

Institutional Animal Care and Use Committee Policies & Procedures

This document includes the policies and procedures that govern oversight of the care and use of live vertebrate animals at the University of Northern Colorado. The use of animals in research, teaching, and testing imposes moral, scientific, and legal obligations for humane care and treatment. The University of Northern Colorado is committed to providing the highest levels of humane treatment and proper care for all vertebrate animals through application of scientific and professional judgment that is based on specific animal needs as well as research and teaching requirements.

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I. GOVERNING REGULATIONS

In accordance with its commitment, and to effectively carry out its responsibility for the humane care and use of animals, UNC designates the Assistant Vice President for Research as the Institutional Official (IO) and responsible party for providing support for the university's Animal Care and Use Program. UNC's Institutional Animal Care and Use Committee (IACUC) is appointed by the President to oversee the use of animals for research, teaching, or testing conducted at UNC facilities or conducted by UNC personnel at other locations. The IACUC derives its authority from the Health Research Extension Act of 1985, the Animal Welfare Act, and any policies or regulations established by the Public Health Service (PHS) and the United States Department of Agriculture (USDA) to implement those public laws.

UNC applies the regulatory requirements of both agencies to the use of all vertebrate animals. adopting the more stringent requirement when there are differences between the two.

A. The Public Health Service (PHS)

The PHS, through the [Office of Laboratory Animal Welfare](#) (OLAW) is charged with implementing the Health Research Extension Act. OLAW regulates all vertebrate species at institutions that receive federal funding through the PHS.

Relevant Regulatory Documents

- [The PHS Policy for the Humane Care and Use of Animals \(PHS Policy\)](#)
- [The Guide for the Care and Use of Laboratory Animals \(the Guide\)](#)
- [2007 AVMA Guidelines on Euthanasia](#)
- [Health Research Extension Act of 1985](#)
- [U.S. Government Principles for Utilization](#)

The [OLAW Tutorial on PHS Policy](#) is a good source of information on PHS requirements.

The PHS and the IACUC

The PHS Policy states, "No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth the compliance with this Policy." The assurance is approved for a specified period of time, not longer than five years, after which time, a new Assurance must be submitted.

UNC's PHS Assurance Number: A4075

PHS Policy requires that the Chief Executive Officer of the institution appoint an IACUC to oversee the institution's animal program, facilities, and procedures. The committee must consist of at least five members including one 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; one practicing scientist experienced in research involving animals; one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and one individual 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.

B. The United States Department of Agriculture (USDA)

The USDA, through the [Animal Plant and Health Inspection Service](#) (APHIS) is charged with implementing the Animal Welfare Act. APHIS regulates any live, warm-blooded animal that is used for research, teaching, testing, experimentation or exhibition except for birds, and rats of the genus *Rattus* and mice of the genus *Mus* that are bred for use in research.

Relevant Regulatory Documents

- [Animal Welfare Act](#) (AWA)
- [Animal Welfare Act Regulations](#) (AWRs)
- [Animal Care Policy Manual](#)

The USDA and the IACUC

The Animal Welfare Act (AWA) requires that institutions using vertebrate animals for purposes of research, teaching, and testing register with USDA. This registration is renewed every three years on or before the renewal date.

UNC USDA registration number: 84-R-0008

The Animal Welfare Act Regulations (AWRs) stipulate, “The Chief Executive Officer of the research facility shall appoint an Institutional Care and Use Committee (IACUC)...” UNC’s IACUC members are appointed by the President, and consistent with the AWRs, the committee consists of at least three members including a Chairperson, Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility; and one member who not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility and who will provide representation for general community interests in the proper care and treatment of animals. The AWRs further stipulate that if the Committee consists of more than three members, “not more than three shall be from the same administrative unit of the facility.” UNC restricts the membership to not more than three members from the same school or administrative division of the University.

The AWRs charge the IACUC to assess the research facility’s animal program, facilities, and procedures.

II. UNC ANIMAL CARE & USE PROGRAM CODE OF ETHICS

- A. There must be a reasonable expectation when live animals are used in research, teaching or testing that such utilization will contribute to the improvement of human or animal health, the advancement of knowledge, or the good of society. The relative value of an activity is a particularly important consideration in potentially painful experiments where there is an ethical obligation to see that the benefits of the research outweigh any pain, discomfort, and distress experienced by the animals.
- B. While there is no alternative to the use of live animals in many research protocols, investigators have an ethical obligation to explore ways in which animals can be partially or totally replaced by other biological or mathematical/computer systems. When a research question can be pursued using reasonably available non-animal or *in vitro* models and still result in sound scientific conclusions, the investigator should choose these alternatives.
- C. It is the investigator's responsibility to select the optimal species for a particular project. In addition, the number of animals utilized in a protocol should be minimized consistent with sound scientific and statistical standards. It is also the investigator's responsibility to consider the source of the animal and ensure that all animals used for experimental purposes are lawfully acquired.
- D. The investigator has an ethical obligation to use techniques that will produce valid results while causing the least possible amount of pain or distress to animals. If a specific procedure can be anticipated to cause pain or distress in humans, it should be expected to cause pain or distress in animals; and the investigator must adequately plan appropriate treatment for relief and, throughout the procedure, must assess and monitor pain and distress using behavioral signs based on the normal behavior pattern of the species under study.
- F. When a procedure causes more than momentary or slight pain or distress to the animal, its intensity and duration must be reduced through the administration of appropriate anesthetics, analgesics, or tranquilizers not only during the time the procedure is being conducted but also until the pain or distress is reduced to an acceptable level following the procedure. If the research involves the use of painful stimuli, the study must be designed to provide a means of escape by the animal.
- G. There is a limitation on the pain to which an experimental animal may be exposed. Investigators should choose the earliest possible endpoint in order to minimize pain and discomfort. An animal that is observed to be in a state of severe pain or distress that cannot be alleviated or reduced to an acceptable tolerance level should be immediately euthanized unless the scientific validity of the research will be compromised by administration of pain relieving drugs or early endpoint in which cases, the experiments must be justifiable in terms of scientific design and value, and the omission of these drugs must be based on documented scientific fact or experimental data and not intuition.

- I. No animal will be subjected to multiple survival surgeries, unless surgeries are interrelated and essential to the primary research objective.
- J. When prolonged physical restraint of an animal is necessary, it is to be used only after alternative procedures have been considered. The animal must first be trained or conditioned to the restraining device, and the animal must be conscious during restraint. To the extent possible, the animal must be able to assume its normal postural adjustments, and the restraining device should result in the minimal restraint necessary while providing maximum security and comfort for the animal.
- K. It is the responsibility of the Investigator to ensure that adequate post-surgical/procedural care is provided to animals. This care must meet acceptable standards in veterinary medicine and be provided for the duration and frequency as necessary.
- L. Euthanasia is the act of painless killing. When animals will be euthanized following research procedures, the proposed method of euthanasia must be consistent with recommendations of the [American Veterinary Medical Association \(AVMA\) Guidelines on Euthanasia](#). If animals are not to be euthanized at the completion of a research protocol, it is the responsibility of the investigator to ensure that the final disposition of the animal is approved by the IACUC.
- M. Procedures involving the use of animals must be performed by or under the immediate supervision of an individual with the appropriate qualifications and experience relative to the procedures.

III. ANIMAL CARE & USE PROGRAM DEFINITIONS

A. Definitions

The following are definitions for terms as used throughout these guidelines.

