

Northern Kentucky University
ASSURANCE OF COMPLIANCE
WITH
PUBLIC HEALTH SERVICE
POLICY ON HUMANE CARE AND
USE OF LABORATORY ANIMALS

Northern Kentucky University, hereinafter referred to as “the University”, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

"The University" includes the following branches and major components of Northern Kentucky University: Highland Heights Campus.

II. INSTITUTIONAL POLICY

A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

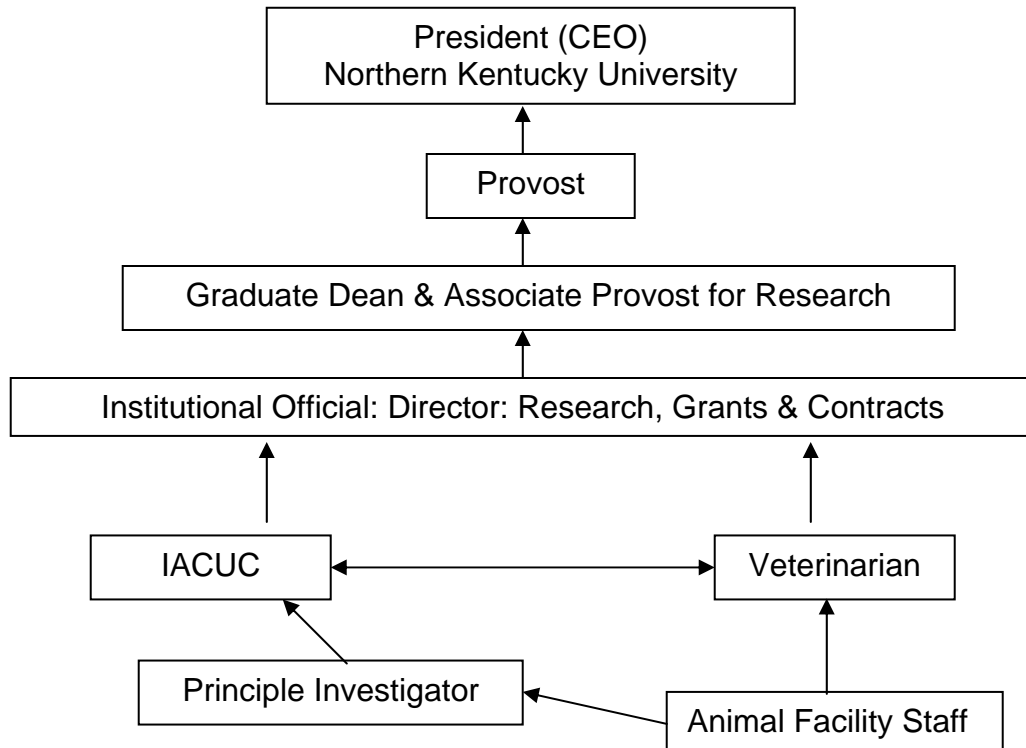
C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals

involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.

D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are:



B. The qualifications, authority, and percent of time contributed by the Veterinarian(s) who will participate in the program are:

Qualifications: John Sector, DVM; 20 years experience in laboratory animal medicine. 10% effort.

Authority: The Veterinarian has delegated program authority and responsibility to implement the PHS Policy and the recommendations of the Guide. The authority of the NKU IACUC Veterinarian is delegated by the Director of Research, Grants and

Contracts. This includes authority to review proposals, visit animal facilities, confer with investigators, and call violations of University policy to the attention of investigators, departmental chairpersons, deans, Director of Research, Grants and Contracts, and the Institutional Animal Care and Use Committee.

Veterinarians have the responsibility for the health care of the animals covered by this assurance. Employees responsible for the daily care (animal facilities staff) are required to examine animals at least once daily, and report any signs of illness to both the duty Veterinarian and the principal investigator. Health care is performed by the veterinary staff and may be assisted by veterinary technicians.

Percentage of Time: Veterinarian visits will be made during walk walk-through (every six months) and when needed. Approximately 10% of the Veterinarian's time will be contributed to the program. Veterinary care will be available at all times and if the Veterinarian is not available, arrangements will be made to provide a back-up Veterinarian from the University of Cincinnati.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. The IACUC is appointed by the President of the University based on recommendations through the Director of Research, Grants and Contracts. Attached is a list of the names, degrees, position titles, specialties and institutional affiliations of the IACUC chairperson and members.

