



Practice and Procedures for the UWF Institutional Animal Care and Use Committee (IACUC)

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This document contains procedures describing how the UWF Institutional Animal Care and Use Committee (referred to hereafter as the Committee) fulfills each of the functions listed in its “Charter” and set forth in the Public Health Service Policy on Humane Care and Use of Laboratory Animals (referred to hereafter as “PHS Policy”).

This description of procedures is required for any Animal Welfare Assurance filed by the University with the Office of Laboratory Animal Welfare (OLAW) as specified in the “PHS Policy” (Section IV.A.1.e; see also “OLAW” Sample Animal Welfare Assurance). Definitions from “PHS Policy” (Section IV.) are used throughout.

1. Activities that Require IACUC Approval

IACUC approval is required before conducting research and teaching activities involving animals if ANY of the following categories apply:

- a. Research, teaching and/or testing with vertebrate animals owned or leased by the University of West Florida (UWF), regardless of funding source.
- b. Clinical trials involving non-UWF owned or leased animals.
- c. Research, teaching and/or testing using vertebrate animals in collaboration with another institution or organization, including commercial entities.
- d. Field research activities using free-living vertebrate wildlife if studies involve more than unobtrusive observation.

If you are not sure if your proposed animal use activity requires IACUC approval, please contact the Office of Research Administration & Engagement.

2. IACUC Meetings

The Committee shall meet and review at least once every six months, but as often as deemed necessary by the Committee Chairperson, the University's program for the proper and humane care and use of animals, using the "Guide for the Care and Use of Laboratory Animals" as a basis for evaluation (See Section IV.A.1.a.-i. of the "PHS Policy" for program components).

3. Semi-Annual Inspections and Program Review

The Committee shall inspect each of the University's animal facilities, including satellite facilities, at least once every six months, but as often as deemed necessary by the Committee Chairperson, and whenever there are any significant modifications to such facilities. The "Guide for the Care and Use of Laboratory Animals" shall be used as the basis for evaluation. To facilitate inspections, the Office of Research Administration & Engagement shall maintain a current listing of all animal care and use facility locations (buildings, room numbers, etc.); their functions (vivarium, maintenance, storage, research lab, instructional lab, etc) the animal species cared for or used at each location; and the responsible personnel (animal caretakers, principal investigators, etc.). Committee members shall be provided updated copies of this listing at the beginning of each academic year, and shall be consulted prior to any significant modifications.

Advanced notice of inspections shall ordinarily be given to Department Chairpersons so that personnel responsible for animal care and use, including principal investigators and caretakers, are present during inspections. Unannounced inspections, when deemed appropriate, shall normally be called by a member of the Committee not associated with a department having an animal facility. Unannounced inspections shall not appear on meeting agendas.

4. Committee Reports

The Committee shall prepare reports of its evaluations of the University's live vertebrate animal program and facilities and submit them to the Associate Vice President for Research, as specified in the "PHS Policy" (Section IV.A.2., Category 2, Section IV.B.3.; and Section IV.F.).

- a. With regard to the University's program for the proper and humane care and use of animals, the reports shall address (among other things) the training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use; specifically, training or instruction in the humane practice of animal care and use, as well as training or instruction in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress.
- b. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the University and made available to OLAW upon request. The reports must contain a description of the nature and extent of the University's adherence to the "Guide" and the "PHS Policy," and must identify specifically any departures from the provisions of the "Guide" and the "PHS Policy," and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, consistent with the "PHS Policy," and, in the judgment of the Committee and the Associate Vice President for Research, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the University's facilities are accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) or another accrediting body recognized by PHS, the report should identify those facilities as such.

5. Institutional Official

The Associate Vice President for Research, or designee, shall keep the Committee fully informed of plans and progress in correcting identified deficiencies as well as any other modifications in the animal care and use program and facilities. Every effort should be made to conform to the recommendations of the "Guide."

