North Dakota State University
A3244-01
Animal Welfare Assurance

I, Dr. Kelly Rusch, as named Institutional Official for animal care and use at North Dakota State University, 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. 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 the University (Colleges, Schools, Departments, etc.) that are physically located on the University’s main campus in Fargo, North Dakota 58108. There are no covered off-campus satellite facilities and/or other covered components.

B. The following are other institution(s), or branches and components of another institution: None / Not Applicable.

While every attempt will be made to ensure a uniform and consistent standard for animal care and use, this Assurance applies to PHS supported activities (i.e. it does not apply to agricultural research, agricultural animal production, equine riding and show events, etc. that are not PHS supported).

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 (subaward) 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:

- **NDSU President**
  Dean L. Bresciani, Ph.D.
  *(Chief Executive Officer)*

- **Vice President**
  Research and Creative Activity
  Kelly Rusch, Ph.D.
  *(Institutional Official)*

- **Research Compliance Administrator**
  Ms. Josie Hayden

- **IACUC**
  Neil Dyer, D.V.M., Chair

- **Attending Veterinarian**
  Scott Walden, D.V.M.

- **Animal Projects Personnel**
  (PIs, research staff, facilities managers, caretakers, students, and general staff)
Each person in the described line of authority maintains an open door policy for comments or concerns about institution-wide animal care and use. Additionally, there are direct and open lines of communication between the Institutional Animal Care and Use Committee (IACUC) and the Institutional Official (IO) and between the Attending Veterinarian (AV) and the IO.

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

1. Scott Walden, D.V. M., NDSU Attending Veterinarian
   Qualifications:
   - Degrees: D.V.M., Iowa State University, 1995; Postdoc, Coulston Foundation, Alamogordo, New Mexico
   - Training and/or experience in laboratory animal medicine: Dr. Walden served as the Clinical Veterinarian at the Coulston Foundation. He served as the Clinical Specialist from 1998-2000 and then as the Assistant Director for Research Animal Resources at the University of Minnesota from 2000 to 2007. Dr. Walden joined NDSU in 2007 as the Director of Animal Resources and the University Attending Veterinarian.
   Authority: Dr. Walden has direct program authority and responsibility for the Institution's animal care and use program including the authority to implement the PHS Policy and the recommendations of the Guide. Dr. Walden, as the Attending Veterinarian for the animal care and use program, is responsible for the development and implementation of the veterinary care program and has unfettered access to all animals at NDSU. He exercises institution-wide authority under the animal welfare laws, regulations, PHS Policy, and applicable guidelines.
   Time Contributed to Program: Dr. Walden is a full time employee of NDSU. Approximately one-hundred percent of his time is contributed to the animal care and use program.

   Qualifications:
   - Degrees: D.V.M., Iowa State University, 1991; Masters, Veterinary Pathology, Iowa State University, 1995, Diplomate, ACVP.
   - Training and/or experience: Dr. Dyer received a B.S. in zoology from North Dakota State University in 1977. Pursuant to that he worked in the zoo field (zookeeper, curator, assistant director) for ten years before entering veterinary school. He graduated with a DVM from Iowa State University in 1991, practiced for two years (mixed-animal practice), then returned to ISU for specialty training in veterinary pathology. The specialty training included coursework in the pathology and disease of many animal species, laboratory animals included. During the training period he worked part-time at a small animal/exotic practice in Ames, Iowa. He obtained a Masters degree in veterinary pathology in 1995, and worked briefly at the veterinary diagnostic laboratory at ISU before being hired as a veterinary pathologist at the NDSU veterinary diagnostic laboratory. He completed board certification in veterinary pathology in 1997, and assumed Director responsibilities for the NDSU laboratory the same year. He has served on the NDSU IACUC since
1997 in a variety of capacities (committee member, AV, IACUC chair, backup AV).

