

**UNIVERSITY OF NEBRASKA MEDICAL CENTER
UNIVERSITY OF NEBRASKA AT OMAHA**

#A3294-01

Animal Welfare Assurance

I, Ernest D. Prentice, as named Institutional Official for animal care and use at the University of Nebraska Medical Center (UNMC) and the University of Nebraska at Omaha (UNO), provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, NSF and HHS Biomedical Advanced Research and Development Authority (BARDA). This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: All components of UNMC are physically located on campuses in Lincoln, Nebraska and Omaha, Nebraska; and all components of UNO are physically located on the respective campus in Omaha, Nebraska. The distance between the Medical Center Omaha and Lincoln Campuses is ~55 miles—less than one hour driving time.

B. The following are other institution(s), or branches and components of another institution:

Therapeutic Vision, Inc. in collaboration with the other "satellite locations"/participating animal clinics. These Covered Components are added solely for the purposes and activities for the specific project on Phase II (and Phase IIB, if funded) Grant #5R44EY018013-04:

- a. VetVision;
- b. Gulf Coast Animal Eye Clinic;
- c. Eye Care for Animals, MD;
- d. Veterinary Eye Specialists of Nebraska;
- e. Eye Care for Animals, AZ;
- f. Eye Care for Animals, San Diego, CA;
- g. Eye Care for Animals, Tustin, CA;
- h. Animal Ophthalmology Clinic, Ltd;
- i. Tampa Bay Veterinary Specialists;
- j. Southern Eye Clinic for Animals;
- k. MedVet Medical & Cancer Center for Pets.

10/18/16

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, and 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 according to the *Guide for the Care and Use of Laboratory Animals (Guide)*.
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub award) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows: (See also Attachment 1)
 - 1. On file 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.
 - 2. The Associate Vice Chancellor for Academic Affairs (AVCAA) serves as the IO. The IO reports directly to the UNMC Chancellor who is the CEO.
 - 3. 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 a Director of Animal Welfare, two IACUC Administrators, and a Protocol Assessment Liaison (PAL) who work closely with the Chair of the IACUC and the AVs.
 - 4. 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, an additional clinical veterinarian who reports to the Director and an Assistant Director for Operations (ADO). CM also includes individuals involved in facility management, husbandry, financial and business services, safety and veterinary technical services. There are approximately 20 animal care technicians in CM.

5. 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. There are approximately five animal care technicians at UNO.

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

1. **Robert S. Dixon, D.V.M., M.S., D.A.C.L.A.M., UNMC Attending Veterinarian and UNMC Director of Comparative Medicine**

Qualifications

- 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 or experience in laboratory animal medicine or in the use of the species at the institution: 46 years of experience in all aspects of laboratory animal medicine.

Authority: Dr. Dixon has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program: Dr. Dixon is a full time employee of UNMC. One-hundred percent of his time is contributed to the animal care and use program.

2. **Noel D. Johnson, D.V.M., M.P.H., D.A.C.L.A.M., UNMC Alternate Attending Veterinarian** Qualifications

- 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 or experience in laboratory animal medicine or in the use of the species at the institution: 17 years of experience in all aspects of laboratory animal medicine.

Authority: 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.

Time contributed to program: Dr. Johnson is a full time employee of UNMC. One-hundred percent of his time is contributed to the animal care and use program. He 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**

Qualifications

- Degrees: D.V.M. Pre-Veterinary/Animal Science Major, Colorado State University, Ft. Collins, CO, 1990-1993; D.V.M., Kansas State University, Manhattan, KS, 1997.
- Training or experience in laboratory animal medicine or in the use of the species at the institution: 12 years of experience in all aspects of laboratory animal medicine; Certified Professional IACUC Administrator 2012.

Authority: 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.

Time contributed to program: Dr. Wells is a full time employee of UNMC. One-hundred percent of her time is contributed to the animal care and use program. She serves as the alternate AV approximately five percent of the time. The rest of the time is devoted to clinical veterinary responsibilities.

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

Qualifications

- Degrees: B.S. in Animal Science University of Nebraska at Lincoln (1983), D.V.M. Iowa State University (1987)
- Training or experience in laboratory animal medicine or in the use of the species at the institution: 9 years of experience in laboratory animal medicine. Internships include nonhuman primates at the Houston Zoo in 1986 and the Henry Doorly Zoo in 1987.

Authority: 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.

Time contributed to program: Dr. Gunkelman is present at the Institution (UNO) an average of approximately eight hours per month. One-hundred percent of this time is contributed to the animal care and use program at UNO. In addition, Dr. Gunkelman contributes on average approximately eight 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. Julie E. Napier, D.V.M.; UNO Alternate Attending Veterinarian

Qualifications

- Degrees: Professional and Academic Degrees: BA in Political Science Colorado State University (1980); D.V.M. Iowa State University (1999)
- Training or experience in laboratory animal medicine or in the use of the species at the institution: 22 years of experience in all aspects of animal medicine at UNO and the Henry Doorly Zoo in Omaha, NE.