- a. At least once every 12 months, the Committee, through the Associate Vice President for Research, shall report in writing to OLAW-OPRR:
 1. any change in the University's program or facilities which would place the University in a different category than specified in its Assurance (see IV.A.2. of the "PHS Policy");

2. any change in the description of the University's program for animal care and use as required by IV.A.1.a.-i. of the "PHS Policy;"
 3. any changes in the Institutional Animal Care and Use Committee membership; and
 4. notice of the dates that the Committee conducted its semi-annual evaluations of the University's program and facilities and submitted the evaluations to the Associate Vice President for Research.
- b. At least once every 12 months, the Committee, if it has no changes to report as specified above, shall submit a letter, through the Associate Vice President for Research, to OLAW stating that there are no changes and informing OLAW of the dates of the required Committee evaluations and submissions to the Associate Vice President for Research.
- c. The Committee, through the Associate Vice President for Research, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. any serious or continuing noncompliance with the "PHS Policy;" any serious deviation from the provisions of the "Guide;" or
 2. any suspension of an activity by the Committee.

Reports shall include any minority views filed by members of the Committee.

6. Reporting Adverse Events, Unanticipated Events, and Concerns

What is an adverse event?

Adverse events are unfavorable or unanticipated signs or outcomes that were not in the approved protocol, where there is direct harm to animals or personnel. Adverse events include suboptimal well-being (i.e., poor welfare), animal death, disease, distress, or trauma that was not the anticipated result of the approved protocol.

What is an unanticipated event?

Unanticipated events occur when new circumstances unexpectedly increase the risk of harm to animals or personnel, even if direct harm does not occur. Examples of UEs are loss of life due to a disease outbreak, a natural disaster, or an equipment failure. An unanticipated event is not necessarily related to noncompliance by the investigator.

Reporting Adverse and or Unanticipated Events

Reporting By Adverse Events and Unanticipated Events must be reported within 24

hours to the IACUC via the Research Compliance Officer or IACUC Chair through the use of the Unexpected Event or Adverse Event form.

Reporting of Concerns by Others

Deficiencies in animal care, use, recordkeeping, or treatment, unanticipated problems and adverse events in animal care or use must be reported, and can be reported confidentially to the [Research Compliance Officer, the Office of Research Administration & Engagement](#), or directly to the [IACUC Chairperson](#). Concerns regarding animal care and use can also be reported anonymously via Ethicspoint by calling toll free at 1-844-858-1413 or by clicking [here](#). No member of the university community bringing forth a legitimate concern will be discriminated against or be subject to any reprisal for reporting such violations.

This reporting-feedback mechanism of observations made regarding the practices of animal care and use within these laboratories, contributes an important oversight, assists in the continuous development of the animal program.

The Research Compliance Officer shall log all concerns and send copies to the Committee Chairperson and Institutional Official. The concerns shall be reviewed by the Committee at its next scheduled meeting, or sooner if deemed appropriate by the Committee Chairperson or the Associate Vice President for Research (see Procedure 7- Recommendations).

Such reports, suggestions, complaints, or compliments are made with protection of the reporting individual from any discrimination or reprisal.

7. Recommendations

Recommendations regarding aspects of the University's animal program, facilities, or personnel training shall be developed during Committee meetings and shall require majority approval. Such recommendations shall be forwarded to the Associate Vice President for Research via copy of the Committee's minutes and/or memo from the Committee Chairperson. The Associate Vice President for Research shall consider the Committee's recommendation and notify all involved parties of the Committee's recommendations and what actions will be taken.

8. IACUC Applications

Prior Committee approval of a project shall be required before any and all purchase, care, and use of animals, regardless of funding source.

a. Principal Investigators

Principal Investigators (PIs) are responsible for ensuring adherence to approved IACUC proposals; compliance with UWF policies and procedures, as well as federal and state regulations and guidelines governing the use of animals; and the humane care and use of animals. PIs may delegate duties

to research personnel, but they remain responsible for all aspects of their research projects, including the actions of project participants.

Principal Investigators must be current UWF faculty. Undergraduate or graduate students, postdoctoral fellows and non-UWF personnel cannot be listed as PI on a UWF IACUC application, but they may be listed as Co-Investigator or as other personnel if there is a UWF faculty member serving as the PI. Permanent senior staff and managers will be considered for Principal Investigator on a case-by-case basis. PIs leaving UWF are responsible for notifying the IACUC Office in advance of their departure date to make arrangements for any current IACUC proposals.

b. Reports

To monitor compliance with this policy, the Office of Research Administration and Engagement shall maintain a record and develop a report for the previous year of any and all purchases, care, and use of animals, along with a list of involved personnel (e.g., principal investigators and caretakers). Content for the report will be developed through the UWF purchasing process. Copies of these reports, with identification of any incidents of failure to obtain prior approval, shall be provided promptly to all members of the Committee.

c. Training

All personnel must have adequate knowledge and experience to perform their duties of animal care, use, and treatment. All personnel involved in live vertebrate animal use, treatment, or care must be sufficiently familiar with the [Guide for the Care and Use of Laboratory Animals](#), and these IACUC Policies and Procedures, so that their care, treatment and use of animals will be in accordance with these principles.

