

Animal Welfare Assurance for Domestic Institutions

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

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS and/or NSF. 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: (1) NCCU Main Campus and (2) NCCU Kannapolis Zebrafish Facility, Kannapolis, NC. The Kannapolis facility is located approximately 120 miles (2 hours driving time) from the NCCU main campus.

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) *Name: Derek Norford*

Degrees:

D.V.M., M.S., Pathology, Ph.D., Comparative Biomedical Sciences

Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Derek Norford has more than 31 years training and/or experience in laboratory or comparative animal medicine and pathology subsequent to receipt of the D.V.M. degree from Tuskegee University in 1985. He completed training in toxicologic pathology in 1988 at North Carolina (NC) State University in Raleigh, NC. He served as Director of the Laboratory Animal Resources Unit and Assistant Professor at NC Agricultural and Technical State University in Greensboro, NC from 1989 to 1996. In this position Dr. Norford served as the Attending Veterinarian to the animal care and use program and taught seven courses in the B.S. Program in Laboratory Animal Science. Dr. Norford received research training in comparative biomedical sciences as a Visiting Associate (1993-1994) and Guest Researcher (1996-2000) at the National Institutes of Health/National Institute of Environmental Health Sciences located in Research Triangle Park, NC. This training culminated in receipt of the Ph.D. degree from NC State University. Currently, he serves as the University Veterinarian and directs the Animal Resources Complex (ARC), the centralized facility housing the animal care program at NCCU. Dr. Norford attends at least one continuing education program annually in laboratory animal medicine to stay abreast of changes in the field and to acquire at least 20 continuing education credits to maintain the NC Veterinary License. He matriculated in online continuing education programs to satisfy requirements as a Category/Accredited Veterinarian of the USDA-AHIS Veterinary Accreditation Program.

Authority:

Dr. Derek Norford has *direct* program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

Dr. Norford serves as the Attending Veterinarian, on a full-time basis. He contributes up to 75% time commitment to maintenance and ongoing development of the animal care program at NCCU. The remaining 25% of his time is devoted to research and training duties at NCCU. Dr. Norford has ready access to the animal facility since his office and laboratory are located within the ARC at NCCU. He is available for contact in case of emergencies related to animal care.

Provisions for veterinary care at the NCCU Kannapolis Zebrafish Facility: Dr. Norford visits the facility at least four times per year (March, June, September and December) or more frequently as needed. Zebrafish technicians oversee the day to day operations under the direction of the Principal Investigator. In case of emergency related to animal husbandry, the zebrafish technician or laboratory manager is initially contacted. The Principal Investigator is subsequently notified by the technician or manager. The University Veterinarian is always available for questions or emergency care via mobile communication (email, text or telephone). The veterinarian will respond in person to emergencies as needed, residing only 76 miles from the Facility. Health surveillance for preventative medicine entails the collection of 5 adult zebrafish two times per year, coinciding with visitation by the Veterinarian, for histopathology. Zebrafish are euthanized using 10 ml tricaine methane sulfonate (4 mg/ml) stock solution to 100 ml tank water at pH 7.0 then fixed for histopathology evaluation. Sick and/or dead fish found in the colony are removed, euthanized and fixed for histopathology.

2) *Back up Veterinarian:* Craig Fletcher

Degrees:

D.V.M., Ph.D., D.A.C.L.A.M

Training or experience in laboratory animal medicine or in the use of the species at the institution:

Craig Fletcher, D.V.M., Ph.D., D.A.C.L.A.M, as Director, Attending Veterinarian, and Assistant Dean for Research Animal Resources at the University of North Carolina at Chapel Hill serves as NCCU's back-up veterinarian. Dr. Fletcher has 16 years of experience attending or using various species in laboratory and comparative animal medicine since graduating from University of Florida with the D.V.M. He completed residency training in Laboratory Animal Medicine, a Ph.D. degree and postdoctoral studies at Johns Hopkins University. He is a diplomat of the American College of Laboratory Animal Medicine.

