



Authority:	Provost and Vice-Chancellor for Academic Affairs
History:	September 2, 2009
Source of Authority:	Animal Welfare Act and Animal Welfare Regulations, Public Health Service Policy on the Humane Care and Use of Laboratory Animals, UNCW Animal Welfare Assurance
Related Policies:	UNCW Conflict of Interest Policy UNCW Research Misconduct Policy
Responsible Office(s):	Research Services and Sponsored Programs

I. Purpose and Applicability

The purpose of this policy is to satisfy requirements of the Animal Welfare Act, Animal Welfare Regulations, and 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 or unfunded activities involving contact with or manipulation of live, vertebrate animals for research, research training, experimentation, teaching, 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

A. IACUC Administration Location

Office of Research Services and Sponsored Programs (ORSSP)

B. Contact Information

Phone Number: 910-962-7774

Institutional Official: Dr. Robert Roer

IACUC Chair: Dr. Tom Lankford

IACUC Co-Chair: Dr. Ray Pitts

Animal Care and Use Administrator & Regulatory Compliance Officer: Leanne Prete

III. Important Definitions

- A. Animal – Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes (PHS Policy).
- B. Animal Facility – Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal 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).
- C. 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.
- D. Quorum – A majority of members of the IACUC.
- E. Researcher – any member of a research team.
- F. Reduction - One of the three alternatives to the use of traditional animal tests in product safety testing. Reduction means decreasing the number of animals to the minimum needed to yield accurate test results.
- G. Refinement - One of the three alternatives to the use of traditional animal tests in product safety testing. Refinement means 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.
- H. Replacement - One of the three alternatives to the use of traditional animal tests in product safety testing. Replacement means 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.
- I. Three R’s – Reduction, refinement and replacement, as defined above.

IV. Compliance with Animal Welfare Assurance

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

V. UNCW IACUC Membership

The chancellor receives a list of interested individuals for committee membership from the faculty senate by July 1 each year. Upon receipt of this list, the chancellor contacts the institutional official (IO) for recommendations based on the needs of the committee as set forth below. Established members in good standing who have fulfilled their terms have the

option of serving an additional term. The chancellor appoints IACUC members by August 1 for a two-year term based upon the IO's recommendations.

A. Pursuant to the PHS Policy, the IACUC must consist of at least five members and must include:

1. A doctor of veterinary medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
2. A practicing scientist experienced research involving animals.
3. A member whose primary concerns are in a nonscientific area.
4. A member who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.
5. An individual who meets more than one of the categories above may fulfill more than one requirement as long as membership consists of at least five people.

B. Appointment of IACUC Chair

The IO appoints an IACUC chair for a one-year term with the option of reappointment. The IACUC chair should be a current IACUC member and a tenured faculty member.

The regulatory compliance officer (RCO) contacts the current IACUC chair each year in the spring to determine if the chair is willing to serve an additional term. If willing, the RCO contacts all IACUC members to solicit input on the chair's performance. IACUC members must be given the option of responding directly to the IO if desired. If the chair is not willing to serve an additional term, the RCO contacts the co-chair as specified below and contacts the IACUC members to solicit nominations for a new chair. The RCO provides the IO with feedback regarding chair appointment.

C. Appointment of IACUC Co-Chair

The IO appoints an IACUC co-chair for a one-year term with the option of reappointment. The IACUC co-chair should be a current IACUC member and a tenured faculty member.

The RCO contacts the current co-chair in the spring of each year to determine if the co-chair is willing to serve an additional term. If the chair has finished his/her term, the RCO may also inquire if the co-chair is interested in serving as chair. If the current co-chair is unable to serve an additional term, or if the current co-chair is willing to serve as chair, the RCO contacts the IACUC members to solicit

nominations for a new co-chair. The RCO provides the IO with feedback regarding co-chair appointment.

D. Alternate Members

Alternate members in good standing may be offered full member terms as openings become available.

D. Active Membership Required

A member may be considered inactive if he or she is not present at three consecutive, regularly scheduled meetings, unless there is a legitimate conflict, or if he or she has not completed the required training. The IO may appoint replacements for inactive members. IACUC meetings will be scheduled at times when the most members are available.

