

# Neuroscience Research Institute of North Carolina

## ASSURANCE OF COMPLIANCE

### PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

Prepared December 30, 2017

Revised May 25, 2018

The **Neuroscience Research Institute of North Carolina**, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

Assurance Number    A-4500-01

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

I, Donald J. Woodward, Ph.D., as named Institutional Official for animal care and use at Neuroscience Research Institute of North Carolina, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

#### **I.     Applicability of Assurance**

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, DHHS, and/or NSF (if applicable). 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:

A. "The Neuroscience Research Institute of North Carolina" includes the single site at Winston Salem North Carolina.

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

## 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:

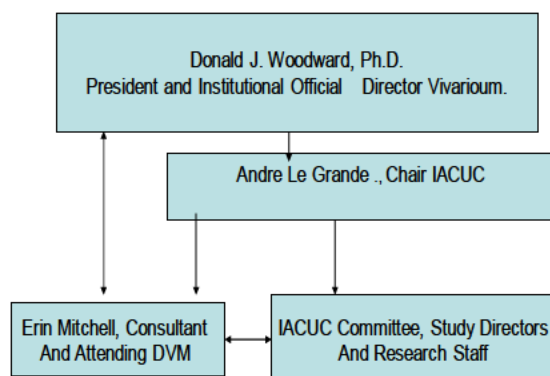
The Institute is currently relatively small, less than ten staff members, and dual roles are played by some individuals.

Donald J. Woodward Ph.D. President of the Neuroscience Research Institute of North Carolina is the Institutional Official for the institution. Dr. Woodward has the requisite budgetary and programmatic authority to make, order, and/or promptly carry out all necessary actions to ensure that Neuroscience Research Institute of North Carolina maintains an acceptable program of animal care and use in accordance with all relevant and applicable regulations.

Donald J. Woodard, Ph.D. directs the animal care and vivarium.

Dr. Erin Mitchell oversees veterinary care of animals housed and used within the facility.

***The IACUC committee reports to the Chair of IACUC, Andre Le Grande DVM, or in some cases the Vice Chair E. Mitchell DVM, and then to Donald Woodward Ph.D. President and Institutional Official.***



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

The Attending Veterinarian (AV) for Neuroscience Research Institute of North Carolina is E. Mitchell DVM. Dr. Mitchell is hired to exert programmatic authority and guidance. *Dr. Erin Mitchell has access to all animals in the program.* Dr. Mitchell also serves as Assistant Director at Wake Forest Health Sciences, Wake Forest School of Medicine. Backup veterinary care is provided by Andre Le Grande DVM.

***The AV reports to Donald Woodward, Ph.D., President of the Neuroscience Research Institute of North Carolina, and the current Institutional Official.*** In addition to serving on the Institutional Animal Care and Use Committee (IACUC), the AV is responsible for oversight of all animal activities. The consultant may be used when special knowledge is required. These activities include the following:

1. Consults with investigators regarding protocol development.
2. Reviews all protocols involving the use of animals.
3. Oversees training of all persons working with animals. Hands on instruction, visual aids, lectures, and publications are used as appropriate in training. Each person handling

animals is certified by the AV as being competent to perform specific tasks prior to being allowed to do so alone on live animals. Adjustments in procedures are added when justified.

4. Meets bi-monthly with the animal care staff and with investigators to examine animals, review surgical procedures, advises on treatment or disposition if necessary. Reviews or advises on development of SOPS and protocols, answers animal research related questions, provides training, and inspects the facility and equipment. The IO provides oversight of the pest control program.

5. Oversees a veterinary medical care program for all rats (the only species currently used) and a quarantine program for newly arrived animals. These programs involve inspection of newly arrived animals by the research staff and consultation with the AV within 72 hrs of arrival if problems or concerns are noted, followed by a six day quarantine period prior to experimental use. All animals are inspected on receipt for lesions and abnormal behavior. At 24 and 72 hours and six days each animal is weighed. These weights are examined to see that each animal is within the ordered weight and is gaining weight as expected of a healthy animal. On a daily basis, seven days a week, all animals are viewed by a trained member of the research staff. Any problems are noted and recorded. The principal investigator is notified and if a health problem is observed, a request for veterinary assistance is acted on. . If deemed necessary, the AV is contacted by phone or email immediately. Otherwise, the AV examines the animal on the visit. Trained staff are authorized to perform euthanasia should an animal be found moribund or in pain which cannot be relieved by reasonable medical treatment. If necessary, tissues, with a description of lesions, can be collected for subsequent examination by the AV. Access to clinical pathology, microbiology and serology services are available via commercial vendors if the AV determines such are required. The AV is available by phone, e-mail, or text for consultation if required.

