THE UNIVERSITY OF NEBRASKA MEDICAL CENTER
ANIMAL WELFARE ASSURANCE #A3294-01
IN ACCORDANCE WITH THE PHS POLICY FOR
HUMANE CARE AND USE OF LABORATORY ANIMALS

I, Thomas H. Rosenquist, Ph.D., as named Institutional Official (IO) for animal care and use at the University of Nebraska Medical Center (UNMC) and the University of Nebraska at Omaha (UNO), hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy. Ernest D. Prentice, Ph.D., is the alternate IO for signature authority. UNMC and UNO have separate AAALAC International accreditation.

I. APPLICABILITY OF ASSURANCE

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 PHS-supported activity by this Institution.

"Institution" includes the following branches and major components of the University of Nebraska Medical Center: All components of the UNMC are physically located on the UNMC campus with the exception of the College of Dentistry (COD) which is physically located on the University of Nebraska Lincoln Campus.

"Institution" also includes the following: All components of the University of Nebraska at Omaha that are physically located on the UNO campus.

There are no UNMC or UNO off-campus satellite facilities or other covered components.

II. INSTITUTIONAL COMMITMENT

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 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 as follows as indicated in the appended diagram of the reporting channels (Attachment 1).

There is a formal written agreement between the UNMC and the UNO that delineates applicable responsibilities. Attached is a letter signed by the Chancellor of UNO acknowledging that the UNO wishes and agrees to be a covered component of the UNMC PHS Assurance (Attachment 2).

The Vice Chancellor for Research (VCR) serves as the IO. The VCR reports directly to the UNMC Chancellor who is the CEO. The Associate Vice Chancellor for Academic Affairs (AVCAA) at UNMC serves as the alternate IO for signature authority in the absence of the IO. The CEO is responsible for appointing the IO and the alternate IO for signature authority.

The UNMC Attending Veterinarian (UNMC AV) and the UNO Attending Veterinarian (UNO AV) report directly to the IO on all matters pertaining to the animal care and use program. The UNMC IACUC is the IACUC of record for both UNMC and UNO. The IACUC has a direct reporting line to both the IO and the UNMC Chancellor. The IACUC has an IACUC Administrator, an IACUC Assistant and a Protocol Assessment Liaison (PAL) who work closely with the Chair of the IACUC and the AVs.

The UNMC AV also serves as the Director of Comparative Medicine (CM). The administration of CM includes an Assistant Director for Clinical Veterinary Medicine (ADCVM) who is a DVM and an Assistant Director for Operations (ADO). An additional clinical veterinarian reports to the ADCVM. CM also includes individuals involved in facility management, financial and business services, safety and veterinary technical services. There are approximately 16 animal care technicians in CM.

The UNO Animal Care Advisory Board (ACAB) is responsible for the daily operation of the UNO animal facilities. The ACAB interacts with the UNO AV and the IACUC.

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


   a. Qualifications

      Professional and Academic Degrees: B.S. in Agriculture (1968), University of Missouri; D.V.M. (1970), University of Missouri; M.S. in Veterinary Surgery (1979), Colorado State University; Laboratory Animal Medicine Residency (1984-87), U.S. Army Medical Research; Institute of Infectious Diseases, Fort Detrick, Frederick, Maryland; Specialty Board Certification: ACLAM (1987).

      Training and/or Experience in Laboratory Animal Medicine: 38 years of experience in all aspects of laboratory animal medicine.

   b. Authority: The UNMC AV has direct program authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of the animal care and use program at UNMC in accordance with the PHS Policy, the Guide, 9CFR2.33 (a) (b) and institutional policies.
c. Time Contributed to Program: Full time employee - 100%


a. Qualifications

Professional and Academic Degrees: B.S., (1985), in Animal Science, University of Minnesota, Mpls/St. Paul, MN; D.V.M., (1989), Iowa State University at Ames; M.P.H., (2006), University of Nebraska Medical Center, Omaha, NE

Training and/or Experience in Laboratory Animal Medicine: 9 years of experience in all aspects of laboratory animal medicine.

b. Authority and Responsibility: The UNMC alternate AV has delegated program authority from the UNMC AV and the IO to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of the animal care and use program at UNMC in accordance with the PHS Policy, the Guide, 9CFR2.33 (a) (b) and institutional policies.

c. Time Contributed to Program: Full time employee - 100%. Serves as the alternate AV approximately 20% of the time. The rest of the time is devoted to clinical veterinary responsibilities.

