# North Carolina Central University
A3626-01
# Animal Welfare Assurance

I, Hazell Reed, 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. 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.

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

## 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."

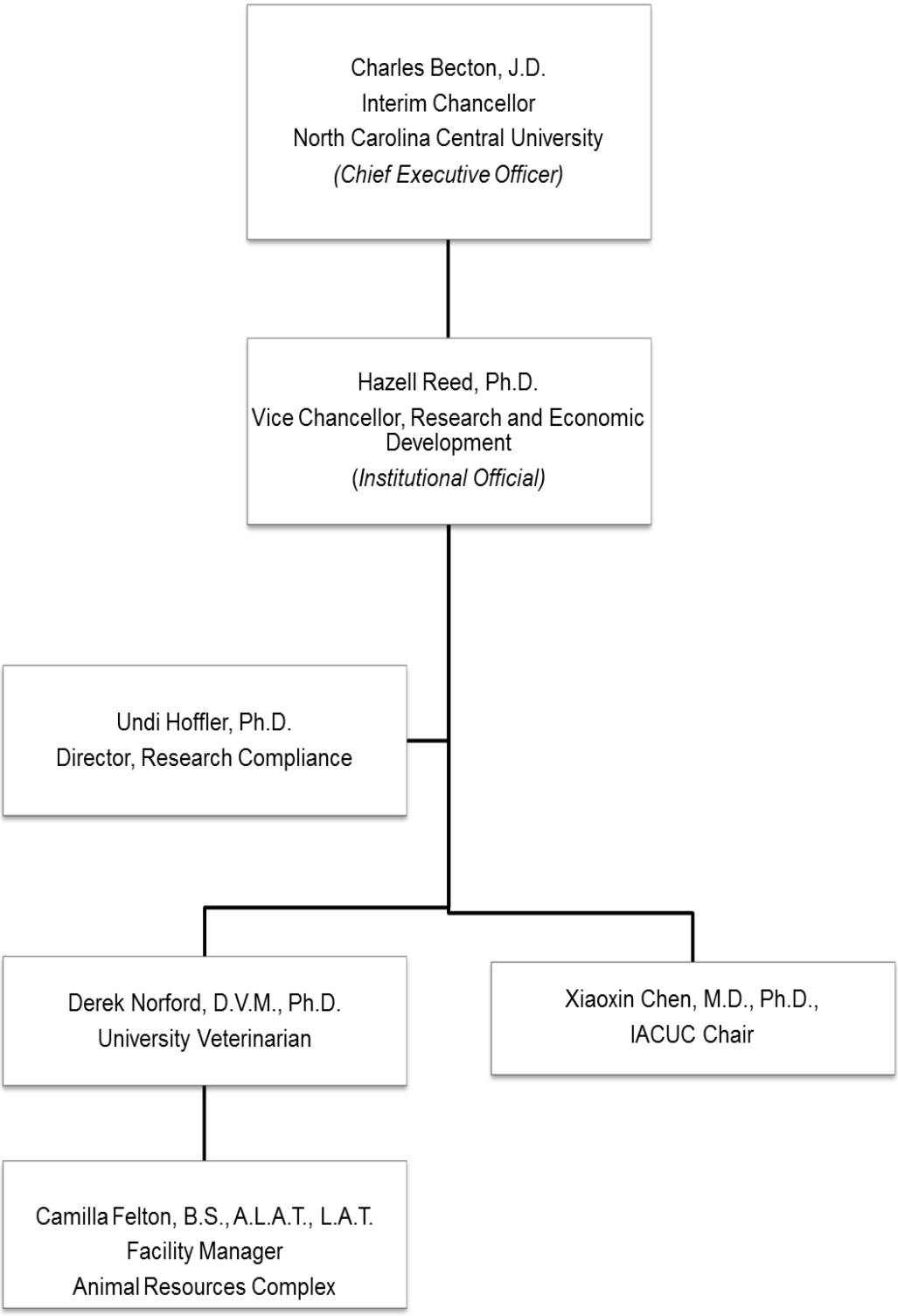
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand 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

*Qualifications:*

- *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 27 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.