At the present time only one veterinarian is involved with this program. Dr. Mitchell spends approximately four hours per month in onsite services and IACUC Committee activities. The AV is on call by phone, text, and email when off site and she provides contact information as necessary when traveling.

Name: Erin Mitchell, DVM North Carolina State University - College of Veterinary Medicine  
Doctor of Veterinary Medicine, May 2004

1)

Erin Mitchell has over 10 years of clinical experience with USDA-regulated and non-regulated laboratory animals species, IACUC protocol review, revision review, and composition. Experienced with USDA and AAALAC site visit. Training provided by Wake Forest University and North Carolina State College of Veterinary Medicine. 20 hours of Continuing Education are obtained each year. Maintains an active North Carolina veterinary license.

Authority: Dr. Mitchell has direct program authority and responsibility for the NRNIC animal care and use program including access to all animals.

Name: Andre Le Grande DVM Qualifications  
Degrees: Doctorate of Veterinary Medicine May, 2014  
School of Veterinary Medicine  
Louisiana State University, Baton Rouge, LA

- 
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
- Completion of ACLAM accredited residency in Laboratory Animal Medicine at Wake Forest School of Medicine. 2 years of clinical and facility oversight of both USDA and non-USDA regulated species. Guided AAALAC and USDA inspection visits and carries North Carolina Veterinary Medical Board License.
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Responsibilities:

IACUC chair and facility inspection Time contributed to program: Part-time

- 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. See below for the list.

This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC includes five members, and its membership meets the composition requirement set forth in the PHS Policy at IV.A.3.b. Attached below is a list of the chairperson and members of the IACUC and their names, degrees, position titles, specialties and institutional affiliations. The non-affiliated public member represents the general community interests in the proper care and use of animals, is also a non-scientist, and is not a laboratory animal user.

The IACUC is responsible for regularly overview and evaluation of the animal care program, and enforcement of compliance issues. The IACUC committee designs, schedules, provides oversight for training; and conducts regular inspections of facilities and animal use and care. The IACUC holds meetings quarterly or more frequently if needed for discussing animal care and use issues and approving new protocols.

Semi-annual IACUC inspections include review of the vivarium and animal laboratories and a review of the institution's animal care program.

The non-affiliated public member represents the general community interests in the proper care and use of animals, is also a non-scientist, and is not a laboratory animal user.

The current non science member is (b) (6)

The IACUC is responsible for regularly overview and evaluation of the animal care program, and enforcement of compliance issues. The IACUC committee designs, schedules, provides oversight for training; and conducts regular inspections of facilities and animal use and care. The IACUC holds meetings quarterly or more frequently if needed for discussing animal care and use issues and approving new protocols.

Semi-annual IACUC inspections include review of the vivarium and animal laboratories and a review of the institution's animal care program.

**D. IACUC Responsibilities and Procedures, Program Reviews.** 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:
- 2) All IACUC members, or a quorum, attend the semiannual inspection. The IACUC procedures for conducting semiannual program evaluations utilize the OLAW sample checklists as tools to assist in conducting thorough semiannual reviews. The checklists are used along with the 8<sup>th</sup> or most recent edition of the Guide which contains the standards, recommendations and the descriptions of outcomes necessary to evaluate and inspect the animals care and use program. The program review checklist covering institutional policies and responsibilities, the checklist for veterinary animal care, and the facility inspection checklist are utilized to help guide the IACUC through a complete inspection. The IACUC each meeting reviews relevant issues related to -Occupational Health and Safety -Veterinary Care Program -PHS Policy/ Animal Welfare Assurance -The Guide -Training Program as may relate to current procedures. The Chair and other members review each of these topics to be discussed and actions taken.

Inspections occur 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:

**IACUC –approved departures** from the PHS Policy and the Guide (that do occur) will be included in the Semiannual Report, with the reasons for each stated.

