

University of Wisconsin-Stevens Point Animal Care and Use Committee Policy and Procedures

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Policy Statement:

This policy and procedure addresses the process under which the University of Wisconsin-Stevens Point (UWSP) Animal Care and Use Committee ("IACUC" or "the Committee") conducts business in the form of member appointment, protocol submission, protocol review, facility inspections and documentation, to assure the ethical and humane treatment of animals on its Campus and satellite facilities by faculty, students and University staff. The UWSP-IACUC uses guidelines provided by the National Research Council publication <u>Guide for the Care and Use of Laboratory Animals 8th ed.</u> ("the ILAR Guide"), to govern the care and use of animals. These are in compliance with the Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture (USDA) under the Animal Welfare Act Regulations (AWAR). Additional species and their protocols not included in the Guide are also specified in this document.

1. Scope & Definitions

1.1 Scope of Policy

It is the intent of UWSP and this Committee to ensure and oversee responsible and ethical treatment of all animals housed on UWSP campuses or otherwise subjected to research, study, demonstration or observation by faculty, staff and students of UWSP.

The UWSP-ACUC is an officially constituted body providing institutional governance to all activities involving animals on campus or in the field by UWSP staff or students for the purpose of research, teaching or care. All vertebrate animal activities under the auspices of UWSP require IACUC approval. This policy applies to all UWSP PI's, Co-PI's and students directly involved in vertebrate animal research, teaching or care on its properties or in the field. This policy complies with the National Research Council's Guide for the Care and Use of Laboratory Animals, the Office of Laboratory Animal Welfare (OLAW), the USDA Animal Welfare Act, and any Universities of Wisconsin policy relating to animal care and use. Any deviations from this policy must be provided in writing to the IACUC and approved by the Committee.

1.2 Definitions

1.2.1 Animals are defined by Public Health Service (PHS) policy (page 8) as any vertebrate animal. This includes all mammals, birds, amphibians, reptiles, fish, and vertebrates not defined in one of these other

categories. While OLAW and AWAR exclude rats and mice bred for research purposes, the NIH Guidelines do not. The UWSP IACUC will, therefore, include these animals under this general policy.

- **1.2.2** APHIS is the Animal and Plant Health Inspection, a division of the United States Department of Agriculture (USDA) and regulates the Animal Welfare Act of 1966 and the Horse Protection Act of 1970.
- 1.2.3 AVMA is the American Veterinary Medical Association
- **1.2.4 AWA** is the **Animal Welfare Act**, passed by Congress in 1966 to stipulate the standard of care for laboratory animals.
- **1.2.5 AWAR** are the **Animal Welfare Act Regulations**, implemented by **APHIS** of the **USDA**. They regulate animal care and use for the purposes of teaching or research by any institutions so engaged.
- 1.2.6 CITES is the Convention on International Trade in Endangered Species of wild flora and fauna.
- **1.2.7 CITI** is the **Collaborative Institutional Training Initiative** a web based IACUC training site used by UWSP and many other institutions across the United States. https://www.citiprogram.org
- **1.2.8 Designated Member Review (DMR)** is a special process by which the Committee may approve protocols outside of regularly scheduled meetings. Its constitution and operation are described below.
- **1.2.9 Field Research** is any act of research, education or testing involving animals in the field that may interfere with normal wild behavior, require handling for the collection of genetic material or data, trapping, tagging, administering anesthetic (including chemical immobilization) or analgesic or inducing behavior modification.
- **1.2.10 Observational Studies** are defined by the USDA, Animal Welfare Act as, "... any study done on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study". This may also be referred to as "Field Studies" in USDA literature. At UWSP, Observational Studies expands the definition to also include captive animals in laboratory and classroom habitats.
- **1.2.11 Animal housing** is defined as areas in which live animals are maintained for periods greater than 12 hours for any reason. Live traps or areas not intended for use as long-term animal containment do not require inspection by IACUC, however live traps and other temporary containment systems must be clean, periodically inspected by the user and humanely functional.
- **1.2.12 Humane Treatment** presumes that any research project using animals uses methodologies to induce the least pain, suffering or distress as part of a responsible project plan.
- **1.2.13 IACUC** is the **Institutional Animal Care and Use Committee** (also, UWSP-ACUC or IACUC), the officially constituted committee responsible for overseeing USDA and PHS policy as it pertains to the use

of live animals in teaching, research, study, transport or demonstration at UWSP or its satellite facilities, by UWSP faculty, academic staff, animal care staff and its students.