*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 at least a 50% time commitment to the maintenance and ongoing development of the animal care program at NCCU. The remaining 50% 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.

*Back up Veterinarian:* Stephen Dempsey, D.V.M., Assistant Vice Chancellor and University Attending Veterinarian at NC State University in Raleigh, NC will serve as the Alternate Veterinarian during periods of unavailability of Dr. Norford. Dr. Dempsey has over 30 years of experience in laboratory animal medicine and pathology. He served as Attending Veterinarian for the program at NCCU prior to the hiring of Dr. Norford as University Veterinarian on July 1, 2000.

*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 400 mg/L MS-222 (tricaine methane sulfonate) 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.

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 Chancellor, as Chief Executive Officer (C.E.O.), has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Section VIII. is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

1) **Review at least once every six months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows**:

● 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 or ARC Facility Manager, at least two other voting members and the Director of Research Compliance.

● 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.

● The program review includes, but not limited to the following:

a) IACUC Membership and Functions;
b) IACUC Records and Reporting Requirements;
c) Husbandry and Veterinary Care (all aspects);
d) Personnel Qualifications (Experience and Training);
e) Occupational Health and Safety; and
f) Emergency and Disaster Planning

● 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 six months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows**:

● 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 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, surgical and procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the 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. The Semiannual Facility Inspection addresses all facets of the following: a) Terrestrial Animal Housing and Support Areas; b) Aquatic Animal Housing and Support Areas; c) Cagewash; d) Special Facilities: Aseptic Surgery; e) Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, and Behavioral Studies.

● Items on the review checklist are evaluated and classified as A (acceptable), M (minor deficiency), S (significant deficiency), or NA (not applicable).

- If deficiencies are noted during the inspection, 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 inspections.

3) **Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows**:

- 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.

- The reports specifically details any IACUC approved departures from the provisions of the Guide and the PHS Policy, and states the reasons for each departure. The reports note when no departures from the Guide and PHS Policy occur. Approved departures for the Guide and PHS Policy are approved as a part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.

- Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such. To address such departures the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.

- The reports distinguish significant from minor deficiencies. If program or facility deficiencies are noted, reports contain a reasonable and specific plan and schedule for correcting each deficiency.

- The reports will contain information identifying whether some or all of the institution's facilities are accredited by AAALAC International. The reports will identify the accreditation status of each facility.

- Copies of the draft reports are reviewed then 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 so state.

- The completed reports are submitted to the Institutional Official in a timely manner following the evaluation.

- Deficiencies identified in institution's animal care and use program will be tracked by the Director of Research Compliance and the ARC Facility Manager to ensure that they are appropriately resolved.

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

- Any individual may report concerns to the Institutional Official (IO), Director of Research Compliance, IACUC Chair, Institutional Veterinarian or any member of the IACUC.

- Notices are located in 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 Committee.

- If necessary the IACUC Chair convenes a 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, in writing, to the IO and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate document. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally.

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 aspects of the institution's animal care and use program, facilities, or personnel training are developed through discussions with the Director of Research Compliance, 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**:

- Protocols proposing to use live vertebrate animals in research, testing, or education are submitted electronically to the Director of Research Compliance or

IACUC Chair in a pdf format. The application undergoes pre-review and is then subject to either Designated-Member review (DMR) or Full-Committee review (FCR).

- 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.

- IACUC members are notified via email by the Director of Research Compliance or IACUC Chair of protocols for review.

- Following any pre-review, the Director of Research Compliance or the IACUC Chair sends the protocol via email to all members. The Chair may identify members to serve as designated reviewers (if DMR is the method of use) or primary reviewers for FCR.

- 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

- IACUC meetings are conducted in person, but members unable to attend may participate via a conference call. Materials needed to contribute to the IACUC meetings are sent via prior email to members participating via conference calling.

- 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.

- Prior to the review, 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 of those protocols.

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

- IACUC meetings are scheduled on a designated day at a pre-established time and place each year. To ensure that a quorum is present, IACUC members are sent reminders, by the Director of Research Compliance or IACUC Chair, at least a week prior to each meeting with a request to inform of their intention to attend. Meetings are only held if a quorum of members attends.

