

N O R T H W E S T E R N

U N I V E R S I T Y

Assurance # D16-00182 (A3283-01)

**Animal Welfare Assurance
in accordance with the PHS Policy
for Humane Care and Use of Laboratory Animals**

Animal Welfare Assurance for Domestic Institutions

I, Milan Mrksich, as named Institutional Official for animal care and use at Northwestern University (NU), 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 Service (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 central and satellite animal facilities and investigator laboratories where vertebrate animal research is conducted on both the Evanston and Chicago campuses.

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

- Rehabilitation Institute of Chicago dba Shirley Ryan AbilityLab
- Ann & Robert H. Lurie Children's Hospital of Chicago, Stanley Manne Children's Research Institute

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:

1. The Vice President for Research (VPR) is the Institutional Official (IO) responsible for the administration of the IACUC and the Center for Comparative Medicine (CCM), the central animal care facility at Northwestern University. The Attending Veterinarian and IACUC regularly communicate directly with the IO.
2. IACUC is a University-wide faculty committee appointed by the IO. The IACUC meets at least once a month and follows OLAW NOT-OD-06-052 "*Guidance on Use of Telecommunications for IACUC Meeting under the PHS Policy on Humane Care and Use of Laboratory Animals*" on the use of telecommunications for all convened IACUC meetings. The IACUC is responsible for reviewing and approving all animal protocols, making recommendations to the IO on all matters relating to the University's animal care and use program, facilities and procedures. The IACUC monitors compliance with animal welfare regulations, PHS policies, USDA guidelines and University policy to ensure adequate care of all live, vertebrate animals held or used for research, testing or educational purposes.
3. The IACUC Office is the designated office of record responsible for the administrative management and record keeping of the Institutional Animal Care and Use Program. All submissions are received, vetted and distributed through this office, and all required records kept for the IACUC are maintained in the IACUC Office. The office coordinates all activities of the IACUC; maintains all required documents; serves as liaison between the committee, external oversight agencies, CCM, research investigators and NU administration, the Office for Research, the Office of Research Integrity, the Office of Research Safety, and the Office for Sponsored Research; the office monitors all aspects of NU Animal Welfare Assurance and applicable laws which pertain to the responsibilities of the IACUC. The IACUC Office maintains an association with all related professional and training organizations for the benefit of the NU research organization; prepares policy documents for review by the IACUC; and schedules semi-annual inspections of central facilities, satellite facilities, investigator laboratories where vertebrate animals are taken for experimentation; and reviews the NU animal welfare program. The IACUC Office regularly informs the IO of all aspects of the Institutional Animal Care and Use Program.
4. The Attending Veterinarian is responsible for the overall administration of the animal facilities. The CCM administrative office is designated to implement proper practices for animal care and use and to monitor the care and use provided to the animals by the CCM staff.

Seven full-time veterinarians and one part-time veterinarian are involved with monitoring and implementing the program for the care and use of laboratory animals at Northwestern University. The Executive Director has direct authority and broad discretion in implementing the University policy on the care and use of laboratory animals, which specifies adherence to PHS policy and the AWA. Reporting to the Executive Director are the Director of Facility Operations, Director of Clinical Operations (a veterinarian), Director of Business Operations and two Assistant Director Clinical Operations (veterinarians). One Assistant Director of Clinical Operations is primarily responsible for Quality and Training and rodent clinical care. The other Assistant Director of Clinical Operations is part time and primarily focuses on clinical care and regulatory support. The Director of Clinical Operations, a veterinarian, has four veterinarians reporting to him that provide clinical care. Two Senior Clinical Veterinarians and two Clinical Veterinarians. The Veterinarians are responsible for veterinary care on the Evanston, and Chicago campuses.

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

Seven full-time veterinarians and one part time veterinarian are dedicated to the animal care program. Six veterinarians participate in providing back-up clinical and veterinary services 24 hours a day, year-round including holidays and emergencies on a rotational basis for the Evanston and Chicago University campuses. Workday emergencies are primarily directed to the Assistant Directors Clinical Operations and the Senior/Clinical Veterinarians providing oversight for each area of the facility; however, all eight veterinarians are available.

