

**North Dakota State University**  
D16-00156 (A3244-01)

## **Animal Welfare Assurance for Domestic Institutions**

I, Colleen Fitzgerald, as named Institutional Official for animal care and use at North Dakota, 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 Public Health Service (PHS), Health and Human Services (HHS), National Science Foundation (NSF) and/or National Aeronautics and Space Administration (NASA). This Assurance covers only those facilities and components listed below.

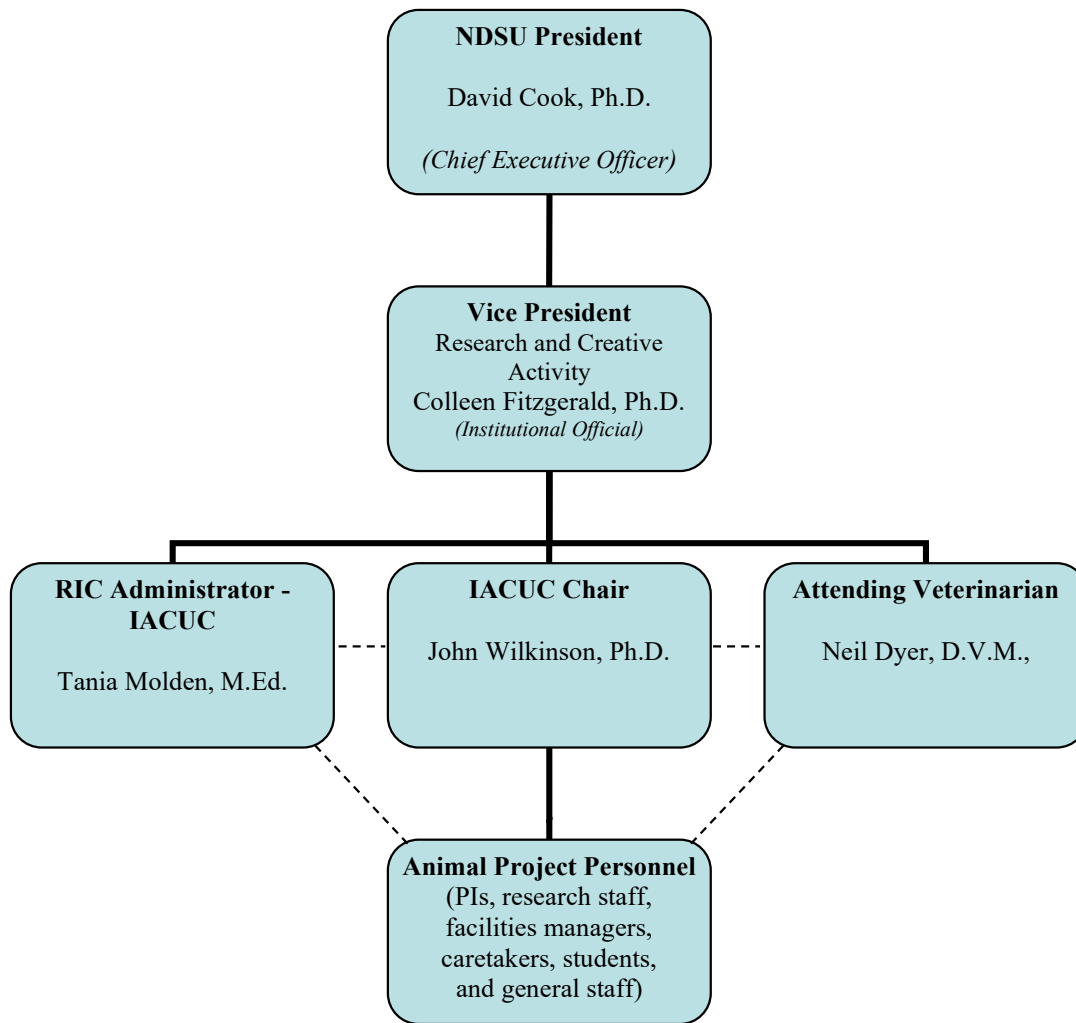
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: All components of the University (Colleges, Schools, Department, etc.) that are physically located on the University's main campus in Fargo, North Dakota 58108. There are no covered off-campus satellite facilities and/or other covered components.
- B. There are no other institution(s), branches, or components of another institution that are covered by this assurance.