Animal Care and Use Program (ACUP)—the combined components of an institution’s operations involved in the care and use of animals for research, teaching, and testing. There may be many components to a Program, but it must include:

1. The designation of an Institutional Official (IO)
2. The appointment of an Institutional Animal Care and Use Committee (IACUC)
3. Administrative support for the IACUC
4. Standard IACUC procedures
5. Arrangements for a veterinarian with authority and responsibility for animals
6. Adequate veterinary care
7. Formal or on-the-job training for personnel that care for or use animals
8. An occupational health and safety program for those who have animal contact
9. Maintenance of animal facilities
10. Provisions for animal care

UNC Animal Care & Use Committee (IACUC) – a committee comprised of at least 5 members who are appointed by the President of the university, and that acts as an advisory board to the Institutional Official and is responsible for overseeing the university’s adherence to all applicable requirements governing the use of vertebrate animals

Animal Use Protocol – the protocol is a written description of a planned research, teaching, or testing activity that involves the use of vertebrate animals. It must provide sufficient detail and documentation to allow members of the IACUC to understand exactly what will be done with/to the animals and why it is necessary; and to determine that the described activities will be conducted in accordance with applicable laws, policies, and regulatory requirements.

Animals – any live vertebrate.

Animal Use – for purposes of this document, animal use refers to the conduct of research, teaching, or testing activities that involve the use of animals in any way.

Animal Welfare Assurance – before issuing a grant or contract for a project that includes the use of animals, the Public Health Service requires the recipient institution and all performance sites involving or using animals to have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). The Assurance must include

1. A commitment that the institution will comply with the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and with the Animal Welfare Act and the Animal Welfare Act Regulations
2. A description of the institution’s program for animal care and use
3. The designation of the Institutional Official responsible for compliance

Complainant – for purposes of this document, complainant refers to an individual who reports a concern or complaint about the way in which animals in the Animal Care and Use Program at UNC are being used or cared for

The Guide – refers to the most current version of the National Research Council publication, *Guide for the Care and Use of Laboratory Animals*, which is intended to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate; and to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles.

Institutional Official (IO) – refers to the formally designated senior official with the authority to administer the Animal Care and Use Program, to allocate the resources necessary to operate the Program, and to make commitments on behalf of the institution to ensure compliance with the Animal Welfare Act Regulations, the Public Health Service Policy, and any other applicable Federal, State, or local laws, policies, and regulations.

Principal Investigator (PI) – refers to the researcher, instructor, or tester who conducts, and/or supervises others who conduct, activities involving animals. Only UNC faculty or staff members serve as PIs. Student investigators may be named as co-investigators, with appropriate direction and supervision provided by the PI.

Non-compliance– refers to the circumstance when animals are used in a manner that is inconsistent with applicable laws, regulations, and/or policies. This includes use of animals beyond the time period specified in the protocol approval. All instances of non-compliance will be reported by the IACUC to the Institutional Official. Some instances might require reporting to other local, state, or federal departments or agencies.

Respondent – for purposes of this document, respondent refers to an individual who is allegedly responsible for the circumstances leading to a reported concern or complaint regarding the care and use of animals, and who may be asked to respond to the complaint.

B. Acronyms

ACUP	Animal Care and Use Program
IACUC	Animal Care and Use Committee
IO	Institutional Official
OLAW	Office of Laboratory Animal Welfare, Office of Extramural Research, U.S. Department of Health and Human Services
APHIS	Animal and Plant Health Inspection Service, U.S. Department of Agriculture
AWA	Animal Welfare Act
AWRs	Animal Welfare Act Regulations

IV. THE INSTITUTIONAL OFFICIAL

The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, which were incorporated into the PHS Policy in 1986, include the first reference to the Institutional Official – “Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:”

Neither the Animal Welfare Regulations nor the PHS Policy specifically prescribes the appointment of an Institutional Official; however the role of the Institutional Official is referred to throughout both documents. The following are just a few of those references:

AWR Section 2.31(c)(3) states that the IACUC shall, “Prepare reports of its evaluations ..., and submit the reports to the Institutional Official of the research facility;” ... “A significant deficiency is one which ... in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.”

AWR Section 2.31(c)(5) states that the IACUC shall, “Make recommendations to the Institutional Official regarding any aspect of the research facility’s animal program, facilities, or personnel training;”

AWR Section 2.31(d)(7) – “If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity;”

PHS Policy Part III.G. defines Institutional Official as “An individual who signs, and has the authority to sign the institution’s Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.”

PHS Policy Part IV.B.3. states that the IACUC shall “prepare reports of the IACUC evaluations conducted as required by ... and submit the reports to the Institutional Official.”

PHS Policy Part IV.F. – “At least once every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW:”

Ultimately, the university is accountable for the humane care and use of animals. The PHS Policy and the AWRs emphasize the responsibilities of an institution’s senior management through an individual designated and the Institutional Official (IO), and the use of the IACUC as an oversight committee to evaluate the Animal Care and Use Program. The IACUC reports directly to the IO who must provide appropriate resources to allow the IACUC to meet its responsibilities. The Attending Veterinarian also reports directly to the IO.

Responsibilities of the Institutional Official

While the institution is responsible for maintaining an Animal Care and Use Program that is in compliance with the PHS Policy and the AWRs, the IO is the individual held responsible on behalf of the institution for ensuring compliance.

Penalties for non-compliance could include OLAW’s withdrawal of the university’s Assurance, which would result in loss of all PHS grant funding (including NIH); and the USDA may impose fines of up to \$10,000 for each violation of the Animal Welfare Act or the AWRs.

The Institutional Official must:

- provide appropriate resources for the Animal Care and Use Program based on the recommendations of the IACUC, the Attending Veterinarian, and the ACUP staff
- define and assign responsibilities and reporting channels for essential program areas such as personnel training, occupational health and safety, and facility maintenance
- sign as the individual responsible for animal welfare at UNC, and submit required IACUC reports to OLAW and APHIS

The Provost has been designated by the President to serve as the Institutional Official for UNC's Animal Care and Use Program.

The IO meets on a regularly scheduled basis with the IACUC Chair to ensure that the program and facilities meet the highest possible standards for animal care and use, and that any identified deficiencies are corrected in a timely fashion.

V. THE INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

AWRs – Section 2.31 (a): The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility’s animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility.

(b) IACUC membership.

(1) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility;

(2) The Committee shall be composed of a Chairman and at least two additional members;

(3) Of the members of the Committee:

(i) At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility;

(ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;

(4) If the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility.

PHS Policy – Part IV.3. – Institutional Care and Use Committee (IACUC)

a. The Chief Executive Officer shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution’s animal program, facilities, and procedures.

b. The Assurance must include the names, position titles, and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:

(1) one 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) one practicing scientist experienced in research involving animals;

(3) one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and

(4) one individual 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.

c. An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b.(1)-(4) of this policy may fulfill more than one requirement. However, no committee may consist of less than five members.

The UNC Institutional Animal Care and Use Committee (IACUC) serves as an advisory body to the university’s Institutional Official, and acts to facilitate research that serves the mission and values of the university; to protect the health and safety of animals and humans involved in animal research, teaching and testing; and to ensure compliance with applicable laws, regulations, and policies governing the use of vertebrate animals in such activities.