The IACUC procedures for conducting semiannual facility inspections require that at least two IACUC members, and the Attending Veterinarian be present for inspections of facilities. No member who wishes to participate in the Program Review or the Facility Inspection is precluded from doing so. Animal health and welfare are evaluated during the inspection. The facilities inspection, conducted at least once in six months, covers the institution's animal facilities. Areas evaluated include animal housing and support areas; cage wash facilities; aseptic surgeries, and procedure areas. Mechanism for reporting concerns include email to members of the IACUC, and direct communication with the Chair of the IACUC or the Institutional official. Procedures for doing so are posted on a prominent board in the facility. .

- 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:

Inspections are made by all members of the IACUC present which includes at a least a Quorum of four of the five members.

Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Institutional Official, Dr. Donald J. Woodward - Director of the Neuroscience Research Institute. Drafts of the proposed reports are reviewed at a scheduled meeting of the IACUC, discussed and edited to satisfy all members. Both significant and minor deficiencies will be designated and a



time schedule assigned by which corrections will be made. Records of evidence of actions to correct 'deficiencies', ( items not in compliance with the PHS Policy, or provision of the guide an use of laboratory Animals or institutional policies) will be assembled by the IACUC. 'Departures' or exemptions made will be noted and reviewed in subsequent meetings of the ACUS. Departures and deficiencies are noted in semiannual reports.

Minority reports will be attached to the draft. All members of the IACUC sign the report and minority views if expressed. These transactions will be communicated to the Institutional Official at least on a quarterly basis.

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

Any concerns involving the health, behavior, and well-being of the Institute's animals , concern for human handlers, or concerns about protocol integrity, are to be reported to the IACUC Chair., Dr. A. LeGrande, or the Director of the Institute and Institutional Official, Dr. D. J. Woodward. Procedures for reviewing concerns are designed to augment the single semi-annual inspection as an avenue for discovering and assessing problems, and may be handled by IACUC, the Director of the Institute, or by the entire assembled staff of the Institute. A non-reprisal policy is in effect, although with this small institute anonymity is difficult to maintain, the attending Vet assists in such matters. Reportable concerns are relayed directly to the Institutional Official and to OLAW as required. In such cases the Board of Directors of the Institute must be informed. The Board has the overall authority and responsibility for fair and reasonable governance as well as protection from any subtle form of reprisal.

- 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:

Make written recommendations to the Institutional Official, Dr. Donald J. Woodward Director of the Institute and the external Board of Directors regarding any aspect of the institution's animal program, facilities, or personnel training. The procedure for making recommendations to Dr. Woodward require written notification either in the form of the semi-annual report itself or in the form a letter expressing IACUC concerns and findings. The report normally will include recommendations for remediation and resolution of the problem, and a stipulated timeline.

- 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 conducts scheduled meetings bi-annually or when new protocols are to be reviewed. A quorum of the members of the IACUC committee must be present. A primary reviewer is assigned to the protocol, and that individual describes the general outline of the protocol. A period of questions and answers follows. A motion to approve, disapprove, or withhold approval is moved and voted on by IACUC members. Modifications requested may be minor with those modifications to be reviewed to secure approval during follow up by the committee. The investigator is then informed in writing of the decision.

**Expedited (Designated Member Reviews - DMR)** of full protocols are used in most situations, with an initial electronic distribution of the protocol under review to all members. Members then have 48 hours to respond and to request a full review. All members of the IACUC may request a review by the full committee. If no request for full IACUC committee review is received, and a written response from each member of the IACUC indicates that an expedited review is appropriate, then a designated member review by a qualified IACUC member is appointed by the Chair. The DMR has the authority to approve the protocol, require modification in (required to secure approval) or request a full committee review of the project. The designated member reviewer then has the authority to prepare an Approval Letter with a three year term. If more than one reviewer participates then all must be unanimous in a decision.

This version of the DMR is a hybrid with features of both the DMR and The FCR as described below and has been recommended by staff at OLAW. The NRINC organization is small and protocols are likely to be submitted by members of the full committee and thus have a conflict of interest. For this reason we first allow the full committee to review the protocol under consideration, and then appoint the DMR to complete the review. This function to separate the final stage of review for the potential conflict of interest by the member of the full committee.