### **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:



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

1) Neil Dyer, D.V.M., M.S., Attending Veterinarian

Qualifications

- Degrees:
  - D.V.M., Iowa State University, 1991
  - M.S. Veterinary Pathology, Iowa State University, 1995
  - Diplomate, American College of Veterinary Pathologists
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  - Dr. Dyer received a B.S. in zoology from North Dakota State University in 1977. Pursuant to that he worked in a zoo for 10 years as a zookeeper, curator, and assistant director. He graduated with his DVM from Iowa State University (ISU) in 1991 and practiced veterinary medicine in a mixed animal practice for two years. He then returned to ISU to pursue a degree in veterinary pathology. The coursework included training in the pathology and disease of many animal species, including laboratory animals. During his master’s program he also worked part-time at a small and exotic animal practice in Ames, Iowa. He obtained his Master’s degree in veterinary pathology in 1997 and assumed Director responsibilities for the NDSU Veterinary Diagnostic Laboratory the same year. Dr. Dyer has served on the NDSU IACUC since 1997 in a variety of capacities including committee member, attending veterinarian, IACUC chair, and back-up AV.

Authority: Dr. Neil Dyer has direct program authority and responsibility for the Institution's animal care and use program including access to all animals and authority to implement the PHS Policy and the recommendations of the *Guide*.

Time contributed to program: Dr. Dyer is a full-time employee at NDSU and is currently serving as the interim AV. He devotes 100% of his time to the animal care program.

2) Name: Back-up Veterinary Care

Back-up veterinary care is provided by local veterinary clinics.

<b>Large Animals</b>			
Clinic	Type of Care	Veterinarian Name	Education, training
Casselton Veterinary Clinic 910 Governor's Drive Casselton, ND 58012 (701)-347-5496	Clinical care for horses	Dr. Darin Peterson	DVM – Ross University College of Veterinary Medicine and completed his final year at Texas A/M.
			Dr. Peterson specializes in equine medicine and surgery
	Clinical care for dairy cattle, beef cattle, sheep and swine	Dr. Justin Galbreath	DVM – University of Minnesota College of Veterinary Medicine
			Dr. Galbreath specializes in livestock medicine and surgery
<b>Rodents and exotic animals</b>			
Animal Health Clinic 1441 S University Dr Fargo, ND 58103	Clinical care for rodents and exotic animals	Dr. Kevin Dill	DVM – University of Minnesota College of Veterinary Medicine
			Dr. Dill specializes in the care of small animals and exotics
<ul style="list-style-type: none"> <li>▪ Drs. Peterson, Galbreath and Dill are currently licensed in North Dakota and Minnesota.</li> </ul>			
<ul style="list-style-type: none"> <li>▪ Drs. Peterson and Galbreath are on call 24/7 with the NDSU Department of Animal Sciences for care of horses and livestock. They have access to all facilities and animals and work in concert with the Attending Veterinarian.</li> </ul>			
<ul style="list-style-type: none"> <li>▪ Dr. Dill is on call 24/7 for the health needs of rodents and exotics on campus. Access to facilities is need based. He works in concert with the Attending Veterinarian.</li> </ul>			