- 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:

The IACUC reviews the program once every six months. This review occurs either at a scheduled meeting of the IACUC or that of a designated subcommittee. The subcommittee is composed of at least four committee members including the IACUC Chair, the Attending Veterinarian and/or ARC Facility Manager, at least two other voting members and the Director of Research Compliance & Technology Transfer. The review is led by the IACUC Chair or a designee. The Committee uses the *Guide* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee uses the Semiannual Program Review and Facility Inspection Checklist from the OLAW website. Since this checklist covers the major topics of the *Guide* and the requirements of the PHS Policy, it is used in conjunction with the *Guide*. The evaluation is divided into review of the Program and inspection of the Facilities. The Semiannual Program Review evaluates all components impacting Institutional Policies and Responsibilities and Veterinary Care. Items on the review checklist are evaluated and classified as A (acceptable), M (minor deficiency), S (significant deficiency), or NA (not applicable). In addition, the evaluation includes a review of the Institution's PHS Assurance. If program deficiencies are noted during the review the Committee develops 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. No member is 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:

The subcommittee composed of the IACUC Chair, Attending Veterinarian or ARC Facility Manager, at least two other voting members and the Director of Research Compliance & Technology Transfer inspects the institution's animal facilities at least once every six months. The inspection of the facilities includes all of the institute's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting animals is also inspected. The Committee uses the *Guide* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee uses the Semiannual Program Review and Facility Inspection Checklist from the OLAW website. All components of the

evaluation— Program Review and Facility Inspection Checklist are evaluated and classified as A (acceptable), M (minor deficiency), S (significant deficiency), C (change in program in accordance with PHS policy IV.A.1.a-i) or NA (not applicable). If deficiencies are noted during the evaluation, the Committee develops a reasonable and specific plan as well as 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. No member is involuntarily excluded from participating in any portion of the inspections. In addition, the evaluation includes a review of North Carolina Central University's PHS Assurance.

- 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:

Individual IACUC members convey his/her observations to the IACUC Chairperson, or designee, who, in turn, drafts reports using the Semiannual Report to the Institutional Official found on the OLAW website. The reports contain changes to the institution's program for animal care and use, a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, details specifically any departures from the provisions of the Guide and the PHS Policy, and states the reasons for each departure. The reports distinguish significant from minor deficiencies. If program or facility deficiencies are noted, reports contain a reasonable and specific plan as well as schedule for correcting each deficiency. Copies of the draft reports are reviewed, revised as appropriate and approved by the Committee. The final reports are signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. The completed reports are submitted to the Institutional Official within 45-60 days following the evaluation.

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

Any individual may report concerns to the Institutional Official (IO), Director of Research Compliance & Technology Transfer, IACUC Chair, University Veterinarian or any member of the IACUC. Notices are located throughout the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. All reported concerns are brought to the attention of the full IACUC Committee. If necessary the IACUC Chair convenes a special meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions are recorded in the IACUC meeting minutes. The Committee reports such actions to the IO and, as warranted, to OLAW.

- 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:

Recommendations on any aspect of the institution's animal care and use program, including but not limited to facilities, or personnel training are developed through collaborative discussions with the Director of Research Compliance & Technology Transfer, IACUC meetings and through electronic communications between members. Once approved by the IACUC, the Chair prepares a report of the recommendations and sends it to the IO.

- 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. The IACUC Chair or designee receives a completed application electronically to use live vertebrate animals in research, testing or education. The application undergoes pre-review and is then subject to either Designated-Member review (DMR) or Full-Committee review (FCR).