Expedited (designated member) reviews of protocol modification requests are commonly used for personnel modifications. They consist of the electronic distribution of the modification request to all IACUC members. Members then have 48 hours to review the modification request and request a full committee review. If no request for full committee review is expressed, the protocol modification goes to designated member review by the IACUC chair or his designee. The designated reviewer has the authority to approve, require modification in (to secure approval) or request full committee review of the research project. All expedited reviews and minor modifications approved administratively are documented on the agenda of the next scheduled meeting of the IACUC.

- 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:

**Full committee Review Procedures (FCR):** The IACUC conducts full committee meetings if there are new protocols to review or modifications of existing protocols to consider.



For a new protocol the document is distributed to all committee members. Requests for modifications of change are reviewed and responded to by the applicant. Then a revised application is again distributed and a second option is provided for an approval, disapproval, or for changes.

**Minor modifications** (E.G. small changes – 10% or less – the number of animals used for rats and mice, change in sex of animals to be used, change in strain of the same species of animal to be used., , source of animals) can be approved administratively by the attending veterinarian with programmatic authority.

**Major protocol modifications** (e.g. large increases in number of animals, change in laboratory personnel, adding new invasive procedures or changing species, changing the route of administration of a compound) all require full IACUC committee review and approval. Protocol modification requests received one week prior to the IACUC meeting will be reviewed.

A quorum of three IACUC members must be present in order to hold an IACUC meeting. Protocol modification requests are reviewed and a period of questions and comments by IACUC members follows.

A motion to (i) approve, (ii) require modifications (to secure approval) or (iii) withhold approval is then moved and voted on by members. Modification requests are either minor (with requests to secure approval to be reviewed and approved during follow up by the IACUC Chair or his designee) or major and must be voted on by the full committee. The investigator is then informed in writing of the IACUC's decision.

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. Information is provided both verbally and in writing as to acceptability of a protocol and progress of the review of the IACUC protocol. Members of the IACUC are informed as to concerns and responses during revision. Revisions are also handled in a similar manner until approval is achieved. Copies of the IACUC approval letter are sent to the PI.
- B. Records of the IACUC proceedings are sent semi-annually to the Institutional Official, currently Donald J. Woodward, Director of the NRINC and to the Board of Directors of the Institute to be used for oversight purposes.

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 each of the 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

The Attending Vet and members of the IACUC perform a continuing biweekly review (Post Approval monitoring) of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4 at least once every three years. A review of active protocols is also conducted at each annual meeting. Records of kept of recommendations of the attending VET and responses to recommendations.

Protocols are approved for a period of three years. Then a complete de novo review of a protocol is conducted as though it were a totally new protocol. The protocol review will follow procedures as described about for DMR or FCR. Protocol renewal requests are distributed at each IACUC meeting, or in a timely fashion, for protocol review. After a period of three years, a new protocol has to be submitted for approval and the process begins anew.

- 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 after review of the matter at a convened meeting of a quorum of the IACUC and with the vote to suspend from a majority of the quorum present. Actions to suspend activity will involve preparation of a full report, along with actions to achieve corrections. In consultation with the Institutional Official and the IACUC a full report of these proceedings will be made to OLAW according to guidelines described at the OIAW Website for PHS Policy. <http://grants.nih.gov/grants/olaw/references/phspol.htm>.

#### **E. Occupational Health and Safety Program.**

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:

NRINC contracts with (b) (4) for construction of facilities and procedures to protect health of staff. Experienced members of the IACUC recommend to the Institutional Official when a consultation is required. Consults have included facilities installation related to direction of air flow, use of fume hoods and handling of biological materials and any other issues that come to the attention of staff. NRINC Staff have found over decades and through experience that continual personal monitoring of routine health care between all staff is essential beyond the service of health care professionals.

The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is established for all members of the Neuroscience Research Institute of NC. The program includes a physical examination and medical and work history prior to work assignment. Periodic physical examinations are given on a case-by-case basis. Prophylactic immunizations, tetanus, and occupational hazards, such as insect bites and allergies are treated by available health clinics contracted for the service

Location of facilities for emergency health care is posted. All employees have access to routine health care advice through personal health insurance and medical care.