E. Removal of Members from the Committee

1. Resignation of Member

If a member needs to resign from the committee before the end of the member's term, the member must notify the regulatory compliance officer (RCO) as soon as the member makes the decision, as resignation could impact the committee's ability to conduct business depending on the designation of the member.

2. Member Termination

If after failed intervention by the RCO and/or chair to alter the issue, the chair and IO deem it to be in the best interest of the committee to remove a member from the committee due to the member's lack of cooperation, lack of participation, noncompliance with IACUC policies, or other issue, the IO will send the member a written notice of membership termination with reasons for the termination. If the terminated member is also a faculty member, the IO will copy the chancellor and the chair of the department to which the member reports. If needed the IO may recommend to the chancellor a new member to replace the terminated member. If the terminated member is also the IACUC chair, the IO may appoint an interim chair until nominations for a new chair can be solicited from the committee and a new chair is formally appointed by the chancellor.

VI. UNCW IACUC Responsibilities

IACUC members are responsible for ensuring that all animal research conducted by UNCW researchers is as humane as possible and consistent with the three R's (see definitions). The IACUC is responsible for being properly trained, reviewing protocols, investigating concerns for animal welfare, communicating with appropriate regulatory and funding agencies, and monitoring post-approval compliance (see appropriate section for further detail).

A. Training

The Collaborative Institutional Training Initiative (CITI) online course is the approved training source for IACUC members. If IACUC members are also PIs, the IACUC member training is in addition to the online training for researchers. IACUC members should also familiarize themselves with the PHS Policy and the UNCW's Assurance.

B. Protocol Review

1. Review new research projects that involve animals being conducted by UNCW faculty, staff, or graduate students or researchers from other institutions who are using UNCW animals or facilities.
 - a. Off-campus field activities involving observation of wild animals are not subject to IACUC review.
 - b. Animals used only for display purposes, such as fish tanks, are not subject to IACUC review. However, researchers must complete a notification form to document the source of the animals and that the animals will not be handled or manipulated for research purposes.
 - c. Only animals approved by the IACUC are permitted in animal housing or experimentation areas.
 - d. State law prohibits pets from being brought into state buildings.

2. Review Considerations

The UNCW IACUC will consider the following factors when reviewing research with animals:

- a. Reduction - the principal investigator (PI) has appropriately justified the proposed number of animals needed and has demonstrated that it is the minimum number needed to yield valid results.
- b. Refinement – the PI has taken care to design the study so that any discomfort, distress or pain to the animals is minimized, and that appropriate housing and enrichment techniques will be provided to maximize animal comfort and natural behavior.
- c. Replacement - the PI has investigated any possible models that avoid the use of animals entirely, and if none are available, has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.

C. IACUC Meeting Minutes

The minutes of IACUC meetings will record the members who attended the meeting, actions taken at the meeting, the outcome of the vote on research protocols including the numbers of members voting for or against approval and abstaining, the basis for

requiring any modifications or revisions in research procedures, documentation of any specific findings required by the federal regulations, and a summary of the discussion.

D. Registering IACUC & Updating Assurance

The UNCW IACUC, through ORSSP, must file an annual report to OLAW and update and renew the Assurance whenever changes are made.

VII. Researcher Responsibilities

Researchers are responsible for designing and implementing research consistent with the three R's (see definitions) so that animals receive the most humane treatment possible. They must also comply with all applicable sections of the *Guide for the Care and Use of Laboratory Animals* ("the Guide") as well as all applicable UNCW policies and procedures, and IACUC decisions, conditions, and requirements. Researchers are responsible for being properly trained, preparing timely research protocols and implementing them as approved, retaining research records, and reporting to the IACUC (see appropriate section for further detail). Researchers should refer to the relevant IACUC policies which follow.

A. Training

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 the RCO or IACUC chair.

2. Training Website

The CITI online course is the approved training source for all members of the research team. It is designed to demonstrate the highest ethical standards and to comply with all laws and regulations. The website can be found at <http://www.citiprogram.org/>. Other forms of training must be approved on a case-by-case basis by the RCO or IACUC chair.

3. Certification of Training

Each person subject to the educational requirements must submit documentation of completion to the RCO. ORSSP will maintain a record of all training documentation received. ORSSP will not forward an Application for the Use of Live Vertebrate Animals ("protocol") to the IACUC for review until all relevant documentation has been received.

