I. Purpose and Applicability

The purpose of this policy is to satisfy requirements of the Animal Welfare Act, Animal Welfare Regulations, Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), and to provide clarification and interpretation of these laws to UNCW Institutional Animal Care and Use Committee (IACUC) members, administrators and researchers.

This policy applies to funded (extramural or internal) or unfunded activities involving the use of live, vertebrate animals for research, research training, experimentation, biological testing, or related purposes by any UNCW faculty, staff or student, or by any researcher from an external institution collaborating with UNCW researchers or using UNCW facilities.

II. UNCW IACUC Administration

UNCW Research Integrity Office (RIO) director or designee will maintain current contact and program information on the UNCW Animal Research (IACUC) website.

III. Important Definitions

A. Animal – Any live, vertebrate animal used or intended for use in research, research training (including teaching), experimentation, or biological testing or for related purposes. Only animals approved by the UNCW IACUC are permitted in animal housing or experimentation areas. This definition excludes:
1. Free-living wild animals observed in their natural habitat during field studies, provided the field study activity is not likely to materially alter or influence the activity of the study animal or other species in the study area and does not have the potential to cause harm (does not involve trapping, capturing, physical/chemical restraint, handling and/or invasive procedures). A field study will materially alter or influence the activity of a study animal if the methods to detect the animal reduce the animal’s chance at survival, the ability to reproduce and/or impacts their migration.

2. Animals used for display purposes only, such as fish tanks/exhibition aquaria where the animals are not research subjects.

3. Pets, meaning domestic or tamed animals owned by an individual, whether UNCW employee, student, or community member, kept for that individual’s companionship or personal enjoyment, provided they are not used as research subjects.

4. Animals that meet the definition of service or emotional support animals per UNCW policy 05.360 Service Animals, Emotional Support Animals, and Pets.

B. Animal Care and Use Program – a program made up of multiple components that work synergistically to support activities involving laboratory animals where the activities have a direct impact on the well-being of animals. The supporting components of a comprehensive animal care and use program include animal and veterinary care, policies and procedures, personnel/program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.

C. Animal Facility – Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal (as defined above) confinement, transport, maintenance, breeding, or experiments, inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours (PHS Policy).

D. Assurance – an agreement with the Office of Laboratory Animal Welfare (OLAW) to operate an animal care program in accordance with certain policies and principles. UNCW's OLAW Assurance # is D16-00502(A3871-01).

E. Attending Veterinarian (AV) – the AV has direct program authority and responsibility for the Institution’s animal care and use program including access to all animals. The AV reports to the IACUC chair and directly to the institutional official (IO) if any violations of the AWA are discovered.

F. Backup Veterinarian – if the AV is unavailable, the Backup AV provides veterinarian services and has direct program authority and responsibility for the Institution’s animal care and use program including access to all animals.

G. Health Evaluation for Researchers – an assessment conducted by a medical professional to determine health risks associated with the use of live vertebrate animals used in research (U.S. Office of Laboratory Animal Welfare, 2018).
H. IACUC: Institutional Animal Care and Use Committee – an administrative body appointed by and reporting to the Institutional Official. Responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the Animal Welfare Act and its Animal Welfare Regulations and the Guide for the Care and Use of Laboratory Animals (the Guide). Its oversight functions include an ongoing assessment of animal care and use.

I. IACUC Member in Good Standing – a member is ‘in good standing’ if s/he:
   1. has not missed three consecutive, regularly scheduled meetings (without a legitimate reason);
   2. has completed all required IACUC training;
   3. attends meetings fully prepared to contribute to discussions;
   4. is in compliance with IACUC policies; and
   5. interacts with researchers, other committee members, and IACUC staff in a respectful and constructive manner.

J. Institutional Official (IO) – the individual who bears ultimate responsibility for the Animal Welfare Assurance Program and is responsible for resource planning and ensuring alignment of program goals with the university’s mission.

K. Noncompliance - Failure to comply with federal regulations, state laws, or UNCW policies or SOPs related to the humane care and use of live, vertebrate animals, and/or the requirements or determinations of the IACUC, or provisions of the approved research, education or training study.

L. Principal Investigator (PI) – the member of a research team who is ultimately responsible for the project. The PI may not be a student. If a student is the primary researcher on a project, the student’s faculty advisor may serve as the PI.