- b. The IACUC Chair or designee pre-reviews the application for completeness or obvious concerns. The Attending Veterinarian may pre-review the application to ensure that proposed procedures necessitating analgesia or anesthesia are adequately addressed. Following any pre-review, the IACUC Chair or designee sends the protocol to all members. The Chair may identify members to serve as designated reviewers (if DMR is the method of use) or primary reviewers for full-committee review.
- c. IACUC meetings are regularly scheduled on a designated day (monthly, 2nd Wednesday) at a pre-established time and place each year. To ensure a quorum is present, IACUC members are sent electronic reminders at least one (1) week prior to each meeting with request to inform of their intention to attend. Meetings are only held if a quorum of members attends.
- d. IACUC meetings are conducted in person; however, members unable to be physically present may participate via conference call. Materials are sent in advance of the meeting via email to members participating via conference call. Note: Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals
- e. Prior to the review using DMR, each IACUC member will be provided with written descriptions of activities (protocols) that involve the care and use of animals and any member of the IACUC may obtain, upon request, full committee review (FCR) of those protocols. If FCR is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications (to secure approval) or request full committee review of those protocols. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. 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 a majority vote of the quorum present. Possible outcomes as a result of FCR include the following: approve, require modifications (to secure approval) or withhold approval. If the outcome of FCR is to require modifications to secure approval, such modifications are reviewed as follows:
 - i. FCR is used in accordance with all applicable procedures delineated in the PHS Policy and as described. Resubmitted protocols (those requiring modifications to secure approval) are reviewed by IACUC members in advance of the next FCR utilizing an approved checklist. Discussions of members' findings are held during convened meetings. Following deliberations, a motion is made and seconded to make a recommendation. A "yea" or "nay" vote on the recommendation posed in the motion is taken and a majority vote of the quorum determines the ruling on the resubmitted protocol.
 - ii. Alternatively, DMR may be used if approved unanimously by members present at the meeting during which the required modifications are identified. All IACUC members have previously agreed in writing that all members present at a convened meeting may decide by unanimous vote use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may request FCR.
- f. Generally, for initial protocol reviews the FCR method is used. However, should a situation warrant, the institution or IACUC may use the designated-member review (DMR). In such instances the protocol will be distributed to all IACUC members to allow members the opportunity to call for FCR. Records of members polled to obtain concurrence to use DMR or concurrence by silent assent after five (5) working days,

and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting. If any member during polling or within five (5) working days believes the protocol should go before a full committee, then its review is deferred to the next full committee IACUC meeting.

- g. No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote unless they are also members of the IACUC.
 - h. In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC conducts a review of those components related to the care and use of animals and determines that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the *Guide* unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
 - i. Procedures with animals avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - ii. Procedures that may cause more than momentary or slight pain or distress to the animals are performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - iii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved are painlessly killed at the end of the procedure or, if appropriate, during the procedure.
 - iv. The living conditions of animals are appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals are directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
 - v. Medical care for animals is available and provided as necessary by a qualified veterinarian.
 - vi. Personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in those procedures.
 - vii. Methods of euthanasia used are consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
 - i. There are no alternate processes or procedures for special or expedited reviews.
- 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:

Review and approval of significant changes are handled in the same manner as initial protocols in accordance with PHS Policy IV.C.1-3 as described above in Section 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:

Investigators are notified by memorandum from the IACUC Chair of the Committee's decision to approve or withhold approval of the protocol or of modifications required to secure approval of the protocol. Copies of all memorandums notifying investigators of IACUC decisions are sent to the Director of Research Compliance & Technology Transfer and IO.

- 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:

Postapproval monitoring of animal research is performed by the animal care staff, the ARC Facility Manager, Attending Veterinarian and Director of Research Compliance & Technology Transfer. Approved protocols cover a three year period. Approved protocols are reviewed by the IACUC prior to years two and three to ensure compliance. To maintain ongoing activities beyond the initial three-year approval period, a new protocol must be submitted, reviewed, and approved as described above in Section D.6.

Activities on approved protocols and documentation of animal as well as surgical care are reviewed by the IACUC during semiannual inspections. Recently implemented is a requirement for reports on the number of animals used for experimental and breeding purposes prior to years two and three of the approval period. This information is also required on the new application requesting approval covering a new three-year period. Experimental and breeding animal numbers used in the third year not renewed for a new triennial will be reported on a close out form.