Authority: 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.

Time contributed to program: Back-up veterinarian. On call basis, as required.

- C.** The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The Chancellor, as Chief Executive Officer (CEO), has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Part VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

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:

- a. The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.
- b. 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.
- c. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
- d. The evaluation will include, but not necessarily be limited to, a review of the following:
 - Institutional and Individual Responsibilities
 - Animal Care and Use Program;
 - Disaster Plans and Emergency Preparedness;
 - IACUC Protocol Review – Special Considerations;
 - IACUC Membership and Functions;
 - IACUC Member Experience and Training;
 - IACUC Records and Reporting Requirements;
 - Husbandry and Veterinary Care;
 - Personnel Qualifications and Training;
 - Occupational Health and Safety (OHS) of Personnel;
 - Facility and Personnel Security;
 - Investigating and Reporting Animal Welfare Concerns
 - IACUC Policies, SOPs, Guidelines, Drug Formularies
- e. In addition, the evaluation may periodically include a review of the Institution's PHS Assurance.
- f. 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.
- g. Subcommittees may be used to conduct all or part of the reviews. However, 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 and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

- a. At least once every six months at least two voting members of the IACUC will inspect all of the institute's animal facilities and animal surgical areas. The areas inspected include, but are not necessary limited to the following: any and all buildings, rooms, areas, enclosures, or vehicles and equipment, including satellite facilities, used for animal confinement, transportation, maintenance, breeding, or experiments inclusive of surgical manipulation.
 - b. 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.
 - c. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
 - d. 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.
 - e. Subcommittees may be used to conduct all or part of the inspections. However, no member will be involuntarily excluded from participating in any portion of the inspections.
 - f. For individual facilities that house or involve only non-USDA covered species, the Institutional Animal Care and Use Committee (IACUC) may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.
- 3. Prepare reports of the IACUC evaluations according to 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:**
- a. 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 as a model.
 - b. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy,
 - c. The reports will identify specifically any departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures the reports will so state. Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.
 - d. Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such, i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.

- e. 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.
- f. If some or all of the institution's facilities are not accredited by AAALAC International the reports will identify those facilities as such.
- g. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee.
- h. 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 so state.
- i. 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.
- j. Deficiencies will be tracked by the IACUC to ensure that they are appropriately resolved.

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 Director of Animal Welfare, the Protocol Assessment Liaison or the IO.
- b. Notices are located in the animal facilities and on the IACUC website 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 IACUC Subcommittee (IS). The IS will consist of the IACUC Chair, the AV, the Protocol Assessment Liaison and members of the IACUC. No IACUC member is excluded from participation.
- 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, and, if necessary and/or requested, any member of the IACUC or other key staff may be involved in the investigation. 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 IS. The IS will make a recommendation to the IACUC.
- h. On behalf of the IS, PAL will produce a report summarizing the investigation, corrective action taken and IS recommendations. This report will be provided to the Principal Investigator (PI) or other involved personnel. The recipient of the IS report will be asked to acknowledge the report, provide any comments and appeal as necessary, in accordance with a set deadline.
- i. All IACUC members will have the opportunity to review the concern and action will be taken, as necessary.
- j. 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.
- k. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to the IO.
- l. OLAW will be notified in accordance with the reporting requirements of the PHS Policy at IV.F.3.
- m. All reports must be maintained on file in the IACUC Office including any associated documentation.
- n. 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 Institutional Official 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:

- a. Recommendations regarding any aspects of the institution's animal program or facilities are reviewed by the Committee, revised as appropriate, and then submitted to the IO.
- b. The committee's recommendations are included in the IACUC meeting minutes or a report of the IACUC's evaluations or a separate letter.

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

a. Submission:

- 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.
- In accordance with IACUC policies, the pain category determines whether the protocol requires review by full committee review (FCR) or whether it may possibly be reviewed by designated member review (DMR).
- Pre-review of submissions is performed on all new submissions by the Director of Animal Welfare, the IACUC administrative office, or as needed by other IACUC members.

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.
- 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 reminds investigators to declare any conflicting interest not previously noted.
- 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.

c. Full Committee Review (FCR):

- Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. 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. The IACUC usually meets once per month with additional meetings to address extenuating circumstances convened when necessary.
- A complete list of protocols scheduled for full IACUC review are distributed via email to all members at least one week prior to the meeting. Specific instructions regarding the review process, due dates, and instructions on how to

access the protocols (which are stored on a secure server that all IACUC members have access to) are provided to all members of the IACUC.

- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
- The IACUC chair, or his/her designee, assigns one or two members and the AV (or one of the alternate AVs) to serve as primary reviewers (not to be confused with designated reviewer). The primary reviewers present their finding to other members of the committee at a properly convened IACUC meeting for discussion.
- 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, and if necessary the consultant may be invited to the Full Committee Meeting. Consultants may not approve or withhold approval of an activity or vote with the IACUC.
- Following review of the protocol, a motion is made and a vote taken to either: 1) approve, 2) require modification(s) to secure approval, or 3) withhold approval. Each of these actions requires agreement by a majority of those members present at the convened meeting.
- Required Modifications Subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:
 - 1) FCR or DMR following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.
 - 2) DMR if approved unanimously by all members at the meeting at which the required modifications are developed delineated AND if all IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
 - 3) If an IACUC uses DMR, the approval date is the date that the designated member(s) approve the study.
 - 4) Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

d. Designated Member Review (DMR):

- A complete list of protocols scheduled for DMR is distributed via email to all members with specific instructions regarding the designated review process, instructions on how to access the protocols which are stored on a secure server that all IACUC members have access to and a deadline to call for FCR which is generally 2-5 business days. Affirmation from all IACUC members is not required (silent assent).
- 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.
- While other IACUC members may provide the DR(s) with comments and/or suggestions for the reviewers' consideration, concurrence to use the DMR method may not be conditioned.
- After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all designated reviewers for review and approval.
- 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 (silent assent), 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 authority to withhold approval.
- The IACUC minutes contain notification of all actions approved by DMR.

e. Special or Expedited Reviews

- As noted above, under extenuating circumstances, the deadline for obtaining concurrence to use DMR 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. There are no other procedures for special or expedited reviews.

f. All Reviews: 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.
- v. 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.
- vi. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- vii. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- viii. Methods of euthanasia used will be consistent with the current American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, 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. Other than the specific exceptions delineated in OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014 and as delineated below and in IACUC approved policies, review and approval of significant 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:

- 1) in the objectives of a study;
- 2) from non-survival to survival surgery;
- 3) resulting in greater discomfort or in a greater degree of invasiveness;
- 4) in the housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- 5) in the species
- 6) in Principal Investigator;
- 7) that impact personnel safety;
- 8) in anesthetic agent(s) or the use or withholding of analgesics;
- 9) in the method of euthanasia;
- 10) in the duration, frequency, or number of procedures performed on an animal
- 11) in approximate number of animals used¹

¹Changes of less than 10% in the approximate number of animals used of mice of the genus *Mus* and rats of the genus *Rattus* that are bred for use in research only may, at the IACUC's discretion, be considered minor (not significant).

c. The specific significant changes described below, may be allowed administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC, referred to as Administrative Veterinary Verification Consultation (AVVC).

- 1) anesthesia, analgesia, sedation, or experimental substances;
 - 2) euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
 - 3) duration, frequency, type or number of procedures performed on an animal
- Review and approval of items 1-3 above may only be handled administratively in consultation with a University of Nebraska veterinarian who is authorized by the IACUC and as described in an IACUC approved written policy(ies) that is compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will include specific evaluation criteria, e.g., published drug formularies, AVMA Guidelines for the Euthanasia of Animals, allowable blood draw data/charts, etc. Such policies will also address possible negative impacts on animal welfare.
 - All such aforementioned written policies related to veterinary verification and consultation and administrative review will be adopted [reviewed and approved] by formal action of the IACUC.
 - All authorizations of individuals by the IACUC to handle changes administratively will be specific (by name or position title and change(s) authorized to handle) and in writing.
 - All such aforementioned policies and authorization of individuals related to administrative review may be approved for a maximum of 36 months only. That is, all such policies expire no later than the three-year anniversary of the IACUC approval.

- If the IACUC wishes to continue the procedures/policies and/or authorizations beyond the expiration date, prior to expiration of the policy, the existing or a new policy must be reviewed and adopted by formal action by the IACUC using FCR or DMR.
- All changes managed by AVVC will be documented in the associated protocol file.

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).
- b. In order to secure approval the investigator is provided with specified, delineated, detailed written modifications/clarifications required by the Committee and must revise the IACUC application and/or respond to conditions set by the IACUC.
- c. 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 person, before a fully convened meeting of the IACUC, or in writing.
- 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 at least once every three years according to PHS Policy IV.C.1-5. The IACUC procedures for conducting continuing reviews are as follows:

Post-approval Monitoring (PAM)

- a. All ongoing activities are monitored continuously by the Comparative Medicine staff.
- b. The Protocol Assessment Liaison conducts random lab visits and serves as a consultant on laboratory and facility semiannual inspections whenever possible.

c. The Director of Animal Welfare monitors IACUC designated Pilot Studies. Monitoring involves questions about whether the study has begun, status of the pilot study, anticipated completion, etc. Relevant aspects are discussed with the veterinarian(s) and the findings reported to the IACUC for action by DMR or FCR, as necessary.

d. Following initial protocol approval, the Director of Animal Welfare contacts investigators to monitor progress and address any questions or concerns the investigator may have related to the study.