M. Quorum – a majority of members of the IACUC.

N. Research Misconduct - Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. Noncompliance of IACUC policies and/or SOPs generally does not constitute research misconduct.

O. Researcher – any member of a research team.

P. The Three Rs – a widely accepted concept referring to three ways of reducing distress to research animals and encouraging the use of alternatives. The Three Rs, reduction, refinement and replacement, are defined as:
   1. Replacement - substituting other systems for whole animal use. Examples include human and animal cell, tissue, and organ cultures; chemical systems; blood products; computer simulations; and plastic organ models.
   2. Reduction - decreasing the number of animals to the minimum needed to yield accurate test results.
3. Refinement - using modern medicine to minimize or eliminate pain and distress and employing housing and husbandry techniques to enrich the captive environment to reduce boredom and promote natural behavior.

Q. Study area – any building room, area, enclosure, or other containment outside of an animal facility in which animals are housed for more than twelve (12) hours (AWAR 1.1).

R. Unanticipated Problems - any unanticipated illnesses or mortality discovered in research animals. The PI must report unanticipated problems to the IACUC and the Attending Veterinarian as soon as the problem is identified.

S. Whistleblower - a person who informs on an individual or an organization engaged in an unethical or illegal activity.

IV. Compliance with Animal Welfare Assurance

The UNCW IACUC program will operate in accordance with the UNCW Animal Welfare Assurance (Assurance) required by and submitted to OLAW. This policy augments the Assurance, which details procedures for annual (a.k.a. continuing) review, program review, facility inspections, occupational health and safety, investigation of concerns, reporting requirements and record retention.

V. UNCW IACUC Membership

The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Established members in good standing who have fulfilled their terms have the option of resigning or serving an additional term. The IO may terminate an inactive member and recommend a new member to the Chancellor to replace the terminated member if needed in order to maintain composition and minimum number requirements of PHS Policy IV.A.3.b.

IACUC staff and members may refer to SOP 5.1 IACUC Membership Selection and Appointment Procedures for specific procedures.

VI. UNCW IACUC Responsibilities and Administrative Functions

A. Responsibilities of the IACUC:

The IACUC will conduct itself in accordance with PHS Policy IV.B.1-8. These responsibilities are detailed in the UNCW Assurance, various sections of this policy and standard operating procedures. Responsibilities are reviewed and discussed during the semi-annual review of the animal care and use program.
B. Administrative Functions of the IACUC include:

1. Scheduling meetings per SOP 6.1 IACUC Meeting and Minutes Procedures;

2. Reviewing new and on-going protocols as well as amendments to previously approved protocols per SOP 6.2 Protocol Review Procedures;

3. Ensuring that all animal research conducted at UNCW is as humane as possible and consistent with the Three Rs (see Definitions);

4. Conducting semi-annual animal facilities inspections per SOP 6.3 IACUC Semi-Annual Facilities Inspection Procedures;

5. Investigating allegations and incidents of noncompliance and/or concerns for animal welfare (see Section XI.C below and related SOP 6.4 Procedures for Investigating Allegations and Incidents of Noncompliance and/or Concerns for Animal Welfare);

6. Communicating with appropriate regulatory and funding agencies.

7. Maintaining institutional registration with OLAW and USDA (when applicable)

8. Submitting annual reports to OLAW by the date established by OLAW and including the information required by PHS Policy IV.F.1-3.

9. Renewing PHS Assurance every four years

10. Retaining IACUC Records

   a. General Responsibilities

      The IACUC is responsible for retention of records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC (PHS Policy IV.E.1-2). Records shall be maintained for the duration of the activity and for an additional three (3) years after completion of the activity. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

   b. IACUC staff will also maintain the following records for at least three (3) years:

      i. The minutes of IACUC meetings recorded per SOP 6.1 IACUC Meeting and Minutes Procedures.

      ii. Semi-annual reports and any recommendations (including minority views) as forwarded to the IO;
iii. Annual reports to OLAW

iv. Updates to the UNCW Assurance

The Assurance will be updated whenever changes are made and renewed prior to expiration.

v. Records of accrediting body determinations, as applicable.