**Authority:** Dr. Dyer provides clinical veterinary care in Dr. Walden’s absence.  
**Time Contributed to Program:** Dr. Dyer is a full-time employee of North Dakota State University. He serves as the Director of the Veterinary Diagnostic Laboratory. As the IACUC Chair and Alternate Attending Veterinarian, Dr. Dyer contributes approximately ten percent (10%) of his time to the animal care and use program.

C. The IACUC at this Institution is properly appointed according to 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 President and C.E.O. 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 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 Animal Care and Use Program.

   b. The Committee uses the Guide and other pertinent resources, e.g., the PHS policy and Code of Federal Regulations (Animal Welfare), as the basis for review.

   c. To facilitate the review the Committee will use a checklist based on the sample OLAW Program Review Checklist from the OLAW website.

   d. The review will include, but not necessarily be limited to, a review of the following:

      i. Animal Care and Use Program;
      ii. Disaster Planning and Emergency Preparedness;
      iii. IACUC Protocol Review—Special Considerations;
      iv. IACUC Membership and Functions;
      v. IACUC Training;
      vi. IACUC Records and Reporting Requirements;
      vii. Veterinary Care (all aspects);
      viii. Personnel Qualifications and Training;
      ix. Occupational Health and Safety (OHS) of Personnel;
      x. Personnel Security;
      xi. Investigating and Reporting Animal Welfare Concerns.
e. In addition, the evaluation will 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. All IACUC members will be invited to participate in each portion of the reviews. 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 members of 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, animal surgery areas, and laboratories where animal activities are conducted. Equipment used for transporting animals is also inspected.

   b. The IACUC will use the Guide and other pertinent resources, e.g., the PHS Policy and the Code of Federal Regulations (Animal Welfare), as a basis for the review.

   c. To facilitate the evaluation, the IACUC will use a checklist based on the Sample OLAW 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 IACUC 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. All IACUC members will be invited to participate in each portion of the inspections. No member will be involuntarily excluded from participating in any portion of the reviews.

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:

   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.

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 report 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 accredited by AAALAC International the report will identify those facilities as such.

g. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the IACUC.

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 a reasonable time--generally not to exceed 60 days following the evaluation.

j. Deficiencies will be tracked by the IACUC Administrator/Attending Veterinarian to ensure that that 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 IO, IACUC Chair, Attending Veterinarian, IACUC Office, or any IACUC member.

b. Concerns may be reported verbally or in writing. Individuals may also report concerns anonymously through the NDSU Fraud hotline.

c. Notices in the animal facilities advise individuals how and where to report animal welfare concerns and state that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.
d. 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.

e. All reported concerns will be brought to the attention of the IACUC. No IACUC member is excluded from participation.

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

g. When an investigation is warranted, it will generally be conducted by the IACUC Administrator and Attending Veterinarian, 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: interview of personnel, observing animals, and reviewing pertinent records. Note: Absent of conflict of interest, no member of the IACUC will be involuntarily excluded from participating in any portion of an investigation.

h. A detailed record of the concern and investigation including corrective action already taken will be prepared by the IACUC Administrator and reviewed by the IACUC and/or IACUC Subcommittee.

i. The IACUC Administrative Office will produce a report summarizing the investigation, corrective action taken and IACUC recommendations. This report will be provided to the Principal Investigator (PI) or other involved personnel. The recipient of the report will be asked to acknowledge the report, provide any comments and appeal as necessary, in accordance with a set deadline.

j. All IACUC members will have the opportunity to review the concern and action will be taken, as necessary.

k. Reported concerns and all associated IACUC actions will be reported to the IACUC and 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. Reports to OLAW will be in writing and through the IO. Preliminary reports may be made verbally.

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 aspects of the institution's animal program or facilities are reviewed by the IACUC, revised as appropriate, and then submitted to the IO.

b. The IACUC's recommendations are included in the IACUC meeting minutes.

