-campus housing and care of outreach animals or pets, where animals will not be handled or manipulated except for routine care, and only by the PI and designated caretakers.
- 12.1.2.2. *Reviewed by:* IACUC Chair or their designee
- 12.1.2.3. *Decision:* made by IACUC Chair on an ongoing basis (no full committee review mandatory)
- 12.1.2.4. *Review Schedule:* upon receipt of application

### 12.1.3. Category 2A:

- 12.1.3.1. *Description:* Pain Category B, and some Pain Category C (see Appendix 2) studies: Observational study with significant manipulations with the potential to cause stress; holding, weighing or physical examinations of animals in teaching or research activities; injections, blood collection or catheter implantation via superficial vessels; observation or positive



reinforcement training of animals in a laboratory setting; feeding studies that do not result in clinical health problems; routine agricultural husbandry procedures approved by the IACUC; live trapping with minimal potential for injury; studies involving clinical signs not judged to involve more than slight pain or distress.

12.1.3.2. *Reviewed by:* Individual IACUC members

12.1.3.3. *Decision:* Made by full IACUC Committee at regular meeting, upon recommendation of individual member

12.1.3.4. *Review Schedule:* Term meeting

12.1.4. **Category 2B:**

12.1.4.1. *Description:* Pain Category C Procedures not covered by Category 2A (see Appendix 2): Animals being bred that will undergo genotyping procedures or will be euthanized for any reason; methods of genotyping or identification (ear notching, banding, tail clipping, tattooing - unless general anesthesia needed); humane euthanasia that meets current AVMA standards; chemical immobilization or restraint, such as for transport or for procedures that are not considered painful but restraint is required for the species to perform the procedure correctly; protocols involving clinical research on client owned animals that are undergoing surgery not related to the research may be included in Review Category 2B.

12.1.4.2. *Reviewed by:* Veterinarian

12.1.4.3. *Decision:* Made by full IACUC Committee at regular meeting

12.1.4.4. *Review Schedule:* Term meeting

12.1.5. **Category 3:**

12.1.5.1. *Description:* Most Pain Category D and E Procedures (see Appendix 2): surgery, anesthesia, euthanasia, death as an end-point.

12.1.5.2. *Reviewed by:* Full Committee

12.1.5.3. *Decision:* Made by full IACUC Committee at regular meeting

12.1.5.4. *Review Schedule:* Term meeting

### 13. Review Criteria and Outcomes of Review

- 13.1. The IACUC's guiding principle for animal use protocol decisions is the weight of harm to animal subjects relative to the relevance of the research to human or animal health, the advancement of knowledge, and the good of society (*OLAW, US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*).
- 13.2. Submitted protocols will be reviewed based on the following criteria:
- 13.2.1. *Potential value of the study* – animal studies should be designed so there is a reasonable expectation that the results will contribute to the enhancement of human or animal health, the advancement of knowledge, or the good of society (as per PHS Policy).
  - 13.2.2. *Species and animal number* – selected species should be appropriate and the number of animals requested should be the minimum required to obtain valid results (as per PHS Policy).
  - 13.2.3. *Unnecessary duplication* – the PI must provide written assurance that proposed animal use activities do not unnecessarily duplicate previous experiments [9 CFR 2.31(d)(1)(iii)].
  - 13.2.4. *Alternatives* – the PI must provide written assurance that they have considered non-vertebrate models for their research or teaching activity. The PI must also have assessed alternative to procedures that cause more than momentary or slight pain and ensured these alternatives are not available [9 CFR 2.31(d)(1)(ii)].
  - 13.2.5. *Housing and Husbandry* – Conditions will be appropriate for the species and will contribute to animal health and comfort [PHS Policy, Section IV.C.1.d and 9 CFR 2.31(d)(1)(vi)].
  - 13.2.6. *Personnel* – Personnel involved in the care and use of animals will be appropriately trained and qualified and supervised [PHS Policy, Section IV.C.1.f and 9 CFR 2.31(d)(1)(viii)].
  - 13.2.7. *Minimization of Pain and Distress* – Procedures should avoid or minimize discomfort, distress or pain to animals. Procedures that cause more than momentary or slight pain or distress will be performed with appropriate sedation, analgesia, or anesthesia, unless the PI provides written scientific justification for why this requirement cannot be fulfilled. In the absence of anesthesia these procedures will not be performed with paralytics alone. Procedures that cause more than momentary or slight pain or distress must be designed in consultation with the Attending Veterinarian. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be euthanized. [PHS Policy, Section IV.C.1 and 9 CFR 2.31(d)(1)].
  - 13.2.8. *Surgery* – Surgery must include appropriate pre-operative and post-operative care in accordance with established veterinary practices.