● IACUC members review the protocols prior to the meetings using an approved checklist. Discussions of the findings by members are held at the meetings. After completion of the discussion, a motion is made and seconded to make a recommendation on the protocol. A "yea" or "nay" vote on the recommendation in the motion is taken and a majority vote of the quorum determines the ruling on the protocol.

● The possible outcomes on FCR includes one of the following: 1) approve; 2) require modifications prior to approval; 3) withhold approval.

● Required Modifications Subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:

1) FCR or DMR following the all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

Or

2) DMR if approved unanimously by all members at the meeting at which the required modifications are developed delineated AND if all IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

3) If an IACUC uses DMR, the approval date is the date that the designated member(s) approve the study.

4) Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

● Generally, for initial protocol reviews the FCR method is used. However, should a situation warrant, the institution or IACUC may use the DMR method. 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.

● 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 in (to secure approval) or request FCR of those protocols.

- Other IACUC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the designated-member review (DMR) method may not be conditioned.

- If multiple designated reviewers are used, after all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all of the designated reviewers for review and approval.

- If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.

- Outcomes of DMR are 1) approval; 2) request additional information from the PI for approval; or 3) refer for FCR.

- There are no alternate processes or procedures for special or expedited reviews.

- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC conducts a review [by FCR or DMR] 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:

  a. Procedures with animals avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

  b. 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.

  c. 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.

  d. 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.

  e. Medical care for animals is available and provided as necessary by a qualified veterinarian.

  f. Personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in those procedures.

g. Methods of euthanasia used are consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

7) **Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities 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 new protocols in accordance with PHS Policy IV.C. See Paragraph III. Section D.6. above.

● Examples of changes considered to be significant include, but are not limited to, changes:

1) in the objectives of a study;
2) from non survival to survival surgery;
3) resulting in greater discomfort or in a greater degree of invasiveness;
4) in the species or in approximate number of animals used[1];
5) in Principal Investigator;
6) in anesthetic agent(s) or the use or withholding of analgesics;
7) in the method of euthanasia; and
8) in the duration, frequency, or number of procedures performed on an animal

[1]Changes of <u>less</u> than 10% in the approximate number of animals used of mice of the genus *Mus* and rats of the genus *Rattus* that are bred for use in research <u>only</u> may, at the IACUC's discretion, be considered minor (not significant).

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.

● In the event that modifications of the protocol are required to secure approval, the investigator would receive a detailed listing of the required modifications via memorandum.

● If approval is withheld, the investigator would receive specific reasons via written communication for withholding approval of the protocol, and the PI is afforded the opportunity to respond either in person or in writing.

- Copies of all memorandums notifying investigators of IACUC decisions are sent to the Director of Research Compliance 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 three years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows**:

- Post approval monitoring of animal research is performed by the animal care staff, the ARC Facility Manager, Attending Veterinarian and Director of Research Compliance.

- Annual reviews - Approved protocols for the use of USDA covered and non-USDA covered species cover a three year period. The protocols are reviewed, by a member or members of the IACUC at least annually and renewed prior to years two (2) and three (3).

- To maintain ongoing activities beyond the initial three-year approval period, a complete review of activities in new protocol submission by the IACUC is conducted just prior to the end of the three year approval for specified protocol.

- Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review.

- If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III. Section D.6. above.

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 Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation, in writing, to OLAW. Preliminary reports may be made telephonically.

- 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:

1. Administration/management

- 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 goal of the OH&S program is to limit exposure of the various hazards arising from the care and use of 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.

- The Director of Research Compliance is responsible for the overall management of the OH&S program for personnel involved in the care and/or use of laboratory animals.

- Ongoing planning and monitoring of the OH&S program is jointly performed by the Director of Research Compliance, IACUC, NCCU Health and Safety, and the NCCU Medical Director.

2. Scope

- All individuals that care for and use laboratory animals at the institution are required to participate in the OH&S program.

- Animal care staff, research personnel, IACUC members, facility services individuals, custodial staff, the Director of Research Compliance and others regularly exposed to hazards associated with the use of laboratory animals enroll in the OH&S program by completion of an initial risk assessment questionnaire.