3. Tami R. Wells, D.V.M.; UNMC Alternate Attending Veterinarian

a. Qualifications


Training and/or Experience in Laboratory Animal Medicine: 4 years of experience in all aspects of laboratory animal medicine.

b. Authority and Responsibility: The UNMC alternate AV has delegated program authority from the UNMC AV and the IO to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of the animal care and use program at UNMC in accordance with the PHS Policy, the Guide, 9CFR2.33 (a) (b) and institutional policies.

c. Time Contributed to Program: Full time employee - 100%. Serves as the alternate AV approximately 5% of the time. The rest of the time is devoted to clinical veterinary responsibilities.

4. Lizabeth Gunkelman, D.V.M.; UNO Attending Veterinarian

a. Qualifications

Professional and Academic Degrees: B.S. in Animal Science University of Nebraska at Lincoln (1983), D.V.M. Iowa State University (1987)
Training and/or Experience in Laboratory Animal Medicine: 1 year of experience in laboratory animal medicine. Internships include nonhuman primates at the Houston Zoo in 1986 and the Henry Doorly Zoo in 1987.

b. Authority and Responsibility - The UNO AV has direct program authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of the animal care and use program at UNO in accordance with the PHS Policy, the Guide, 9CFR2.33 (a) (b) and institutional policies.

c. Time Contributed to Program: Dr. Gunkelman is present at the Institution (UNO) an average of approximately 8 hours per month. 100% of this time is contributed to the animal care and use program at UNO. In addition, Dr. Gunkelman contributes on average approximately 8 hours per month to the program while off-site reviewing protocols, attending IACUC meetings at UNMC and providing consultation on various program related topics.

5. Dr. Julia E. Napier, D.V.M.; UNO Alternate Attending Veterinarian

a. Qualifications

Professional and Academic Degrees: BA in Political Science Colorado State University (1980); D.V.M. Iowa State University (1999)

Training and/or Experience in Laboratory Animal Medicine: 10 years of experience in all aspects of animal medicine.

b. Authority and Responsibility: The UNO alternate AV has delegated program authority from the UNO AV and the IO to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of the animal care and use program at UNO in accordance with the PHS Policy, the Guide, 9CFR2.33 (a) (b) and institutional policies.

c. Time Contributed to Program: Back-up veterinarian. On call basis, as required

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their designation, degrees, profession, titles or specialties, and institutional affiliations (Attachment 3).

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 reviews are as follows: The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and
Training); and d) Occupational Health and Safety. In addition, the evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the reviews.

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 semianual facility inspections are as follows: At least once every six months the IACUC will visit all of the institution's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting the animals is also inspected. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the inspections.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows: Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, identify specifically any departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will 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 the report will identify those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. The completed reports will be submitted to the Institutional Official within 60 days following the evaluation. However, if during the inspection significant deficiencies are identified, the IACUC Chair will verbally notify the IO as soon as possible.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

   a. Any individual may report concerns to the UNMC IACUC Administrative Office, the AVs, the clinical veterinarian, any IACUC member, Comparative Medicine staff, the Protocol Assessment Liaison or the IO.

   b. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.
c. The IACUC Chair must be notified as soon as possible of all concerns or problems involving the care and use of animals. The IO will be notified immediately of all serious concerns or problems. Documentation must be maintained on file in the IACUC Administrative Office.

d. All reported concerns will be brought to the attention of the full committee. If necessary and/or requested by any committee member, the IACUC chair will convene a meeting to discuss, investigate, and address any reported concern.

e. The concern or problem will be immediately addressed by appropriate intervention or investigation.

f. When an investigation is warranted, it will be conducted by the Protocol Assessment Liaison or an IACUC Compliance Subcommittee. The Compliance Subcommittee will consist of the IACUC Chair, AV, other members of the IACUC as necessary and the Protocol Assessment Liaison. The investigation will include but is not limited to; 1) interview of personnel; 2) observation of animals; and 3) review of pertinent records. Note: Absent a conflict of interest, no member of the IACUC will be involuntarily excluded from participating in any portion of an investigation.