- **1.2.14 Institutional Officer (IO)** is currently the Vice Chancellor for Personnel Budget and Grants at UWSP. The IO may suspend any activity involving animals which does not follow a written protocol submitted to the IACUC or which abrogates a particular project or protocol. The IO can serve as an advisor to Principal Investigators and to the IACUC. The IACUC submits to the IO a semiannual report on its activities, including protocols submitted for its approval.
- 1.2.15 NIH, PHS and OLAW. NIH is the National Institutes of Health, the home of the Office of Laboratory Animal Welfare (OLAW), who publish the Guide under the auspices of the Public Health Service (PHS) for the humane treatment of laboratory and research animals.
- **1.2.16 Principal Investigator (PI)** is the lead scientific authority on projects which include animals, who are responsible for submitting protocols and renewals outlining animal use to the IACUC.
- **1.2.17** *Guide for the Care and Use of Laboratory Animals* (the Guide), published by the Institute for Laboratory Animal Research (ILAR) of the National Academy of Sciences. is in its 8th Edition, 2011. Its purpose is to "... assist institutions in caring for and using animals in ways judged to be scientifically, technically and humanely appropriate." The Guide is the primary resource for laboratory-animal husbandry at UWSP.
- **1.2.18 UWSP Campus,** for the purposes of this policy, will include all physical space considered property of the University of Wisconsin-Stevens Point as well as satellite properties directly managed by UWSP or by its staff.

2. Constitution and Responsibilities

2.1 Committee Membership

The membership of the UWSP-ACUC must include Committee Chair, an IO, a community member not affiliated with UWSP ("Public members should not be laboratory animal users, affiliated in any way with the institution, or members of the immediate family of a person who is affiliated with the institution" (PHS Policy)), a Veterinarian (DVM) familiar with laboratory animals, a non-scientist, preferably an ethicist or clergy and a minimum of one research scientist who uses animals in their research. Our preference is for more than one research scientist with expertise in specific investigative content such as fisheries, wildlife, laboratory rodents, etc. A fully- constituted IACUC includes a minimum of 5 and a maximum of 11 voting members and the IO. The UWSP-IACUC Chair is appointed or removed by the IO. Terms of the Chair or its members are indefinite. In scenarios where there is both a chair and co-chair, each has the authority to complete chair-related signatures for protocol documentation. However, a chair/co-chair cannot sign documents related to their own research projects or lab inspection reports, and in such cases the other chair or a designated IACUC member would sign.

2.2 A Quorum for a Convened IACUC Meeting

A quorum for a convened IACUC meeting would be more than one-half of the voting members of the fully-constituted membership. Any member or members submitting a protocol for review to the IACUC as a PI or Co-PI must recuse themselves from voting on the protocol on which they are named. The remaining members must constitute a quorum before a decision on the protocol is made. A quorum must be established for decisions on protocols, policies, and procedures as related to animal care, or in animal use for research, testing, and teaching.

2.3 Principle Responsibilities of the UWSP-IACUC

- **2.3.1** Ensure the humane and ethical treatment of vertebrate animals involved in research, teaching, demonstration, observation or care while under the auspices of UWSP.
- **2.3.2** Monitor the environment and care provided for vertebrate animals on campus and its satellite facilities. This takes place during semi-annual facility inspections.
- **2.3.3** Disseminate information regarding approved methods of animal care to individuals who use animals in research, teaching or observation. This can be completed through sharing SOP (Standard Operating Procedures).

- **2.3.4** Facilitate and establish mechanisms to protect personnel from occupational health and safety hazards that may be associated with the use of animals.
- **2.3.5** Post-approval monitoring of protocols. Review and investigate animal welfare concerns.