Continuing / Periodic Protocol Review

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

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

c. 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 at least once every 12 months.

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. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.

- b. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
- c. The IACUC may suspend the entire protocol or any component of a protocol.
- d. 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.
- e. 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 in writing to OLAW. Preliminary reports may be made verbally. Suspensions shall also be reported to USDA if the activity/species is USDA regulated.
- f. An IACUC suspension can only be lifted by the full IACUC at a convened meeting.

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

1. Administration/management

- a. The Director of CM in coordination with Employee Health manages the Occupational Health and Safety Program (OHSP), and the IACUC maintains oversight of the program.
- b. Ultimately, the overall responsibility to ensure that all of the entities are fulfilling their respective responsibilities lies with the Institutional Official.

2. Scope

- a. It is the policy of the University of Nebraska Medical Center (UNMC) and University of Nebraska at Omaha (UNO) Institutional Animal Care and Use Committee (IACUC) to minimize the risk of injury to personnel who have contact with animals/animal tissues or fluids, to promote health, and to protect university property.
- b. Personnel with animal or animal tissue/fluid contact are required to enroll in the Occupational Health and Safety Program (OHSP) and obtain medical clearance before access to animal facilities is granted. Enrollment also requires scheduled periodic health evaluations/status reviews to obtain information that can be used to verify a change in work or health status and/or to verify the success of the OHSP in reducing occupational related illness and injury. 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 OHS seminar or viewing the video tape of the seminar on-line.

c. The program participation requirements are based on the type of animals personnel are or will be exposed to and/or the degree of exposure. A questionnaire (one for initial entry and one for periodic updates) is used to determine this degree of risk and the appropriate category. Enrollment in the OHSP and maintenance of medical clearance is a condition of continuing employment.

3. Health Histories and Evaluations

a. The individual's health history and the physical examination are assessed and evaluated according to the functional requirements of the position, and the type of animal contact. The physician will determine if program participants should submit a serum sample for storage based on risk assessment.

b. 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.

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

d. 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.

e. 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.

f. Macacine Herpesvirus 1 (Herpes B-virus): Participants are apprised of training required prior to animal contact and 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.

4. 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 of CM and the CM Safety/Compliance Program Manager are active members 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 CM Safety/Compliance Program Manager. The OSP identifies the safety requirements/procedures for safe animal care within the facilities and are posted on the entry door to the animal room.

b. 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 most recent edition of the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," 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.

c. Specific OSP 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.

d. 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/qualified consultant from the College of Public Health develop the protocol. The protocols are posted on the entry door to the animal room.

e. 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.

f. 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. OSP are developed between the animal care staff, appropriate safety personnel, bio-safety, and the investigator prior to the use of hazardous substances in animals.

5. Procedures in Place to Alleviate Hazards and Minimize Risks.

a. Risks are mitigated through institutional policies, engineering controls, work practices, and personal protective equipment. It is the responsibility of principal investigators to ensure that laboratory staff are informed of and participate in the UNMC/UNO OHSP.

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

- c. 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.
- d. 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/Compliance Program Manager, properly train all involved parties prior to beginning a study. If an accident occurs, appropriate safety personnel are to be notified immediately.
- e. Personnel who work with nonhuman primates other than macaques must be trained in topics such as taxonomy and behavior, cognition, psychological well-being, zoonosis, and safe practices for dealing with primates.
- f. 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.
- g. UNMC has additional online training requirements including the following annual mandatory courses: (1) Blood borne Pathogen and Tuberculosis training for all individuals in the research field; (2) Annual IBC General Biosafety; (3) Annual IBC BL3 containment for personnel using BSL3 agents and (4) Annual Radiation Safety.
- h. 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., training and fit-testing for personnel using respirators).
- i. 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.
- j. 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).
- k. All staff is trained to wash their hands/dispose of gloves prior to leaving an animal room/work area.

l. 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.

m. The door to rooms used for the study of hazardous materials are kept closed and locked and are appropriately posted with an OSP. 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.

n. 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.

o. 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.

6. Immunizations

a. All participants will have the following vaccinations documented:
Tetanus Prophylaxis, Hepatitis B (as required), Rabies/ Measles (as required)

7. Precautions taken during pregnancy, illness or decreased immune-competence

a. Training for personal health related conditions (i.e. pregnancy illness or immune-competence). All employees are required to fill out a Confidential Health Questionnaire which asks if you are pregnant or immunocompromised. Employee Health then provides training or referral to one's own physician. Recommendations for specific safety precautions or work limitations will be conveyed by the health care provider to the person's supervisor.

8. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used

a. All personnel including facilities maintenance are required to enroll in the OHSP prior to having access to animal housing or animal use areas.

b. In situations where non-university personnel (e.g., visitors, contractors, etc.) must access the animal facilities, they are briefed on appropriate precautions and provided any appropriate PPE and are then are permitted in for a limited amount of time. A member of the animal care staff will be available for escort if needed. If there is extensive or prolonged work to be done, the animals are removed from the room(s).

9. Availability and procedures for treatment of bites, scratches, illness or injury

- a. Personnel are advised to report all injuries to Comparative Medicine and their supervisor. First aid kits are available for the treatment of minor injuries. All personnel are encouraged to see a health care provider for injury evaluation at Employee Health, Monday – Friday or the UNMC Emergency Department after hours or on weekends.
- b. First aid kits are located in each CM break area and maintained by the CM Safety/ Compliance Program Manager or their designee.
- c. For all serious and/ or potentially life threatening injuries, personnel are directed to call Emergency Dispatch at 9-5555 or proceed to the UNMC Emergency Department. For guidance related to any potentially infectious/ hazardous material exposure, call the OUCH pager, 24-7: 402-888-OUCH (6824).
- d. 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 Macacine herpesvirus 1 has occurred. The Non-Human Primate Exposure/Bite Scratch Medical Treatment Kit and specific procedures are available in all required areas.

10. Procedures/program for reporting and tracking injuries and illnesses

- a. If any employee or student suffers an injury (e.g., animal bite) or is exposed to a hazardous biological or chemical agent which is a threat to health and safety, they must report it immediately to their direct supervisor and appropriate emergency medical services. Tracking of injuries and illnesses is the responsibility of the institution's employee health department.

11. Other Pertinent Information Regarding the OHSP

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. There are multiple rooms which can be changed from positive to negative pressure depending on the research protocol and applicable hazards. All non human primate housing areas contain ante-rooms. CM has two portable self-contained sinks for use in these rooms when required.
- c. The UNMC animal facility also has an ABSL-3 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.

d. Approved OSP are followed. For those agents that may have a volatile or dust borne hazard, the animals are held in ducted biosafety cabinets exhausted to outside 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. OSP are posted.

e. 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.

f. Personnel who interact with non-human primates are provided with shoe covers, gloves, dedicated lab coats or Tyvek suits, face masks, goggles or face shields, as appropriate. 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. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in Part X., the Facility and Species Inventory table.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

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

requirements for dogs, primate environmental enrichment, and dealing with observed and suspected non-compliance.

c. In order to provide specific training in humane bio 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, and/or CM Technical Services provide "hands-on" training for investigators and other personnel as needed. At UNO, the AV 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. At UNO the AV and AAALAS certified facility animal care technician(s) provide training for facility animal care technicians.

3. IACUC Members

a. All IACUC members are provided electronic or hard copies of the following:

- 1) PHS Policy;
- 2) Guide for the Care and Use of Laboratory Animals;
- 3) ARENA/OLAW IACUC Guide book;
- 4) USDA Regulations;
- 5) USDA Animal Care Policies; and
- 6) A copy of this Animal Welfare Assurance.

b. All new IACUC members undergo an orientation conducted by the IACUC Chair; including participation by the Director of Animal Welfare, the veterinarians, the IACUC Administrators 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. In the fall

of 2013, the institution held Fundamentals and Challenges training for IACUC members and investigators. Another course will be scheduled in the near future.

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

4. All Personnel

The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). Specifically, as applicable, training and instruction of personnel includes guidance in at least the following areas:

- a. Humane methods of animal maintenance and experimentation, including:
 1. The basic needs of each species of animal;
 2. Proper handling and care for the various species of animals used by the facility;
 3. Proper pre-procedural and post-procedural care of animals; and
 4. Aseptic surgical methods and procedures;
- b. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
- c. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
- d. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
- e. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 1. on appropriate methods of animal care and use;
 2. on alternatives to the use of live animals in research;
 3. That could prevent unintended and unnecessary duplication of research involving animals; and
 4. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations
- f. All personnel are informed to go to the IACUC Website, Comparative Medicine Website, Research Support Services to access the OLAW Assurance, IACUC Policies and SOPs, Forms, Education and additional guidance information.

5. 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

A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be re-evaluated by the IACUC at least once every six months according to 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 PHS Policy and 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.

B. This Institution is Category 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 records for a minimum of three years:

1. A copy of this Assurance and any modifications made to it, 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 granted or withheld
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Ernest D. Prentice, 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 3 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. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual 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)
2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
3. Any change in the IACUC membership
4. 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, Ernest D. Prentice, Ph.D.
5. Any minority views filed by members of the IACUC

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 VI.A. and VI.B. (above) should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Ernest D. Prentice, Ph.D.