g. A detailed record of the concern and investigation including any corrective action already taken will be prepared and reviewed by the IACUC Chair, the AV, and the Protocol Assessment Liaison.

h. The concern will then be reviewed by the IACUC at a convened meeting and action will be taken, as necessary.

i. Following IACUC review, the IACUC Chair will send a letter to the investigator outlining the concern and the IACUC’s recommendation including further corrective action, if necessary. The letter will require a written response from the investigator acknowledging receipt of the letter and confirmation that the concern is being/has been addressed.

j. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to the IO.

k. CLAW will be notified in accordance with the reporting requirements of the PHS Policy at IV.F.3.

l. All reports must be maintained on file in the IACUC Office including any associated documentation.

m. The identity of the whistle blower or individual bringing the concern to the attention of the IACUC will be protected in accordance with the institution’s whistle blower policy and any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.

5. Make written recommendations to the IO regarding any aspect of the Institution’s animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:
Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the committee and then submitted to the IO. The committee's recommendations are included in the IACUC meeting minutes or a report of the IACUC's evaluations or a separate letter.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

a. All personnel proposing to use a live animal in research, training, education, experimentation, biological testing or for related purposes must submit a completed IACUC Application form (hereafter referred to as protocol) to the IACUC Administrative Office. The principal investigator designates the pain category which, in turn, determines in accordance with IACUC policies whether the protocol requires review by designated member review (DMR) or full committee review (FCR).

b. IACUC approval criteria:

The IACUC will ensure that protocols meet the requirements of the PHS Policy at IV.C.1; the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training; The Guide; and ethical principles which govern the use of animals at the institution.

c. Designated Member Review (DMR):

Each eligible protocol is distributed to the entire IACUC with specific instructions regarding the designated review process and a deadline to call for FCR which is generally 2-5 business days. Affirmation from all IACUC members is not required.

Under extenuating circumstances, the deadline can be reduced by the IACUC Chair/designee to one day with affirmation required from all members regarding their decision whether or not to call for FCR.

At least one member of the IACUC is assigned by the chair as the designated reviewer (DR) who is qualified to conduct the review. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.

Any member of the IACUC can make the decision to send the protocol for FCR at any time during the set deadline period. If no member of the IACUC refers the protocol to full committee for review at a convened meeting, at the end of the set deadline period the assigned IACUC DR has the authority to approve, require modifications in (to secure approval) or request full committee review.

The DR does not have the power to withhold approval.

The IACUC minutes contain notification of all actions approved by DMR.
d. Full Committee Review (FCR):

Protocols scheduled for full IACUC review are distributed to all members of the IACUC at least one week prior to the meeting. The IACUC usually meets once per month with additional meetings to address extenuating circumstances convened when necessary.

The IACUC chair, or his/her designee, assigns at least two members to serve as primary reviewers (not to be confused with designated reviewer). Usually, the AV is one of the two. The primary reviewers will present their finding to other members of the committee at a properly convened IACUC meeting.

When it is determined that consultants or experts will be required to advise the IACUC in its review of a protocol, the protocol shall also be distributed to the consultants or experts prior to the meeting.

A simple majority of the membership of the IACUC constitutes a quorum and is required in order to convene a meeting for the review of protocols.

For a protocol to be approved, it must receive the approval of a majority of those members present at the convened meeting. No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. At the beginning of each meeting the Chair of the IACUC will remind investigators to declare any conflicting interest not previously disclosed.

The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

e. In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

i. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

ii. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

iii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
iv. The living conditions of animals will be appropriate for their species and 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 being maintained or studied.

v. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

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

vii. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

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 IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

a. Proposed significant changes must be submitted to the IACUC by completing a Request for Change form and revising the approved protocol by incorporating the change. Submissions are reviewed by either FCR or DMR as described previously in Section III.D.6. The IACUC utilizes DMR for most changes.

b. Determination of what constitutes a significant change is based upon guidance provided by OLAW. Examples of changes considered to be significant include, but are not limited to, changes: in the objectives of a study; from non survival to survival surgery; resulting in greater discomfort or in a greater degree of invasiveness; in the species or in approximate number of animals used; in Principal Investigator; in anesthetic agent(s) or the use or withholding of analgesics; in the method of euthanasia; and in the duration, frequency, or number of procedures performed on an animal.