2.4 The Duties of the UWSP-IACUC

- **2.4.1** Review, at least once per year, this policy.
- **2.4.2** Inspect, at least once every six months, UWSP campus research animal facilities, facilities where animals are housed for reasons of teaching, observation or research and surgical facilities. See "Animal housing" in Definitions section 1.2 above.
- **2.4.3** Prepare a report of animal activities to the I.O. Every six months complete the Semiannual Report: report reflects December-May (sent out by end of June) and June-November (sent out by end of December). Facility inspections take place November and May to incorporate into Semiannual Report. Semi-annual reviews and inspections follow the guidelines outlined in Office of Laboratory Animal Welfare (OLAW) (link sited below in 4.5).
- **2.4.4** Make recommendations to the IO regarding any aspect of the research facilities, animal programs, physical plant or personnel training.
- **2.4.5** Review, and if warranted, investigate concerns or complaints involving animal welfare on the UWSP campus and satellite stations.
- **2.4.6** Review, approve, or require modifications to approve or withhold approval of any proposed UWSP activity involving research, teaching or observation of live vertebrate animals. Approval is based on a written protocol submitted to the Committee.
- **2.4.7** Suspend any non-approved activity involving any vertebrate animal used in research, teaching or observation by UWSP staff, students or its animal care staff. The suspension may be issued directly by the IO or by the IACUC. The IO does not have individual power to resume a suspended animal activity and the suspension may only be lifted by the IACUC. Animal activities can only be resumed after a new protocol has been submitted & approved by the IACUC.
- **2.4.8** Perform other duties as required.

3. Submitting a Protocol for Review

3.1 Who must submit a protocol?

IACUC oversight and an approved protocol is required for the following activities regarding live vertebrate animals:

- **3.1.1** Research or teaching activities involving the use of animals owned, leased or managed by UW-Stevens Point.
- **3.1.2** Research, teaching or collection of animals done on properties owned, leased or managed by the UW-Stevens Point.
- **3.1.3** Research, teaching or collection of animals done by UW-Stevens Point Faculty, its staff or students.
- **3.1.4** Research, teaching or collection of animals done with intramural or extramural funds administered through UW-Stevens Point.
- **3.1.5** Field research that involves capturing, tagging, banding, handling, behavior modification, sedation, blood or tissue collection of animals.
- **3.1.6** Research, teaching or collection done in collaboration with another institution, organization (i.e. WDNR, US Wildlife Federation, etc.) or private commercial entity, must have UWSP IACUC approval prior to animal use activity. A PI or Co-PI may choose to submit a protocol for review and approval with the collaborating institution/organization/company's IACUC. Documentation of the off-campus protocol approval must be on file with the UWSP IO prior to the animal activity.

3.2 Activities not requiring IACUC approval

- **3.2.1** Research and/or teaching activities using tissue or blood from cadavers or dead animals not euthanized under the ownership or property of UWSP for the specific purpose of obtaining such samples. Blood, tissue or cadavers purchased from licensed dealers and provided to UWSP already dead and preserved do not require IACUC approval but, depending on preservative, may require Bio-safety approval. Animals that are property of UW-Stevens Point and have died of natural causes or disease may be necropsied with professional supervision or preserved, provided a record of this event is kept on file and applicable Bio-safety forms have been submitted.
- **3.2.2** Standard or emergency Veterinary or professional animal welfare procedures to prevent or treat an acute or chronic animal health or welfare concern.
- **3.2.3** Activities that require record retrieval or data obtained from animal related records.
- **3.2.4** Any activity that uses invertebrate animals.

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- **3.2.5** Any activity that requires the removal of animals from buildings or the management of wild animals on any UWSP-owned property, the primary purpose of which is management and not teaching or research.
- **3.2.6** Non-research, non-teaching or non-testing activities involving privately-owned animals: Privately-owned animals brought in as part of campus club activity, require written approval from a club advisor and completion of a Notification of Animal Activity Form through UWSP's Risk Management office. The welfare and liability of these animals and those who interact with personal animals brought on campus are the responsibility of the individual animal owners. Animal owners are subject to Board of Regents policy UWS 18.08.1: Conduct on University Lands-Animals. The animal owner and UWSP representative are required to consult with Risk Management regarding review, who will consult with IACUC and Veterinary professional as needed.
- **3.2.7** Observational studies are exempt from an IACUC approved protocol. However, a signed "Field/Study Exemption Protocol" form must be approved and on file and reassessed every three years if the activity is continuous and indefinite.