- 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 that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Assurance, the IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

The University Veterinarian or IACUC Chair may suspend ongoing animal related activities, subject to rapid review by the IACUC.

- 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:

The occupational health and safety (OH&S) program is established to protect NCCU personnel from biological, chemical, and physical hazards associated with working with laboratory animals. The IACUC in consultation with NCCU Health and Safety is responsible for implementation of the OH&S program related to the use of animals in research. All individuals that care for and use laboratory animals at the institution are required to participate in the OH&S program. This may

include, but is not limited to animal care staff, investigators, research assistants, students, post-doctoral fellows, visiting scientists/faculty and volunteers. Department heads, facility managers, and supervisors may identify additional employees whose contact with laboratory animals, tissues or waste from laboratory animals warrant participation in the program. Individuals who are involved in infrequent contact (e.g. maintenance, University police) will not be required to enroll in the program. Prior to contact, they will be provided with information about any health considerations relative to the animals and precautions to reduce hazards by ARC and OH&S staff. Following review of the potential hazards and risks, individuals are required to affirm their acceptance of this information through their signature. The goal of the OH&S program is to limit exposure of the various hazards arising from the care and use of laboratory animals. The program is based on the potential risk of exposure to biological and chemical hazards associated with the use of laboratory animals at NCCU. Biological hazards identified include allergens from rodents (primarily urinary proteins and rat saliva). In order to minimize exposure to biological hazards from rodents, a cage and rack system vented through the animal facility's exhaust system is used coupled with the performance of many experimental procedures or husbandry activities within Class II, Type A1 or Type A2 biological safety cabinets. The potential infection of personnel using zebrafish with *Mycobacterium marinum* is a biological hazard. Personal protective equipment is also used to minimize exposure to biological hazards. Potential chemical hazards include exposure to toxic compounds used in sanitation practices or experimental activities. Chemical hazards associated with the use of laboratory animals at NCCU include sodium hypochlorite (bleach), chlorine dioxide (clidox), isoflurane, carbon dioxide, oxygen/nitrogen gas mixtures, disinfectant containing isopropanol and Alkyl (C12-16) dimethyl benzyl ammonium chloride (Odor Ban). To minimize exposure, chemicals are used appropriately to ensure safety. Carbon dioxide is used only in well-ventilated areas and isoflurane is scavenged to control hazardous exposure. The ARC Facility Manager, Attending Veterinarian, IACUC and Director of Research Compliance & Technology Transfer, in concert with NCCU Health and Safety are continuously engaged in risk assessment and the identification of hazards associated with the use of laboratory animals at NCCU. Adjustments to the OH&S Program are made as needed. Procedures using animals housed in the ARC are only performed within the facility or an IACUC approved procedure room.

All individuals proposing to be involved in the care and use of laboratory animals must complete an initial risk assessment questionnaire which is reviewed by an occupational health professional. Individuals working daily with laboratory animals in the ARC are initially medically cleared through a pre-placement physical examination and completion of an extensive background questionnaire at Duke Occupational and Environmental Medicine. Current tetanus inoculations are required for all individuals working with rodents at NCCU. The medical assessment determines whether an individual is required to wear special respirators. Once identified the individuals contact NCCU Health and Safety for fitting of special respirators. Following this initial assessment, individuals engaged in animal care and use are monitored annually through a questionnaire and referred to Duke Occupational and Environmental Medicine if requested or determined necessary. Individuals (including personnel who are/or considering to become pregnant, using laboratory animals are also trained on potential zoonoses, chemical safety, and waste disposal of hazards through web-based (American Association for Laboratory Animal Science (AALAS) Learning Library) and in-house training activities. All individuals are required to read the Laboratory Safety Plan of the ARC containing information regarding chemical hazards.

Training in OH&S is designed to inform research and animal care personnel of specific hazards intended for experimental use. Standard Operating procedures (SOPs) are designed in collaboration with ARC Facility Manager, Attending Veterinarian, Director of Research Compliance & Technology Transfer and NCCU Health and Safety for approval by the IACUC. Once the use of hazardous agents is approved, training using the appropriate SOPs for those persons who will/or have the potential to be exposed is conducted by OH&S staff.