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:

i. All personnel proposing to use a live vertebrate animal in research, research training, experimentation, biological testing, or related activities must submit a completed Animal Care and Use Application form (hereafter referred to as protocol) to the IACUC Administrative Office.

ii. Protocols can be submitted in paper copy or electronically through NDSU email.

iii. Before the protocol is posted for review, the IACUC Administrator and/or Attending Veterinarian conduct a pre-review

iv. In accordance with IACUC policies, the pain category determines whether the protocol requires review by full committee review (FCR) or whether it may be reviewed by designated member review (DMR).

v. IACUC members are notified of protocol review via email. An email notification is sent to all IACUC members with an electronic copy of the protocol attached.

vi. Protocols are distributed to IACUC members electronically.

b. IACUC Approval Criteria:

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

ii. No IACUC Member may participate (other than to provide requested information) in the review of any protocol in which that member has a
conflicting interest nor may a member who has a conflicting interest contribute to the constitution of a quorum. This also applies to alternate members, non-voting members, ex-officio members, consultants or any other guest in attendance. The conflicted IACUC member must excuse (recuse) him/herself from deliberation, discussion, and vote related to such protocol. At the beginning of each meeting the IACUC Chair calls for conflict of interest disclosures.

iii. 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):

i. Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. A simple majority of the voting 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.

ii. An electronic copy of the protocols scheduled for full IACUC review are distributed via email to all members at least one week prior to the meeting.

iii. 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.

iv. The IACUC Chair, or his/her designee, assigns two members to serve as technical reviewers. The reviewers present their findings to other members of the committee at a properly convened IACUC meeting for discussion.

v. 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 (with prior approval from the IACUC Chair/AV) prior to the meeting, and if necessary the consultant may be invited to the meeting. Consultants may not approve or withhold approval of an activity or vote with the IACUC.

vi. 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.
vii. Review of 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 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 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 require FCR of the protocol.

3. 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)

i. A complete list of protocols scheduled for DMR is distributed via email to all members with specific instructions regarding the designated review process. A deadline to call for FCR is generally five business days. Affirmation from all IACUC members is not required (silent assent). Prior to the review, each IACUC member will be provided with a list of proposed activities/projects to be reviewed and written descriptions of activities/projects (protocols) that involve the care and use of animals shall be provided or available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review (FCR) of those protocols.

ii. 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.

iii. If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

iv. At least one member of the IACUC is assigned by the Chair or his/her designee as designated reviewers (DR) that are qualified to conduct the review.

v. While other IACUC members may provide the DRs with comments and/or suggestions for the reviewers' consideration, concurrence to use DMR method may not be conditioned.
vi. After all required modifications are made; a final revised protocol with all required modifications is submitted to all designated reviewers for review and approval.

vii. The DRs decisions’ must be unanimous; if not, the protocol will be referred for FCR.

viii. 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 DRs have the authority to 1) approve, 2) require modifications in (to secure approval) or 3) request full committee review.

ix. The DRs do not have the authority to withhold approval.

x. The IACUC minutes contain notification of all actions approved by DMR.

e. All Reviews: In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct review [by FCR or DMR] 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 the 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 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 in Protocol form. Submissions are reviewed by either FCR or DMR as described previously in Section III.D.6.

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:

   i. in the objectives of a study
   ii. from non-survival to survival surgery;
   iii. resulting in greater discomfort or in a greater degree of invasiveness;
   iv. in the species or in approximate number of animals used;
   v. in Principal Investigator;
   vi. in anesthetic agent(s) or the use or withholding of analgesics;
   vii. in the method of euthanasia; and
   viii. 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 modifications in (to secure approval), or withhold approval (disapproval).

b. If the IACUC’s decision is to require modifications to secure approval, the required modifications are delineated in the written notification from the IACUC. In order to secure approval the investigator must revise the IACUC Application and/or respond to other 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 writing.

d. When requested, the investigator may also appeal, in person, before a fully convened meeting of the IACUC.

e. Applications and proposals that have been approved by the IACUC may be subjected 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.

f. 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 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 by the animal care and use 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 Annual Update form 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. These annual reviews are conducted by a voting member or members of the IACUC.

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 continue beyond the expiration date, prior to expiration of the original or preceding protocol a new protocol must be submitted, reviewed and approved as described in Section III.D.6 above.
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 a previously approved activity 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 PHS Policy, but 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.