D. The IACUC will:

1. 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. The IACUC procedures for conducting semiannual program evaluations are:
 - a. The semiannual program review is conducted at a convened meeting (regular or special) where a majority of the committee is present.
 - b. Each member receives or has received a copy of the Guide, the previous semiannual program and facilities inspection report, the IACUC policies and procedures manual (containing their charges and responsibilities), and NKU's Institutional Animal Care and Use Program Evaluation checklist (modeled after that suggested by the OLAW) which reviews all aspects of the animal use program including administration.
 - c. In addition, agenda items for IACUC meetings include review, discussion, and/or recommend revisions to improve the level of care and to insure compliance.

2. 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. The IACUC procedures for conducting semiannual facility inspections are:
 - a. At scheduled intervals, at least once every six months, each facility or area will be completely inspected by no less than two (2) IACUC members and the results discussed at a convened meeting (regular or special). All members of the IACUC are invited to participate in the semi-annual inspection of the animal facilities.
 - b. Included in the facilities inspections are inspections of animal care records, animal facility staff interviews, and random interviews with investigators holding active animal use protocols and other laboratory staff involved with animal care and utilization.
 - c. Any item not in compliance with the Guide will be recorded and submitted to the Director of Research, Grants and Contracts along with recommended corrective actions; major deficiencies will also be reported to OLAW.
 - d. The date(s) of each inspection will be included with the annual Assurance Document update (submitted before January 30 for the previous year). NKU's semiannual facilities inspection is normally conducted in conjunction with their semiannual program evaluation.
3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Director of Research, Grants and Contracts, Mary Ucci. The IACUC process for developing reports and submitting them to the Institutional Official is:
 - a. The Chair prepares a draft report based, in part, upon the facilities inspection reports and applicable program review results.
 - b. At a convened meeting, the draft report along with any additional facilities inspection or program review information is discussed and compiled into a final report.
 - c. This report, identifying significant and minor deficiencies, if any, along with any minority opinions and/or recommendations, are endorsed by the Committee and forwarded to the Institutional Official. Any deficiencies identified will be designated as minor or significant and will include a reasonable plan and schedule for correction.
4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are:

- a. NKU has adopted a policy and has developed procedures for investigating concerns involving the care and use of animals at Northern Kentucky University. The IACUC will be the committee that provides access to information and a channel through which complaints may be directed, anonymously if so desired and without fear of reprisal, regarding the care and use of animals. at Northern Kentucky University (Standard Operating Procedures). This is a publicly available document (distribution by the Office of Research, Grants and Contracts (RGC) and published on their web page) that is available to all investigators.
 - b. Concern(s) involving the care and use of animals may be submitted to the IACUC or the Office of Research, Grants and Contracts.
 - c. All such concerns will be presented to the IACUC for review, discussion, and suggested resolution, all of which will be recorded and kept on file. Every concern of which the IACUC is made aware will receive attention and responses will be documented.
 - d. All appropriate parties, including the Institutional Official and appropriate (e.g., Federal) oversight agencies, will be made aware, in writing, of the outcome(s).
 - e. Dependent upon the nature of the concern, the manner expressed and by whom, the IACUC or the Institutional Official will respond to those initiating the concern(s).
5. Make written recommendations to NKU's Institutional Official, the Director of Research, Grants and Contracts, Mary Ucci, regarding any aspect of the institution's animal program, facilities, or personnel training. Recommendations to the Institutional Official will be made in writing and records will be kept of all such correspondence.
 6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are:
 - a. Completed requests for approval of animal utilization are submitted to the Office of Research, Grants and Contracts by the Principal Investigator (PI) for each project.
 - b. Copies are provided to all IACUC members for discussion at the next scheduled meeting (within 45 days of proposal submission), such discussion being lead by a 'primary reviewer'. The primary reviewer is an IACUC member, assigned by the Chair, and not associated with the protocol. If any question arises prior to the IACUC meeting, additional details and/or a meeting with the PI is requested.

- c. A majority vote of the members present is required to approve a Committee action. Minority opinions are allowed to accompany any action.
 - d. Outcomes of the IACUC's deliberation (i.e., approval, approval pending modifications to secure approval, action deferred, or action withheld) are communicated to investigators, in writing, with required modifications or reasons for the IACUC's decision itemized. After the investigator has satisfactorily addressed the IACUC committee's required modifications, the investigator resubmits the protocol to the IACUC Chairperson. All members of the IACUC are requested to participate in DMR process and if none requests a full committee review, the Chair, or a designated reviewer, reviews the protocol for adherence to IACUC requirements and responds appropriately (i.e., approval or approval pending additional modifications). If unable to approve, the designated member will request full committee review. The Chairperson will reconvene the IACUC for additional review until the protocol has been modified to the approval of the designated member reviewer or committee.
 - e. Review may be conducted through a designated member review process. Prior to the designated-member review, all IACUC members shall be given a copy of the proposed research project and afforded an opportunity to comment and/or request full Committee review within a designated period of time. If no member requests a full committee review, the Chair designates a member to conduct the review process on behalf of the committee. This designated reviewer has authority to approve, require modifications, or call a full committee review.
 - f. Reapproval of an existing (expiring/renewing) study may be conducted by designated-member review. Prior to designated-member review, all IACUC members shall be given a copy of the proposed action and afforded an opportunity to comment and/or request full Committee review.
 - g. Complete approval (i.e., having no remaining conditions and/or restrictions resulting from a review) of the proposed activity MUST occur before any animal may be utilized.
7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing such proposed significant changes in ongoing research projects are identical to the procedures outlined in Item III.D.6 (above).
8. Notify investigators and the institutional official in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the

PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institutional official of its decisions regarding protocol review are:

- a. Notification of investigators and the institution of IACUC decisions shall be the responsibility of the RGC, Northern Kentucky University.
 - b. All such correspondence shall include any required modifications needed to secure approval or any reasons for protocol deferral or action withheld and giving investigators the opportunity to respond in person or in writing.
9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4. at least once every three years. The IACUC procedures for conducting continuing review are:
- a. Continuing reviews will be conducted at less than twelve (12) month intervals. Investigators will be notified by the RGC in writing prior to the expiration date and requested to submit a completed questionnaire and summary of the previous period's activities.
 - b. With the exceptions noted below, continuing reviews will be conducted administratively by two (2) committee members (one of which should be the Veterinarian) with notification of the IACUC - unless full Committee review is requested by either administrative reviewer.
 - c. Continuing review of protocols involving the following procedures shall be reviewed by the full Committee (See Item III.D.6., above) in lieu of an administrative review:
 - 1) Pain Category "D"
 - 2) neuromuscular blocking agents
 - 3) multiple survival surgeries
 - 4) Primates

Such full Committee review may result in additional clarifications/information being requested from the investigator before a final recommendation can be given.

- d. All correspondence regarding continuing reviews shall be handled by RGC as previously described (Item III.D.8.).
- e. Each Animal-use protocol shall be unique and shall be active for a maximum period of three (3) years. At the end of this three-year period, it shall be automatically inactivated and all animal activities covered under it shall be considered complete. Ongoing or additional animal activities as

may be required by the specific protocol must be submitted as a new animal use protocol, which will be assigned a new AUP number.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are:

- a. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC present. A majority vote is required and a minority opinion shall be allowed for opposing view point(s). If a suspension is authorized, all activity will immediately cease. The IO, in consultation with the IACUC, will review the reasons for suspension and take appropriate action and report that action with a full explanation to OLAW.
- b. If circumstances involving animal health, safety, and/or welfare dictate, the Veterinarian, a subcommittee of the IACUC or the Institutional Official may temporarily suspend an activity. Such suspension and supporting evidence shall be reviewed by the full IACUC as in Item a. above.
- c. All affected parties including, but not limited to, the investigator, the Institutional Official, and the appropriate oversight (e.g., Federal) agencies, shall be notified of the reasons for the suspension, any applicable corrective action(s) and any further action(s) anticipated.

E. The individual(s) authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is the Director of Research, Grants and Contracts who also serves as the Institutional Official.

F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is:

Prior to employment, a medical history, physical examination, drawing of a serum sample, zoonotic disease and hazards briefing are completed before each employee begins working with animals.

During employment: Personnel, except for those having documented medical contra-indications or special waivers, are required to be immunized against tetanus and rabies and to undergo an annual physical exam. There is an established procedure for reporting job related injury or illness to the Office of Research, Grants and Contracts and the University's Environmental Safety Department. The NKU Training and Standard Operating Policy Manual, a copy of which is located in each animal facility, provides guidelines for obtaining treatment for minor and critical injuries. In addition to basic first aid instructions; animal facility personnel are instructed to contact the animal facility supervisor immediately. For critical injuries, personnel are instructed to report to NKU Health Services or, if necessary, contact

NKU Department of Public Safety or 911 for assistance in obtaining emergency care. A record is kept of job-related as well as job-unrelated illnesses/accidents and of annual physical exams done by the University or a private physician. The Office of Research, Grants and Contracts is responsible for monitoring the program.

Personal Hygiene: the occupational safety and health program provides guidance in the area of personal hygiene and this is addressed in all animal facility training programs. **Personal Protective/Work Clothing Provided:** Uniforms and lab coats are provided for animal-use personnel and laundered by the institution. Research staff are provided with disposable outer clothing. Staff wear disposable gloves, gowns, face masks and shoe covers. Respirators are available if required.

Policies Regarding Eating, Drinking and Smoking in Animal Facilities: Eating and drinking areas are provided in employee lounges and offices. Eating, drinking and smoking are not allowed in research labs or animal housing areas.