A. IACUC Roles and Responsibilities

The IACUC is responsible for reviewing all research, teaching, or testing activities in which animals are used as research subjects. IACUC oversight covers all use of live vertebrate animals

by UNC personnel whether in UNC facilities, at other institutions, or in the wild as a part of field research. The IACUC is responsible for reviewing and approving all animal use prior to the start of the work, and for continuing oversight of approved projects. The IACUC conducts an annual review of each approved protocol, and if a project is continuing, requires submission of a new protocol every three years to comply with PHS policy as well as to vigilantly oversee the use of animals.

Not only is the IACUC responsible for ensuring that the protocols conform to acceptable standards and meet regulatory requirements, it also ensures that the animal care program is in compliance. In this regard, the IACUC undertakes semi-annual program reviews and facilities inspections. This includes review and oversight of the activities of the Animal Care and Use Program Office as well as a review of animal care policies and procedures to ensure continued adherence to the highest standards of animal care and use. The results of these reviews are communicated to the Institutional Official for his/her consideration and action. Additionally, they form the basis for the required annual reporting to OLAW and USDA.

As part of its charge, the IACUC is expected to oversee the ACUP on a continual basis and to report problems to the Institutional Official.

The IACUC's many responsibilities can be summarized under the following general areas:

- Review the university's program for the humane care and use of animals at least every six months.
- Prior to commencement of animal work and at least every six months, inspect all of the University's animal facilities, including all locations in which animals are housed and/or manipulated.
- Prepare reports of program reviews and facility inspections that identify minor and significant deficiencies and that include a plan and schedule for correcting each noted deficiency.
- Review and investigate reported concerns involving the care and use of animals and reports of noncompliance received from laboratory or research facility personnel or employees.
- Make recommendations to the Institutional Official regarding any aspect of the animal program, facilities, or personnel training.
- Review and approve or disapprove those components of proposed activities, or modifications to previously approved activities, related to the care and use of animals, including post-approval monitoring of approved activities.
- Suspend activities involving animals they are not being conducted according to an approved protocol, applicable laws, regulations, and/or policies.
- Prepare and submit required reports to Federal regulating agencies.

B. IACUC Membership

The composition of the UNC IACUC will be in accordance with the combined requirements of the PHS Policy and the USDA regulations. The size of the IACUC will be at the discretion of the

Institutional Official; but at a minimum, will always include no less than five members, and include at least one of the following required members:

1. a doctor of Veterinary Medicine, with training or experience in laboratory animal sciences and medicine, and who has direct or delegated program responsibility for activities involving animals at the institution
2. a practicing scientist experienced in research involving animals
3. a member whose primary concerns are in a nonscientific area
4. an individual 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) to represent community interests and concerns
5. a chairperson

In accordance with the Animal Welfare Act Regulations, the IACUC will not include more than three members of the same school or administrative division of the University.

C. IACUC Appointments

As required by the Animal Welfare Act and the Health Research Extension Act, the University of Northern Colorado President, acting as CEO, appoints the Chairperson and the members of the IACUC, and has designated the Provost as the Institutional Official.

Based upon the recommendations of the Institutional Official and the IACUC Chair, UNC's President appoints all members and alternate members of the IACUC.

1. Chairperson:

a. Appointment:

The chairperson is appointed to serve a term of three years. The appointment may be renewed in the event there is not a vice chairperson prepared to move into the position of chairperson.

b. Qualifications: The chairperson should:

- be a full-time, tenured faculty member; however, if there is no qualified tenured faculty member available to serve as chair, the President may choose to appoint an otherwise qualified faculty or administrative staff member
- have prior experience on an IACUC
- have attended an IACUC training event such as the Annual PRIM&R IACUC Conference within three years prior to appointment as chair

c. Responsibilities: The chairperson:

- consults with the Institutional Official to recommend membership changes to the President
- consults with the Institutional Official to make recommendations to the President for the vice-chair position
- advises the Institutional Official on matters relating to support for the IACUC
- establishes the agenda for IACUC meetings

- convenes and chairs meetings or designates an acting chair if both the chairperson and vice-chairperson are unable to attend meetings
- guides IACUC deliberations
- leads the IACUC in investigations of complaints and allegations of non-compliance
- issues official communications regarding IACUC decisions and concerns to the Institutional Official, researchers, program staff, and the Attending Veterinarian as applicable
- acts as spokesperson on behalf of the IACUC

2. Vice Chairperson

a. Appointment:

The vice chairperson is appointed to serve a term of three years. If, for any reason a chairperson is not able to serve his/her full three-year term, the vice chairperson completes the remaining time on that term or until a new chair is appointed.

b. Qualifications: The vice chairperson:

- is a full-time faculty member or other qualified staff member.
- has served on the IACUC for at least one year
- attends some formal training such as the Annual PRIM&R IACUC Conference, preferably during the first year of term as vice-chair

c. Responsibilities: The vice chairperson:

- in the absence of the IACUC chairperson, the vice chairperson:
 - serves as chairperson at convened IACUC meetings
 - attends administrative meetings upon request
 - acts as chairperson in any situation where it is a conflict of interest for the chair to perform his/her duties

3. Attending Veterinarian with Program Authority

Not having a veterinary college, UNC contracts with a Doctor of Veterinary Medicine who is experienced in laboratory animal science to serve as the ACUP Attending Veterinarian and to fill the required veterinarian position on the IACUC.

a. Appointment:

The Attending Veterinarian (AV) is appointed to serve a four year term with unlimited reappointments. An independent contractor agreement is generated annually to compensate the veterinarian for his/her services.

b. Qualifications: To fulfill the PHS and USDA requirements, the AV:

- has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or
- has received a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or
- has received equivalent formal education as determined by USDA

- is experienced or has received training in the care and management of species being attended; and
 - has been given direct or delegated authority for activities involving animals at UNC
- c. Responsibilities: Regarding his/her role on the IACUC, the veterinarian has the same responsibilities as other members of the IACUC in addition to the following:
- conducts a preliminary review of all new protocols, third-year resubmission protocols, and such other protocol actions as the chairperson may request for the purpose of identifying problems and working with investigators to resolve concerns prior to distribution of protocols to the full committee

4. Voting Committee Members

- a. Appointments:
- Other voting members of the IACUC are appointed to serve 3 year terms. b. Qualifications:
 - The individual(s) appointed to fill the role of scientist are practicing scientists experienced in research involving laboratory animals.
 - The individual(s) appointed to fill the role of unaffiliated member are not affiliated with UNC in any way other than as a member of the IACUC, and are not a member of the immediate family of a person who is affiliated with the university
 - The individual(s) appointed to fill the role of non-scientist bring a non-scientific perspective on the use of animals for laboratory research to the committee
- c. Responsibilities:
- Attend regularly scheduled IACUC meetings
 - Notify the IACUC Administrator and the alternate member if attendance at a meeting is not possible
 - Read all protocols distributed to committee members
 - Review and respond in a timely manner regarding assigned protocols
 - Attend and participate actively in program reviews and facilities inspections
 - Participate in investigations of complaints and allegations of non-compliance, as requested
 - Lead and/or participate in subcommittees, as requested
 - Participate annually in IACUC-approved documented training

5. Alternate Committee Members

It is UNC's policy to appoint an alternate IACUC member for every regular voting member of the committee whenever possible. Each alternate member is appointed to represent one or more voting member/s. An alternate member must be qualified to fill the same role on the committee as the voting member he/she represents. An alternate member has only one vote and may be counted toward a quorum only once, regardless of the number of voting members he/she may represent. The alternate members vote counts only if they do not exceed the "3 from each unit" rule. Alternate members are encouraged to participate in

all IACUC activities, but vote only when the regular members they represent are absent. An IACUC member and his/her alternate do not count toward a quorum or act in any official capacity at the same time. The alternate to the IACUC Chair votes for the Chair in his absence, but does not run the meeting.