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 IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached 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 6 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. PHS Policy, Animal Welfare Act) as the basis for review.
  - c. To facilitate the review the committee will use a checklist based on the sample Program Review Checklist available on 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
    - iv. IACUC Protocol Review-Special Considerations
    - v. IACUC Membership and Functions
    - vi. IACUC Training
    - vii. IACUC Records and Reporting Requirements
    - viii. Veterinary Care
      - 1. Clinical Care and Management
      - 2. Animal Procurement and Transportation/Preventive Medicine
      - 3. Surgery
      - 4. Pain, Distress, Anesthesia, and Analgesia
      - 5. Euthanasia
      - 6. Drug Storage and Control
    - ix. Occupational Health and Safety of Personnel
    - x. Personnel Security
    - xi. Investigating and Reporting Animal Welfare Concerns
  - e. In addition, the evaluation will include a review of the Institutions Animal Welfare Assurance.
  - f. If program deficiencies are noted during the review, they will be categorized as minor or significant. 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 review. No member will be involuntarily excluded from participating in any portion of the reviews.
- 2) Inspect at least once every 6 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 members of the IACUC will visit all of the Institution's facilities where animals are housed or used, for example, 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 will also be inspected.
  - b. The committee uses the *Guide* and other pertinent resources (e.g. PHS Policy, Animal Welfare Act) as the basis for review.
  - c. To facilitate the inspection, the committee will use a checklist based on the sample Facility Inspection checklist available on the OLAW website.
  - d. If deficiencies are noted during the inspection, they will be categorized as minor or significant. 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. All IACUC members will be invited to participate in the inspections. No member will be involuntarily excluded from participating in any portion of the inspections.
- 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. IACUC members will discuss their observations and evaluations during a full-board meeting. The evaluations will be recorded in a report using the Semiannual Report to the Institutional Official template provided on the OLAW website

- b. The report 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 any departures from the *Guide* and the PHS Policy and state the reasons for each departure. If there are no departures the report will so state. Departures must be approved as part of the protocol, protocol amendment or other written documentation using an IACUC approved review process.
  - d. Departures from the provisions of the *Guide* that are not IACUC approved are considered deficiencies and addressed as such. The IACUC will develop a reasonable plan and schedule for discontinuing the departure or having the departure properly reviewed and approved.
  - e. The reports will distinguish minor deficiencies from significant 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 AALAC International the report will identify those facilities as such.
  - g. Reports will be reviewed, revised as appropriate, and approved by the IACUC at a convened meeting.
  - h. The final report will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the report will so state.
  - i. The completed reports will be submitted to the Institutional Official within a reasonable time-not to exceed 60 days following the evaluation.
  - j. Deficiencies will be tracked by the IACUC Administrator/Attending Veterinarian to ensure that they are appropriately addressed.
- 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 a concern to the Institutional Official, IACUC Chair, Attending Veterinarian, IACUC Office, or any IACUC Member.
  - b. Concerns may be reported verbally or in writing. Individuals may also report a concern anonymously through the NDSU Fraud Hotline.
  - c. Notices in animal facilities advise individuals how and where to report animal welfare concerns and states that any individual who, in good faith, reports an animal welfare concern will be protected against reprisal.
  - d. The IACUC Chair, Attending Veterinarian, and IACUC Administrative Staff 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 for reported concerns must be maintained 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 be conducted by the IACUC Administrator, the Attending Veterinarian in conjunction with facility staff and IACUC members as necessary or requested. The investigation will include but is not limited to: interviewing personnel involved, observing animals and determining if their welfare has or is being jeopardized, reviewing pertinent records and initiating any necessary immediate preventative/corrective action. Note: absent of conflict of interest, no IACUC member will be involuntarily excluded from participating in any portion of an investigation.
  - h. A detailed report of the concern and investigation including corrective action already taken will be prepared by the IACUC Administrator/Designee and reviewed by the IACUC and/or subcommittee. A copy of the report will be provided to all IACUC members.
  - i. The IACUC Office will produce a report summarizing the investigation, corrective action taken and IACUC recommendations. This report will be provided to the Principal Investigator (PI) and/or other involved personnel. The recipient(s) of the report will be asked to acknowledge receipt of the report, provide any comments, and appeal as necessary, in accordance with a set deadline.