- The assessment questionnaire is distributed to the enrollees by the Director of Research Compliance.

3. Health Histories and Evaluations

- 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 the Medical Director. The assessment questionnaire is used to determine exposure risk levels of all individuals.

- 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. Health histories and evaluations are used to determine potential adverse effects of exposure to hazards associated with the care and use of laboratory animals. These also provide baseline data of the health status of individuals working in the care and use of laboratory animals at the NCCU. Health records are maintained by Duke Occupational and Environmental Medicine.

- 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 completion of a questionnaire sent by the Director of Research Compliance or a designee. The questionnaires, reviewed by the Medical Director, are to identify changes in levels of exposure and the onset of on health effects due to exposure to hazards associated with animal care and use. Individuals are referred to Duke Occupational and Environmental Medicine if requested or determined necessary.

4. Hazard Identification and Risk Assessment

- The OH&S program is based on the potential risk of exposure to biological and chemical hazards associated with the use of laboratory animals at NCCU.

- The ARC Facility Manager, Attending Veterinarian, IACUC and Director of Research Compliance, in concert with NCCU Health and Safety are continuously engaged in risk assessment and the identification of hazards associated 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.

- Ongoing hazard identification and risk assessment occurs through protocol reviews by the IACUC and evaluations of standard operating procedures in the animal facilities by the Attending Veterinarian and ARC Facility Manager, and Director of Research Compliance.

- Biological hazards identified include allergens from rodents (primarily urinary proteins and rat saliva). The potential infection of personnel using zebrafish with Mycobacterium marinum is also a biological hazard.

- 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, tricaine methanesulfonate (MS-222), carbon dioxide, oxygen/nitrogen gas mixtures, disinfectant containing isopropanol, and Alkyl (C12-16) dimethyl benzyl ammonium chloride (Odor Ban).

- Major physical hazards identified include rodent bites, sharp items (such as broken glass, syringes, needles, and scalpel blades), ignited flammable materials

(Class A-C), compressed gas cylinders, ergonomically-based injuries from animal care and use tasks, misuse of the cage washer, autoclave units and other ARC equipment.

- Hazard identified and exposure risks due experimental procedures are determined from protocol reviews and post approval monitoring by the IACUC, ARC staff, Director of Research Compliance, and Health and Safety personnel.

5. Procedures in Place to Alleviate Hazards and Minimize Risks

- Procedures in place are delineated under the following items:
    1) Institutional policies;
    2) Engineering methods
    3) Equipment and procedures
    4) Training
    5) Use of Personal Protective Equipment (PPE)
    6) Personal hygiene requirements

1. Institutional policies
    a) Only animal care and use activities approved by the IACUC may be performed at the institution
    b) 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
    c) Personnel must be trained in the hazards and risks associated with the care and use of animals
    d) Eating, drinking, cell phone usage and excessive noise are not allowed in the animal holding and procedure rooms
    e) Biological waste is boxed for pickup then incineration by a commercial vendor

2. Engineering methods
    a) The ARC has a dedicated air handling system providing 100% coarse-filtered fresh air
    b) The HVAC operates as variable-volume system
    c) 10-15 air changes occur in each animal room
    d) Airflow in each animal room and the refuse access of the cage washer/autoclave suite is negative to the hallway
    e) Airflow in the two procedure rooms and clean access of the cage washer/autoclave suite is positive to the hallway

3. Equipment and procedures
    a) Animals are housed, a cage and rack system vented through the animal facility's exhaust system
    b) Cages should only be opened under the laminar flow hood in the animal holding room
    c) Animal procedures in the room are performed under the hood.

d) Class II, biological safety cabinets, located in each animal room, quarantine area, and necropsy/procedure suite and procedure/surgical suite, are used to perform many experimental procedures and/or husbandry activities
e) A Waste Disposal Unit (Class II) is used for cage dumping in the refuse access area of the cage washer/autoclave suite
f) Chambers for $CO_2$ inhalation are used in well-ventilated areas only
g) Isoflurane anesthesia is provided using two SurgiVet Vaporizers each set up with a SurgiVet AES Scavenger system