Title: Associate Vice Chancellor, Academic Affairs

Name of Institution: University of Nebraska Medical Center; University of Nebraska at Omaha

Address:

ARS 3005
987830 Nebraska Medical Center
Omaha, NE 68198

Phone: 402-559-6045

Fax: 402-559-3300

E-mail: edprenti@unmc.edu

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature:



Date: August 15, 2016

B. PHS Approving Official (to be completed by OLAW)

Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare, NIH
6705 Rockledge Drive-Suite 360-MSC 7982
Bethesda, Maryland 20892-7982

Eileen M.
Morgan -S

Digitally signed by Eileen M. Morgan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010142050, cn=Eileen M. Morgan -S
Date: 2016.10.24 10:21:44 -04'00'

Signature:

Date:

Assurance Number: D16-00189 (A3294-01)

Effective Date:

10/20/16

Expiration Date:

10/31/20

VIII. Membership of the IACUC

Date: October 2016			
Name of Institution: University of Nebraska Medical Center; University of Nebraska at Omaha			
Assurance Number: A3294-01			
IACUC Chairperson			
Name*: William G. Chaney			
Title*: Exec. Chair; Professor, Biochemistry & Molecular Biology			Degree/Credentials*: Ph.D.
Address*: (street, city, state, zip code) University of Nebraska Medical Center 987830 Nebraska Medical Center Omaha, NE 69198-7830			
E-mail*: wchaney@unmc.edu and/or iacucora@unmc.edu			
Phone*: (402)559-6657 (402)559-6046		Fax*: (402)559-3300	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Robert S. Dixon	D.V.M., M.S.	UNMC Attending Veterinarian, Director, Comparative Medicine, Associate Professor, Surgery	Veterinarian
Lizabeth S. Gunkelman	D.V.M.	UNO Attending Veterinarian	Veterinarian
1. Vice Chair	Ph.D.	Professor, Internal Medicine	Scientist
2.	B.S.	Agricultural Journalist	Nonscientist and Non-affiliated Member
3. Vice Chair	Ph.D.	Associate Professor, Genetics, Cell Biology and Anatomy	Scientist
4.	Ph.D.	Assistant Professor, Cellular Integrative Physiology	Scientist
5.	Ph.D.	Research Assistant Professor, Eppley Institute	Scientist
6.	Ph.D.	Associate Professor, Pathology Microbiology	Scientist
7.	Ph.D., M.S.	Assistant Professor, College of Dentistry	Scientist
8.	Ph.D.	Professor, Pharmaceutical Sciences	Scientist
9.	Ph.D.	Associate Professor, Pharmacology/Exp Neuroscience	Scientist
10.	Ph.D.	Associate Professor, Psychology UNO	Scientist
11.	B.S.	Landscape Architect	Nonscientist and Non-affiliated Member
12.	D.V.M.	Assistant Director, Comparative Medicine	Veterinarian
13.	D.V.M., C.P.I.A.	UNMC Clinical Veterinarian	Veterinarian

Date: October 2016

Name of Institution: University of Nebraska Medical Center; University of Nebraska at Omaha

Assurance Number: A3294-01

ALTERNATE MEMBERS

1.	Ph.D.	Associate Professor, Pharmacology and Experimental Neuroscience	Alternate Scientist
2.	Ph.D.	Professor, Psychology, UNO	Alternate Scientist
3.	Ph.D.	Associate Professor, Genetics, Cell Biology and Anatomy	Alternate Scientist
4.	Ph.D.	Professor, Genetics, Cell Biology and Anatomy	Alternate Scientist
5.	Ph.D.	Professor, Biochem and Molecular Biology	Alternate Scientist
6.	Ph.D.	Assistant Professor, Biochem and Molecular Biology	Alternate Scientist
7.	BChE, BS, MS	Engineering Manager	Alternate Non-affiliated Member
8.	Ph.D.	Assistant Professor, Pharmaceutical Science	Alternate Scientist

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

Veterinarian A veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Scientist A practicing scientist experienced in research involving animals.

Nonscientist A member whose primary concerns are in a nonscientific area. In evaluating the qualifications of an individual to serve as a nonscientific member, the CEO should consider appointing those with a naïve attitude with regard to science and scientific activities. A person without scientific training meets the Policy's intent, such as an ethicist, lawyer, or member of the clergy, as the Policy gives as examples. Some other examples include librarians, those working in business or finance, or instructors in English, history, or other liberal arts disciplines. When the rationale for categorizing an individual as a nonscientist is not apparent based on their occupation or training, the institution should maintain written documentation of the reason for the categorization.