An animal may only be used in more than one major operative procedure from which it is allowed to recover if the PI has provided written scientific justification for multiple major survival surgeries and the Attending Veterinarian has determined that multiple major survival surgeries are required to protect the health and wellbeing of the animal [9 CFR 2.31(d)(1)].

- 13.2.9. *Legality* – All animal use activities described in the protocol must be fully compliant with USDA Regulations, PHS Policy, and other applicable federal, state, and local laws and regulations, including those regarding procurement.

### 13.3. Outcomes of Review

- 13.3.1. *Approved* – the protocol application is approved with no modification.
- 13.3.2. *Approved pending minor modification or clarification* – The protocol application is conditionally approved pending PI clarification or modification as requested by the IACUC. The committee Chair will provide the PI with a written report detailing requested modification or clarification. The PI must provide written clarification and/or modification to the proposal as directed by the committee. The committee Chair will notify the PI when the conditions have been fulfilled and the protocol is activated.
- 13.3.3. *Tabled* – The protocol application requires additional information and/or the IACUC has a significant concern. The committee Chair will provide the PI with a written report detailing missing application information and/or the committee's concerns. The PI must revise and resubmit the protocol application with a letter that clearly identifies application changes and how they address issues brought forth in the committee Chair's written report. The revised protocol will be reviewed by the whole committee.
- 13.3.4. *Review Declined* – The protocol application is missing significant information such that a proper review cannot be performed. Alternately, the PI has failed to follow application instructions. The committee Chair will provide the PI with a written report detailing reasons why the protocol application was returned without review. The PI must revise and resubmit the protocol application, as appropriate.
- 13.3.5. *Disapproved* – The committee Chair will provide the PI with a written report detailing reasons why the protocol application was disapproved. The PI has the right of appeal to the IACUC.

- 13.4. At any point during the review process the IACUC has the right to request the presence of the PI (including at scheduled IACUC meetings) to address concerns and/or answer questions that the committee may have.

### 13.5. Rights of Appeal

- 13.5.1. A PI has the right to appeal the decision of the IACUC within a reasonable period of time.
- 13.5.2. The PI must request an appeal in writing to the committee Chair. The appeal letter will be disseminated to members of the IACUC.
- 13.5.3. At the next full committee meeting the PI will be given an opportunity to present information, seek clarification on the decision, discuss the protocol or amendment, and ask or answer questions.
- 13.5.4. The PI will then be asked to leave the meeting and the full committee will vote on whether the protocol or amendment should receive another review. The committee Chair will prepare a letter notifying the PI of the committee vote.
- 13.5.5. If the committee vote is affirmative, the PI will have seven calendar days to modify their protocol and resubmit it for full committee review. If the vote is negative, the PI may not resubmit the protocol.