1. Name: Dr. Lisa Forman, Executive Director and Attending Veterinarian

Qualifications

- Degrees: DVM, MS, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Completed a three year, NIH-sponsored post-doctoral laboratory animal training program at the University of Michigan (1995-1998). She has over 20 years of experience in laboratory animal medicine and 30 years' experience in animal research and has been employed by NU since 1998.

Responsibilities:

Dr. Forman has direct authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use including animal husbandry, nutrition, sanitation practices, zoonosis control, and hazard containment. She has full access to all animals. In fulfilling her duties and responsibilities she: a) maintains current information on regulations, licensing, registration, and accreditation; b) maintains liaison with pertinent professional organizations; c) implements institutional animal welfare policies; d) obtains and maintains all necessary licenses, registrations, permits, and certificates required for the Institution; e) maintains records pertaining to the acquisition, transport, and clinical care of animals; f) acts upon IACUC-generated reports of deficiencies in animal care or facilities; g) offers continuing guidance to all personnel involved in the care and use of animals with respect to appropriate handling, immobilization, sedation, analgesia, anesthesia, and euthanasia; h) provides veterinary and professional consultation for all Institution-sponsored projects including the design, construction and repair of animal facilities; i) ensures that necessary facilities and technical staff are available to perform a wide range of clinical services; j) ensures that continuing training programs in animal care are provided for all CCM employees; k) provides guidance and oversight to surgery programs and post-surgical care; l) ensures that daily monitoring of all animals is conducted to assess their health and well-being; and (m) ensures that surveillance is maintained over all animal facilities as well as animal care and use, and that deficiencies are corrected in a timely manner.

Time contributed to program:

Full time veterinarian 100% dedicated to the animal care and use program.

(b) (6)

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. A list of the chairperson and coded membership of the IACUC and their degrees, profession, titles or specialties, and institutional affiliations is included in Section VIII "Membership of the IACUC".

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:

Using the 8th edition of the *Guide* and the OLAW checklist, members of the IACUC review the following items when performing the program review:

- a. Animal Care and Use Program;
- b. Disaster Planning;
- c. IACUC including protocol review, investigating and reporting concerns;
- d. IACUC function and membership, training, records;
- e. Veterinary Medical Care;
- f. Personnel qualifications and training; and
- g. Occupational health and safety.

The IACUC office prepares the semi-annual program review and distributes it to a subcommittee of the IACUC for review. All IACUC members are invited to participate in the semiannual program review. The final program review documents are provided to the entire committee electronically for review and discussion at a convened meeting prior to forwarding the report along with any minority views to the IO with recommendations for improving the program.

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:

All IACUC members are invited to participate in the semi-annual inspections. An inspection team consists of committee member(s) and/or ad hoc consultants. Housing, support and procedure areas where USDA covered species are used are inspected by teams composed of two voting members. Support personnel who may assist with the inspection process include IACUC Office staff as scribes and CCM personnel. Using a modified version of the OLAW checklist, the teams semiannually inspect all animal facilities, which are any and all buildings, rooms, areas, enclosures, or vehicles including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation.

The IACUC Office prepares the inspection reports from the notes taken during the inspection. The responsible investigator or the Attending Veterinarian and CCM facility manager is notified of the findings and is requested to provide a correction plan and a timetable for completion. The IACUC Office monitors the corrections until they have been completed. A report of the inspection findings is made available to the entire Committee for review at a convened meeting.

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:

The IACUC office prepares a summary that includes the status of the AAALAC accreditation of all facilities, semiannual program review and inspection reports and distributes to the entire committee for review and discussion at a convened meeting. The semiannual program review documents are signed by a majority of voting members prior to forwarding the report along with any minority views to the IO with recommendations for improving the program. If physical signatures are not possible, documentation of electronic signatures are kept on file in the IACUC office. The summary also includes:

- a. Deficiencies noted in the program review or inspection reports are designated as minor or significant and include a plan for correction and timetable for completion;