C. Individual member responsibilities include:

1. Maintaining status as Members in Good Standing (see Definitions and SOP 5.1 IACUC Membership Selection and Appointment Procedures);

2. Being properly trained
   a. Required Online Training

      IACUC members must complete two online courses approved by the IACUC, "Working with the IACUC," and “Essentials for IACUC Members” which are provided by the Collaborative Institutional Training Initiative (CITI Program). If an IACUC member is also a PI, the IACUC member training is in addition to the required training for researchers.

   b. New Member Orientation

      New members meet with IACUC staff for one-on-one training on PHS Policy, UNCW’s Assurance, and this UNCW IACUC Policy. IACUC members receive copies of, and must familiarize themselves with, the PHS Policy, the Guide for the Care and Use of Laboratory Animals, as well as UNCW’s approved Animal Welfare Assurance.

   c. Other Training

      Members may also be offered other training opportunities such as attending conferences and workshops when opportunities and funding are available.

VII. Researcher Responsibilities

A. Being properly trained and ensuring that members of their research team are properly trained;

1. General Requirements

   All persons (faculty, staff or students) who will handle live, vertebrate animals must receive the training described below or other form of training as approved by IACUC staff or IACUC chair.

   a. On-Line Training
The online course, “Working with the IACUC”, provided by the Collaborative Institutional Training Initiative (CITI) is required for all members of the research team. It is designed to demonstrate the highest ethical standards and to comply with all laws and regulations. Other forms of training may be required/recommended by the IACUC.

The principal investigator (PI) of the study may require additional CITI courses for research team members. In all instances, any additional training must be approved on a case-by-case basis by IACUC staff or IACUC chair.

b. Certification of Training

Each person subject to the educational requirements must submit documentation of completion to IACUC staff if it is not already on file. RIO will maintain a record of all training documentation received. The IACUC will not approve an Application for the Use of Live Vertebrate Animals (“protocol”) until all relevant documentation has been received.

B. Completing a health risk assessment and ensuring that all members of the research team have completed a health risk assessment in accordance with SOP 7.1 Health Risk Assessment Procedures;

C. Receiving and ensuring that all research team members receive health and safety training offered by the UNCW Office of Environmental Health and Safety, as appropriate;

D. Receiving any additional training as needed for the approved research project;

E. Ensuring all research and educational activities involving animals are fully described on the current protocol forms available on the IACUC website prior to implementing the activities in accordance with SOP 7.2 Protocol Development, Submission and Modification Requirements;

F. Identifying hazards, assessing risks, providing training on injury prevention, and ensuring day-to-day safety during animal activities;
   1. PIs of individual research studies have day-to-day responsibility for safety in their animal facilities, including identifying hazards, assessing risks and providing training on injury prevention.

   2. PIs must identify on the protocol all health and safety concerns associated with protocol activities and certify that members of the research team have been appropriately trained so that risks are minimized.

G. Obtain IACUC approval for all activities involving live vertebrate animals, and implement all methods and procedures as approved by the IACUC;

   1. Research must be implemented as approved except where necessary to eliminate apparent immediate hazards to the animals.
2. Emergency deviations from an approved protocol must be reported to the IACUC staff as soon as possible. The PI must provide justification for the deviation.

3. PIs must store controlled substances as specified in DEA regulations.

H. Retaining research records;
   PIs are responsible for retaining copies of all communications with the IACUC, all approved protocols, all amendment requests/approvals and all relevant documentation throughout the research and for an additional 3 years after the research is complete.

I. Reporting to the IACUC the progress of approved research, deviations from the approved protocol and any unanticipated problems to the IACUC.
   1. Annual Review
      The PI is responsible for reporting the progress of approved research to the IACUC, as often as and in the manner prescribed by the IACUC, but no less than once per year.
      The PI is required to submit a new protocol for review and approval by the committee at the end of the three (3) year cycle for continuing projects.

   2. Unanticipated Problems
      The PI must report to the IACUC and Attending Veterinarian any unanticipated illnesses or mortality discovered in animals as soon as the problem is identified.

   3. Protocol Closure
      The PI must notify the IACUC staff upon the termination of the research project, departure of the PI from the institution and/or change in the PI for the study.