**All health related injuries are reported, reviewed, and adaptive measures taken during ACUC meetings. Staff are required to complete an appropriate Laboratory Animal Training Association, (LATA) Occupational Health and Safety Module to deal with proper methods of dealing with biological hazards. The program is designed to mirror that at adjacent Wake Forest Health Science.**

*Expertise is available as needed to consult on health related precaution. Access to emergency medical care with phone numbers and locations is posted in an accessible place in the facility. Senior staff is routinely instructed to monitor health of other staff and recommend timely options for care. These measures provide instructions for care in case of pregnancy, illness or immune competence.*

- E. The IACUC Handbook of Policies and Standard Operating Procedures contains a warning form that is used on any site where biohazards are present. It identifies the personal protections that must be worn when working in that location. The NR Inst. of NC uses only rats and mice.

General procedures are in accord with recommendations of the Institute of Laboratory Animal Resources Guidelines with training have been followed according to the *Guide* and the National research Council document, 'Occupational Health and Safety in the Care and Use of Research Animals, NRC. Recent edition.

Special Procedures have been implemented in addition to training. Phone numbers to provide access to immediate medical care are prominently posted. Immunization for tetanus is required. Fountains for face and body wash are provided to deal with spills.

Special clothing and face masks are provided to minimize contact with rat hair and tissues. The HVAC system has been designed to provide negative air pressure on all rat housing cages, rooms and individual chambers where rodents remain for any significant time. Thoren isolation cages are used with HEPA filters at the air intake and exits. Air from the cages or rooms is ventilated directly outside the building to avoid contamination of the building air with particles from the rodents. Air flow to the experimental rooms is HEPA filtered. Our experience has been that rat allergies represent a significant occupational hazard and such measures are designed to minimize this danger. Visitors do not smell rodent odors. The Attending Veterinarian is routinely consulted as to potential health hazards from animals. The Attending Vet maintains a bite kit for rodents. Health Consultants are available from nearby (b) (4)

- 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.  
The total gross square feet of the Vivarium is 400 square feet. With a capacity for housing 144 rats.

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

The training or instruction of scientists, animal technicians, and other personnel involved in animal care, treatment, or use is a requirement at the Institution. All staff are required to participate in appropriate training courses contracted for the Institute with the advice and recommendation of the Attending Veterinarian, Erin Mitchell DVM and the consultants. Laboratory animal Training Modules suitable for research with rodents is required.

Content includes: IACUC Review , PHS Policy Review, AAALAC history and purpose, Attending Veterinarian responsibilities, alternatives to painful procedures, appropriate numbers and use of animal species, Drug use/Drug violations, surgery and aseptic techniques, occupational health, and effective euthanasia.

Members are supported to attend AICUC 101 training. The OLAW/ARENA IACUC Guidebook is provided. The approved Assurance application is made available to members of the IACUC. The Chair and attending Vet are encouraged to provide updates and information related to training.,

Training and review of methods of minimizing pain and stress to animals and use of numbers of animals is a constant feature of continuing professional education\*

The Institutional Official and all staff members with exposure to animals have attended IACUC101 Training. ACUC members are encouraged to attend an equivalent Basic Training Course for IACUC members.

#### **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.

This Institution is Category 2 — not accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). An NRINC internal review indicated that the facility and procedures would qualify when application is made to do so. As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached for Jan 2018.

#### **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, Donald J. Woodward Ph.D.
  5. Records of accrediting body determinations

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

## **VI. Reporting Requirements**

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, Donald J Woodward, Ph.D., will submit an annual report to OLAW by January 31 of each year. The annual report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
  - 3. Any change in the IACUC membership
  - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, *[Insert name or title of the Institutional Official signing the Assurance]*.
  - 5. Any minority views filed by members of the IACUC
  - 6. A written notification is made when there are no changes.
- 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 will include any minority views filed by members of the IACUC.