- b. Departures, along with a reason for the departure from PHS Policy and/or the *Guide*, are identified during the protocol review process using the OLAW help sheet and should a departure be identified it would be reviewed and approved by the IACUC;
 - c. Minority views.
- 4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
 - a. Any person having reason to question the humane or ethical treatment of animals at Northwestern University may choose from several options to report their concerns: the anonymous web based "Ethics Point", the "IACUC Hotline", reporting in person to the IACUC Office, a member of the IACUC, Attending Veterinarian, or logging a report with the Office for Research Integrity, who will forward it to the IACUC Office. The office will gather initial information for presentation to the committee;
 - b. An IACUC subcommittee reviews all complaints and documentation and if warranted forwards issues to the full IACUC Committee for discussion. If warranted, a subcommittee of the IACUC will be convened and if the incident is judged to be inconsistent with the policy of Northwestern University or applicable federal regulations regarding the humane and ethical treatment of animals, appropriate measures will be taken;
 - c. Serious violations and recommendations for correction and possible subsequent action will be forwarded to the IO and, if warranted, the IO will notify the Office for Laboratory Animal Welfare (OLAW), USDA and AAALAC and, if warranted, the funding agency.
 - d. Northwestern's Nonretaliation Policy outlines mechanisms for anonymous reporting, compliance with applicable whistleblower policies, nondiscrimination and protections from reprisal of the concerned party and consequences for retaliation against the concerned party.

- 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:

The IACUC submits recommendations in writing to the IO and includes a description of the actions endorsed by the IACUC to make such improvements or corrections and a suggested timetable for action.

- 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:

The IACUC uses an electronic protocol management system, hereinafter referred to as eIACUC. The investigators must submit an Animal Study Protocol, hereinafter referred to as the protocol, for proposed work involving animals regardless of funding source or purpose (research, testing or education). The IACUC shall evaluate all components related to the care and use of animals to determine that the proposed research, testing or teaching protocol will be conducted in accordance with institutional policies, PHS Policy, and the Animal Welfare Act (insofar as it applies to the research project), and that the protocol is consistent with the *Guide*, unless an acceptable justification for a departure is presented in writing. All protocols are reviewed every three years.

When the protocol is received by the IACUC Office the staff screen the protocol to ensure completeness and grant-protocol congruency, as required by funding sources. A copy of the protocol is distributed using eIACUC to the entire committee whose members have up to three business days to request Full Committee Review (FCR). If no member requests FCR, Designated Member Review (DMR) will proceed. At least one qualified DMR is assigned to each protocol by the IACUC Chair or, when the Chair is not available, a Vice Chair as designated by the Chair. Additionally, a voting veterinarian or alternate non-voting veterinarian may consult during review of a protocol.

In the event that more than one DMR is assigned, the protocol is routed simultaneously for review to the DMR(s) and any consulting reviewer(s) using eIACUC. Any comments received from IACUC members during the review period are provided to the DMR(s) for consideration. The DMR(s) enter protocol modification requests in eIACUC; these modifications are available simultaneously to the DMR(s) and any consulting reviewer(s), hence the DMR(s) and consulting reviewer(s) receive identical versions of the revised protocol for review. The DMR(s) have the authority to require modifications to secure approval, approve or move the protocol to FCR. Approval is granted only after unanimous vote of the DMR(s).

A majority of the protocols are processed using DMR, however, the following categories for new or renewal protocols are designated automatically for full committee review: a.) primate protocols; b.) all experimental procedures categorized as USDA level "E"; c.) protocols containing any significant food and/or water restriction or fasting as defined in the IACUC policy titled "Fasted Animals and Animals on Special or Restricted Diets or Fluids"; d.) toe clipping. Approval for protocols receiving FCR is by a vote of a majority of the quorum present at a convened meeting. A quorum is considered to be a simple majority of the total voting members.

Outcomes for FCR review include approval, modifications required to secure approval or withhold approval. All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest except to provide information as requested by the IACUC, nor may a member who has a conflict of interest contribute to constitution of a quorum when voting. When a member recuses themselves due to conflict of interest, if quorum is maintained during the recused member's absence the protocol will be discussed or, in the event of a loss of quorum, the matter will be deferred until quorum is attained.