Included in the OH&S training are precautions for personnel who are pregnant and those considering pregnancy. These precautions include preventing exposure to potential mutagens and other chemicals that may pose risks, especially during the first trimester of pregnancy. Individuals who are ill or immunocompromised are not allowed in the ARC.

All individuals that enter rodent rooms must don personal protective equipment including coveralls, shoe covers, masks, gloves, and bonnets. Only disposable laboratory coats are used within the ARC. The animal care staff works in uniforms provided and laundered by a commercial vendor. Prior to using biological and chemical hazards in animal experimentation the investigator is required to obtain approval of policies and practices including disposal of hazardous materials from NCCU Health and Safety. Most procedures on live animals, some surgeries and all necropsy examinations are performed using one of the several Class II biological safety cabinets in the ARC. All biological waste is boxed for pickup then incineration by a commercial vendor. Individuals working with zebrafish are required to wear gloves.

All illness and injury (including bites and scratches) from animal care and use are required to be reported promptly to ARC staff and NCCU Health and Safety. A report is completed to document the occurrence and records maintained in the ARC and NCCU Health and Safety. Medical treatment is provided as needed for illness and injury resulting from exposure to biological, chemical, and/or physical hazards in the use of laboratory animals. If the injured is an NCCU student, the incident occurred during normal business hours and emergency care is not needed, the student will be taken to Student Health Services. If, however, the problem occurred after normal business hours, the student would contact University Police for transport to the closest hospital emergency room. Employee or faculty would seek treatment during or after normal business hours at Duke Occupational Health Medicine or an emergency room, respectively.

- 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:

Animal Care and Use Personnel – Federal regulations mandate that individuals who use animals in training and research be qualified to humanely perform the appropriate procedures. Training or experience in the care and use of laboratory animals must be documented prior to conducting protocol related activities at NCCU. The training program is conducted by the ARC Staff. The program covers the laws and regulations covering laboratory animal care and use with an emphasis on contents of the *Guide*, particularly the 3R's. The program includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). The program requires completion of 4-5 web-based courses presented by the American Association for Laboratory Animal Science (AALAS Learning Library) augmented with handouts introducing aspects of the humane care; regulations in the use of animals in research; and methodology. Applied training for individuals new to the use of animals in the ARC is required for introduction to policies and procedures of the facility. A training syllabus, transcripts from AALAS courses, and a form used for documenting experiences related to the use of laboratory animals in research serves as a record for training.

Specialized training can be provided by the ARC for research personnel. Investigators are tasked with ensuring that students, post-doctoral fellows, and research scientists working under their direction are also adequately trained in specialized experimental techniques approved on their animal use protocols.

Individuals new to the use of zebrafish are required to read a review of the related husbandry, *Aquaculture* 269:1-20, 2007 and complete AALAS web-based training courses on ethics, *Working with Laboratory Zebrafish* and *Aquatic Animal Husbandry and Management*. These individuals also train under the guidance of experienced zebrafish users at NCCU and are taught the physical, chemical, and biological elements of zebrafish management.

IACUC Member Training - NCCU's IACUC is committed to ensure the animal care and use program remains in compliance with mandates of the PHS Policy. All voting IACUC members are trained by taking two courses through the AALAS Learning Library, entitled *Essentials for IACUC Members* and *Working with the IACUC – Non VA version*. Members may also (attend the IACUC

101 and 201 workshops (based on fund availability), sponsored by Public Responsibility in Medicine and Research (PRIMR), Applied Research Ethics National Association (ARENA) and OLAW, or comparable workshops such as IACUC 2012, a two-day workshop sponsored by the North Carolina Association for Biomedical Research.