4. Health and Safety Training

PIs are required to ensure that all members of the research team have completed appropriate health and safety training offered by the UNCW Office of Environmental Health and Safety.

B. Submission of Forms to the IACUC

1. PIs are responsible for ensuring that all of their research activities involving animals are submitted to and approved by the IACUC using the current forms available on the IACUC website (<http://www.uncw.edu/orssp/conduct-animal.html>). PIs from other institutions may submit their institutional forms if they have already obtained IACUC approval from their home institution and the form required by the home institution provides substantially the same information as the UNCW form. PIs from other institutions must receive written UNCW IACUC approval before starting any activities using UNCW animals or facilities.
2. If a PI desires review at a specific meeting, the PI must submit all necessary forms electronically by the submission deadlines posted on the IACUC website and submit the signed hard copy prior to the meeting. The IACUC cannot ensure placement of a protocol on a meeting agenda if submitted after the corresponding deadline.
3. Amendments to approved protocols must be submitted and approved prior to implementation of any changes. Amendments must be fully described and submitted in writing to the RCO. Submission by email is acceptable. Significant changes to approved procedures may require resubmission of the full protocol form.
4. PIs should refer to their protocols by UNCW protocol number in all communication with the IACUC and ORSSP.

C. Risk Identification

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.

D. Implementation of Research

1. Deviation from Approved Protocol

Research must be implemented as approved except where necessary to eliminate apparent immediate hazards to the animals. If an emergency deviation is seen by the PI to be warranted, the PI must notify the RCO of the deviation as soon as possible.

2. Euthanasia

The PI must use a method of euthanasia that is consistent with the most recent AVMA Guidelines on Euthanasia. If the PI needs to use a method other than one approved by the AVMA, the PI must provide a justification to the IACUC.

E. Storage of Controlled Substances

PIs must store controlled substances as specified in DEA regulations (<http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfr.htm>).

F. Reporting

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 RCO will prompt the PI when annual review is due.

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.

G. Retention of Records

PIs are responsible for retaining copies of all communications with the IACUC, all approved protocols, and all amendment requests until the research is complete and the IACUC has been notified of its completion.

VIII. Categories of Research Review at UNCW

Based on the Animal Welfare Regulations, 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 below.

1. Activities Requiring Full Review

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.

2. Meeting Procedures

- a. The UNCW IACUC will have a standing meeting at least three times per year to consider new and continuing research planned for that semester that requires full IACUC review. The dates of these standing meetings will be announced on the IACUC website (<http://www.uncw.edu/orssp/conduct-animal.html>).

- b. IACUC meetings are open to the public to the extent allowed under North Carolina's Open Meetings Act.
- c. A majority of the members of the IACUC (a quorum) must be present in order for the IACUC to conduct business at a convened meeting. Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures), the IACUC may not take further actions or votes unless the quorum can be restored.
- d. A member may count toward a quorum when the member cannot physically attend a meeting but can be present by speaker-phone, provided the member can hear all discussion and interject comments and concerns as needed.
- e. IACUC members who are also researchers on projects under review may not participate in the vote on their own research and may not be present when the vote takes place.
- f. IACUC members may not participate in the vote when the IACUC reviews research in which they have a conflicting interest, and such should be noted in the IACUC meeting minutes.
- g. Members of the IACUC who vote to disapprove a protocol shall submit their reasons in writing to the IACUC chair within 7 days of the meeting.
- h. PIs may be invited to meetings to explain projects and answer questions. PIs may not be present when the IACUC votes on projects. If an IACUC member wishes to ask a PI to address specific journal findings during a convened meeting, the IACUC member must provide the PI and the other committee members with a copy of the journal at least 2 days prior to the meeting.

B. 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.

1. When a protocol qualifies for designated review, the RCO will send a copy of the protocol to all members and query the members to determine if designated review is authorized.
2. When authorization for designated review is solicited, any IACUC member may request review of the protocol at a convened meeting for any reason. If a member requests review at a convened meeting, a meeting will be scheduled if necessary to review the protocol.
3. If no member requests review at a convened meeting, the RCO will ask the chair to designate a reviewer or reviewers for the protocol.