Required Training Courses:

1. Primary investigators, co-investigators, and assistants working with vertebrate animals for research must complete the required [CITI \(Collaborative Institutional Training Initiative\)](#) course: “Working with the IACUC”.
2. If animal protocols include the following species, listed investigators, co-investigators and assistants must take the corresponding species specific CITI course:
 - Frogs, Toads or other Amphibians
 - Mice (Family: Muridae Cricetidae)
 - Rats (Genus: Rattus)
 - Hamsters (Family: Muridae)
 - Guinea Pigs

- Fish
 - Zebrafish
 - Wildlife Research
3. Investigators and personnel working on animal protocols that include antibody production, aseptic surgery, or procedures that include more than momentary pain and distress must take the corresponding CITI course.

The Office of Research Administration and Engagement shall ensure that department chairpersons and those using animals have access to copies of the [“U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training;”](#) the [“Guide for the Care and Use of Laboratory Animals;”](#) the complete “Charter and Policy and Procedures for the UWF Institutional Animal Care and Use Committee;” and any other pertinent information deemed necessary. A physical copy of the UWF Policy and Procedures for the Institutional Animal Care and Use Committee and the Guide for the Care and Use of Laboratory Animals will be permanently located in each location where animals are used and/or housed.

The Office of Research shall also ensure that all Committee members have access to, in addition to the documents in the preceding paragraph, the [Public Health Service Policy on Humane Care and Use of Laboratory Animals,](#)” the latest [American Veterinarian Medical Association \(AVMA\) Guidelines for the Euthanasia of Animals,](#) the University’s current “Animal Welfare Assurance,” and the [UWF Institutional Animal Care and Use Application.](#)

d. Application Process

To apply for the purchase, care, and use of live vertebrate animals, the UWF Institutional Animal Care and Use Application, in addition to an associated grant application or proposal, research protocol, or laboratory syllabus must be emailed to the Research Compliance Officer. As specified in the “PHS Policy” (Section IV.C.), the Committee shall review the submitted material to determine that the proposed activities are in compliance with the “PHS Policy.” In making this determination, the Committee shall confirm that the activity will be conducted in accordance with the Animal Welfare Act, insofar as it applies to the activity, and that the activity is consistent with the “Guide” unless acceptable justification for a departure is presented. Further, the Committee shall determine that the activity conforms to the University’s Animal Welfare Assurance and meets the requirements set forth in the “PHS Policy” (Section IV.C.1.a.-g.) which implement the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.”

A grant application or proposal involving live vertebrate animals shall not be mailed to an agency until a completed UWF Institutional Animal Care and Use Application has been emailed to the Research Compliance Officer. When considering granting agency deadlines, at least one month should be allowed for the Institutional Animal Care and Use Committee to complete its review of an application.

e. Review Process

To initiate review, the Office of Research Administration & Engagement shall provide each Committee member with a list of the UWF Institutional Animal Care and Use Applications to be reviewed, along with the UWF Applications and those sections of associated grant applications and proposals that relate to the care and use of animals, research protocols, and laboratory syllabi. Within five working days, the Committee members shall review the material for each application and transmit to the Office of Research Administration & Engagement their decision to either request a convened meeting of the committee to discuss the application under review, or provide comments for the designated reviewer. Proposed protocols with an USDA Pain & Distress category of E or above shall automatically require a convened meeting. Withholding approval shall require convening the Committee as a whole. The Office of Research Administration and Engagement shall notify the Committee Chairperson of the members' decisions.

If full Committee review of an application is not requested, the Chairperson, or designee, shall designate at least one member of the Committee, qualified to conduct further review, who shall have the authority after considering the decisions of other Committee members to either approve, require modifications in to secure approval, or request full committee review of an application. All Committee members shall be promptly notified of the decision.