In order to meet IACUC responsibilities, members are provided copies of the following: 1) the PHS Policy for the Humane Care and Use of laboratory Animals; 2) the current edition of the *Guide*; 3) 2nd Edition of ARENA & OLAW Institutional Animal Care and Use Committee Guidebook; and 4) a copy of this Assurance. Updates of relevant laws, policies and guidelines or new issues impacting deliberations of NCCU's IACUC are shared during monthly IACUC meetings. These include, but not limited to appropriate sections from issues of the trade journal *Lab Animal* and *Journal of the American Association for Laboratory Animal Science*.

New IACUC member orientation is conducted one-on-one with the Director of Research Compliance & Technology Transfer. The primary objectives of this training are to introduce members to the role of the IACUC; provide basic information necessary for IACUC members to conduct their responsibilities; and provide a forum for response and discussion of members' concerns and questions. Training consists of the following: a description of the IACUC, its composition and responsibilities; presentation of federal regulations and IACUC resources (AWA, PHS Policy on Use of Laboratory Animals, Guide, the 3 R's, AVMA Euthanasia); review of a mock IACUC protocol and discussion of FCR and DMR procedures/outcomes; explanation of semiannual program evaluation and facility inspection; introduction to on-line training modules through AALAS Learning Library; and discussion of real and apparent conflicts of interests.

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.

[From the following two paragraphs, retain the one that is applicable and delete the one that is not applicable.]

- (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, Undi Hoffler, Ph.D.
 5. Records of accrediting body determinations


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

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 - 3. Any change in the IACUC membership
 - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Undi Hoffler, Ph.D.
 - 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy
 - 2. Any serious deviations from the provisions of the *Guide*
 - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Undi Hoffler, Ph.D.	
Title: Director, Research Compliance and Technology Transfer	
Name of Institution: North Carolina Central University	
Address: (street, city, state, country, postal code) 1801 Fayetteville Street Hubbard-Totton Suite 309 Durham, NC 27707	
Phone: 919-530-6893	Fax: 919-530-6894
E-mail: uhoffler@nccu.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: 1/24/2017

B. PHS Approving Official (to be completed by OLAW)	
 Neera Gopee, D.V.M., Ph.D., DACLAM, DABT Veterinary Medical Officer Office of Laboratory Animal Welfare (OLAW) 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 gopeenv@od.nih.gov	
Signature: 	Date: 01-24-2017
Assurance Number: D16-00378 (A3626-01)	
Effective Date: 01-24-2017	Expiration Date: 01-31-2021

VIII. Membership of the IACUC

Date: October 31, 2016			
Name of Institution: North Carolina Central University			
Assurance Number: D16-00378 (A3636-01)			
IACUC Chairperson			
Name*: Xiaoxin Chen			
Title*: Associate Professor of Biology, Principal Investigator, Cancer Research Program			Degree/Credentials*: M.D., Ph.D.
Address*: (street, city, state, zip code)			
North Carolina Central University Julius L. Chambers Biomedical/Biotechnology Research Institute 700 George Street Durham, NC 27707			
E-mail*: lchen@nccu.edu			
Phone*: 919-530-6425		Fax*: 919-530-6429	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Xiaoxin Chen	M.D., Ph.D.	Associate Professor, Biology	Chair, Scientist
Derek Norford	D.V.M., Ph.D.	University Veterinarian and Director of ARC	Veterinarian
M3	Ph.D.	Associate Professor, Biology	Scientist
M4	B.S., A.L.A.T., L.A.T.	Research Operations Manager	Non-scientist
M5	M.S.	University Health Physicist	Non-scientist
M6	Ph.D.	Associate Professor, Biology	Scientist
M7	Ph.D.	Associate Professor, Biology	Scientist
M8	Ph.D.	Associate Professor, Chemistry	Scientist
M9	B.A.	Administrative Assistant	Nonaffiliated & Nonscientist
M10	Ph.D.	Associate Professor, Pharmaceutical Sciences	Alternate Scientist
M11	M.S.	Research Specialist	Alternate Scientist

* This information is mandatory.

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

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

**** PHS Policy Membership Requirements:

Veterinarian 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.

Contact #1	
Name:	
Title:	
Phone:	E-mail:
Contact #2	
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.