

DRAFT

**NORFOLK STATE UNIVERSITY
700 PARK AVENUE
NORFOLK, VIRGINIA**

**Assurance of Compliance with Public Health Service (PHS) Policy
on the Humane Care and use of Laboratory Animals**

Institutional Animal Care and Use Committee

Guidelines for Protocol Submission

**OFFICE OF THE ASSOCIATE VICE PRESIDENT FOR
RESEARCH AND TECHNOLOGY**

January 2006

I. Function of the NSU IACUC

The NSU Institutional Animal Care and Use Committee (IACUC) executes its function in accordance with the principals and/or regulations established by the National Research Council's "Guide for the Care and Use of Laboratory Animals" (revised 1996), the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (revised 1986, reprinted 1996), the United States Department of Agriculture (USDA), the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), the Animal Welfare Act (AWA); Public Law 99-198) and the Health Extension Act of 1985 (Public Law-99-158). **The Public Health Service Policy on the utilization of animals applies to all living vertebrate species.** Copies of these policies, principal, regulations, and law are available from the Office of Research.

II. Animal Research at Norfolk State University

Norfolk State University (NSU) supports the humane use of animals in research and teaching to further our scientific knowledge of living organisms. This knowledge is necessary to not only provide the scientific foundation of new scientific discoveries, but also to contribute to the conquering of disease and alleviate suffering for humans and animal alike. Although it is hoped that one day the use of animals will no longer be necessary to achieve these goals, presently there is no other way to obtain the scientific information. Computer programs and models have their role in teaching and should be substituted for live animals whenever possible, but these methods are inadequate to generate new knowledge which can only come from the study of living organisms themselves. Cell culture and other *in vitro* techniques are used when appropriate, but cannot substitute for "whole" animals in all experiments. Animal research has been extremely successful in the production of all types of medical treatments from surgical procedures to drugs and vaccines which have wiped out the devastating effects of many diseases.

The animals used in research and teaching at NSU are obtained from commercial breeders. None are supplied by the local pounds or animal shelters. The animals are housed and fed according to rules established in the National Institutes of Health (NIH) "Guide", which stipulates adequate sized cages, controlled temperature, humidity, air circulation, sanitation and lighting, along with a proper diet. The animal care facility will uphold the standards of the American Association for the Accreditation of Laboratory Animal Care (AAALAC). The facility will be under the direction of a full-time veterinarian.

All research and teaching protocols involving the care and use of animals will be reviewed by the IACUC before they are initiated. The Committee is composed of faculty members from various disciplines, a veterinarian, and non-scientists from outside the institution. A staff member from the Office for Research will also attend the Committee meetings. The Committee reviews the protocols to assure that the animals will be properly treated to alleviate pain, that appropriate medical care of the animals will be provided, and that personnel are trained to perform the procedures on the animals. If the animals are euthanized at the termination of the experiment, it must be done humanely, in accordance with the recommendations of the American Veterinary Medical Association (AVMA). **The Institutional Animal Care and Use Committee and/or the institutional veterinarian are empowered to stop an experiment in the case of improper treatment of an animal**

III. Policy of an Established Institutional Animal Care and Use Committee (IACUC)

A. The Chief Executive Officer (i.e., President) of the research or teaching 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 or teaching facility.

B. IACUC Membership

1. The members of each Committee shall be appointed by the Chief Executive Officer (i.e., President) of the research or teaching facility;
2. The Committee shall be composed of a Chairperson 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 or teaching facility.
 - ii. At least one shall not be affiliated in any way with the institution 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 research or teaching facility.

C. IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research or teaching facility, shall:

1. Review, at least once every six months, the research and/or teaching facility's program for humane care and use of animals, using title 9, chapter I, subchapter A-Animal Welfare, as the basis for evaluation;
2. Inspect, at least once every six months, all of the research and/or teaching facilities 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.

3. Prepare reports of its evaluation conducted as required by paragraphs (c) (1) and (2) of this section, and submit the reports to the Office of Research and

Technology; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research and/or teaching 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 and/or teaching 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 and/or teaching 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 judgement of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If the 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 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;**

4. Review, and, if warranted, investigate concerns involving the care and use of animals at the research and/or teaching facility resulting from public complaints received and from reports of noncompliance received from laboratory, research, or teaching personnel or employees;

5. Make recommendations to the Institutional Official (i.e., President) regarding any aspect of the research and/or teaching facility's animals program, facilities, or personnel training;

6. Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, as specified in paragraph (d) of this section;

7. Review and approve, required modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing research and teaching activities; and

8. Be authorized to suspend an activity involving animals in accordance with the specifications set forth in paragraph (d) (6) of this section.

D. IACUC Review of Activities Involving Animals

1. To approve proposed activities (e.g., grant application and teaching laboratories) or propose 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. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

- i. Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals;
- ii. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available;
- iii. The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;
- iv. Procedures that may cause more than momentary or slight pain or distress to the animals will:
 - a. Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;
 - b. Involve, in their planning, consultation with the attending veterinarian or his or her designee;
 - c. Not include the use of paralytics without anesthesia;
- v. 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;
- vi. The animals' living conditions will be appropriate for their species in accordance with part 3 of this chapter, and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;
- vii. Medical care for animals will be available and provided as necessary by a qualified veterinarian;

viii. Personnel conducting procedures on the species being maintained or studies will be appropriately qualified and trained in those procedures.

ix. 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 aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures;

x. No animals will be used in more than one major operative procedure from which it is allowed to recover, unless:

a. Justified for scientific reasons by the principal investigator, in writing;

b. Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or

c. In other special circumstances as determined by the APHIS Administrator on an individual basis. Written request and supporting data should be sent to the Administrator, APHIS, USDA, 6505 Belcrest Road, Room 268, Hyattsville, MD 20782.

xi. Methods of euthanasia used must be in accordance with the definition of the term set forth on 9 CFR part 1, 1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the principal investigator.

2. Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If the full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in that activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.

3. The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC;

4. The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. The IACUC may consider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator;

5. The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

6. The IACUC may suspended 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 suspended 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;

7. If the IACUC suspends an activity involving animals, the Director of the Office for Research, 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; and

8. Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approved by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

E. A proposal to conduct an activity (research and/or teaching) involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

1. Identification of the species and the approximate number of animals to be used;
2. A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;
3. A complete description of the proposed use of the animals;
4. A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of the scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and
5. A description of any euthanasia method used.

IV. Guidelines for Submission to the IACUC

1. Meetings: The IACUC will meet at the end of each month to consider proposed activities. Forms should be submitted two weeks in advance to allow distribution and review before the meeting. The principal investigator may attend the meeting to address issues that cannot be clarified beforehand.

2. Veterinarian Review: To facilitate the review process and ensure that adequate facilities are available, principal investigators should submit a draft of the review form to the attending veterinarian at least one week prior to submitting the final document to the Office for Research (OR). The intent is to have veterinary issues resolved prior to submission of the protocol to the IACUC.

3. Personnel Training: All personnel working, directing, or planning work with animals must complete the Animal Care and Use Training Program. This program consists of a Tier I, which all personnel must complete and a Tier II tape which must be reviewed if you are working the following animal species: hamster, guinea pig, rabbit, dog, cat, and non-human primates. It is the responsibility of the principal investigator to see that the appropriate Tier II materials have been viewed by all laboratory personnel working with animals.

4. Signature: For purpose of an application, a PRINCIPAL INVESTIGATOR is defined as a NSU faculty member or Research Fellow with scientific and budgetary control and responsibility for the research or teaching project, including signing the requisitions for purchase of animals. A TECHNICAL COORDINATOR is the person executing the experiment and may be a NSU faculty member, fellow, student or laboratory technician. The DEPARTMENT HEAD is the Chairperson of the Department in which the principal investigator has a primary academic appointment.

5. Approval Period: Approvals will be for a period of one year, subject to renewal by submission of the Annual Review Form for a maximum of 2 to 4 renewals. Please note that the total number of animals requested in the initial review form will be based on a three-year or five-year grant proposal or project.

6. Annual Review Procedure: Principal investigators should plan to submit materials to the IACUC for annual review at least one month prior to the expiration of the current approval period. In doing so, the principal investigator should keep in mind that the materials should be delivered to the OR for processing at least two weeks prior to the meeting at which the principal investigator seek review.

- Projects terminated or completed require submission of the complete original annual review form plus 1 copy to the OR.
- Projects with changes require submission of the complete original annual review form plus several copies (for the IACUC members) to the OR.
- Projects without changes require submission of the completed original annual review form plus 1 copy to the OR.

7. Amendment Procedure: Prior to implementation, the principal investigator is responsible for submitting (in the form of a letter) all proposed changes to the IACUC Chairperson in care of the Office for Research. Upon receipt, the IACUC Chairperson will review the proposed changes to determine if the protocol should be addressed by the full Committee. Full Committee reviews will be required in cases where significant alterations are made from the protocol. As such, it is more expedient to initially submit an amendment to the full committee when changes involve compound issues.

Upon approval of the change, the Chairperson will notify the principal investigator by letter (copies of the amendment letter and approval letter will be forwarded to the OR). **A change may not be made to the original protocol without prior notification and approval of the IACUC.**

8. Survival Surgery: All survival surgery (including on rodents) must be performed aseptically. The experimental narrative must explicitly state that survival surgery will be performed aseptically.

9. Analgesia: Post-surgical analgesia must be provided following all survival surgery, unless the scientific purpose of the study would be confounded. The use or exclusion of analgesia by the staff must be discussed if the study involves survival surgery.

10. Post-surgical Observations: A written record of post-surgical observations must be maintained for non-rodent mammalian species. This record must always be accessible by the staff of the Animal Facility.

11. Housing: Approval protocols by the IACUC does not guarantee usage of the animal facilities. The principal investigator must independently schedule the use of the Animal Facilities with the staff person.

12. Expedited Process: The principal investigator should consult with the institutional veterinarian to have veterinary issues resolved prior to submission of the protocol. **PROTOCOL MUST BE TYPED, NOT HAND-WRITTEN.** Attach a memo to protocol alerting Committee members that the protocol is to be reviewed through the IACUC and explain the necessity for expedited review. Thereafter, hand deliver (e.g., do not send through campus mail) a copy of the protocol to each member of the IACUC Committee. Deliver the original protocol to the Office for Research. From the date of receipt of the protocol by all Committee members, one week is required for a decision to be made. The Committee and/or each individual member reserves the right to defer consideration of the protocol at the next regular IACUC meeting. A principal investigator can request a "special" meeting of the IACUC.