VIII. Categories of Research Review at UNCW

Per PHS Policy IV.C.1-4 and USDA Animal Welfare Regulations §2.31(c), the UNCW IACUC will use the following categories of review in evaluating research protocols:

A. Review at a Convened Meeting (Full Review)
   IACUC protocols will be reviewed at a convened meeting unless the committee authorizes review of a protocol by Designated Review as outlined in C. Designated Review below.
Activities requiring *Full Review* include but are not limited to non-routine or harmful invasive procedures, prolonged restraint (does not include standard tethering systems for rats), use of animals with a serious natural or experimental disease maintained for an extended time (such as naturally occurring or experimentally induced paralysis), the use of hazardous agents (carcinogens, radioisotopes, etc), and methods of euthanasia other than those proposed by the AVMA, unless the method was previously reviewed and authorized by the UNCW IACUC.

The IACUC staff will implement the process according to the **SOP #6.2 Protocol Review Process** (see SOP Section V.A 1-3, Full IACUC Review).

B. Designated Review Subsequent to Full Review

If it is determined during a convened meeting that a protocol being reviewed cannot be approved without substantial modifications, the IACUC chair may designate one or more reviewers to complete the review through the *Designated Member Review (DMR)* process. As allowed by PHS Policy, all members of the IACUC have agreed *in advance in writing* that the quorum of members present at a convened meeting may authorize the DMR process by unanimous vote of the quorum. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request Full Review of the protocol.

IACUC staff will implement the process according to the **SOP #6.2 Protocol Review Process** (see SOP Section V.B Designated Member Review).

C. Designated Review

*Designated Review* is a thorough review of animal research conducted by at least one member of the IACUC, as designated by the IACUC chair. The reviewer(s) must be qualified to review the specific protocol and will act on behalf of the IACUC. The reviewer(s) have the authority to approve, require additional information and/or modifications, or request full committee review. The reviewer(s) do not have the authority to withhold approval but must instead refer the review to the full IACUC.

IACUC staff will implement the process according to the **SOP #6.2 Protocol Review Process** (see SOP Section V.B Designated Member Review).

**IX. Research Protocol Evaluation Process and Requirements**

A. Electronic Submission

All animal research protocols and any required attachments must be submitted electronically by the submission deadline(s) posted on [the IACUC website](#).
If funded, the research protocol application must include (1) the name of the funding agency, (2) the associated proposal number in the UNCW grant tracking system and (3) a copy of the grant proposal.

B. Incomplete Submissions

IACUC staff will notify PIs of incomplete protocol submissions. If the protocol remains incomplete after 30 days from notification, it will be removed from review.

C. Pre-Review by Attending Veterinarian (AV)

The Attending Veterinarian (AV) conducts a pre-review of each new protocol and provides comments and any recommendations for protocol improvement electronically to the PI.

The PI may revise the protocol based on the AV’s comments and recommendations and resubmit the protocol to the RIO IACUC staff by the final submission deadline posted on the IACUC website.

D. Submission of Signed Electronic Copy

The PI must submit a signed electronic copy of the protocol before the IACUC can grant approval.

E. Review Results

Following IACUC review, the PI will be notified in writing as soon as possible of the results of the review.

1. Protocol Approval

   a. When the protocol is approved, the IACUC chair or designee will send the PI a memo specifying the dates of approval and expiration and a signed copy of the approved protocol.

   b. All IACUC approvals are effective for three years unless a shorter duration is deemed appropriate by the IACUC.

   c. All IACUC approvals are subject to continuing review at least once per year.

2. Modifications and Clarifications

   a. When IACUC approval is contingent upon modifications to the research procedures, the PI will be contacted and informed of the required modifications. It is the responsibility of the PI to make these changes and forward revisions to IACUC staff.

   b. When revisions are received, the chair or designee may determine if the modifications satisfy the requirements stipulated by the committee.
c. Animal activities cannot begin until the IACUC approves such modifications. Once the modifications are approved, the IACUC chair or designee will send the PI a memo specifying the dates of approval and expiration and a signed copy of the approved protocol.

3. Protocol Disapproval

If approval for a protocol is withheld, the IACUC chair or designee notifies the researcher in writing, along with the reason(s) approval was not granted. The researcher is given the opportunity to respond. Approval may only be withheld after full IACUC review.

If the protocol is disapproved, the PI will be notified in writing of the reason(s). The PI will also be given an opportunity to respond in person or in writing to the concerns of the IACUC that led to disapproval. Following the PI’s response, the IACUC will vote on the protocol again as soon as possible or at the next regularly scheduled meeting.

F. Review of Protocol Amendments

1. All proposed amendments to an approved protocol must be submitted to and approved by the IACUC prior to their implementation.