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:

Investigators must submit a revised protocol identifying the significant change(s) in the ongoing activities regardless of funding source or purpose (research, testing or education). Revisions are made directly to the protocol and are tracked and documented by eIACUC, the electronic protocol management system. In accordance with OLAW notice NOT-OD-14-126, *Guidance on Significant Changes to Animal Activities*, the IACUC has an approved policy that authorizes all veterinarians associated with the animal care program to verify significant changes to previously approved animal activities using Veterinary Verification Consultation (VVC). The investigator submits a revised protocol using eIACUC that tracks all protocol changes. Significant changes allowed by VVC include anesthesia, analgesia, sedation, stock or strain, experimental substances, euthanasia method, or in the duration, frequency, type or number of previously approved procedures. The veterinarian uses the IACUC policies, guidelines, Approved Animal Procedures (AAPs), SOPs, formularies, AVMA Guidelines for Euthanasia, Guide, and the AWAR to verify the significant changes are appropriate. Protocol revisions that do not involve changes to the approved animal activities, including changes to funding sources, protocol titles, personnel, contact information, typographical and grammatical corrections and one-time ten percent animal number increase during the three-year approval period are processed by IACUC office staff. Changes from non-survival to survival surgery, procedures that result in greater pain and distress or invasiveness, changes in housing,

species, study objectives, Principal Investigators (PI) or changes that impact personnel safety are permitted only by DMR or FCR. All other protocol revisions are reviewed in accordance with the DMR and FCR procedures described in Section III.D.6.

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:

The IACUC Office uses eIACUC to issue notification letters following the IACUC meeting and/or when all criteria for approval or of modifications required to secure approval have been met. If approved, pending modifications, or approval withheld, investigators are notified of the committee's action on their proposal in writing through eIACUC. If approval is withheld, the investigator may respond in writing to the Committee the protocol is resubmitted for consideration. The investigator must submit a corrected protocol for review prior to formal approval being granted. The IO receives monthly reports indicating decisions regarding protocol review.

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:

All protocols expire after three years from date of approval. If the investigator requests a renewal of the protocol for continuing activities, it receives a three-year de novo review as described in section D.6 of this document.

Ongoing animal activities where vertebrate animal research is conducted are visited by NU's Post Approval Monitoring (PAM) Program in which a PAM team member reviews approved protocols and observes procedures.

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:

The IACUC may suspend an activity it previously approved if it determines that the activity is not conducted in accordance with the approved protocol or applicable provisions of the Animal Welfare Act, the *Guide* and/or the Institution's Animal Welfare Assurance. The IACUC may suspend an activity only after review of the matter at a convened meeting and a majority vote of the quorum present. The attending veterinarian cannot officially suspend an activity, only the full committee has the authority to do that. Under NU policy, the Attending Veterinarian and, with authority and direction, the Veterinary staff have the authority and obligation to halt any activity that may threaten the well-being of (an) animal(s), and then must immediately notify the IACUC of any such action(s). If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for suspension, require appropriate corrective action and report that action with a full explanation to the PHS Office for Laboratory Animal Welfare (OLAW).

- 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. All personnel who are exposed to animals or have frequent contact with animals are enrolled in the Occupational Health Program. The program is contracted and coordinated with medical health professionals (Northwestern Corporate Health and Omega). Northwestern Corporate Health has a representative responsible for the oversight of occupational health program in coordination with the IACUC office, CCM and IBC. Enrollment includes completion of a health questionnaire, which is evaluated by contracted medical professionals (Northwestern Corporate Health and Omega) skilled in evaluating occupational health programs. The health

questionnaires are confidentially submitted directly by research personnel to the health care providers for evaluation. The IACUC partners with health service providers for initial and triennial evaluation. Participation in the occupational health program is documented for all personnel. Individuals who are pregnant, immunodeficient or have other illness are advised by the occupational health provider on additional safety precautions as appropriate. Individuals with special conditions (pregnancy, immunodeficiency or other illnesses) are advised by health care providers to consult with their supervisor or PI and personal physician as necessary and appropriate.