## 14. Conflicts of Interest and Recusal Process

- 14.1. Committee members may not participate in the review, deliberation, or approval of any activity for which they have a conflict of interest. This includes, but is not limited to, protocols for which they are listed as PI or Co-PI.
- 14.2. The committee member must recuse themselves and be excused from meetings while the matter is being considered. The excused member will not count toward a quorum.
- 14.3. In the case of the Chair recusing themselves, the Chair will temporarily delegate their duties (including, but not limited to, review and approval of Category 1 protocols) to another impartial member of the IACUC. This delegation of duties will be recorded in writing.
- 14.4. If an individual submitting a protocol believes that a member of the committee has a conflict of interest that will affect impartiality, they may request that the committee member be excluded from deliberation, review, and voting. The committee member may voluntarily recuse himself/herself or a majority vote by a quorum allows the committee to sustain or reject the request. Committee members accused of a conflicting interest must be excluded from the deliberation and vote regarding their own impartiality.

## **15. Protocol Approval Duration**

- 15.1. Protocols approved by the WOU IACUC will be valid for a duration of 3 years, unless there is a change in:
  - 15.1.1. Methods or Protocols
  - 15.1.2. Identity of PIs / Co-PIs
  - 15.1.3. A significant discovery that would allow for improved animal welfare
  
- 15.2. In which case, PI's will be required to submit an Amendment to their Protocol for approval by the WOU IACUC.

## **16. Approved Protocol Numbering System**

- 16.1. Approved protocols will be given a unique number containing the last two digits of the year the application was approved and the application number (starting with 1 and continuously increasing; e.g., 23-1, 23-2, etc.)

## **17. Annual Review of Approved Protocols**

- 17.1. All previously approved protocols must be reviewed by the committee on an annual basis.
  
- 17.2. PIs are responsible for submitting an annual report to the IACUC describing the status of ongoing protocols and must include at minimum, the following information:
  - 17.2.1. The number of animals utilized in each USDA Pain category in that calendar year.
  - 17.2.2. Any minor changes to the approved protocol that does not merit an official "Modification Request Form". Major changes should be submitted as a Request for Modifications (see policy X "*Modification of an Approved Protocol*").
  - 17.2.3. Any other information requested by the IACUC.
  
- 17.3. Review by the IACUC should take into account any new methodologies that may have come available that year that might improve animal welfare.

- 17.4. If deemed appropriate as a result of the annual review, the IACUC may request the PI modify their protocol and submit a “Modification of an Approved Protocol Form”.

**18. Modification of an Approved Protocol:**

- 18.1. Requests for modification of an approved protocol must be made and reviewed by the IACUC if any of the following “significant changes” are proposed:
- 18.1.1. Changes from nonsurvival to survival surgery.
  - 18.1.2. Changes resulting in greater pain, distress, or degree of invasiveness.
  - 18.1.3. Changes in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC.
  - 18.1.4. Changes in species.
  - 18.1.5. Changes in study objectives.
  - 18.1.6. Changes in principal investigator.
  - 18.1.7. Changes that impact personnel safety.
- 18.2. Additionally, “minor changes” should also be reported to the IACUC via email ([iacuc@mail.wou.edu](mailto:iacuc@mail.wou.edu)), but do not necessarily have to undergo formal committee review. These minor changes can include the addition or deletion of personnel besides Principal Investigators, change in title of personnel, minor changes in housing within the approved animal housing facility, and changes in animal number outside of the range of values provided, etc.
- 18.3. The IACUC will ultimately decide whether or not a change is deemed “significant” or “minor”, and therefore what degree of review the “request for modifications” should undergo.

**19. Reporting and Investigation of Allegations of Non-Compliance or Improper Animal Use**

- 19.1. Reporting Mechanism
- 19.1.1. Procedures to report animal welfare concerns must be conspicuously posted at every animal holding and research facility and on a publicly-accessible portion of the WOU website.
  - 19.1.2. An online form will be created to gather animal welfare concerns. The option must be given to report concerns anonymously.
  - 19.1.3. Any member of the committee who receives oral or written notification of an animal welfare concern shall either direct the individual to complete the online form, or, if the individual does not feel comfortable doing so themselves, will complete the online form on their behalf.

- 19.1.4. Discrimination or reprisal against individuals who report real or perceived violations in good faith is strictly prohibited.