- j. Reported concerns and all associated IACUC actions will be relayed to the IACUC and recorded in the IACUC meeting minutes. The committee will report such actions to the IO.
  - k. OLAW will be notified in accordance with the reporting requirements of the PHS Policy. The IO will submit reports in writing to OLAW; preliminary reports may be submitted verbally.
  - l. All reports including any associated documentation must be maintained on file in the IACUC Office.
  - m. The identity of the whistleblower or individual bringing the concern to the attention of the IACUC will be protected in accordance with the Institution's whistleblower 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, facilities or personnel training are reviewed by the IACUC, revised as appropriate, approved, and 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 or experimentation, biological testing or related activities must submit a completed Animal Care and Use Application (hereafter referred to as protocol) via the online IACUC protocol submission system, Novelution.
    - ii. The IACUC Administrator/AV/Designee conducts a pre-review of the protocol before it is posted for review.
    - iii. In accordance with IACUC policies, the pain category will determine if the protocol is reviewed via designated member review (DMR) or full-committee review (FCR).
    - iv. IACUC members are automatically emailed via Novelution that a protocol is ready for review. All IACUC members may access an electronic copy of the protocol in Novelution.
  - b. IACUC Approval Criteria
    - i. The IACUC will ensure that protocols meet the requirements of the PHS Policy, the *Guide* and the Institution's Guiding Principles which govern the care and 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 conflict of interest. This applies to alternate members, non-voting members, ex-officio members, and consultants. The conflicted individual will excuse (recuse) themselves from deliberation, discussion, and vote related to the protocol in which they are conflicted and will not contribute to the constitution of a quorum.
    - 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 members. A simple majority of the voting membership of the IACUC constitutes a quorum. The IACUC typically holds one meeting per month with additional meetings scheduled to address extenuating circumstances.

- ii. Protocols (and all meeting materials) scheduled to be reviewed at the IACUC meeting are available to all IACUC members via the Novelution meeting management interface at least one week prior to the meeting.
- iii. Any use of telecommunications will be in accordance with the NIH Notice NOT-OD-06-052 of March 24, 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/Vice-Chair assigns two members to serve as technical reviewers. The reviewers present their findings for discussion to the members present at the convened meeting.
- v. At the beginning of each meeting the IACUC chair calls for disclosure of any conflict of interests regarding any agenda item.
- vi. When it is determined that a consultant will be required to advise the IACUC in its review of a protocol, the protocol will be distributed to the consultant or expert prior to the meeting. If necessary, the consultant may also be invited to attend the meeting. Consultants may not approve or withhold approval of an activity or vote with the IACUC.
- vii. Following the review of a 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 member present at the convened meeting.
- viii. 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 outlined in the PHS Policy and the Institution's Guiding Principles.
  - 2. DMR if approved unanimously by all members at the meeting which the required modifications are developed 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 modifications are required 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 revised protocol.
  - 3. Minor modifications of an administrative nature (i.e. typographical or grammatical errors, required signatures, training verification, etc.) may be confirmed by the IACUC Administrator/support personnel.

d. Designated Member Review (DMR)

- i. Protocols scheduled for DMR are available to all IACUC members via Novelution. All committee members are notified via email that the protocol is ready for Designated Member review. This email contains specific instructions regarding the DMR process. Assigned reviewers receive an additional email notifying them of their assignment. A deadline to call for FCR is generally five business days. Affirmation from all IACUC members is not required (passive assent).
- ii. Under extenuating circumstances, the deadline can be reduced by the IACUC Chair/Vice Chair to one day with affirmation required from all IACUC members regarding their decision 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 the majority of the quorum present.
- iv. At least one member of the IACUC, that is qualified to conduct the review, is assigned by the Chair/Vice-Chair as the designated reviewer.
- v. Other IACUC members may provide the assigned reviewer(s) with comments and/or suggestions for consideration.
- vi. After all required modifications are made to the protocol; the revised protocol will be reviewed by the assigned reviewers and if acceptable, approved.
- vii. If multiple reviewers are assigned, their decisions must be unanimous. If the reviewers' decisions are not unanimous, the protocol will be referred to FCR.