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 noncompliance. 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 temporary or permanent suspension of an activity due to noncompliance with PHS Policy, the 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.

d. 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 frequent contact with animals is as follows:

1. Administration/management

a. The occupational health and safety program for all personnel who work in laboratory animal facilities or have contact with animals is administered under the University Police and Safety Office (UP & SO) with assistance from the IACUC Administrative office.

b. The Safety Office is responsible for the overall management (development, implementation, monitoring, etc.) of the occupational health and safety program.

2. Scope

a. It is the policy of the North Dakota State University (NDSU) Institutional Animal Care and Use Committee (IACUC) to minimize the risk of injury to personnel who have contact with animals, to promote health, and to protect university property.

b. Personnel with animal contact are required to enroll in the Occupational Health and Safety (OHS) Program and obtain medical clearance before beginning work with animals at NDSU. Enrollment requires personnel to be re-evaluated if there
has been a change in their health status or if there has been a change in their work assignment.

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 Hazard and Risk Assessment form is used to determine the degree of risk. Enrollment in the OHS Program and maintenance of medical clearance is a condition of continued work with animals.

3. Health Histories and Evaluations

a. The Institution does not require pre-employment physicals, but does require the employee complete and submit a Health Assessment Form to Sanford Occupational Health or Essentia Occupational Health for review.

b. If so indicated through the medical review, employees will be offered and informed of the need for a physical examination, immunizations and/or additional testing. Vaccinations are recommended if research is to be conducted on infectious diseases for which effective vaccines are available. The history of Tetanus immunizations is conducted at the time of initial assessment. Additional Tetanus immunizations are administered as needed.

c. Individuals who wish to decline completing the Health Assessment must do so in writing.

d. A new health assessment is completed when one or more of the following changes occur: the type of activity, type of animal and/or a change in the individual’s health status. Health history forms are maintained by Sanford Occupational Health and/or Essentia Occupational Health. Sanford Occupational Health and/or Essentia Occupational Health complete the Health Assessment Report to Supervisors form. The form is sent to departments and/or Principal Investigators and filed.

4. Hazard Identification and Risk Assessment

a. Departments and/or Principal Investigators provide new hires with a completed hazard and risk assessment to identify the potential hazards and risks that may be encountered on the job.

b. A new hazard and risk assessment is completed when one or more of the following changes occurs: the duration of animal exposure, the type of activity, type of animal and/or a change in the individual’s health status.

c. The Safety Office helps to identify potential occupational health hazards to ensure adequate measures are taken to properly protect employee health and safety. Measures taken to minimize exposure include the following: education, protective clothing, gloves and hand washing. A Safety Office representative serves as a consultant for the IACUC.
d. Allergic reactions are among the most common conditions that adversely affect the health of personnel working with laboratory animals. Major sources of allergens include rodent urine and saliva and animal dander. Measures taken to minimize exposure include the following: education, protective clothing, gloves, and hand washing. To reduce aerosol exposure appropriate hoods or laminar flow benches/cabinets, and/or other respiratory protection, e.g., N95 masks, are worn when performing cage changing and/or handling dirty bedding.

5. Training

a. Training programs are offered by UP&SO and the IACUC office. The training programs are mandatory for all covered personnel. The programs include training topics ranging from air quality to species specific zoonotic modules.

b. Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals. If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/her health care professional, human resources, etc.

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

a. Housekeeping and maintenance staffs are not routinely allowed access to the animal facilities.

b. In situations where housekeeping, maintenance, or other non-animal care and use personnel must access the animal rooms, they are briefed on appropriate precautions and provided any appropriate PPE and are then permitted in for a limited amount of time.

c. 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 prior to the individuals being allowed in the room.