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a. Appointments:

Alternate members are appointed to the IACUC following the same procedures for appointment of regular voting members.

b. Qualifications:

Alternate members have the same qualifications as the regular members for whom they serve as the alternate.

c. Responsibilities:

Alternate members are responsible for performing any duties of the regular voting members they represent when the regular voting members are absent or have a conflict of interest.

6. Ad Hoc Members

Non-voting attendees may be invited to participate in IACUC functions. Examples of such attendees include, but are not limited to, representatives from Building Trades, Environmental Health & Safety, or University Counsel.

7. Consultants

The IACUC may choose to invite internal or external consultants to assist in its duties. Such consultants cannot vote, but can provide expert opinion on issues before the committee.

8. Removal of Members from the Committee

The President of the university is the only individual authorized to remove a member of the IACUC from the committee; however, the IACUC may recommend removal of any IACUC member it determines is not responsibly fulfilling his/her duties.

Reasons for removal may include:

- Repeated failure to attend IACUC meetings
- Failure to complete training *activities*
- Repeated failure to complete assigned projects in a timely manner

D. IACUC Meetings

The IACUC meets at least once every 6 months, and a schedule is maintained by the IACUC Administrator, which includes meeting dates, protocol review and annual review submission. The chair may call special meetings as needed.

Principal Investigators or their representatives are encouraged to attend meetings at which their protocols are being reviewed in order to answer any questions and resolve concerns of IACUC members regarding the protocols.

VI. PROGRAM REVIEW & INSPECTION OF ANIMAL FACILITIES

AWRs Section 2.31(c)(1) – The IACUC shall, “Review, at least every six months, the research facility’s program for humane care and use of animals, using title 9, chapter I, subchapter A – Animal Welfare, as a basis for evaluation;”

AWRs Section 2.31(c)(2) – the IACUC shall, “Inspect, at least once every six months, all of the research facility’s animal facilities, including animal study areas, using title 9, chapter I, subchapter A – Animal Welfare, as a basis for evaluation; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection:”

AWRs Section 2.31(c)(3) – the IACUC shall “Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility’s programs and facilities; and Provided further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility’s adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, 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 with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;”

PHS Policy Part IV.B.1. – the IACUC shall, “review at least once every six months the institution’s program for humane care and use of animals, using the Guide as a basis for evaluation;

PHS Policy Part IV.B.2. – the IACUC shall, “inspect at least once every six months all of the institution’s animal facilities (including satellite facilities) using the Guide as a basis for evaluation.

PHS Policy Part IV.B.3. – the IACUC shall, “prepare reports of the IACUC evaluations conducted as required by IV.B.1. and 2. of this Policy, and submit the reports to the Institutional Official;(NOTE: The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OLAW upon request. The reports must contain a description of the nature and extent of the institution’s adherence to the Guide and this Policy and must identify specifically any departures from the provisions of the Guide and this Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, 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 institution’s facilities are accredited by AAALAC International or another accrediting body recognized by PHS, the report should identify those facilities as such.)

At least every six months the UNC IACUC conducts a review of the university’s Animal Care and Use Program and inspects all facilities where animals are manipulated or housed for more than 12 hours using AWA and/or The Guide as a basis for evaluation.

A. Semi-annual Program Reviews

The semi-annual reviews of the University's Animal Care and Use Program are conducted during scheduled IACUC meetings, and are led by the Chair of the IACUC. Prior to a scheduled review, all members of the IACUC are provided with the ACUP Review Form so that they may note any concerns they may have regarding the program and be prepared to discuss them during the review.

The program review is started by presenting the status of deficiencies noted in the previous review. All members of the IACUC are encouraged to participate in the reviews and to voice their opinions.

Key aspects of the ACUP covered in the reviews include:

- IACUC membership, functions, and procedures
- IACUC records and reporting
- Personnel qualifications and training
- Occupational health and safety of personnel
- Veterinary care
- Veterinary medical care
 - Preventive medicine and animal procurement and transportation
 - Surgery
 - Pain, distress, analgesia, and anesthesia
 - Euthanasia
 - Drug storage and control

B. Facility Inspections

The IACUC inspects the central Animal Research Facility, as well as any area where animals are manipulated or housed for periods longer than 12 hours. Investigators are responsible for informing the IACUC of all areas where manipulations are performed or animals housed as stated in their approved protocol. An updated list of all areas requiring inspection is maintained by the IACUC Administrator.

Inspection teams include at least two members of the IACUC, usually the attending veterinarian and at least one additional IACUC member.

The inspection schedules will be announced by email to all committee members, and no member will be excluded from an inspection should he/she want to participate. All members of the IACUC are encouraged to participate in inspections and to express their opinions.

At least one week prior to scheduled inspections, the IACUC Administrator will provide members of inspection teams with lists of the facilities they are to inspect, including room number, function of the room, species, and any deficiencies identified during the previous inspection and the current status of those deficiencies.

Following the AWRs and the *Guide*, inspection teams review each area for issues such as general cleanliness, proper storage of food, proper storage of drugs, proper disposal of animal waste, lack of clutter, and conditions that pose a threat to the wellbeing of animals (e.g.,

storage of flammable or toxic substances next to animal cages). The teams also determine whether surgical procedures are performed using proper aseptic techniques (e.g., use of gloves, masks, sterile instruments, isolated area for surgery) as required, whether the areas where the animals are maintained satisfy the criteria for sanitation and impervious surfaces, and whether animals are being housed outside of approved housing facilities.

In addition to inspecting the facilities, inspection teams may question the ACUP Manager or PIs and members of their research teams about the standards of animal care and use, the specific procedures being performed (e.g., means of euthanasia, pain/distress experienced by the animals, or the training and qualifications of persons handling the animals) and the content of the approved protocol. All members of the research team should be familiar with their protocols, and PIs are to have copies their approved protocols readily available as reference tools in their laboratories. The IACUC Administrator will maintain copies of approved protocols in the Animal Research Facility.

Each team completes an inspection form and indicates, by room, any deficiencies that are identified, providing a detailed description of each deficiency and designating it as minor or significant. The completed inspection forms are then submitted to the IACUC Administrator who prepares a report for review by the full committee at the next scheduled meeting.

VI. REVIEWING REPORTED COMPLAINTS AND CONCERNS

Section 2.31 (c)(4) of the AWRs states that the IACUC must “review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees.”

Part IV.B.4. of the PHS Policy states that the IACUC must “review concerns involving the care and use of animals at the institution.”

Consistent with its commitment to humane animal care and use, the university encourages anyone who perceives a problem with the way in which animals are housed, handled, or used in research, teaching, or testing to report concerns to the IACUC. Concerns may be reported directly to the IACUC or a complainant may choose to discuss his/her concerns with the individual's supervisor, the Director of Compliance and Operations, the Attending Veterinarian, the Institutional Official, the IACUC Chair, or the department's IACUC members or chairs that will forward them to the IACUC. The mechanism for reporting concerns to the IACUC are posted in the animal facility and available on the IACUC website. Anonymous concerns are accepted and can be sent to IACUC at Campus Box 110.