## 19.2. Procedures for Investigation

- 19.2.1. The committee Chair and the Attending Veterinarian will review any complaint and categorize it as:

- 19.2.1.1. *Non-event* – A report that requires no further action due to a lack of variability or credibility, or a report that involves matters outside the purview of this policy.

- 19.2.1.1.1. The report will be discussed at the next regularly-scheduled meeting of the IACUC and included in the IACUC Chair's quarterly report to the IO.

- 19.2.1.2. *Accident* – an isolated incident without malice aforethought or gross negligence and little likelihood of repetition.

- 19.2.1.2.1. The report will be discussed at the next regularly-scheduled meeting of the IACUC and included in the IACUC Chair's quarterly report to the IO.

- 19.2.1.3. *Potential Concern* – an incident or ongoing situation where mistreatment, negligence or non-compliance is credibly documented and/or verified.

- 19.2.1.3.1. The IO and the full committee will be notified that a potential concern regarding animal welfare has been raised.

- 19.2.1.3.2. The committee Chair, the Attending Veterinarian, and one other committee member selected by the chair will investigate the incident or situation and report their findings at the next regularly-scheduled meeting of the IACUC.

- 19.2.1.3.2.1. If the allegation involves any member of the IACUC (including the Chair), that member will recuse themselves and a different committee member will be selected to investigate.

- 19.2.1.4. *Emergency* – an incident or ongoing situation where the health of animals and/or humans is in clear jeopardy.

- 19.2.1.4.1. The IO and the full committee will be notified that a serious concern regarding animal welfare has been raised.

- 19.2.1.4.2. The Attending Veterinarian will take immediate action to secure animal health and welfare.

- 19.2.1.4.3. The committee Chair, the Attending Veterinarian, and one other committee member selected by the chair will investigate the incident or situation.
  - 19.2.1.4.3.1. If the allegation involves any member of the IACUC (including the Chair), that member will recuse themselves and a different committee member will be selected to investigate.
  - 19.2.1.4.4. An emergency meeting of the full IACUC will be convened as soon as the investigating sub-committee has compiled a report of their findings.
- 19.2.1.5. *Unapproved Animal Use Activity* – an incident or ongoing situation where animals are used for teaching, research, or outreach and there is no approved protocol for these activities.
  - 19.2.1.5.1. The committee Chair, the Attending Veterinarian, and one other committee member selected by the chair will investigate the incident or situation and report their findings at the next regularly-scheduled meeting of the IACUC. The report will be included in the IACUC Chair’s quarterly report to the IO.
    - 19.2.1.5.1.1. If the allegation involves any member of the IACUC (including the Chair), that member will recuse themselves and a different committee member will be selected to investigate.
    - 19.2.1.5.2. The committee will act to suspend all animal use activities that lack protocol approval, and temporarily take steps to ensure the maximum welfare of the animals until a protocol can be approved.
    - 19.2.1.5.3. The committee Chair will notify the PI of the suspension within 24 hours.
    - 19.2.1.5.4. The committee Chair will help the PI become compliant with WOU animal use policy and direct them to complete an IACUC proposal.
      - 19.2.1.5.4.1. All animal use activities must cease until such time as the IACUC has approved that proposal.
- 19.3. Regardless of categorization, the Attending Veterinarian has the authority to immediately suspend any animal use activity and request an emergency meeting of the full committee. The Veterinarian-authorized suspension will remain in effect until a full committee meeting is convened. A decision of the full committee regarding the suspended animal use activity will supersede the previous Veterinarian-authorized suspension.