3.3 Protocol Preparation

3.3.1 New Protocol Forms (Initial or every third year for continuing projects). A new animal use protocol must be submitted and approved prior to starting work with any vertebrate used for research, teaching, study or testing. Newly approved proposals are valid for a period of three years with annual renewals. Significant changes to approved protocols require submission of a Protocol Modification Form. In general, protocol forms require the PI to provide the following: (a) A scientific rationale for the use of animals in the study. (b) A discussion of alternatives to the use of animals and a justification for the numbers of animals required. (c) Personnel involved, their expertise with the chosen animal(s) and required training. (d) A detailed description of the methodologies, their effects, if any, on the animals, how investigators will minimize any distress or pain placed on the animals. A detailed description of euthanasia methods and disposition of the carcass if applicable. (f) Starting and end dates for the project, unless on-going.

There are three different Animal Use forms to be used, depending on the study design, found on the UWSP-ACUC web page: <u>IACUC Forms & Documents</u>. Submissions using an outdated form will be returned to the PI, with a request to use the current versions of the protocol forms. The PIs should choose one of the following New Animal Use forms according to their study design:

Laboratory Research Protocol Application Form. This form is geared toward laboratory animal users or for animal research procedures conducted in a classroom or laboratory setting. Users of this form will likely introduce pain, distress, or must provide analgesia, physical restraints, chemical immobilization, and/or must observe the restrained/immobilized animal to collect data or make observations. This form also covers invasive techniques and surgeries on laboratory animals.

Field Research Protocol Application Form. This form is designed to benefit wildlife researchers (i.e., research conducted on vertebrate animals from wild populations.) The Committee examines carefully the overall rationale for the study as well as the methods used in the trapping, confinement, manipulations and surgical procedures. As in the other forms, there must be adequate justifications for any procedure (e.g., trapping, handling, tagging, etc.) that may interfere with the animal's well-being.

Exemption Form for Observation ONLY Studies This form is used if the study does not interfere with, subvert, or materially alter the behavior of any living vertebrate animal in its surroundings, that is, studies in which the PI's interaction with the animals is purely observational. Studies that involve trapping, netting, diverting, etc., must complete the Field Research Protocol application.

- **3.3.2 Protocol Renewal Form.** If the project is on-going, and does not significantly change from year to year, it must be renewed annually for up to 3 years, using the Protocol Renewal Form.
- **3.3.3 Protocol Modification Form.** Significant modifications to any approved animal use proposal can be submitted on the Protocol Modification Form for the Committee or designated members to review. Major changes requiring a modified proposal include study design changes that do not change the study objective. Examples of study modifications requiring submission of a Protocol Modification Form include: the introduction of a new or improved technique, inclusion of tissue or blood collection on animals already handled for other types of data collection, a change from tissue to blood collection, a change in study sites or animal species, an addition of more than 10% of the total number of approved animals, significant personnel changes (such as the PI). If study objectives are modified from the original protocol, an appropriate New Animal Protocol must be completed by the PI and reviewed by the Committee.

3.4 Protocol Review and Approval Process.

An approved protocol or approved exemption form by the IACUC is required in order for a Principal Investigator to begin research, teaching or demonstration projects using animals. An approved protocol fulfills the regulatory criteria of AWAR and PHS policies.

The Committee may review protocols either at a constituted face to face meeting or by a Designated Member Review (DMR) process. Approvals are for three years post-approval and are subject to annual review process. Pls are required to submit a Renewal form annually to reflect Year 1 and Year 2 of their project. As a protocol's expiration date approaches, a new protocol application is completed by the PI and submitted to IACUC to be reviewed and approved. Upon approval, the protocol is given a new number and the project can continue for another three years. (See 3.4.3.3 below for further information.)