2. All personnel are required to take Occupational Health and Safety training in the AALAS learning library which provides an overview on precautions for known potential animal risks (zoonosis, allergies and hazards). Further information on precautions, allergies, zoonosis, personal hygiene practices, appropriate PPE and equipment use is provided by CCM during vivarium orientation.
3. Personnel working with non-human primates are annually required to attend primate refresher and bite exposure response training and to have an annual TB test.
4. In the event of animal bite, scratch or injury or illness, research staff are instructed to go to the occupational health provider or emergency room for evaluation. Research staff are responsible for reporting injuries to the supervisor, research safety and risk management.
5. The principal investigator shall be responsible for ensuring that all persons listed in the protocol under his/her direction shall comply with the provisions of the Occupational Health Program. Any principal investigator who fails to carry out this responsibility will be denied the use of animals until full compliance has been established.
6. The occupational health requirements are determined by the level of risk associated with each animal species and the extent of animal handling. The program is designed to protect both personnel and laboratory animals. Personnel involved with non-human primates receive annual primate training. Personnel include those individuals involved in direct care of animals and their living quarters, and those individuals who have direct contact with animals (live or dead), their viable tissues, body fluids or wastes. This includes individuals who must enter animal areas to provide program or support services. Zoonotic diseases and traumatic injury are of principal concern. Other safety considerations include equipment, noise levels, toxic chemicals, radiation exposure, and allergens.
7. Visitors that do not handle animals or have infrequent exposure to animals such as maintenance, police and safety, security, summer students, and visiting faculty, receive an abbreviated training provided by CCM staff prior to entry into the facility during which the types of potential hazards that might be encountered are explained, and provided a copy of the CCM Visitor Hazard Information sheet (per requirement of the IACUC Vivarium Visitor Policy). Relative risk for staff and others who have need to enter facility and research areas is assessed via review of answers provided on occupational health questionnaires, assessment of facility and research areas, and specific tasks associated with the individual's job description for potential hazards. Assessments are performed by CCM husbandry and veterinary staff in concert with Research Safety and the Institutional Biosafety Committee.

Occupational healthcare services include the following:

- a. Completion of a Medical Survey by all personnel working with animals. Individuals designated for an initial visit will receive, as determined by the level of risk, the following: i.) physical exam and evaluation; ii.) primate users will receive a PPD skin test or QuantiFERON (serology) test for TB. If there is a history of a recent treatment for TB or a positive test (PPD or QuantiFERON) or BCG vaccination, a chest x-ray will be taken.
- b. All primate users and CCM personnel who have contact with the animals will receive an annual TB test. For all other animal users, a TB test and/or physical exam will be performed based on a risk assessment.
- c. For existing personnel, OHS screening is conducted triennially.

8. The Research Safety (RS) provides oversight, services, and training to faculty, staff and students in biological, chemical and radiological safety. Research registration and training is mandatory. Periodic audits and reviews are conducted to identify potential problems and ensure necessary federal, state and local compliance with various rules and regulations. The RS reviews all animal protocol applications that contain hazards to ensure the compliance of safety issues with federal, state and local regulations and partners with the Center for Comparative Medicine.
 9. The RS furnishes guidelines and training in the safe use of ionizing radiation, hazardous chemicals, blood borne pathogens and other biological agents. All individuals who use any source of ionizing radiation (including x-ray machines and irradiators) must complete a registration form and undergo training. The Chemical and Biological Safety Officer reviews and approves Safety Plans that detail laboratory hazards. The Safety Plans will be reviewed on an annual basis and are approved prior to the use of animals. The RS annually inspects all chemical fume hoods. Biological safety cabinet performance is certified by a designated outside contractor.
- 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.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

The IACUC requires, and the IACUC Office staff verifies, that all investigators and research laboratory staff working with animals have taken on-line training modules in the AALAS Learning Library (Library) on occupational health, basic IACUC policies, "All NU Animal Users Required Courses" and any species-specific required courses. Required courses include a review of the Public Health Service Policy on Humane Care and Use of Laboratory Animals, U.S. Government Principles, and the 3 R's including the appropriateness of the numbers and species proposed in research protocols. Additionally, if a new researcher will be performing survival surgery with anesthesia on any species, they are required to take NU's "Principles of Aseptic Technique", "Pain Management and Perioperative Care" and the CCM "Introduction to Aseptic and Surgical Technique" wet lab. Personnel with experience are allowed to test out of the required training, however must be deemed competent by a member of the CCM veterinarian or PAM team. Training on specific laboratory procedures and the proficiency of laboratory personnel are also documented, by the PI or research personnel.