The Institutional Animal Care and Use Committee (IACUC) reviews all reported concerns regarding the care and use of animals. UNC takes all reasonable steps to ensure that no one reporting a complaint is discriminated against or subjected to any reprisal. Complainants are treated with fairness and respect, and when an allegation has been made in good faith, reasonable steps are taken to protect the position, confidentiality, and reputation of the complainant.

Issues that may lead to reported concerns or complaints include, but are not limited to:

- neglect of or cruelty to animals
- conduct of activities involving animals without an IACUC approved Animal Use Protocol
- conduct of activities involving animals other than as described in an approved animal use protocol
- continuing to engage in approved protocol activities beyond the approved time period specified in a protocol
- inadequate record keeping
- conduct of activities involving animals by inadequately trained personnel
- conduct of activities involving animals by personnel not approved by the IACUC
- Or other infractions of university or regulatory policies or procedures

A. Publicizing Procedures for Reporting Concerns

Signs are posted in all animal facilities and study areas clearly explaining the policy and procedures for reporting complaints related to the use of animals at the University of Northern Colorado.

1. The IACUC Administrator is responsible for posting signs in the primary animal research facility and any satellite facilities that are not under the direct supervision of an investigator.
2. Investigators and instructors are responsible for posting signs in rooms where animals undergo any manipulation, where animals are housed for periods of 12 hours or longer, or where animals are used for teaching or demonstration purposes.
3. The IACUC Administrator is responsible for updating signs when necessary, and distributing copies of current signs to all individuals responsible for posting.

B. Procedures for Reporting Concerns

1. Anonymity

- a. Concerns may be reported anonymously.
- b. The Institutional Official, members of the IACUC, Animal Program staff members, and animal researchers are informed of the need to protect a complainant's anonymity.
- c. Complainants are to be informed that investigation procedures are made part of IACUC meeting minutes and any reports submitted by the IACUC to government agencies (USDA, PHS, etc); that these documents may be made public under the Freedom of Information Act and/or CORA.

2. Submitting Concerns

- a. Concerns may be submitted to any member of the IACUC.
- b. Concerns may be submitted in writing; however, if a concern is submitted verbally, the complainant must specify that he/she is requesting an investigation, and the person receiving the concern should attempt to gather as much information as possible in order to put it into a detailed written description. At a minimum, the concern should identify:

- individual(s) against whom the concern is directed, if known
 - the alleged misconduct
 - evidence that would allow the IACUC to determine if the complaint warrants further investigation to support allegations
 - names and contact information for any additional persons, if any, who are capable of providing supporting information.
- c. A concern may be returned to the submitter for clarification if the IACUC determines it does not provide adequate information. A concern returned for clarification must be resubmitted within 10 days..
- d. Investigators are informed that a concern has been submitted and there will be follow up with the IACUC.

C. Review of Reported Complaints

1. Conflict of Interest

If a concern is submitted against an IACUC member, that member recues him/herself from all proceedings concerning that complaint. If the subject of a complaint is the Chair of the IACUC, the Vice Chair will act as Chair during review of the complaint

2. Initial Review

Concerns of possible misuse or harm to animals or non-compliance should be brought to the attention of the IACUC. The Chair and the Attending Veterinarian conduct an initial review to determine two points. First, are animals at risk if the activities in which they are involved are allowed to continue? Second, does the assertion have merit to require further investigation?

To answer these questions the Chair and AV may elect to:

- interview the complainant
- interview the subject of the complaint and others who may have knowledge of the circumstances of the complaint
- examine research records on the protocol involved in the complaint
- inspect research facilities and equipment related to the complaint

This initial investigation is to take place within three days of receiving the initial complaint. The IACUC Chair or AV may temporarily suspend the animal use if the initial investigation uncovers information supportive of possible immediate harm to animals. Procedures for suspending animal activities are presented in Part VII of these guidelines.

Following the initial investigation a description of the concern and a description of the findings from the investigation are submitted to the IACUC for review at the next regularly scheduled meeting. The respondent and any other individuals known to have relevant information may be invited to present information to the committee. If the IACUC determines that further investigation of a complaint is needed, the Chair appoints an investigating team consisting of no less than two IACUC members.

Investigating a Concern: Within 28 days of commencing the investigation, the investigating committee concludes the investigation and prepares a written report that:

- summarizes the nature of the complaint or dispute
- summarizes steps taken during the course of the investigation
- states whether there has been a violation of an approved protocol, university or ACUP policies/procedures, the governing federal regulations/policies, or any pertinent state or local law

Where appropriate and feasible, all relevant documents and other materials supporting the findings of fact are reviewed during the course of the investigation are attached to the report. The report draws no conclusions regarding the lawfulness of conduct giving rise to or involved in the complaint.

The investigation report is submitted to the IACUC Chair for review by the IACUC

Following IACUC review one of the following actions takes place:

a. The protocol is allowed to continue.

This action is taken when the IACUC determines there is no concern of noncompliance. Written notice of the decision is sent by the Chair to the investigator, the complainant, and the IO stating that the IACUC determined there was no merit to the complaint.

b. The protocol is suspended pending corrective action

This action is taken only when a quorum of the IACUC determines by a majority vote that animal health or welfare is or may be in danger or that activities are being conducted that are not compliant with an approved protocol, but that corrective action could be implemented to resolve the problem(s).

Written notice of a vote to suspend is immediately sent by the Chair to the respondent, the respondent's Director and Dean, and to the IO stating that:

- i. the protocol is immediately suspended and the specific reason(s) for the suspension;
- ii. all work other than routine daily animal care is stopped;
- iii. all animals are being transferred to a holding protocol pending corrective action; and
- iv. within two weeks the investigator will be notified of the corrective action that will be required to reinstate the protocol.

Following a suspension, the IACUC informs the IO to review the reasons for suspension and to appropriate corrective action. Within two weeks of the notice of suspension, the Chair notifies the respondent of the required corrective action, and the schedule for completing it, to seek reinstatement of protocol approval. If corrective action is not completed by the scheduled dates, the protocol will be terminated.

The Chair prepares a report of the suspension, describing a full explanation of events from the time the complaint was received, and explaining the reasons for suspension and the corrective action taken. The report is submitted by the Institutional Official to the USDA APHIS if USDA covered species were involved, to the PHS if the suspended

activities were supported by PHS funding, and/or to any Federal agency funding the activities.

c. The committee may review and respond to the Institutional Official with concerns regarding animal care and use at UNC.

VIII. SUSPENDING ANIMAL ACTIVITIES

Section 2.31 (c)(8) of the AWRs states that the IACUC is to “be authorized to suspend an activity involving animals in accordance with the specifications set forth in paragraph (d)(6) of this section.

Section 2.31 (d)(6) states that “The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

Part IV.B.8 of the PHS Policy states that the IACUC is to “be authorized to suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy.”

Part IV.C.6. states that “the IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution’s Assurance, or IV.C.1.a.-g. of this Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.”

Although rare, a suspension of animal use may be necessary when evidence exists that harm has occurred, or is believed likely to occur, to an animal being used in a research, teaching, or testing activity; or that animal activity is being conducted that is not in compliance with an approved protocol, with the AWRs, or the PH Policy. In such circumstances, and when the Chair or AV determine (through the process described in Part VI.2.), there is probable concern for the immediate welfare of animals, the IACUC, through this policy, authorizes the Chair to temporarily suspend animal use. In cases of animal welfare issues, the AV is authorized to temporarily suspend the use of animals.