3.4.1 Submission Dates

During the academic year (September-May), the Committee will meet monthly to approve protocols submitted since the previous meeting. Protocols received 1 week or more prior to a meeting date will be considered, in order for the agenda to be assembled and pre-reviewers assigned. During interim periods (winter break, spring break, and summer), the Committee will use a Designated Member Review process. (See 3.4.4 below.)

3.4.2 Principal Investigator (PI) responsibilities

The PI is responsible for submitting animal care and use protocols and renewals in a timely fashion as described above. The PI is responsible for overseeing the protocol and noting any deviations that change the rationale, procedures, agents, personnel, number of animals, etc. If these changes are significant, the PI is responsible for submitting a written modification to the protocol to the IACUC Chair(s) for approval.

3.4.3 Full Committee Reviews

Full Committee Review (FCR) must be completed for all new animal use protocols as well as triennial review resubmissions, with the exception of scenarios described in 3.4.1 above. A quorum of committee members must be present to conduct FCR. FCR will take place during each monthly IACUC meeting. Primary reviewers may be assigned to one or more protocols. Principal Investigators will be invited to attend the meeting during which their protocol is reviewed. Principal Investigators, or Primary reviewers, will begin the FCR process by providing a brief summary of the project for the committee members. Committee members will then discuss the appropriateness of the following details as relevant: 1) training of personnel, 2) number of animals used in study, 3) USDA pain categorization, 4) justification of chosen species, 5) study objectives, 6) study procedures, 7) study location or housing of animals, 8) animal pain and distress determination, 9) euthanasia or endpoint for animals, 10) personnel safety precautions for field studies, 11) alternative to animal use for USDA Pain Category D or E animals, 11) surgical procedures, and 12) risks of exposure to hazardous materials. Following discussion, IACUC

members will vote on full approval, approval pending revisions and resubmission, or denial of approval of the reviewed protocol.

- **3.4.3.1** The proposal can be denied approval, following which, the committee will inform the PI of the denial and reason for this choice of action. If the PI chooses to submit a similar proposal at a later date, that proposal is approached as a new protocol and is given a new number.
- **3.4.3.2** The committee may require that the proposal be resubmitted with revisions as requested by the IACUC in order to secure approval. The PI is notified of the revisions requested and is given 14 business days to resubmit revisions. Should the IACUC take this course of action, the committee may review revisions at the next convened meeting or may vote to use the designated member review to complete the process. The PI should not accept this as an approval until all revisions are reviewed and an approval is secured. This process may be lengthy with multiple communications between IACUC and the PI. No animals under the proposed protocol can be used until an approval is secured. If changes are adequate, the IACUC will provide the PI with a letter of full approval.
- **3.4.3.3** The third decision the IACUC committee may take is an Approval. Administrative changes can be made with the PI's approval but no other changes are necessary and the PI may begin their work upon receipt of an approval letter.

3.4.4 Designated Member Reviews (DMR)

Designated member reviews (DMR) are most commonly used during interim periods (Winter Break, Spring Break and summer), with the exception of scenarios where full committee or Veterinarian consultation is needed. During those periods, the chair & co-chair are automatically reviewers, unless other members are designated by the chair(s). (For example, if a chair is out of office, or the document is submitted by a chair for their lab or research project.)

During the academic year, scenarios where DMR can occur are time-sensitive modifications or new projects that require approval prior to the next IACUC meet, both at the discretion of the chair(s). When a time-sensitive submission is received, either the chair(s) or IACUC administrative support emails the entire committee to request their review if submission can move forward as DMR. The committee is given 3 business days to respond "no concern", and any non-responses are considered support to move forward with DMR. Any IACUC member stating uncertainty or concern with a protocol submitted under DMR, automatically requires that submission to be reviewed at a convened IACUC meeting.