8. Notify investigators and the Institution 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 IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

a. The IACUC Chair or his/her designee shall notify the investigator in writing of the IACUC's decision to approve the protocol, require modification in (to secure approval), or withhold approval (disapproval). In order to secure approval the investigator must revise the IACUC application and/or respond to other conditions set by the IACUC.

b. The IACUC Chair or his/her designee shall provide the investigator with the reasons, in writing, for the IACUC's decision to withhold approval of a protocol and shall provide an opportunity for the investigator to respond and appeal in writing.

c. When requested, the investigator may also appeal, in person, before a fully convened meeting of the IACUC.
d. Applications and proposals that have been approved by the IACUC may be subject to further review by officials of the institution who can overturn an IACUC approval. However, those officials may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the IACUC.

e. The IO receives a copy of the IACUC meeting minutes that records all decisions regarding protocol review and activities.

9. Conduct continuing review of each previously approved, ongoing activity covered by the PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

a. All ongoing activities are monitored continuously by the Comparative Medicine staff.

b. At the time of initial review and approval, the IACUC will set a continuing review date for each protocol.

c. Investigators are required to submit an application for Continuing Review in accordance with the continuing review dates set by the IACUC.

d. The IACUC will re-review all protocols no less often than every three years. If the protocol involves USDA regulated species, continuing review will be conducted no less often than annually.

e. Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6 above. All applicable requirements (laws, regulations, policies, etc.) in place at the time of the [de novo] review shall apply.

f. Annual and three year continuing reviews are conducted by either FCR or DMR.

g. Reviewers are assigned to review the Continuing Review application which includes a copy of the currently approved updated protocol in accordance with previously described procedures for FCR and DMR in Section III.D.6.

h. Protocols not re-approved by the set continuing review date are designated as "approval expired." Animals are placed on a holding protocol and no animal work is permitted until the protocol is re-approved.

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

a. An activity involving animals can only be suspended at a convened meeting of the IACUC. The IACUC may suspend the entire protocol or any component of a protocol.

b. The IO has authorized the IACUC chair/designee or the AV to immediately halt any activity involving animals if animal welfare is jeopardized or there is evidence of serious non-compliance. Such actions will be promptly reported to the IACUC.
c. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Assurance, the IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW. Suspensions shall also be reported to USDA if the activity/species is USDA regulated.

d. An IACUC suspension can only be lifted by the full IACUC at a convened meeting.

E. The occupational health and safety program for personnel working in laboratory animal facilities who have contact with animals is as follows:

The Director of CM in coordination with Employee Health manages the occupational health and safety program.

1. Hazard Identification and Risk Assessment

a. The Institutional Bio-safety Committee (IBC) reviews applications and investigator qualifications for use of bio-hazardous agents, including recombinant DNA, that are introduced into animals. An application is submitted to the committee by the Principal Investigator and the committee must approve it before the project can be initiated. The Director, Comparative Medicine is an active member of the IBC. Following approval, Operational Safety Protocols (OSP) for all ASBL-2 and higher are developed in collaboration with the CM Director and the Safety and Compliance Coordinator. The OSPs identify the safety requirements/procedures for safe animal care within the facilities and are posted on the entry door to the animal room.

b. Specific Operational Safety Protocols detailing the safety aspects for providing animal care are developed between the CM Director, Safety and Compliance Coordinator, and the Principal Investigator. The protocols are posted on the entry door to the animal room.

c. The treatment of animals with hazardous agents (carcinogens, mutagens, teratogens, etc.) must comply with safety protocols approved by the Office of Chemical and Radiation Safety. The Principal Investigator, the Director of CM, the Safety/Compliance Coordinator and the Director of Chemical Safety develop the protocol. The protocols are posted on the entry door to the animal room.

d. All hazardous wastes are identified, handled, tracked, and disposed of according to UNMC/UNO policy and monitored by the Office of Campus Safety and the Chemical and Radiation Safety Department.

e. It is the responsibility of the investigator to ensure that recommended practices are followed and that all personnel who work with hazardous agents are informed of the attendant risks and are appropriately trained regarding their handling and use. Operational Safety Protocols are developed between the animal care staff, appropriate safety personnel, bio-safety, and the investigator prior to the use of hazardous substances in animals.

f. Specific safety procedures are in place for personnel when handling macaque non-human primates or their cages and/or tissues/ fluids/excretions/secretions, and when a potential exposure to Cercopithecine herpesvirus 1 has occurred. The Non-Human Primate
Exposure/Bite Scratch Medical Treatment Kit and specific procedures are available in all required areas.