19.4. Outcomes of Investigation:

- 19.4.1. Subsequent to any investigation, the IACUC has the authority to suspend any animal use activity that does not comply with an approved protocol, the AWA, *The Guide*, this policy document, or other WOU policies.
- 19.4.2. An activity may be suspended only after the full committee has reviewed the manner and a majority of the quorum has voted in favor of suspension, except where stated otherwise in these policies.
- 19.4.3. If the IACUC suspends an animal use activity, the IO, in consultation with the committee, shall review the reason for suspension, take corrective actions, and if required, report the suspension and corrective active with full explanation to APHIS, OLAW, and/or agencies funding that activity.
- 19.4.4. The PI overseeing the suspended activity may appeal the suspension in writing to the committee Chair. An appeal review will be conducted at the next full committee meeting.
- 19.4.5. The IO will make final recommendations and communicate those recommendations to the IACUC and others the IO deems appropriate.

**20. Internal Review of IACUC Policies**

- 20.1. Using the AWA, AWAR, PHS Policy, *The Guide*, the *Ag Guide*, the NRC's *Occupational Health and Safety in the Care and Use of Research Animals*, and the PHS Semiannual Program Review and Facility Inspection Checklist as a basis for evaluation, the IACUC must review university policies governing animal use and research at least once every six (6) months.
- 20.2. In addition, the IACUC must review reports submitted by personnel using animals at the university and from persons responsible for oversight of animal research at the university. Evaluated program components include protocol compliance records, veterinary care and animal health records, personnel training records, chemical hygiene records, and facility inspection records as appropriate.
- 20.3. Semi-annual program reviews should occur during a convened meeting of the full committee.
- 20.4. Anonymous minority opinions must be recorded in the meeting minutes and in the semi-annual program review report submitted to the IO.

- 20.5. A semi-annual program review report must be submitted to the IO.
  - 20.5.1. The report shall identify all program and facility deficiencies and include minority opinions presented by members of the committee during the review procedure.
  - 20.5.2. The report shall include a plan and timeline for corrective action for all deficiencies.
  - 20.5.3. If required, failure to correct deficiencies will be reported to the IO and federal agencies regulating animal use and care (OLAW and USDA).

## **APPENDICES**

## Appendix 1: Clarifying Examples of PIs and Training Scenarios:

- A student enrolled in BI 360 wants to conduct a mini-research project on examining the impact of two different foods on the swimming behavior of goldfish housed in the animal room on campus
  - PI = the Instructor of the course
    - Responsibilities of the instructor:
      - Basic and fish-specific CITI training
      - Training the student; overseeing the research and housing of the fish.
  
- A student enrolled in BI 406 (independent study) wants to conduct an independent field study on their own where they will be independently trapping and measuring turtles at Minto Brown Park in Salem. The professor overseeing the course will sometimes be at the trapping sessions, but not always. The student will also have a friend come out sometimes to help.
  - PI = the student and the instructor.
    - Both the student and the instructor are responsible for taking both the basic and reptile-specific CITI training modules
    - Both the student and the instructor are responsible for the conduct of the friend who volunteers sometimes, but the volunteer is not considered a PI.

## Appendix 2: Pain Categories and their Relationship to Review Categories

### Notes:

- **Federal animal welfare regulations** (CFR Ch.1, 2.36(b) (5-7) require that USDA-registered research facilities report an annual census of regulated animals used in research and teaching, the species used, and the number of animals placed in each of the four “Categories of Pain and Distress” (B,C, D and E).
- The Pain Category levels and examples described below are based off of those found on the North Carolina State University website:  
<https://research.ncsu.edu/administration/compliance/research-compliance/iacuc/iacu>

[c-procedures-and-guidance/classification-of-animal-use-by-pain-and-distress-categories](#).

- Please note that Review Category levels (Policy 12. Categories of Review) are not the same as Pain Category levels; review category levels split up the pain categories based on what level of review WOU IACUC has deemed necessary for the application.