Additionally, research personnel working with primates complete an annual refresher training. A lab training documentation sheet is used to document lab-specific procedural training. Research personnel must also enroll in Occupational Health Program as described in E.1-3 of this document. All research personnel approved for satellite space use undergo training on the IACUC approved animal facility Satellite SOP. All research personnel are required to complete a facility orientation provided by the CCM training office. Additional training sessions, including hands-on training, are offered by CCM, which may be optional or required depending on what is described in a protocol and dependent on IACUC and CCM policies.

New IACUC members have a one-on-one training session with the Director of IACUC, Office staff, and the Chair or a committee member. During new member orientation, each member is given copies or electronic link of all pertinent federal and local regulations and policies, including the Guide, Institutional Animal Care and Use Guidebook, Animal Welfare Act, Animal Welfare Regulations, and PHS Policy. New members complete IACUC member training courses assigned in AALAS. Each member has access to the approved PHS Assurance and receives a new member training packet that provides an overview of the constitution of the IACUC, member responsibilities, sample questions to ask to obtain the right information during protocol reviews, the 3 R's, and the Nine Government Principles.

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

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 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, Milan Mrksich.
 5. Records of accrediting body determinations.
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements


- A. The Institutional reporting period is the calendar year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW by 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, Milan Mrksich.
 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 1. Any serious or continuing noncompliance with the PHS Policy
 2. Any serious deviations from the provisions of the *Guide*

3. Any suspension of an activity by the IACUC

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

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Milan Mrksich, Ph.D.	
Title: Vice President for Research	
Name of Institution: Northwestern University	
Address: IACUC 750 N. Lake Shore Drive, Rubloff (b) (4) Chicago, IL 60611	
Phone: (b) (6)	Fax: (b) (6)
E-mail: milan.mrksich@northwestern.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: (b) (6)	Date: 5/16/22

B. PHS Approving Official (to be completed by OLAW)	
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	
Signature: Paula E. Knapp - S 	Date: May 23, 2022
Assurance Number: D16-00182 (A3283-01)	
Effective Date: May 23, 2022	Expiration Date: May 31, 2026

VIII. Membership of the IACUC

Date: December 2, 2021			
Name of Institution: Northwestern University			
Assurance Number: D16-00182 (A3283-01)			
IACUC Chairperson			
Name*: CJ Heckman			
Title*: Professor		Degree/Credentials*: Ph.D.	
Address*: Northwestern University Department of Physiology 310 E. Superior St., 5 th floor Chicago, IL 60611			
E-mail*: c-heckman@northwestern.edu			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)			Veterinarian
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Non-affiliate
			Member
9 – Lisa Forman	DVM, ACLAM	Executive Director CCM/Attending Veterinarian	Veterinarian
(b) (6)			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Member
			Veterinarian
(b) (6)			Scientist
			Non-Scientist

	(b) (6)	Scientist
		Scientist
		Scientist
		Scientist
		Member
		Alternate for #15
		Alternate for #15
		Alternate for #1, #9, #16
		Alternate for #8, #23
		Alternate for #15
		Alternate for #1, #9, #16
		Alternate for #15
		Alternate for #15
		Alternate for #2, #3, #4, #5, #6, #10, #11, #12, #13, #14, #17, #19, #20, #21, #22
		Alternate for #1, #9, #17
		Alternate for #2, #3, #4, #5, #6, #10, #11, #12, #13, #14, #17, #19, #20, #21, #22
		Alternate for #8, #23
		Alternate for #1, #9, #16

* 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.