If there is a suspension issued by the Chair or AV as outlined in this policy, the matter is referred to the full committee at the next regularly scheduled meeting. .

A full suspension by the IACUC is imposed only after review of the issue at a convened meeting of a quorum of the full committee with a vote for suspension by a majority of the members present.

During a suspension of a protocol, activities involving animals are stopped, and the routine care and maintenance of the animals continues to be the responsibility of those same individuals who were responsible prior to the suspension, unless it was deficiencies in the routine care and maintenance that caused the suspension, in which case the IACUC Administrator, the Attending Veterinarian, or the person designated by the Chair take over animal care.

When a protocol is suspended, no further research or activities involving animals may be undertaken. The investigator has 30 days from the date of the the suspension to determine disposition of the animals, during which time the routine care and maintenance of the animals is taken over by the ACUP manager and the Attending Veterinarian or their designees. If animals' disposition has not been determined after 30 days, the ACUP manager and/or the Attending Veterinarian perform or oversee euthanizing or other disposition of the remaining

animals, and the investigator is charged a per animal or per cage fee based on current standard rates for like animals. The IO and appropriate funding agencies are then notified.

IX. RECOMMENDATIONS TO THE INSTITUTIONAL OFFICIAL

Section 2.31 (c)(5) of the AWRs and Part IV.B.5. of the PHS Policy state that the IACUC is to “make recommendations to the Institutional Official regarding any aspect of the research facility’s animal program, facilities, or personnel training.”

The Chair of the IACUC meets with the Institutional Official at least once every six months to discuss issues of concern regarding the Animal Care and Use Program and to review the status of the IACUC’s recommendations included in the semi-annual program reviews and facility inspection reports. The chair will provide a written report to the committee regarding the meeting with the IO.

The Attending Veterinarian reports directly to the IO any problems he/she has identified with the health, safety, or veterinary care of the animals, making recommendations for corrections and improvements.

X. ANIMAL USE PROTOCOL SUBMISSION AND REVIEW

Section 2.31(d) of the AWRs states that “In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; provided, however, that field studies as defined in part 1 of this subchapter are exempt from this requirement.”

Parts IV.B.5 and 6 of the PHS Policy state that it is a function of the IACUC to “review and approve, require modifications in (to secure approval), or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals as specified in IV.C. of this Policy” and to “review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities”.

UNC IACUC approval is required prior to beginning research, teaching, or testing activities that involve animals and that are supported by UNC. When UNC Investigators perform such activities at, or under the jurisdiction of, another institution, the UNC IACUC accepts the approved animal use protocol from the other institution if (1) the work of the UNC Investigator is described in the protocol and (2) the other institution has an approved OLAW Assurance and is a registered USDA facility.

The IACUC reviews those components of activities related to the care and use of animals to determine that the proposed activities are in compliance with the AWA, the AWRs, the PHS Policy, the NIH *Guide*, and applicable UNC policies and procedures.

Protocols must include a complete description of the proposed use of the animals; and, unless a protocol includes an acceptable justification for a departure from any of the following, it must demonstrate to the IACUC that the proposed activities will meet all of these requirements:

- Procedures involving animals are designed and performed with due consideration of their scientific relevance to human or animal health, the advancement of knowledge, or the good of society
- The investigator certifies in writing that the proposed activities do not unnecessarily duplicate work that has been accomplished previously by the investigator or any other individual(s).
- There is an adequate rationale for using animals to conduct the proposed activities.
- The animals selected for use are of an appropriate species and quality, and the minimum number of animals will be used, to obtain valid results.
- Procedures using animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.
- The investigator has searched for alternatives to procedures that will or may cause more than momentary or slight pain or distress to the animals; and if no alternatives are available or appropriate, those procedures will be performed with appropriate sedation, analgesia, or anesthesia unless there is a justifiable scientific reason for withholding relief.

- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- Methods of euthanasia will be consistent with current recommendations of the AVMA Panel on Euthanasia unless a deviation is justified for scientific reasons.
- The animals' living conditions will be appropriate for their species and will contribute to their health and comfort.
- The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species.
- Veterinary medical care for the animals will be available and provided as necessary by a qualified veterinarian.
- Investigators and other personnel conducting procedures on the animals will be appropriately qualified and experienced for conducting those procedures.
- Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques.
- Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose and which will be operated and maintained under aseptic conditions. Surgery on rodents, non-major operative procedures, and operative procedures conducted at field sites will be performed using aseptic procedures.
- No animal will be used in more than one major operative procedure from which it is allowed to recover unless it is justified for scientific reasons; it is required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or there are other special circumstances that have been determined to be necessary by the Regional Administrator of USDA APHIS for the specific protocol.

B. Protocol Submission Dates

An annual calendar of IACUC meeting dates is posted on the UNC IACUC website at the beginning of each academic year. Most protocols that are received at least two weeks before a scheduled meeting date are reviewed at that meeting. *However, if a protocol involves complex or controversial procedures, the investigator should consult with the IACUC Administrator who helps to determine if additional lead time is necessary.* Investigators should also be aware that protocols going through Designated Member Review may be returned by the reviewers for Full Committee Review, possibly delaying the review and approval process.

While the IACUC makes every effort to review protocol applications to meet the investigators' needs, it does not guarantee that protocols will be reviewed. PIs are encouraged to submit protocols as early as possible to avoid delays in starting their work.

C. Protocol Submission Process

1. New protocols, renewal protocols, and requests to make significant changes to previously approved protocols, must be submitted for IACUC review and approval.
2. The PI completes the current version of the appropriate Animal Use Protocol Application or Protocol Modification form and all applicable appendices. All forms are available on the UNC IACUC website.
3. The completed protocol is submitted to the IACUC Administrator who then sends the protocol to the AV for a veterinary review. Prior to submission to the IACUC, every protocol must be reviewed by the AV. It is the PI's responsibility to schedule a veterinary consultation that allows time for any necessary revisions, submission to the IACUC, and review and approval before work is started.
4. A completed protocol is submitted, as an email attachment, to the IACUC Administrator who records the date the protocol was received. The IACUC Administrator reviews the protocol for completeness and to determine the appropriate procedure for review and approval. If the protocol is incomplete, the IACUC Administrator notifies the PI by email, noting the deficiencies. A copy of the notice is maintained in the protocol file.
5. The IACUC Administrator submits the protocol to the AV for a veterinary review. The PI is informed if there are any veterinary issues that need to be addressed before the protocol is sent out to the full committee for review. Once those areas are addressed the protocol is sent to the full committee for review.
6. If the PI does not return a revised protocol to the IACUC Administrator at least two weeks prior to a scheduled IACUC meeting, it is not reviewed until the next scheduled meeting.
- 6.

D. Protocol Review Categories

The PHS Policy and the AWRs permit only two methods of IACUC review and approval of animal use protocols – convened meeting of the IACUC and designated review in lieu of a convened meeting.

1. **UNC Designated Member Review (DMR)**

UNC's Designated Member Review process is used when:

- the pain category for the protocol is B or C. Some category D protocols may go to Designated Member Review providing they do not have the potential to become a category E protocol. The Chair will make a decision on Category D protocols.