2. Personnel Training

   a. The UNMC/UNO Occupational Health and Safety programs are required by all personnel who work in laboratory animal facilities, and who have animal contact, or who are at substantial risk of acquiring a zoonotic disease from animals or tissues or body fluids used in biomedical research or both.

   b. When certain hazardous agents are placed into animals (e.g. pathogenic organisms, carcinogenic materials and radioactive materials), specific principles and procedures are followed to prevent infection or contamination of other animals/humans within the facility. It is the responsibility of the investigator to ensure that UNMC/UNO policies and procedures are followed and that all personnel who work with hazardous agents are informed of the attendant risks and are appropriately trained regarding their handling and use.

3. Description of Educational Programs

   a. UNMC/UNO OHS enrollment consists of: a) completing a specific health history questionnaire that is submitted directly to UNMC Employee Health Services/UNO Health Services, and b) attending an Occupational Health and Safety seminar or viewing the video tape of the seminar on-line.

   b. The Principal Investigator or Instructor is responsible for any hazards created by research, teaching or testing activities. The principal investigator anticipates problems when the protocol is submitted to the IACUC where personnel or animals are involved. The PI, in collaboration with the CM Director and the Safety and Compliance Coordinator, properly train all involved parties prior to beginning a study. If an accident occurs, appropriate safety personnel are to be notified immediately.

   c. Personnel who work with nonhuman primates other than macaques must be trained in topics such as taxonomy and behavior, cognition, psychological well-being, zoonoses, and safe practices for dealing with primates.

   d. Personnel who participate in a protocol that will use macaque non-human primates are required to complete specific zoonotic disease and safety training, which must be provided by a veterinarian.

   e. UNMC has additional online training requirements including the following annual mandatory courses: (1) Bloodborne Pathogen and Tuberculosis training for all individuals in the research field; (2) Annual IBC General Biosafety; (3) Annual IBC BL3 containment for personnel using BSL2 and above agents and (4) Annual Radiation Safety.

   f. UNO has additional training provided by the Office of Environmental Health, Safety, and Security (EHSS). EHSS conducts safety audits of the animal care program, identifies sources of work-place hazards, and assists in training staff and clearly identifying these risks (e.g., the potential for hot water burns in and around the cage washers).

   g. Personnel are instructed in the proper safety procedures for each protocol that involves the use of hazardous materials. In some circumstances, the investigator and his/her research
staff are required to provide animal care when certain hazardous materials have been introduced into animals e.g., MPTP. This determination is made by the CM Director following consultation with applicable Hazardous Agent/Materials Committees/Officer(s).

4. Personal Hygiene and Protection

a. Fume hoods, bio-safety cabinets and protective clothing including gloves, gowns, masks, respirators, N95 masks, eye protection, Tyvek suits, and shoe covers are provided to all personnel as needed. Personnel must dress accordingly to enter animal holding areas. Street clothing must be covered with appropriate attire, e.g., a laboratory coat or gown.

b. All staff is trained to wash their hands/dispose of gloves prior to leaving an animal room/work area.

c. UNMC/UNO are clean air facilities. Smoking is permitted only in designated outside areas. Eating, drinking, smoking, or personal items such as coats, cosmetics, etc., are prohibited in any animal room.

5. Medical Evaluation and Preventive Medicine for Personnel

a. The components of the physical examination are based on the functional requirements of the position, the type of animal contact, and the individual's prior medical history. The physician will assess if program participants should submit a serum sample for storage based on risk assessment.

b. Immunizations. All participants will have the following vaccinations documented:

   Tetanus Prophylaxis
   Hepatitis B (as required)
   Rabies/ Measles (as required)

c. Participants with suspected allergies will be encouraged to seek evaluation by health treatment personnel including employees at risk for developing work related allergies or those with a history of pre-existing allergies, asthma, seasonal rhinitis or eczema. Allergy testing may be requested as a part of the risk assessment.

d. Personnel who will have contact with sheep and goats will be assessed for their risk relative to Q-fever.