If full committee review of an application is requested, approval may be granted only after review at a convened meeting of a quorum (majority) of the Committee, and with the approval vote of a majority of the quorum present. The Chairperson shall attempt to convene a meeting of the Committee within two weeks.

No member may participate in the Committee review or approval of an application in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information when requested by the Committee; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The Committee may invite principal investigators

and consultants to assist in the review of specific issues.

- f. Thesis research conducted under the sponsorship of a faculty member who has already received IACUC approval shall be exempt from committee review. This assumes the thesis research to be conducted is actually a part of a research investigation that has already received IACUC approval, making it unnecessary for the research to be reviewed again. The research investigation must be active at the time the thesis research is to be conducted and the thesis student shall be added as a co-investigator/other personnel to the approved faculty protocol via amendment.
- g. The Committee shall notify the Associate Vice President for Research Administration in writing of its decision to approve or withhold approval of an application/proposal related to the care and use of live vertebrate animals, or of modifications required to secure Committee approval. This shall be done via a copy of the IACUC approval letter sent to the Primary Investigator. If the Committee decides to withhold approval, or require modifications in order to secure approval, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. If modifications are required, the procedure to be followed to apply for approval shall be the same as that described above under Procedure 6 (d) for initial approval.
- h. An application/proposal that has been approved by the Committee may be subject to further appropriate review by the Associate Vice President for Research. However, the Associate Vice President may not approve an activity involving the care and use of animals unless the Committee has first approved it nor may s/he disapprove an activity that has been approved by the Committee without discussion with the Committee. Such discussion will be followed by a second vote by the Committee to either override or support the Associate Vice President for Research's decision. The Associate Vice President for Research shall notify the applicant and Committee in writing of the decisions of the Committee and the Office of Research. This shall be done within two working days from the decision via a written letter.

9. Purchase or Acquisition of Animals

The University's Purchasing Department shall not order any live vertebrate animals until receiving written notification from the Associate Vice President for Research that both the Office of Research and the Institutional Animal Care and Use Committee has approved an application/proposal, and thus the care and use of a specific number of specified animals, for a specific project by a specified principal investigator, and for a specific period of time. This notification may be communicated

by means of a copy of an approved UWF Institutional Animal Care and Use Application.

Newly acquired animals either obtained privately, or from the wild, for research may not be housed in university owned or leased spaces without prior approval of an IACUC application.

10. Continuing Review

The IACUC must conduct a continuing review of each previously approved ongoing activity annually; this includes a complete review of an approved protocol in accordance with the PHS Policy IV.C.1-4. Annual review documentation, submitted by the researcher, for all ongoing activities is reviewed by the IACUC as part of post-approval monitoring. The IACUC review of this documentation can be conducted via Full Committee Review or Designated Member Review (except for USDA-covered species, which are always reviewed by Full Committee Review) as designated by the Chair. All annual reviews are recorded in the IACUC meeting minutes, which are reviewed and approved by the committee. No animal activities are allowed to continue beyond the protocol expiration date.

A calendar of approval periods and anniversary dates shall be maintained by the Office of Research Administration & Engagement. A current copy of the calendar shall be provided to all Committee members at the beginning of each academic year.

The maximum approval period for a project shall be three years. The procedure to be followed to apply for continuation of a project beyond an approval period shall be the same as that described above for initial approval.

11. Amendments

Prior Committee approval shall be required for changes in any and all care and use of animals in ongoing activities, regardless of the funding source. The procedure to be followed is to complete the Amendment Request form and email it to the Research Compliance Officer. The Committee may request that additional information be provided in support of the request. The sharing or exchanging of approval with another principal investigator shall require prior approval of the Committee.

The UWF IACUC has developed two classifications of amendments - significant and minor - based upon the perception of risk. Proposed amendments classified as significant are reviewed and approved by the designated member review process or at a convened IACUC meeting. Proposed minor amendments are reviewed and approved by the IACUC Chair. Proposed minor administrative amendments are reviewed by the Research Compliance Officer.

IACUC reserves the right to require a new application if the proposed modification(s)

falls outside of the objectives, purpose, or aims stated in the original protocol. The IACUC Chair holds the final discretion on the classification of the amendment as significant or minor and whether the proposed modification requires a new application.