During the 3 business days, a minimum of 2 IACUC members are designated by the Chair(s) as DMR reviewers. After 3 business days, if the committee replies "no concerns", the protocol is reviewed by

the designated member reviewers, who have 5 business days to complete review. The reviewers must provide a written statement of either (1) DMR approval, or (2) outline revisions requested. The DMR has only two decisive outcomes, and cannot deny approval. If there are concerns, it goes to Full Committee Review.

If there are revisions, admin support or the chair(s) notify PI of revisions and request resubmission. The resubmission is sent to the DMR reviewers as well as notification out to the entire committee. Once DMR reviewers approve of the document, and there are no concerns raised by other committee members, admin support sends a letter of approval for chair(s) signature. When signed, admin sends approval to PI with notification project can commence.

3.4.5 Veterinary Verification and Consultation

Veterinary verification and consultation may be used to make protocol changes in the following cases: 1) anesthesia, analgesia, sedation, or experimental substances; 2) euthanasia by any method approved in the most recent AVMA Guidelines for the Euthanasia of Animals; and 3) duration, frequency, type, or number of procedures performed on an animal. Consultation with the Veterinarian must be documented by including their signature on the protocol or modification. The IACUC Chair(s) must also be notified of these changes via submission of a Modification Form. Additional guidance can be found from OLAW: Making changes: when is VVC appropriate? A word from OLAW. Lab Animal 46(3). (2017) doi:10.1038/laban.1197

3.4.6 Post approval monitoring (PAM) is a PHS requirement of all IACUCs. Monitoring protocols beyond their approval is a mechanism to ensure animal welfare compliance as stated in the approved protocol. To fulfil this requirement, PIs are required to complete annual Renewal Forms informing IACUC of the animals used, unexpected events, and needs for modifications to the original protocol.

3.5 Protocol Appeals Process

If a protocol is denied approval, PIs can appeal the FCR decision. Appeals are handled by the chair(s) of the IACUC and will be considered under the Guidelines set by the Office of Laboratory Animal Welfare (OLAW) & Public Health Service (PHS) Policy on Humane Care and Use of Animals as cited below in 4.5 & 4.14.

4. Personnel, Resources, and References

4.1 UWSP-ACUC Institutional Officer: Katherine Jore (715-346-3710):

http://www.uwsp.edu/acadaff/orsp

- **4.2** IACUC Chair(s) and Current Members: <u>IACUC Committee Office of Research and Sponsored</u>
 Programs | UWSP
- **4.3** CITI Collaborative Initiative for Training Institute: https://www.citiprogram.org
- **4.4** NIH Grants: https://grants.nih.gov/grants/oer.htm
- **4.5** Office of Lab Animal Welfare (OLAW): https://grants.nih.gov/grants/olaw/olaw.htm
- **4.6** Institutional Animal Care and Use Committee Guidebook: Office of Laboratory Animal Welfare; Institutional Animal Care and Use Committee Guidebook
- **4.7** Guidelines to the Use of Wild Birds in Research: Guidelines to the use of wild birds in research The Ornithological Council
- **4.8** Guidelines for Use of Live Amphibians and Reptiles in Field Research, 2011: GUIDELINES-FOR-USE-OF-LIVE-AMPHIBIANS-AND-REPTILES-IN-FIELD-RESEARCH.pdf
- **4.9** Guidelines on American Society of Ichthyologists and Herpetologists (Field & Lab): General Resources American Society of Ichthyologists and Herpetologists
- **4.10** Guidelines for the Use of Fishes in Research 2014: https://fisheries.org/docs/wp/Guidelines-for-use-of-Fishes.pdf
- **4.11** Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research, 2016: 2016 Guidelines of the American Society of Mammalogists for the use of wild mammals in

research and education

4.12 AVMA Guidelines for the Euthanasia of Animals, 2020:

https://www.avma.org/KB/Policies/Documents/euthanasia.pdf

4.13 Guide for the Care and Use of Laboratory Animals, 8th Edition:

https://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth

4.14 PHS Policy on Humane Care and Use of Laboratory Animals, 2015

https://grants.nih.gov/grants/olaw/references/phspol.htm

4.15 Universities of Wisconsin Policies https://www.wisconsin.edu/regents/policies/