Hazard Identification and Risk Assessment: The record of circulation used for all protocols involving animals has spaces to indicate whether hazardous agents are used. If a hazardous agent is proposed, the protocol is referred to the University's Environmental Safety Office. The Office of Research, Grants and Contracts is notified if such a protocol is used. Appropriate control measures are instituted depending on the protocol. These methods include environmental and personnel monitoring by the University Environmental Safety Office.

Personnel Training: When hazardous agents are used, personnel must be trained in the specific protocol for the agent. Personnel receive training for specific biohazardous protocols that are approved by the Biosafety Committee. An OSHA course for all new university employees contains information on the possibility of diseases caused by exposure to animals. It includes information on allergies, bites and scratches, zoonotic diseases, exposure to biohazards, and special precautions for pregnancy and immune suppression. The existence of a program in Employee Health Services to address injuries, allergies and illnesses is explained. The IACUC SOP's and Investigator Handbooks contain basic information on biohazards and zoonoses.

G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached table.

H. As part of this institution's program for animal care and use, all personnel involved in animal use activities (the IACUC, investigators, technicians and animal care personnel) are required to participate in a training program offered by the Office of Research, Grants and Contracts prior to any animal use. This program, modeled after the core program delineated in Education and Training in the Use of Laboratory Animals: A Guide for Developing Institutional Programs, National Academy Press, Washington,

D.C., 1991, includes a combination of lecture and written reference information. The topics covered include:

1. familiarization with the intent and requirements of the Animal Welfare Act, Animal Welfare Regulations, Public Health Service Policy on the Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and other applicable regulations and guidelines;
2. an overview of the various methods of monitoring compliance including those used by the United States Department of Agriculture, the Office for Laboratory Animal Welfare, and Northern Kentucky University, and the potential penalties imposed by each organization;
3. a description of the responsibilities of the University, the Institutional Animal Care and Use Committee, the University Veterinarian, technicians and animal care personnel;
4. a discussion of the ethical and scientific issues involved with the use of laboratory animals in research, education, and testing including various ethical approaches and responsibilities and the responsibility of providing proper animal care and husbandry for valid research results;
5. humane methods of animal maintenance and experimentation including methods that will minimize or eliminate the use of animals, or limit or minimize animal pain or distress;
6. a presentation of available resources that should be used to identify potential alternatives to animal use or duplication of research, educational, or testing procedures including the National Library of Medicine, the National Agricultural Library, the University Library resources, and internet resources;
7. a discussion of animal pain and distress including the responsibilities of all involved to minimize pain and distress and the various methods by which pain and distress can be minimized;
8. a description of the proper use of tranquilizers, analgesics, anesthetics, and paralytics including responsibilities for monitoring effectiveness and animal health and sources for assistance and guidance;
9. proper pre- and post-surgical care including monitoring, the use of analgesics, and where to obtain guidance and assistance;
10. proper aseptic surgical procedures and methods including acceptable surgical locations for various species, requirements for aseptic surgery, responsibilities of all involved, and where to obtain assistance and guidance;

11. methods of euthanasia and requirements for appropriate training;
12. a discussion of potential human health hazards including zoonoses, animal inflicted injuries, and allergies along with a description of the available occupational health program for all personnel with animal contact;
13. an emphasis on each individual's responsibility to ensure humane animal care and use and the methods and individuals available for reporting perceived deficiencies in animal care and treatment.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2, as Category 2, all of this institution's programs and facilities, including satellite facilities, for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations will be submitted to the Director of Research, Grants and Contracts, Mary Ucci. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request. The most recent annual report of the IACUC is attached.

V. RECORD KEEPING REQUIREMENTS

- A. This institution will maintain for at least three years:
 1. A copy of this Assurance and any modifications thereto, as approved by PHS.
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Director of Research, Grants and Contracts, Mary Ucci.
5. Records of accrediting body determinations.

B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:

1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Director of Research, Grants and Contracts, Mary Ucci.

B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.
2. Any serious deviations from the provisions of the Guide.
3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Mary Ucci
Title: Director, Research, Grants and Contracts
Address: Northern Kentucky University
AC 616
Phone: 859-572-5136
Fax: 859-572-6188

Signature: Mary Ucci Date: 6/1/02

B. PHS Approving Official

Name: **Eileen M. Morgan-Senior Assurance Officer** —
Title: **Division of Assurances, OLAW** —
National Institutes of Health —
Address: **RKL1, Suite 360-MSB 7982** —
6705 Rockledge Drive —
Bethesda, MD 20892-7982 —

Phone: 301-451-0384

Signature: 301-402-7065 Date: 7-2-07

C. Effective Date of Assurance: 7-02-07

D. Expiration Date of Assurance: 7-31-11