- each IACUC member is provided with a copy of the protocol and given the opportunity to request a full committee review within the time allotted by the IACUC Chair (minimum of 3 business days)

- no member requests full committee review

- a. If, after a protocol is submitted, the IACUC Administrator determines that the protocol's appropriate USDA pain and distress category is B or C, he/she immediately distributes the protocol, as an email attachment, to all members of the IACUC, notifying them (i) that the protocol is eligible for DMR, (ii) that if they wish to call for a full committee review of the protocol, they must reply by email with that request within the time period specified by the IACUC Administrator (not to be less than three (3) business days), of the date of the email notification, and (iii) that any member not responding within the specified time period will be considered a no call for full committee review.

The Attending Veterinarian informs the IACUC Administrator of any questions/concerns he/she may have.

- b. If any member of the IACUC calls for a full committee review within the specified time period, the protocol review process will change from DMR to Full Committee Review (see part 2, below).
- c. If no member of the IACUC calls for a full committee review within the specified time period, the IACUC Administrator immediately notifies the IACUC Chair who appoints one or more qualified members of the IACUC to serve as Designated Reviewer(s) (DRs).
- d. The IACUC Administrator notifies the DR(s) appointed by the Chair, sending each of them (i) a complete copy of the protocol with attachments, (ii) an explanation of any concerns expressed by the AV, and (iii) a protocol review checklist.
- e. DRs are encouraged to communicate with each other regarding any aspect of the protocol; they may seek advice of the Attending Veterinarian other IACUC members, and they may seek advice outside of the IACUC but must not reveal the PI's identity. A DR may contact the PI directly if he/she wishes; however, under no circumstances does the DR indicate to the PI the status of the review.
- f. DRs are authorized to (i) approve the protocol or (ii) require modification to secure approval, which must be communicated by e-mail to all DR's, or (iii) return the protocol for full committee review.
- g. If there are two or more DRs, they must all agree on the action taken. If they cannot agree, the protocol must be returned for full committee review.
- h. DR(s) complete their review of the protocol within five (5) business days of the date of notification by the IACUC Administrator. Each DR returns a completed protocol review checklist to the IACUC Administrator by email, indicating on the checklist his/her decision to approve the protocol or to return the protocol for FCR.

2. UNC Full Committee Review (FCR)

Protocols that are not eligible for DMR or that receive a request for full committee review must be reviewed at a convened meeting of the IACUC with a quorum present. Protocols require full committee review if:

- the proposed activities may involve accompanying pain or distress to the animals that will be relieved by appropriate use of sedatives, analgesics or anesthetics (USDA pain and distress category D) that has the potential for becoming a category E, or they may involve accompanying pain or distress to the animals for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the research, teaching or testing results, and, therefore would not be administered (USDA pain and distress category E);
-

a. FCR Preliminary Review

- i. If, after a protocol is submitted, the IACUC Administrator determines that the protocol falls under USDA pain and distress category D or E, he/she notifies the IACUC Chair and sends him/her a copy of the protocol. The IACUC Administrator notifies the Attending Veterinarian (AV) and sends him/her a copy of the complete protocol and all attachments by email.
- ii. The IACUC Chair selects one member of the IACUC to serve as lead reviewer (LR) on the protocol, and informs the IACUC Administrator who then notifies the LR on behalf of the Chair, sending a complete copy of the protocol and all attachments.
- vi. The IACUC Administrator emails a copy of the protocol to each member of the IACUC with attachments, and a protocol review checklist.
- vii. Prior to the scheduled meeting, IACUC members may contact the IACUC Administrator or the AV with questions/concerns about the protocol.
- vii. The IACUC Administrator notifies the PI of the date and time that the IACUC will review his/her protocol and invites him/her to be present to respond to the committee's questions and concerns following their initial discussion of the protocol.

b. FCR Final Review

- i. All protocols requiring Full Committee Review are brought before the committee at a convened IACUC meeting.
- ii. If the PI is a member of the IACUC, he/she leaves the meeting during the initial discussion of the protocol. Any other member of the IACUC with a conflict of interest concerning the protocol also leaves the meeting during deliberations and voting.
- iii. The lead reviewer presents an overview of the protocol, and the AV presents a summary of his/her preliminary review, explaining any unresolved concerns.
- iv. Following initial discussion by the IACUC, if there are remaining concerns or questions, and if the PI is available, he/she is invited into the meeting to respond. The PI leaves the meeting after addressing the committee's questions and before a vote is called.

- v. If a quorum remains after final deliberations, the Chair calls for a motion. Committee members who have temporarily left the meeting due to a conflict of interest are not counted in the quorum.
- vi. If a quorum is not present for a vote, action on the protocol is deferred. If a quorum is present, the chair calls for a motion. The only allowable actions are to:
 - Approve the protocol as submitted – all review criteria, based on the PHS Policy and the AWRs have been adequately addressed in the protocol, and no revision is required for approval; OR
 - Require modification to secure approval - the protocol is approvable contingent upon receipt of a very specific modification (e.g., receipt of assurance that a procedure will be conducted in a fume hood), or clarification of a specific point. Any motion to require modification to secure approval states that a revised protocol addressing the requested modifications will be reviewed by Designated Reviewers; OR
 - Withhold approval – the protocol has not adequately addressed all of the requirements of the PHS Policy and the AWRs as applicable. Any motion to withhold approval states specifically the reason(s) for doing so; OR
 - Defer the review – the protocol requires substantial clarification, the IACUC wishes to seek additional expertise, or some other reason prevents the IACUC from making a judgment on the protocol. Any motion to defer review states specifically the reason(s) for doing so.
- vii. For a motion to pass, a majority of the members present for the vote must vote in favor of the motion. *For reasons other than conflict of interest*, abstentions from voting do not alter the quorum or change the number of votes required to pass a motion.

Example: A seven member IACUC has only four members present to vote. Those four members make up the required quorum, and it takes a majority of three of those members to pass the motion. If one of the four abstains from voting, it does not alter the quorum and the vote can go ahead; however, although only three members are voting, the majority of three votes is required in order to pass the motion. If that member must recues themselves from the vote, they do not count towards the quorum, and because there are only three members present, no action can be taken.

E. Follow-up to Review & Approval

1. Follow-up to Designated Member Review

- a. Within three business days of protocol approval by DMR, the IACUC Administrator assigns a permanent protocol number, logs the date of approval, and emails an approval letter to the PI. The IACUC administrator prints a final copy and obtains signatures of the

PI, Chair, Veterinarian, and ACUP Manager. The original signed copy is kept in the IACUC office, a copy is given to the PI, and a copy is placed in the appropriate housing rooms. It is recommended that the PI maintain a complete, current copy of the approved protocol in any applicable study area(s). and for ensuring that students and others under his supervision who work with the animals have read and understand the protocol and know where to locate a copy for reference if needed.

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- b. When DRs do not approve a protocol within the allocated review period, the IACUC Administrator immediately notifies the PI that the protocol has been returned from DMR and will be sent through full committee review.
- c.