Contact #1	
(b) (6)	
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

Date: December 2021			
Name of Institution: Northwestern University			
Assurance Number: D16-00182 (A3283-01)			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
(b) (4)	67,706	Dogs, Zebrafish, Mice, Pigs, Rabbits, Rats	Dogs = 15 Mice = 27,483 Pig = 5 Rabbits = 0 Rats = 188 Zebrafish = 990
	1,621	Mice	Mice = 268
	363	Pigs	Pig = 0
	11,835	Cats, Ferrets, Gerbils, Ground Squirrels, Guinea Pigs,	Cats = 1

(b) (4)		Macaques, Mice, Rabbits, Rats, <i>Xenopus</i> Frogs	Ferrets = 10 Gerbils = 2 Ground Squirrels = 71 Guinea Pigs = 0 Macaques = 9 Mice = 748 Rabbits = 10 Rats = 168 <i>Xenopus</i> Frogs = 35
	20,368	Deer Mice, Macaques, Mice, Rabbits, Rats	Deer Mice = 4 Macaques = 3 Mice = 4,615 Rabbits = 1 Rats = 13
	6,185	Mice, Rats, Zebrafish	Mice = 26 Rats = 0 Zebrafish = 267
	4,750	Ferrets, Lamprey fish, Mice, Rats, <i>Xenopus</i> Frogs	Ferrets = 0 Mice = 205 Rats = 0 <i>Xenopus</i> Frogs = 66 Fish = 0

*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.

Stanley Manne Children's Research Institute™

May 5, 2022

Division of Assurances
Office of Laboratory Animal Welfare National
Institutes of Health Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Animal Welfare Assurance # A3995-01

To Whom it May Concern,

This letter serves to inform the Division of Assurances of the Office of Laboratory Animal Welfare that Ann & Robert H. Lurie Children's Hospital of Chicago, Stanley Manne Children's Research Institute intends to become a covered entity of Northwestern University (assurance number A3283-01) and will follow the guidance of the Institutional Official and Institutional Animal Care and Use Committee and all applicable policies and procedures and subsequently inactivate our assurance (assurance number A3995-01). This agreement will remain in effect until reviewed on or before May 2026.

Sincerely,

(b) (6)

Cassandra L. Lucas, PhD, CRA
Chief Operating Officer
Stanley Manne Children's Research Institute
Ann & Robert H. Lurie Children's Hospital of Chicago 225 E
Chicago Ave, Box 205
Chicago IL 60611-2991

(b) (6)

Stanley Manne Children's Research Institute

225 East Chicago Avenue, Box 205, Chicago, Illinois 60611
T: 312.503.7060 | F: 312.503.7059 | luriechildrens.org/research

Ann & Robert H. Lurie Children's Hospital of Chicago
Ann & Robert H. Lurie Children's Hospital of Chicago Foundation

 Ann & Robert H. Lurie
Children's Hospital of Chicago®

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 10/30/2023

Animal Research Program Agreement

Northwestern University ("NU") and the Rehabilitation Institute of Chicago doing business as Shirley Ryan AbilityLab ("SRALab") agree that SRALab shall be a covered component of the NU animal research program under NU's Public Health Service ("PHS") Assurance #A3283-01 ("NU's Assurance").

Both parties agree that all SRALab animal protocols shall be submitted to, reviewed and approved by the NU Institutional Animal Care and Use Committee ("IACUC"). All SRALab animal research will be conducted in NU facilities. SRALab shall not house or conduct research on live animals in its facilities.

SRALab research involving live animals will be conducted in accordance with the standards set forth by the *Guide for the Care and Use of Laboratory Animals*; the Animal Welfare Act (7 U.S.C. 54) and implementing regulations (9 CFR, Part 2, Subpart C); the Association for Assessment and Accreditation of Laboratory Animal Care International ("AAALAC"); PHS *Policy on Humane Care and Use of Laboratory Animals*; and NU policies and procedures.

NU shall maintain its:

1. NU Assurance, including SRALab as a named covered component;
2. AAALAC Accreditation;
3. USDA Registration.

This Agreement replaces all prior agreements between the parties related to this subject matter and shall be effective on the latest date executed below.

NORTHWESTERN UNIVERSITY

(b) (6)

By

Milan Mrksich
Vice President for Research
Institutional Official

REHABILITATION INSTITUTE OF CHICAGO

(b) (6)

By

Richard L. Lieber, Ph.D.
SVP, Research & Chief Scientific Officer

Date: 5/16/2022

Date: 5/12/2022