Non-affiliated The nonaffiliated member must represent the general community interests in the proper care and use of animals. The nonaffiliated member must not be (1) a laboratory animal user or former user, (2) affiliated with the institution, or (3) an immediate family member of an individual affiliated with the institution. Immediate family includes parent, spouse, child, and sibling. In evaluating the qualifications of an individual to serve as a nonaffiliated member, the CEO should confirm the appointee has no discernible ties or ongoing affiliation with the institution. Regarding service of former employees or students as nonaffiliated members, the appointing official must be assured that the person is not in any way obligated to the institution. Real or perceived conflicts of interest must be avoided to ensure the IACUC's and the institution's integrity. Appointment of an individual who is unambiguously unaffiliated is the most effective way to fulfill the intent of the Policy

All members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: M. Elizabeth Blackburn, CPIA	
Title: IACUC Administrator	
Phone: 402-559-6046	E-mail: bblackbu@unmc.edu
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

Date: October 2016			
Name of Institution: University of Nebraska Medical Center; University of Nebraska-Omaha			
Assurance Number: A3294-01			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
Durham Research Center I (UNMC)	31,580	Mouse Rat Hamster NHP – Rhesus Macaque African Clawed Frog	16,120 450 27 18 2
Durham Research Center II (UNMC)	24,690	Mouse NHP – Rhesus Macaque Cynomolagus Macaque Rabbit	12,100 12 23 6
Eppley Science Hall (UNMC)	4,963	Swine	3
Wittson Hall (UNMC)	11,591	Mouse Rat	1150 100
Lied Transplant (UNMC)	3,745	Procedure Only	0
4230 Quarantine Building (UNMC)	11,292	Mouse	125
College of Dentistry (Lincoln, NE) (UNMC)	2,328	Mouse	175
Allwine Hall, 5 th floor (UNO)	1600	African Clawed Frog Marmoset	2 50
Allwine Hall (UNO)	5392	Rats Zebra Finch Minnows Zebra Fish Mice	400 60 1170 1400 465

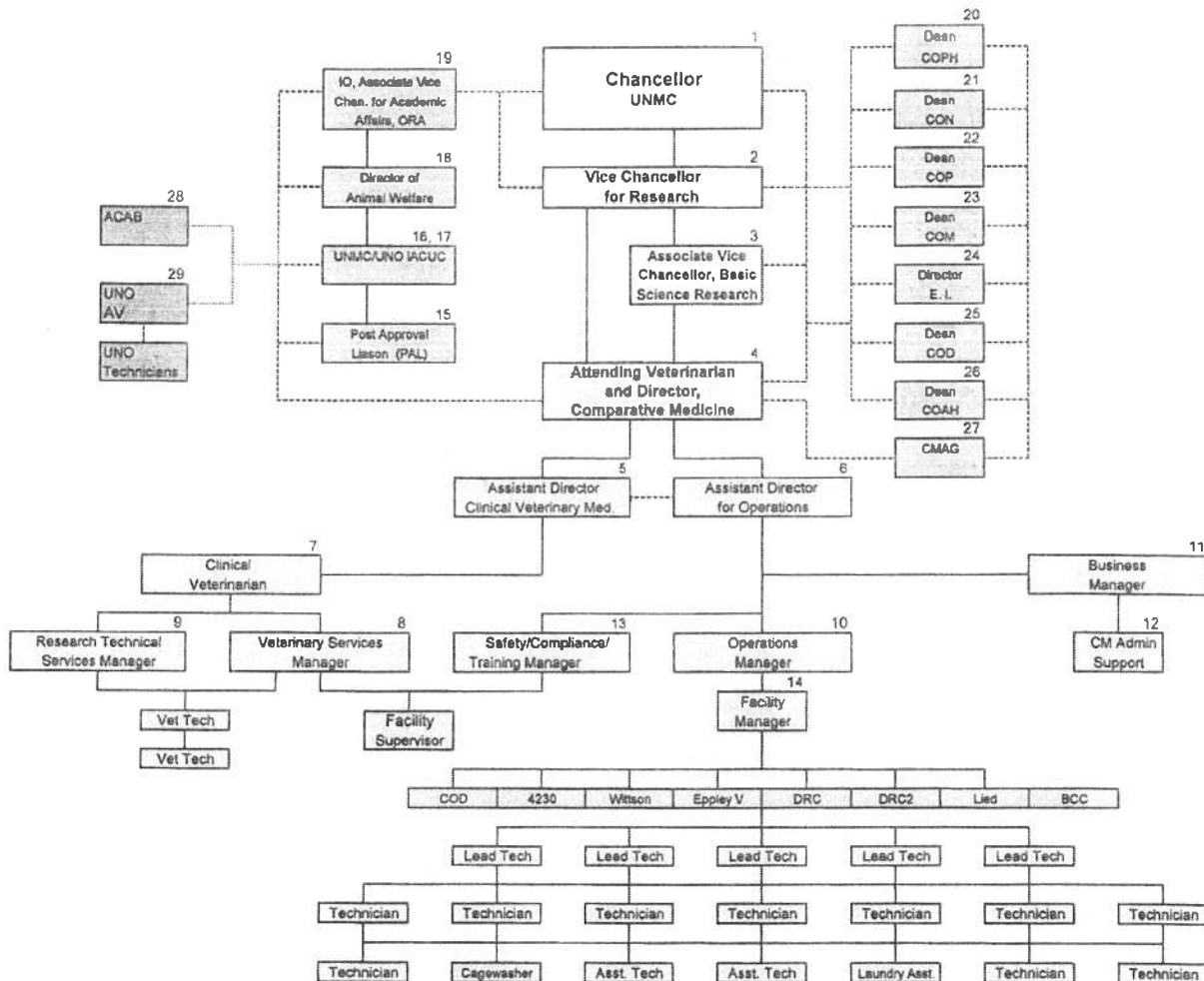
Unless otherwise indicated, mice and rats means mice of the genus *Mus* and rats of the genus *Rattus* that are purposely bred for research.