e. Tuberculosis: This zoonotic disease can be devastating in a monkey colony. Because of the significant hazard associated with tuberculosis, special precautions are taken for individuals working with non-human primates or their products or care devices. Tuberculin skin testing is performed for all employees or participants with non-human primate, product or device contact. No person with active TB will be allowed into a non-human primate facility.

f. Rubeola (measles): Measles can be a deadly disease to nonhuman primates. Persons with active cases of measles will be prohibited entry to any non-human primate facility. All employees working in rooms containing non-human primates must have documented proof of immunity or be vaccinated.
g. Cercopithecine Herpesvirus 1 (Herpes B-virus): Participants are apprised of the issues surrounding this disease which can result from bites, scratches, needle sticks and mucosal exposure from rhesus, cynomologus and other "Old World" monkeys of the genus Macaca. Since there is no vaccine for this disease, training in proper primate handling and care is provided. Additionally, wound management procedures are re-enforced during primate training sessions required by the IACUC and Comparative Medicine.

6. Animal Experimentation Involving Hazards

a. The IACUC identifies studies where hazardous materials are used in living animals at the time of protocol review. For biological agents, safety guidelines are based on the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories" 1999 and subsequent revisions, and current NIH Recombinant DNA Guidelines. The Radiation Safety Office provides guidelines for the use of radioisotopes in animals and monitors their use. The Chemical and Radiation Safety Office and the Campus Safety Office monitor the use of toxicological hazards.

b. The AV, Assistant Director for Operations, the Safety/Compliance Coordinator and the Facilities Manager/s are responsible for ensuring that all personnel follow UNMC/UNO polices and procedures and Standard Operating procedures (SOPs).

c. The door to rooms used for the study of hazardous materials are kept closed and locked and are appropriately posted with an Operational Safety Protocol. Each animal cage is properly identified with a cage card and the hazardous materials used. All personnel entering the room must wear proper personal protective equipment (PPE) in accordance with the posted OSP.

d. For radiologic hazards a license must be obtained by the Principal Investigator. A permit must be obtained for each person working under the principal investigator. Application forms are obtained from the Radiation Safety Officer, Chemical and Radiological Safety Office.

e. Waste gaseous anesthetics from anesthesia machines in the animal facilities are either exhausted through an in-house vacuum circuit or via weight monitored charcoal F-Air canisters.

7. Facilities, Procedures, and Monitoring

a. All employees are instructed to immediately report or correct any unsafe or potentially unsafe working condition. There are some risks associated with housing and handling large animals such as non human primates, swine, sheep, or dogs.

b. The UNMC animal facility has three rooms that can be used for studies that involve hazardous agents. These rooms are of similar design and construction as the other animal rooms. These three rooms have a small ante-chamber that must be passed through in order to gain access to the main animal room. These antechambers have positive air pressure to both the animal room and the corridor. These rooms do not contain floor drains. CM has two portable self-contained sinks for use in these rooms when required.

The UNMC animal facility also has an ABSL-3/Select Agent animal holding area. This facility contains three animal holding rooms with ante-rooms, lockers, shower, and autoclave.
There is a procedure/laboratory room that contains a chemical fume hood, bio-safety cabinet and stainless steel cabinetry. This facility was commissioned by the CDC in May, 2006.

c. Approved Operational Safety Protocols are followed. For those agents that may have a volatile or dust borne hazard, the animals are held in chemical hoods within the animal room for a prescribed period, usually 48 hours. Animals injected with bio-hazardous agents are housed in appropriate facilities. Depending on the agents used, animals are housed in static or ventilated micro-isolator cages. Operational Safety Protocols are posted.

The Radiation Safety Office provides the PI and Comparative Medicine with an RSO Form 35 that details the procedures to be followed when handling and housing animals that have been administered radioisotopes. An OSP is then posted on the animal room door.

d. Personnel who interact with non-human primates are provided with shoe covers, gloves, dedicated lab coats, face masks, and either goggles or face shields. Total eye protection is required if personnel may be exposed to liquid splashes. Primate exposure/Bite Scratch Medical Treatment kits are provided. All cases involving animal bites/wounds are referred to employee/student health for treatment and evaluation.

F. Animal Care and Use Facilities

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, by species, of animals in each facility may be found in Attachment 4.