- viii. Any member of the IACUC can make the decision to send the protocol to FCR at any time during the set deadline period. If no member of the IACUC refers the protocol to FCR (passive assent) during the deadline period the assigned reviewers have the authority to 1) approve, 2) require modifications in (to secure approval) or 3) request FCR.
  - ix. The assigned reviewers do not have the authority to withhold approval.
  - x. All actions approved via DMR are reported to the IACUC in the IACUC meeting consent agenda.
- 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 according to 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 Amending the current Protocol form. Submissions are reviewed by the FCR, DMR, (as described above) or Veterinary Verification and Consultation (VVC) methods in accordance with the OLAW NOT-OD-14-126 (August 26, 2014) entitled *Guidance on Significant Changes to Animal Activities* and as outlined in the Institution's Guiding Principles.
  - b. Significant changes reviewed via the VVC process are handled administratively in consultation with the AV and/or other veterinarians serving on the IACUC. The veterinarians are not conducting DMR, but are serving as subject matter experts to verify that compliance with the IACUC reviewed and approved policies and procedures is appropriate for the animals in each circumstance. Consultation with the veterinarian(s) is documented. The veterinarians may refer any significant change request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC reviewed and approved policies and procedures. The submission and review process is as follows:
    - i. An amendment to the protocol is submitted.
    - ii. Requests fitting the criteria for VVC are assigned to the VVC process. All veterinarians serving on the IACUC and the IACUC Chair are notified of the review assignment. Access to the amendment request is obtained through Novelution.
    - iii. The AV and/or veterinarian(s) verify the requested change has been approved by the IACUC in the VVC Policy and is consistent with the references or guidance documents for that change also in the VVC Policy.
    - iv. whether to approve the change in protocol request or to refer the request to DMR or FCR.
    - v. VVC will not be used to add a new procedure that:
      - 1. Constitutes a significant change
      - 2. Was not previously approved on the protocol
  - c. Significant changes reviewed via the DMR or FCR methods include:
    - i. From non-survival to survival surgery;
    - ii. Resulting in greater pain, distress, or degree of invasiveness;
    - iii. In housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
    - iv. In species;
    - v. In study objectives;
    - vi. In Principal Investigator (PI); and
    - vii. That impact personnel safety (e.g. change in biosafety level)
  - d. Significant changes reviewed via the VVC method include:
    - i. Anesthesia, analgesia, sedation or experimental substances that are in accordance with Veterinary Drug Handbook/Plumb's Veterinary Drugs and/or Laboratory Animal Anesthesia.
    - ii. Euthanasia in accordance with the AVMA Guidelines for the Euthanasia of Animals and the NDSU Euthanasia Guiding Principle
    - iii. Duration, frequency, type (e.g. blood collection site or volumes, route of administration or volumes, and dosages) or procedures performed on an animal.
    - iv. Increasing food/fluid restriction prior to a procedure to more than 12 hours with adequate justification.



- v. Number of procedures performed on an animal excluding surgical procedures contingent upon them not exceeding IACUC regulations and guidelines.
  - vi. Additional strains or source of animals
  - vii. Change to space requirements if restriction is justified and not excessive based on veterinary consultation.
  - viii. An increase in the previously approved animal numbers; not to exceed 10% of the originally approved number of animals.
  - e. Changes reviewed and approved administratively without consultations or notifications include:
    - i. Correction of typographical errors
    - ii. Correction of grammar
    - iii. Change in personnel, other than the PI. (Administrative review will ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in the Occupational Health and Safety (OHS) Program and meet any other criteria required by the IACUC).
    - iv. In housing and or use of animals in a location that is part of the anima program overseen by the IACUC.
  - f. All actions approved via DMR and VVC are reported to the IACUC in the IACUC meeting consent agenda.
- 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 according to 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 Office notifies the investigator in writing of the IACUC's decision to approve the protocol, require modifications in (to secure approval), or to withhold approval.
  - b. If the IACUC's decision is to require modifications to secure approval, the required modifications are delineated in a written notification from the IACUC and Review Comments are documented in the electronic protocol. In order to secure approval, the investigator must revise the protocol or change request and/or respond to other conditions set by the IACUC.
  - c. The IACUC Office will provide the investigator with the reasons, in writing, for the IACUC's decision to withhold approval of a protocol or change request 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 IACUC 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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:
- a. All ongoing activities are monitored by the animal care and use staff, AV and IACUC Office staff. Monitoring methods include:
    - i. Review of annual reports
    - ii. semi-annual facility inspections
    - iii. Attending Veterinarian rounds
    - iv. adverse event reporting and tracking
  - b. At the time of initial review and approval, the IACUC will set a continuing review date for each protocol.