## VII. Institutional Endorsement and PHS Approval

<b>A. Authorized Institutional Official</b>	
Name: Donald J. Woodward, Ph. D.	
Title: President	
Name of Institution: Neuroscience Research Institute of North Carolina	
Address: (street, city, state, country, postal code) 101 N. Chestnut St. Suite 200 Winston Salem, NC 27101	
Phone: (b) (6) cell Work (b) (6)	Fax:
E-mail: (b) (6)	
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: May 23 , 2018

<b>B. PHS Approving Official</b> (to be completed by OLAW)	
 <b>Dr. Venita B. Thornton - Senior Assurance Officer</b> <b>Office of Laboratory Animal Welfare</b> <b>National Institutes of Health</b> <b>6705 Rockledge Drive</b> <b>RKL1, Suite 360, MSC 7982</b> <b>Bethesda, MD 20892-7982</b> (b) (6)	
Signature:	Date: May 31, 2018
Assurance Number: D16-00755 (A4500-101)	
Effective Date: May 31, 2018	Expiration Date: March 31, 2022



## VIII. Membership of the IACUC

Date: Dec 20, 2017			
Name of Institution: Neuroscience Research Institute of North Carolina			
Assurance Number: A4500-01			
<b>IACUC Chairperson</b>			
Name*: <b>Andre Le Grande, Doctor of Veterinary Medicine</b> May, 2014 School of Veterinary Medicine Louisiana State University, Baton Rouge, LA			
Title*: <a href="mailto:alegrand@wakehealth.edu">alegrand@wakehealth.edu</a>			Degree/Credentials*: D.V.M.
Address*: (street, city, state, zip code) Wake Forest School of Medicine Medical Center Boulevard Winston-Salem, NC 27157			
E-mail*: <a href="mailto:alegrand@wakehealth.edu">alegrand@wakehealth.edu</a>			
Phone*:		Fax*:	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)			Scientist
Donald J. Woodward	Ph.D.	Professor and Director	Scientist
Erin Mitchell	DVM, North Carolina State University - College of Veterinary Medicine Doctor of Veterinary Medicine, May 2004	Attending Vet. Vice Chair of IACUC	Attending Vet
(b) (6)			Non Scientist/Non-Affiliated member


\* This information is mandatory.

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

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

\*\*\*\* [PHS Policy](#) Membership Requirements:

- Veterinarian*      veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
- Scientist*          practicing scientist experienced in research involving animals.
- Nonscientist*      member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
- Nonaffiliated*      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>	
Name: Donald J. Woodward, Ph. D.	
Title: President Director	
Phone: (b) (6)	E-mail: (b) (6)
<b>Contact #2</b>	
Name:	
Title:	
Phone:	E-mail:

## X. Facility and Species Inventory

[illegible]

\*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.

**Memorandum to:** Donald J. Woodward PhD. Institutional Official  
Neuroscience Research Institute of North Carolina  
Assurance A4500-01

**From:** Institutional Animal Care and Use Committee

**Subject:** Semiannual Report of the Program Review and Facility Inspection

**Date:** 1/29/2018

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)), Section [IV.B.1.-3.](#), the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)), and the Animal Welfare Act ([AWA](#)) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

**Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy [IV.A.1.a.-i.](#)): [optional]**

NA

**I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA**

Departures from the PHS Policy, the *Guide*, and the AWA.

Select A or B:

- ☒ A. There were no departures during this reporting period.  
☐ B. The following departures have been reviewed and approved by the IACUC: *[include reason for each departure]*

**II. Deficiencies in the Institution's Animal Care and Use Program**

Animal Care and Use Program Review Date(s):

Select A or B:

- ☒ A. There were no deficiencies in the program during this reporting period.  
☐ B. The following deficiencies have been identified: *[describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]*

### III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s):

Select A or B:

☒ A. There were no deficiencies in the animal facility during this reporting period.

☐

☐ B. The following deficiencies have been identified: *[describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]*

### IV. Minority Views

Select A or B:

☒ A. No minority views were submitted or expressed.

☐

☐ B. The following minority views were expressed: *[insert minority views here or attach]*

### V. Status of AAALAC Accreditation *[identify accredited facilities, if applicable]*

NA

### VI. Signatures *[signatures of a majority of the IACUC members required by AWAR (§2.31,c,3), if applicable]*

Names of IACUC Members

Signatures

Dr. Andre Le Grande DVM Chair	<div>(b) (6)</div>
(b) (6)	
Erin Mitchell, DVM	
(b) (6)	
Donald J Woodward, Ph.D.	