IX. Research Protocol Evaluation Procedures

A. Submission requirements

To begin the review process, the PI must submit an electronic copy of the protocol form and any applicable attachments to the RCO in ORSSP by the initial submission deadline posted on the IACUC website (<http://www.uncw.edu/orssp/conduct-animal.html>). If the project is sponsored, the PI must submit a copy of the grant proposal with the protocol form.

B. Incomplete Submissions

The RCO will notify PIs of incomplete protocols. If the protocol remains incomplete after 30 days from notification, it will be removed from review.

C. Pre-Review by Attending Veterinarian (AV)

Upon receipt of a new protocol, the RCO forwards the electronic file to the AV for an initial review. When review is complete the AV sends the PI a form showing any recommendations for protocol improvement. AV recommendations are optional; the PI is not required to make changes. If the PI chooses to revise the protocol based on the AV's recommendations, the PI must resubmit the protocol by the final submission deadline posted on the website.

D. Submission of Signed Hard Copy

The PI must submit the signed hard copy of the protocol after all revisions are made and prior to the meeting date.

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. If the protocol is approved, the IACUC chair will send the PI a memo specifying the dates of approval and expiration.
- 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 the RCO.

- b. When revisions are received, the chair or designate 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 approval memo specified above will be sent to the PI through campus mail.

3. Protocol Disapproval

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

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

1. Submission Requirements

Requests to amend an approved protocol must be made in writing and directed to the RCO. Requests sent by email are acceptable.

2. Extent of Changes

a. Minor or Administrative Changes

The RCO may review and approve minor or administrative changes to protocols.

Examples of minor or administrative changes are additions or deletions of personnel when appropriate training is documented, adding or changing to a previously approved facility, and a very slight increase in number of animals needed (not more than 10% increase in the total number of animals or no more than five animals if $N < 10$).

b. Moderate Changes

The chair may review or designate a member to review and approve moderate changes to protocols.

Examples of moderate changes are harvesting additional tissues, taking additional measurements, altering the operant schedule (e.g. fixed ratio to variable interval), altering a surgical approach, additional noninvasive sampling, using a different gender animal, making a minor change in species

(rat to mouse), making a moderate increase in number of animals needed (10% - 25% increase in the total number of animals or more than five animals if N<10).

c. Major Changes

Changes deemed to be major by the chair may require review by the full committee on a revised protocol form. The PI must attach a memo to the revised protocol form outlining and justifying the changes requested.

Examples of major changes are changes to the objectives of the study, changing from nonsurvival to survival surgery, changes in the degree of invasiveness of a procedure or discomfort to an animal, a major change in species (mice to dogs), change in the duration, frequency, or number of procedures performed on an animal, more than a 25% increase in the total number of animals needed.

X. Veterinary Care Program

The IACUC shall contract a qualified doctor of veterinary medicine to serve as the attending veterinarian (AV). 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 the RCO 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.

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

The IACUC chair, IO, ORSSP, or full IACUC may request an investigation of a research project. Investigations are handled in accordance with this institution's Assurance.

5. Audit of Research Projects

A. General Procedures

1. The IO, full IACUC, or IACUC chair 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. ORSSP, Internal Audit or the chancellor can also initiate an audit randomly, as part of an investigation, or for any other reason.
3. The PI is expected to cooperate fully with auditors.

B. IACUC and ORSSP Audit Report

1. The RCO will conduct ORSSP 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 ORSSP, the RCO will generate a written report and send it to the PI. Copies will be submitted to the individual requesting the audit and the IACUC chair. A copy will be filed in ORSSP.
4. The IACUC chair will determine if the findings warrant an investigation for noncompliance. If so, the investigation will proceed in accordance with this institution's Assurance.

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 to request an investigation prior to generating a formal report.

6. 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 ORSSP. Complaints should be directed to the RCO in ORSSP (910-962-7774 or pretel@uncw.edu). 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 (<http://www.uncw.edu/orssp/conduct-animal-fwa.html>).

7. Appeals

The researcher/PI may appeal any action by the IACUC in writing to the RCO within 10 business days. The IACUC's decision will stand until the appeal can be properly evaluated.