ORGANIZATIONAL CHART

Institutional Animal Care and Use Program

UNIVERSITY OF NEBRASKA MEDICAL CENTER

August 2016



- 1 Chancellor: Jeffery Gold, M.D.
- 2 Vice Chancellor for Research: Jennifer L. Larsen, M.D.
- 3 Associate Vice Chancellor for Basic Science Research: Kenneth W. Bayles, Ph.D.
- 4 Attending Veterinarian and Director, Comparative Medicine: Robert S. Dixon, D.V.M., M.S., DACLAM
- 5 Assistant Director, Clinical Veterinary Medicine: Noel D. Johnson, D.V.M., MPH, DACLAM
- 6 Assistant Director for Operations: Joseph F. Krajicek III, B.S., A.A.S., CMAR, RLAT
- 7 Clinical Veterinarian: Tami Wells, D.V.M., CPIA
- 8 Veterinary Services Manager: Jane G. Fesler, A.A.S., RLAT
- 9 Research Technical Services Manager: Kristin LeLand Wavrin, B.S.
- 10 Operations Manager: Theresa Larson, B.A., RALAT
- 11 Business Manager: Tricia L. Rump, BSBA., CMAR, RALAT
- 12 CM Administration Support: Sonia Ditter
- 13 Safety/Compliance Manager: Miriam McCann, B.A., LATG
- 14 Facility Manager: Connie Arnold, B.S., RLATG, ILAM
- 15 Post Approval Liason (PAL): Traci Clemons, RLATG, CPIA
- 16 Executive IACUC Chair: William G. Chaney, Ph.D.
- 17 UNMC/UNO IACUC: Administrator; Beth Blackburn, CPIA
- 18 Director of Animal Welfare: Manju George, BVSc & AH, MVSc, Ph.D.
- 19 Institutional Official; Associate Vice Chancellor for Academic Affairs and ORA: Ernest D. Prentice, Ph.D.
- 20 Dean, College of Public Health: Ali S. Khan, M.D., M.P.H.
- 21 Dean, College of Nursing: Juliann G. Sebastian, RN, Ph.D., FAAN
- 22 Dean, College of Pharmacy: Courtney Fletcher, Pharm. D.
- 23 Dean, College of Medicine: Bradley E. Britigan, M.D.
- 24 Director, Eppey Institute: Kenneth H. Cowan, M.D., Ph.D.
- 25 Dean, College of Dentistry: Janet M. Guthmiller, D.D.S., Ph.D.
- 26 Dean, College of Allied Health: Kyle P. Meyer, Ph.D., DT
- 27 Comparative Medicine Advisory Group: Kenneth W. Bayles, Ph.D., Chair
- 28 UNO Animal Care Advisory Board
- 29 UNO Attending Veterinarian: Elizabeth S. Gunkelman, D.V.M.

August 9, 2016

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs
IACUC Institutional Official
University of Nebraska Medical Center

Dear Dr. Prentice:

Please be advised, for the record, that the University of Nebraska at Omaha (UNO) will continue to apply for PHS funded grants using the University of Nebraska Medical Center (UNMC) Animal Welfare Assurance #A3294-01 in full accordance with all the requirements of the PHS Policy for Humane Care and Use of Laboratory Animals.

The UNMC/UNO Institutional Animal Care and Use Committee (IACUC) is UNO's IACUC of record and Ernest D. Prentice, Ph.D. is the named Institutional Official (IO) for animal care and use at UNO and UNMC.

Sincerely,



John Christensen, Chancellor
University of Nebraska at Omaha