7. Injury and Illness

a. All NDSU personnel have access to the Sanford Occupational Health and/or Essentia Occupational Health when job related injuries or illnesses occur.

b. Injuries occurring on the job will be treated by the Sanford Occupation Health Center, Essentia Occupational or personal healthcare provider; emergencies are taken directly to Sanford Emergency Center located 2.5 miles from campus or Essentia Health Center located 8 miles from campus.

c. Employees must file an "Incident Report" within 24 hours of the injury or job related illness.
d. The Safety Office receives the reports and submits to the North Dakota Risk Management within 24 hours.

e. The Claims Management Specialist monitors medical treatment and the return to work program. This requirement is covered during the Safety Office Baseline Safety Training.

F. The total gross number of square feet in each animal 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. IACUC Members

   a. Each IACUC member will be provided with a copy of the following:

      i. The PHS Policy for the Humane Care and Use of Laboratory Animals;

      ii. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;

      iii. The ARENA/OLAW IACUC Guidebook;

      iv. The AVMA Guidelines on Euthanasia;

      v. A copy of this Assurance.


   b. All new IACUC members undergo an orientation session conducted by the IACUC Administrator or his/her designee.

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

   d. Continuing education is offered to IACUC members at scheduled IACUC meetings.

   e. Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting, or similar course is encouraged.

   f. All members of the IACUC will complete Essentials for IACUC Members course found on the Collaborative Institutional Training Initiative website, www.citiprogram.org.

2. Animal Care and Use Personnel
a. A copy of the current NDSU Assurance is available to all personnel involved in animal care and use on the NDSU website.

b. All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Application form.

c. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be available for IACUC review.

d. Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol.

e. All persons involved in animal care and use will be required to complete the Working with the IACUC course found at the Collaborative Institutional Training Initiative (CITI) website, www.citiprogram.org. The training course includes information on federal mandates, veterinary consultation, alternatives, avoiding unnecessary duplication, USDA pain/distress categories, endpoint criteria, surgery, antibody production, collecting blood samples, occupational health and safety, using hazardous and toxic agents in animals, housing social animals, housing rodents on wire floors, dog exercise, prolonged restraint, euthanasia, and reporting misuse, mistreatment, or noncompliance.

f. Training in experimental methods, i.e., specific animal manipulations and techniques and in the care of new and nontraditional laboratory animal species, will be conducted by the Attending Veterinarian, based on the types of research being conducted and the species being used at the institution.

g. Animal care staff personnel must have a species specific training certificate on file in the IACUC office in order to work with animals.

h. The Attending Veterinarian verifies the PI is competent to conduct the activities listed in the protocol. Protocol activities may include, but are not limited to, husbandry, record keeping, injections, vaccination, euthanasia, sampling techniques, anesthetics/analgesics, surgery, gavage, fluid and diet restriction and prolonged restraint. Once the PI has a completed training certificate on file, the PI can conduct the training with their animal care staff.

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 six months and will be reevaluated 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 according to 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 2 — not 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. The report of the most recent evaluations (program review and facility inspection) is attached.

V. Recordkeeping Requirements

A. This Institution will maintain for at least 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, Dr. Kelly Rusch

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. 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, Dr. Kelly Rusch

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

<table>
<thead>
<tr>
<th>Name: Kelly A. Rusch, Ph.D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title: Vice President for Research and Creative Activity</td>
</tr>
<tr>
<td>Name of Institution: North Dakota State University</td>
</tr>
<tr>
<td>Address: (street, city, state, country, postal code)</td>
</tr>
<tr>
<td>1735 NDSU Research Park Dr.</td>
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<tr>
<td>NDSU Dept 4000 PO Box 6050</td>
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<tr>
<td>Fargo, ND 58108-6050</td>
</tr>
<tr>
<td>Phone: 701-231-6542</td>
</tr>
<tr>
<td>E-mail: <a href="mailto:Kelly.rusch@ndsu.edu">Kelly.rusch@ndsu.edu</a></td>
</tr>
</tbody>
</table>

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: 5/14/14 |

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

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

| Signature: | Date: 5/14/14 |

Assurance Number: A3244-01

Effective Date: 5/12/14  Expiration Date: 5/31/18