- i. USDA regulated protocols will be reviewed annually. Investigators will submit the Annual Update form. The form will be reviewed via the DMR process.
      - ii. Non-USDA regulated protocols will be re-reviewed once every three years via the DMR or FCR methods.
    - c. Protocols are approved for a maximum of three years. All protocols expire no later than the three-year anniversary of the initial approval date. If activities outlined in the protocol will continue beyond the expiration date, investigators will be required to submit a new protocol. The protocol must be reviewed and approved prior to the expiration date.
- 10) Be authorized to suspend an activity involving animals according to 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 the activity is not being conducted in accordance with the approved protocol, the applicable provisions of the *Guide*, the PHS Policy, the Animal Welfare Act, this Assurance, or the Institution's Guiding Principles. The IACUC may only suspend an activity after the matter is reviewed at a convened meeting of a quorum of the IACUC and the majority of the quorum present votes to suspend.
  - b. The IO has authorized the IACUC Chair/Vice Chair 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, the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with full explanation in writing to OLAW. Preliminary reports may be made verbally.
  - d. An IACUC suspension can only be lifted by the 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:
  - a. Administration/Management
    - i. The Occupational Health and Safety (OHS) Program for all personnel who work in laboratory animal facilities or have contact with animals is administered under the University Police and Safety Office (UPS0) with assistance from the IACUC Office.
    - ii. The UPS0 is responsible for the overall management (development, implementation, monitoring, etc.) of the OHS program.
  - b. Scope
    - i. It is the policy of the Institution's IACUC to minimize the risk of injury to personnel who have contact with animals, to promote health, and to protect university property.
    - ii. Personnel with animal contact are required to enroll in the 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 (e.g. new facility or new species).
    - iii. The program participation requirements are based on the type(s) of animal(s) personnel are or will be exposed to and/or the degree of exposure.
    - iv. Enrollment in the OHS program and maintenance of medical clearance is a condition of continued work with animals.
  - c. Health History Evaluation
    - i. The Institution does not require pre-employment physicals, but does require the employee complete and submit a Health Assessment form to the Safety Office who in turn submits the form to Sanford Occupational Health or Essentia Occupational Health for review.
    - ii. 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.

- iii. Individuals who wish to decline fulfilling the medical providers' recommendations must do so in writing.
  - iv. 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.
  - v. Providers at Sanford Occupational Health and/or Essentia Occupational Health report their assessment to departments and/or Principal Investigator (PI).
- d. Hazard Identification and Risk Assessment
- i. Departments and/or PIs provide new employees with a completed hazard and risk assessment to identify the potential hazards and risk that may be encountered.
  - ii. 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 individuals' health status.
  - iii. The Safety Office in conjunction with the AV 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, personal protective equipment (PPE), and handwashing.
  - iv. Animal bites and needle sticks are among the most common conditions that adversely affect the health of personnel working with laboratory animals. Measures are taken to train and retrain personnel in proper animal restraint procedures and animal behavior to minimize the occurrences.
- e. Training
- i. Training programs are offered by the Safety and IACUC Offices. The training programs are mandatory for all covered personnel. The programs include training topics ranging from air quality to species-specific zoonosis.
  - ii. 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 healthcare 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 healthcare professional, etc.
- f. 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.
- i. Housekeeping or maintenance staff are not routinely allowed access to the animal facilities.
  - ii. 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 permitted access for a limited amount of time.
  - iii. 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.
- g. Injury and Illness
- i. All Institutional personnel have access to the Sanford Occupational Health and/or Essentia Occupational Health when a job-related injury or illness occurs.
  - ii. Injuries occurring on the job will be treated by Sanford Occupational Health, Essentia Occupational Health or personal healthcare provider. Emergencies are taken directly to Sanford Emergency Center located 6.5 miles from campus or Essentia Health Center located 6.6 miles from campus.