2. Follow-up to Full Committee Review

- a. Follow-up to Approval: Within three business days of protocol approval by FCR, the IACUC Administrator assigns a permanent protocol number to the protocol, logs the date of approval, and emails an approval letter to the PI. The IACUC administrator prints a final copy and obtains the signatures of the PI, Chair, Veterinarian, and ACUP Manager. The original signed copy is kept in the IACUC office, a copy is given to the PI, and a copy is placed in the appropriate housing rooms.
- b. Follow-up to Require Modifications to Secure Approval: Within three business days of the IACUC's vote to require modifications to secure approval of a protocol, the IACUC Administrator prepares a clear description of the specific modifications requested by the IACUC and emails it to the Chair and the Investigator

The PI submits a revised protocol that addresses the modifications requested by the IACUC to the IACUC Administrator, and review process, Designated or Full Committee, begins as stated in the IACUC's motion to require modifications

- c. Follow-up to Withholding Approval: Within three business days of the IACUC's vote to withhold approval of a protocol, the IACUC Administrator prepares a clear statement of the specific reasons for the IACUC's decision and emails it to the Chair and the PI, inviting the PI to respond to the IACUC's decision in writing, or in person at the next scheduled IACUC meeting. The Chair notifies the IO in writing of any decision to withhold approval of a protocol, including the reasons for doing so.

If the PI chooses to respond, the IACUC reviews his/her response and any additional information submitted by the Investigator at the next scheduled IACUC meeting. The committee may reconsider its decision in light of information provided by the Investigator. The committee's deliberations and any vote to change a decision to withhold approval are documented in the minutes of the meeting.

XI. RECORDKEEPING

The regulatory requirements for IACUC recordkeeping are referred to throughout the Animal Welfare Act Regulations and the Public Health Policy. Specific references are provided in the narrative below.

A. IACUC Meeting Minutes

Section 2.35 (a)(1) of the AWRs requires the research facility to maintain “Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations.”

Part IV.E.1.b. of the PHS Policy requires the institution to maintain “minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.”

1. Contents of IACUC Minutes

IACUC minutes are meant to provide an accurate and complete record of IACUC deliberations and actions, and should preclude unintentional confusion or misinformation. UNC IACUC minutes include the following:

- a. Listing of members present, absent, guests present, etc.
- b. State that previous minutes were approved as distributed or modified to secure approval at future meeting.
- c. Categories of animal use protocol or modification reviews – see below for recommended dispositions:
 - i. New Protocols
 - Approved following convened meeting
 - Approved by designated review, following convened meeting
 - Approved by designated review, in absence of call for full committee review
 - Modification(s) required for approval following convened meeting
 - Approval withheld following convened meeting
 - Approval withheld by designated review, following convened meeting
 - Approval withheld by designated review, in absence of call for full committee review
 - ii. Protocol Modifications (significant changes)
 - Approved following convened meeting
 - Approved by designated review, following convened meeting
 - Approved by designated review, in absence of call for full committee review
 - Modification(s) required for approval following convened meeting
 - Approval withheld following convened meeting
 - Approval withheld by designated review, following convened meeting
 - Approval withheld by designated review, in absence of call for full committee review
 - iii. Protocol Amendments (minor changes)
 - Administratively approved since last meeting (see IACUC approved policy #)
 - iv. Annual reviews with significant change(s)
 - Approved following convened meeting
 - Approved by designated review, following convened meeting

- Approved by designated review, in absence of call for full committee review
 - Modification(s) required for approval following convened meeting
 - Approval withheld following convened meeting
 - Approval withheld by designated review, following convened meeting
 - Approval withheld by designated review, in absence of call for full committee review
- v. Annual reviews with minor or no changes
 - Administratively approved since last meeting
 - d. Note when members with conflict recues from voting
 - e. Note whether votes were unanimous or included nays or abstentions
 - f. Protocol references include protocol number, title, and eventual approval date
 - g. Listing of protocols awaiting reply from PI since last meeting
 - h. Program Review or Facility Inspection
 - Note discussion of any newly identified program/facility deficiencies
 - Note follow-up of correction of deficiencies noted in earlier semiannual reviews/inspections
 - i. Announcements
 - j. Other business
 - k. Date, time and location for next meeting

2. Review and Approval of Minutes

- a. The IACUC Administrator prepares a draft of the minutes of each meeting of the IACUC and distributes it to all members of the committee two weeks prior to the next scheduled IACUC meeting.
- b.
- c. The minutes of each meeting are reviewed and approved by the IACUC at the following scheduled meeting.
- d. A hard copy of minutes from each IACUC meeting is retained in the ACUP Office for not less than three years from the date of approval. The IACUC Administrator is responsible for keeping the minutes on file for the prescribed three years.

B. Animal Use Protocol Records

Section 2.35 (a)(2) of the AWRs requires the research facility to maintain “Records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether the IACUC approval was given or withheld.”

Part IV.E.1.c. of the PHS Policy requires the institution to maintain “records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.”.

1. All documentation, including copies of email correspondence, print correspondence, and written descriptions of verbal deliberations, related to the submission, review and approval of animal use protocols is retained in the ACUP Office for the duration of the activities covered by the protocols and for three years after the activities are completed.

2. Records are maintained for all protocols submitted to the IACUC, including those for protocols which never used animals.
3. The IACUC Administrator is responsible for maintaining records and making them available for review, should it be required, during the prescribed period.

C. Semi-annual Program Review and Facility Inspection Reports

Section 2.35(a)(3) of the AWRs requires the research facility to maintain "Records of semiannual IACUC reports and recommendations (including minority views), prepared in accordance with the requirements of ...this subpart, and forwarded to the Institutional Official."

Part IV.E.1.d. of the PHS Policy required the institution to maintain "records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official."

Within one week of a program review or facility inspection, the IACUC Administrator develops and submits to the Chair a draft report that:

1. Provides an update to the previously submitted program review or facility inspection report, noting which deficiencies have been corrected and which are pending
2. Contains a description of the nature and extent of UNC's adherence to the Animal Welfare Act, the PHS Policy, and the *Guide*; and identifies any specific departures from those regulatory documents, providing a reason for each departure
3. Describes each identified deficiency, designating whether it is minor or significant (a significant deficiency is one that, in the judgment of the IO and the IACUC, is or may be a threat to the health or safety of the animals)
4. Outlines a reasonable and specific plan and a schedule with dates for resolution of each deficiency, identifying the individual(s) responsible for correcting the problem(s). Any significant deficiency that is not resolved according to corrective action plan and schedule must be reported, by the IACUC through the IO, to the USDA, PHS, and any federal agency providing funding for activities related to the uncorrected deficiency. These reports must be made in writing and within 15 days of the scheduled correction date.
5. Identifies and describes any minority opinions voiced by IACUC members during the program review or facility inspection.

Following approval by the Chair, the IACUC Administrator distributes the draft report to the full committee by email. A majority of the members of the IACUC must sign each report before it is submitted in writing to the Institutional Official. Electronic signatures are accepted as official.

Principal Investigators and the ACUP Manager are informed by email of deficiencies observed in their areas, and are asked to report back by email to the IACUC Administrator when the noted corrections have been accomplished.

The IACUC Administrator informs the Chair by email when corrections of deficiencies have not been completed by the scheduled dates.

Copies of Program Review and Facilities Inspection reports are maintained in the ACUP Office for at least three years following the resolution of all deficiencies identified in the reports. The

reports are made available upon request to representatives of USDA, the PHS, and any Federal funding agencies.

D. Investigation of Reported Concerns/Complaints

Official records of all reported concerns and investigations are maintained by the IACUC Administrator for at least three years following the final disposition of the review or investigation and any corrective action taken.

Records include copies of all written correspondence, interviews, reports, photographs, minutes of IACUC meetings and meetings of investigating teams, and any other documentation related to the review and/or investigation of a reported concern.