Procedures	Federal Pain Category	WOU IACUC Review Category
<ul style="list-style-type: none"> <li>• Observational Study only, with manipulations designed to have no or minimal stress</li> <li>• Use of outreach animals</li> </ul>	<i>None</i>	Category 1A
<ul style="list-style-type: none"> <li>• Housing and care of outreach animals and pets</li> </ul>	<i>None</i>	Category 1B
<ul style="list-style-type: none"> <li>• Animals being bred, conditioned or held for use in teaching, testing, experiments, research or surgery but not yet used for such purposes.</li> </ul>	Category B	Category 2A
<ul style="list-style-type: none"> <li>• Observational study with significant manipulations with the potential to cause stress</li> <li>• Holding, weighing or physical examinations of animals in teaching or research activities</li> <li>• Injections, blood collection or catheter implantation via superficial vessels</li> <li>• Observation or positive reinforcement training of animals in a laboratory setting; feeding studies that do not result in clinical health problems</li> <li>• Routine agricultural husbandry procedures approved by the IACUC</li> <li>• Live trapping with minimal potential for injury</li> <li>• Studies involving clinical signs not judged to involve more than slight pain or distress.</li> </ul>	Category C	Category 2A

<ul style="list-style-type: none"> <li>● Animals being bred that will undergo genotyping procedures or will be euthanized for any reason;</li> <li>● Methods of genotyping or identification (ear notching, banding, tail clipping, tattooing - unless general anesthesia needed)</li> <li>● Humane euthanasia that meets current AVMA standards</li> <li>● Chemical immobilization or restraint, such as for transport or for procedures that are not considered painful but restraint is required for the species to perform the procedure correctly</li> <li>● Protocols involving clinical research on client owned animals that are undergoing surgery not related to the research may be included in Review Category 2B.</li> </ul>	<p>Category C</p>	<p>Category 2B</p>
<ul style="list-style-type: none"> <li>● Animal use activities that involve accompanying pain or distress to the animals and for which appropriate anesthetics, analgesics, tranquilizing drugs and/or humane endpoints are used to avoid pain, distress or discomfort.</li> <li>● Survival surgical procedures where perioperative pain or distress is alleviated (e.g., catheter cut-down, laparoscopy or biopsies).</li> <li>● Non-survival surgical procedures</li> <li>● Retro-orbital blood collection in mice and rats</li> <li>● Exsanguinations under anesthesia</li> <li>● Tail clipping in rodents 21 days old and over, or tattooing that requires general anesthesia</li> <li>● Induction of a disease, infection or genotype that causes pain or distress that is alleviated with the use of pain-relieving drugs or humane euthanasia as soon as signs of pain and/or distress develop</li> </ul>	<p>Category D</p>	<p>Category 3</p>
<ul style="list-style-type: none"> <li>● Animal use activities that involve accompanying pain or distress to the animals and for which appropriate</li> </ul>	<p>Category E*</p>	<p>Category 3</p>

<p>anesthetic, analgesic, tranquilizing drugs or other methods for relieving pain or distress are <b>not</b> used.</p> <ul style="list-style-type: none"> <li>● Research or testing procedures that require death as an endpoint or continuation without pain-relieving intervention, even after clinical signs of pain or distress are evident</li> <li>● Induction of disease, infection, or a genotype that results in pain or distress which may not be alleviated with the use of pain-relieving drugs or humane euthanasia as soon as signs of pain and/or distress develop</li> <li>● Application of noxious chemicals or stimuli (e.g., electrical shock) when the animal cannot avoid/escape the stimuli and/or it is severe enough to cause pain or distress</li> <li>● Novel, prolonged restraint</li> <li>● Exposure to extreme environmental conditions</li> <li>● Food or water deprivation beyond that which is necessary for routine pre-surgical preparation or is deemed stressful to the animal</li> <li>● Euthanasia by non-AVMA approved methods</li> <li>● Any procedures for which needed analgesics, anesthetics or tranquilizers must be withheld for justifiable purposes</li> </ul>		
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**\*Note:** *Category E procedures require strong scientific justification as to why pain-relieving drugs or other methods for relieving pain cannot be used. This includes citation(s) to published studies if applicable — describing the alternatives that were considered and how alternatives will be used whenever possible, clarifying whether animals will be euthanized when moribund, and if not, what information is to be gained in the interval between moribundity and death.*