- iii. Employees must file an Incident Report within 24 hours of the job-related injury or illness.
  - iv. The Safety Office receives the reports and submits to North Dakota Risk Management within 24 hours.
  - v. The Loss Control & Claims Specialist files workers' compensation claims, monitors all medical treatment and coordinates the Return-to-Work Program.
- 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 the attached Facility and Species Inventory table.  
[Complete the Facility and Species Inventory table provided (see Part X.).  
Note: list common names for animal species, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog.  
Note: animal areas (buildings/rooms) may be represented by a number or symbol in this submission to OLAW.]
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
- a. IACUC Members
    - i. Each IACUC member will be provided with a copy of the following:
      - 1. The PHS Policy for the Humane Care and Use of Laboratory Animals
      - 2. The Guide for the Care and Use of Laboratory Animals
      - 3. The Guide for the Care and Use of Agricultural Animals in Research and Teaching
      - 4. The AVMA Guidelines on Euthanasia
      - 5. A copy of the Institution's Animal Welfare Assurance
    - ii. All new IACUC members undergo an orientation session conducted by the IACUC Administrator/Designee.
    - iii. All IACUC members are provided electronic copies of relevant articles and notified of new guidance issues by OLAW and USDA.
    - iv. Continuing education is provided to IACUC members at scheduled IACUC meetings.
    - v. All members of the IACUC are required to complete the Collaborative Institutional Training Initiative (CITI) Essentials for IACUC Members course, which includes training on the Three Rs.
  - b. Animal Care and Use Personnel
    - i. A copy of the current Animal Welfare Assurance is available to all on the Institution's IACUC website.
    - ii. All personnel working with animals must be identified on the protocol.
    - iii. A description of each individual's qualifications, experience and training with specific animal species and procedures must be available for IACUC review.
    - iv. Protocol-specific training requirements will be identified during protocol review. The training requirements will be a condition of protocol approval.
    - v. All animal care and use personnel will be required to complete the relevant CITI course. Required courses include the Working with the IACUC course, the Rodent Research Course, and the Wildlife Research Course. The courses include information on federal mandates, veterinary consultation, alternatives, avoiding unnecessary duplication, occupational health and safety, euthanasia, reporting misuse, mistreatment, or noncompliance and the Three Rs.
    - vi. Species and project specific training will be provided by the AV, IACUC Designated Trainers, or consultants.
    - vii. All training must be documented and maintained by the PI, facilities, and IACUC Office.

#### **IV. Institutional Program Evaluation and Accreditation**

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 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.

- (1) 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) was submitted.

## V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 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, Colleen Fitzgerald.
  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 federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 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, Colleen Fitzgerald.
  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**

<b>A. Authorized Institutional Official</b>	
Name: Dr. Colleen Fitzgerald	
Title: Vice President, Research and Creative Activities	
Name of Institution: North Dakota State University	
Address: <i>(street, city, state, country, postal code)</i>  1735 NDSU Research Park Dr. NDSU Dept. 4000, PO Box 6050 Fargo, ND 58108-6050	
Phone: 701-231-6542	Fax: 701-231-8098
E-mail: ndsu.research@ndsu.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: 05/17/2022

<b>B. PHS Approving Official</b> <i>(to be completed by OLAW)</i>	
<p>Name/Title: Paula Knapp, Senior Assurance Officer Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD 20892-6910 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672</p>	
Signature:	Date: May 24, 2022
Assurance Number: D16-00156 (A3244-01)	
Effective Date: May 24, 2022	Expiration Date: May 31, 2026