G. Training Program

1. Personnel Conducting Procedures on Live Animals

a. In order to provide fundamental training in the humane care and use of laboratory animals, UNMC/UNO maintains a website that includes comprehensive guidelines and policies regarding the care and use of live vertebrate animals. This information is available to all personnel who will be involved with the care and/or use of laboratory animals. Contents include the following: current federal policies/regulations governing the care and use of laboratory animals, institutional policies and ethical principles governing animal care and use, research and testing methods that minimize animal pain and distress, non-animal alternatives, educational resources, species information, principles of anesthesia/pain monitoring, pre and postoperative care, AVMA recommendations regarding euthanasia, and IACUC and CM policies.

b. The IACUC requires completion of an IACUC Basic online training course offered through the AALAS Learning Library for all personnel prior to their participation in animal-use protocols. This training course includes information on Federal regulations, selection of species, appropriate animal numbers, proper use of anesthetic and analgesic agents, production of antibodies, euthanasia, exercise for dogs, primate environmental enrichment, and dealing with observed and suspected non-compliance.

c. In order to provide specific training in humane biomed methodology (restraint, individual animal identification, injection techniques, blood sampling and euthanasia) for the various species of animals used at UNMC/UNO, a series of species-specific training videotapes and AALAS Learning Library courses are available to all personnel.
d. The Director of CM and/or an assigned veterinarian provides "hands-on" training for investigators and other personnel as needed.

e. The qualifications and training of personnel conducting procedures on live animals are thoroughly assessed as part of the IACUC protocol review process and individual protocols are either not approved until the IACUC is satisfied with the competency level of all the listed personnel or individual personnel are required to undergo training before they are permitted to interact independently with a live animal. When additional training is required, the IACUC is responsible for assuring the availability of appropriate training and participation by investigators and research technicians as required. Documentation of this training is maintained on file in the IACUC Administrative Office.

2. Animal Facility Personnel

The Director of CM provides training for the facility animal care technicians; most of whom are AALAS certified.

3. IACUC Members

a. All IACUC members are provided electronic or hard copies of the PHS Policy, the Guide, The ARENA/OLAW IACUC Guidebook, the Institution's Animal Welfare Assurance, USDA Regulations, USDA Animal Care Policies.

b. All new IACUC members undergo an orientation conducted by the IACUC Chair, the veterinarians, the IACUC Administrator and the Protocol Assessment Liaison.

c. All IACUC members are given electronic copies of relevant articles and new guidance issued by OLAW and USDA.

d. In June of 2007 the institution held customized IACUC 101 training for IACUC members and investigators with participation from both OLAW and USDA. This course will be repeated in the future.

e. Completion of an online training course offered through the AALAS Learning Library is required for all IACUC members.

4. Documentation – Records of all training materials provided to IACUC members as specified in Section G.3.a and c are maintained on file. Attendance rosters are maintained for all training sessions. Documentation of all training will be maintained by the Institution and will be available to OLAW upon request.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. 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's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category One (1)—accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. RECORDKEEPING REQUIREMENTS

A. This Institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by the 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 Institutional Official, Thomas H. Rosenquist, Ph.D.

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. This Institution's reporting period is January 1st through December 31st. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31st of each year. The report will include:

1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation 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 change in the IACUC membership. If there are no changes to report, this Institution will provide 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 Institutional Official, Thomas H. Rosenquist, Ph.D.

B. The IACUC, through the Institutional Official, will promptly provide OLAW 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 sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

   Name: Thomas H. Rosenquist, Ph.D.
   Title: Vice Chancellor for Research
   Name of Institution: University of Nebraska Medical Center; University of Nebraska at Omaha
   Address: ARS 2051
             987878 Nebraska Medical Center
             Omaha, NE 68198
   Phone: 402-559-4032
   Fax: 402-559-3990
   E-mail: throseng@unmc.edu
   Signature: [Signature]
   Date: 10/1/18

B. PHS Approving Official

   Eileen M. Morgan
   Director, Division of Assurances, OLAW
   National Institutes of Health
   RKL1, Suite 360-MSC 7982
   6705 Rockledge Drive
   Bethesda, MD 20892-7982

   Signature: [Signature]
   Date: 10/10/08

C. Effective Date of Assurance: 10/10/08

D. Expiration Date of Assurance: 10/30/12