- a. Significant Amendment to Protocol:** Changes that have, or have the potential to have, negative impact on animal welfare. In addition some activities that may not have a direct impact on animal welfare are also considered to be significant. Examples include, but are not limited to:

Administrative:

- Change in Principal Investigator
- Change in study objectives

Species:

- ≥15% increase in the original number of animal species
- Change in species (addition/deletion of)
- Increased proportion of expected animal deaths

Procedure

- Increased overall invasiveness of a procedure
- Addition of or increase in a painful/distressful procedure
- Addition of major procedures requiring anesthesia with recovery, hazardous or infectious agents
- Addition of non-invasive procedure
- Withholding analgesia

Animal Maintenance

- Changes in animal care and monitoring practices
- Change in field site
- Change in husbandry (e.g. addition of a new diet)
- Addition of a hazardous material that requires special handling of animals or bedding

Drugs/Chemicals

- Change of drug classification or regimen
- Change or addition of hazardous chemicals

Euthanasia/End Points

- Change in or addition of euthanasia procedures from an AVMA 'Acceptable Method'; to an AVMA 'Conditional Method' (AVMA Guidelines)

- b. Examples of Minor Amendment to Protocol:**

Administrative:

- Personnel changes (excluding PI)
- Reduction in the proposed number of animals
- Refinement in techniques to be less invasive
- Change in strain of mouse
- Change in protocol title

Species:

- 11% -15%* increase in the original number of animal species
- Addition of another strain/stock of same species
- Decreased proportion of expected animal deaths

Procedure:

- Change in minor procedures
- Additional noninvasive specimens collected/analyzed
- Addition of surgery or procedure that is less invasive than already on the approved protocol
- Repetition of an already approved experiment

Animal Maintenance

- Change in animal care facility, housing unit or research facility

*IACUC Chair reserves the right to determine if the change is major or minor, based on species

12. Final Report

If an IACUC protocol has been completed or will not be renewed before the protocol expiration date, a final progress report must be submitted to the Research Compliance Officer within 30 days.

13. Suspension

The Committee may suspend an activity that it previously approved if it determines, after appropriate review, that the activity is not being conducted in accordance with applicable federal, state, and local regulations; e.g., the Animal Welfare Act, the "Guide for the Care and Use of Laboratory Animals," the University's Animal Welfare Assurance, and the "PHS Policy" (Section IV.C.1.a.-g.) which implements the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training." The Committee may suspend an activity only after review of the matter at a convened meeting of a quorum (majority) of the Committee and with the suspension vote of a majority of the quorum present.

If the Committee suspends an activity involving animals, the Associate Vice President for Research, in consultation with the committee, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the Office of Laboratory Animal Welfare (OLAW).

14. Satellite Facilities

It is the general policy of the UWF IACUC to centralize animal facilities as much as possible. Satellite animal facilities will be approved only where there is rigorous scientific justification for the exception, and the appropriate environment, housing, care and oversight can be provided as required by all applicable law and current UWF policies. All satellite facilities at the University must be approved by the UWF IACUC. Anyone performing animal research must follow their home-institution's policies, procedures and guidelines, as well as those of the host-institution, with the institution that owns the animals maintaining primary oversight responsibility.

Wherever possible and appropriate, UWF's IACUC will accept the review and approval of the offsite institution's IACUC or comparable regulatory committee upon submission of appropriate documentation demonstrating the support and collaboration of the offsite institution and compliance with federal regulations governing the ethical care and use of animals.

Federal regulations require that all research funded by the Department of Health and Human Services (DHHS) be conducted only at assured institutions. Therefore, if a UWF project funded by federal money involves a subcontract to another institution for live-animal research, that institution must provide evidence of an Animal Welfare Assurance (domestic institutions) or a Statement of Compliance (foreign institutions) with the Office of Laboratory Animal Welfare (OLAW).

15. Maintenance of IACUC Records

The Office of Research Administration & Engagement is responsible for the maintenance of adequate documentation (as specified in the PHS Policy Section IV.E.) of IACUC activities, including the following.

- Copies of all research or educational projects submitted to the IACUC;
- Agendas and Minutes of IACUC and actions taken by the IACUC;
- Evaluations of reviews and inspections;
- Copies of all correspondence between the IACUC and the Associate Vice President for Research or his/her designee;
- All correspondence and reports submitted to USDA and OLAW and
- A list of IACUC members.

The records required by this policy shall be retained for at least three (3) years after the expiration of the protocol and shall be kept in Research Administration & Engagement.