**VIII. Membership of the IACUC**

Date: January 2022			
Name of Institution: North Dakota State University			
Assurance Number: D16-00156			
<b>IACUC Chairperson</b>			
Name*: John Wilkinson			
Title*: Associate Professor		Degree/Credentials*: Ph.D.	
Address*: ( <i>street, city, state, zip code</i> ) 1231 Albrecht Boulevard Fargo, ND 58102			
E-mail*: john.wilkinson@ndsu.edu			
Phone*: 701-231-6354		Fax*: 701-231-8098	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Neil Dyer	D.V.M.	Attending Veterinarian	Attending Veterinarian
John Wilkinson	Ph.D.	Associate Professor	Scientist
Lisa Christianson	D.V.M.	Associate Professor of Practice	Veterinarian
123250	DVM	Extension Veterinarian	Veterinarian
123242	Ph.D.	Assistant Professor	Scientist
123192	Ph.D.	Associate Professor	Scientist
123243	Ph.D.	Associate Professor of Practice	Scientist
123230	Ph.D.	Assistant Research Extension Center Specialist	Scientist
123245	D.V.M.	Director Veterinary Diagnostic Laboratory	Veterinarian
123244	Ph.D.	Assistant Professor Mayville State University	Non-Affiliated/Scientist
123203	M.S.	Research Administration Essentia Health	Non-Affiliated
123258	B.S.	IT Manager	Non-Scientist
123254	B.S.	Graduate Student	Scientist
123255	M.S.	Graduate Student	Scientist
123180	B.S.	Farm Manager	Non-Scientist /Alternate
123169	Ph.D.	Associate Professor	Scientist/Alternate



123153	B.S.	Instructor/Lecturer	Scientist /Alternate
123197	Ph.D.	Associate Professor	Scientist /Alternate
123251	Ph.D.	Livestock Systems Specialist	Scientist /Alternate
123241	D.V.M.	Pathologist	Veterinarian /Alternate
123246	D.V.M.	Laboratory Manager	Veterinarian /Alternate
123212	B.A.	Pastor	Non-Scientist/Non-Affiliated/Alternate
123224	Ph.D.	Professor Mayville State	Scientist /Alternate/ Unaffiliated
123256	B.S.	Graduate Student	Scientist/Alternate
123257	B.S.	Graduate Student	Scientist/Alternate

\* 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:

<i>Veterinarian</i>	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.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: 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.

<b>Contact #1</b>
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Name: Tania Molden	
Title: Research Integrity and Compliance Administrator - IACUC	
Phone: 701-231-8114	E-mail: tania.molden@ndsu.edu
<b>Contact #2</b>	
Name: Kristy Shirley	
Title: Research Integrity and Compliance Manager	
Phone: 701-231-8995	E-mail: Kristy.shirley@ndsu.edu

**X. Facility and Species Inventory**

Date: January, 2022			
Name of Institution: North Dakota State University			
Assurance Number: D16-00156			
Laboratory, Unit, or Building*	Gross Square Feet [ <i>include service areas</i> ]	Species Housed [ <i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i> ]	Approximate Average Daily Inventory
9123	7312	Cattle	37
		Swine	9
		Mice	123
		Chicken	75
9124	4000	Sheep	84
9125	2880	Sheep	68
9136	7200	Dog	8
		Cat	8
9137	1815	Leopard Geckos	150
		Garter Snake	6
		Gopher Snake	1
		Ball Python	2
		Cane Toads	7
		Whites Tree Frogs	5
		Tiger Salamanders	3
		Great Plains Toads	2
		Milk Snake	2
		Hognose Snake	1
		Pine Snake	1
		Box Turtle	3
		House Snake	15
		Softshell Turtle	1
		Legless Lizard	2
		Sand Boa	2
		Bearded Dragon	1
9138	1020	Mice	1180
		Rat	150

\*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.