2. Requests to amend an approved protocol must be made in writing and directed to IACUC staff. Requests sent by email are acceptable.

3. When a proposed change is submitted, IACUC staff refer to SOP #6.2 Protocol Review Process (see SOP Section VI.) and direct request accordingly based on the nature of the changes requested.

X. Veterinary Care Program

The IACUC shall contract a qualified doctor of veterinary medicine to serve as the Attending Veterinarian (AV). The AV reports to the IACUC chair and directly to the IO if any violations of the AWA are discovered. The AV shall serve as advisor to the IACUC and animal researchers at UNCW. The AV shall have the authority to report directly to the IO and to halt any research that violates the approved protocol, the Guide, PHS Policy, or UNCW policy. The AV shall keep IACUC staff apprised of any veterinary call and shall notify the IACUC chair and IO immediately upon suspending any research.

XI. Reporting Unanticipated Problems with Animals

A. General Requirements
Any unanticipated problems involving animal illness or death, regardless of causality, must be reported to the IACUC and the AV by the PI as soon as the problem is identified.

IACUC staff will implement the reporting process detailed in SOP 6.4 Procedures for Investigating Allegations and Incidents of Noncompliance and/or Concerns for Animal Welfare.

B. Temporary Suspension of Protocol

If the IACUC chair or AV believes the event signals continued danger to the animals, the IACUC chair or AV may temporarily suspend the protocol until a further decision can be reached. The IACUC chair must convene a meeting if a temporary suspension is issued, the risk to animals is determined to be significant, or the AV or IO requests a meeting.

C. Investigation of Research Project

Only the full IACUC may request an investigation of a research project. Investigations will be conducted in accordance with SOP 6.4 Procedures for Investigating Allegations and Incidents of Noncompliance and/or Concerns for Animal Welfare (see SOP Section V).

XII. Audit of Research Projects

A. General Procedures

1. The IO, full IACUC, AV, IACUC chair, RIO, Chancellor, or Internal Audit may request an audit of or seek verification on any study that has been approved by the IACUC for any reason, including:

   a. randomly selected projects,
   b. complex projects involving unusual procedures on animals,
   c. projects conducted by PIs who previously have failed to comply with the requirements of the PHS Policy, the Guide or the requirements or determinations of the IACUC, and
   d. projects where concern about possible material changes occurring without IACUC approval have been raised based upon information provided in continuing review reports or from other sources.

2. The PI is expected to cooperate fully with auditors.

B. IACUC and RIO Audit Report

1. IACUC staff will conduct RIO audits along with at least one IACUC member.
2. The audit may consist of reviewing documents such as laboratory logs and purchase orders, and/or observing laboratory procedures.

3. Following audit by the IACUC or RIO, IACUC staff will generate a written report and send it to the PI. Copies will be submitted to the individual requesting the audit (if applicable) and the IACUC chair. A copy will be filed in RIO.

4. The IACUC chair or designee will determine if the findings warrant an investigation for noncompliance. If so, the investigation will proceed in accordance with SOP 6.4 Procedures for Investigating Allegations and Incidents of Noncompliance and/or Concerns for Animal Welfare (see SOP Section V).

C. Request for Investigation

If at any time an auditor suspects a serious noncompliance or practice that may jeopardize the welfare of animals or research team members, the auditor may contact the IACUC chair or IO to request an investigation prior to generating a formal report.

XIII. Noncompliance

A. Unapproved Research

1. Research conducted without IACUC approval must stop until IACUC approval is obtained.

2. IACUC approval cannot be given for research that has already been completed.

B. Reporting Noncompliance

Noncompliance with the foregoing policy, this institution’s Assurance, the PHS Policy and/or the Guide must be reported immediately. Any individual who is concerned about the conduct of research involving animals should promptly notify the IACUC or RIO. Complaints should be directed to IACUC staff. Complaints may be filed anonymously. All reported concerns, subsequent findings of noncompliance, and responsive actions taken by the committee will be handled in accordance with this institution’s Assurance.

XIV. Appeals

The researcher/PI may appeal any action by the IACUC in writing to IACUC staff within 10 business days. The IACUC’s decision will stand until the appeal can be properly evaluated. Appeals will be handled in accordance with SOP 6.4 Procedures for Investigating Allegations and Incidents of Noncompliance and/or Concerns for Animal Welfare (see SOP Section VI).