4. Training
   a) Individuals using laboratory animals are also trained on allergen development, 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.
   b) All individuals are required to read the Laboratory Safety Plan of the ARC containing information regarding chemical hazards
   c) Personnel are trained by the ARC staff to properly perform euthanasia, anesthesia, and animal handling, and other applicable experimental techniques
   d) The personnel read the ARC Standard Operating Procedures to become familiar with tasks related to animal husbandry including equipment operations
   e) Personnel are provided with hands on training in the operation of equipment associated with animal care and use

5. Use of Personal Protective Equipment (PPE)
   a) PPE is also used to minimize exposure to biological hazards
   b) Individuals are trained in the proper use of PPE by the ARC staff
   c) All individuals that enter rodent rooms must don PPE including coveralls, shoe covers, masks, gloves, and bonnets.

6. Personal hygiene requirements
   a) Rodent animal care technicians work in uniforms provided and laundered by a commercial vendor
   b) Only disposable laboratory coats are used within the ARC
   c) Individuals working with zebrafish are required to wear gloves

6. Immunizations

- Current tetanus inoculations are required for all individuals working with rodents at NCCU.

7. Precautions taken during pregnancy, illness or decreased immunocompetence

- Females must report a change in pregnancy status to ensure that the proper precautions are taken such as preventing exposure to potential mutagens other chemicals putting unborn individuals at risk

- Individuals ill or with decreased immunocompetence are not be allowed in the animal facility

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

- These individuals are made aware of potential hazards and risks in the animal facilities

- Training in the appropriate practices including the proper use of PPE is provided as needed to minimize exposure to hazards

9. Availability and procedures for treatment of bites, scratches, illness or injury.

- Treatment of bites, scratches, illness or injury in personnel occurs at Duke Occupational Health Medicine

- Minor injuries in students may be treated at the Student Health Services

10. Procedures/program for reporting and tracking injuries and illnesses.

- All injuries and illnesses from animal care and use are reported as soon as possible to the ARC Facility Manager, Attending Veterinarian, and Director of Research Compliance, NCCU Health and Safety, the IACUC, and the IO

- A report is completed to document the event and records maintained by the ARC, Director of Research Compliance, and the IO

- Copies of the report are sent to Human Resources and other offices as mandated by current policies at the institution

11. Other Pertinent Information Regarding the OH&S Program

- All injuries from exposure to biological, chemical, and/or physical hazards from use of laboratory animals at NCCU are reported and medical treatment is provided as needed

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 Section X., the Facility and Species Inventory table.

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

**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.

● Investigators involved in animal use will be provided a copy of this Assurance for distribution to personnel on their protocol. The ARC staff will be provided access to this Assurance to ensure knowledge of the various facets of the animal care and use program

● The IACUC verify that individuals are adequately trained to perform their duties through a designee witnessing carrying out the activity. The appropriate designee could be from the ARC staff, the ARC Facility Manager, Attending Veterinarian, Director of Research Compliance, or other individual with the requisite experience to adequately assess their ability to perform their duties.

● 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). Specifically, as applicable, training and instruction of personnel includes guidance in at least the following areas:

1. Humane methods of animal maintenance and experimentation, including:

   a. The basic needs of each species of animal;
   b. Proper handling and care for the various species of animals used by the facility;
   c. Proper pre-procedural and post-procedural care of animals; and
   d. Aseptic surgical methods and procedures;

2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be

discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:

a. On appropriate methods of animal care and use;
b. On alternatives to the use of live animals in research;
c. That could prevent unintended and unnecessary duplication of research involving animals; and
d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

● The program requires completion of four or five 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) the 2nd edition of the 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 have been shared at meetings. These include, but not limited to appropriate sections from issues of the trade journal *Lab Animal* such as Protocol Reviews and Regulation Watch.

## IV. Institutional Program Evaluation and Accreditation

A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every six months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

B. This Institution is Category 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 three years:

1. A copy of this Assurance and any modifications made to it, as approved by the PHS

2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations

3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, the Vice Chancellor, Division of Research and Economic Development.

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, the Vice Chancellor, Division of Research and Economic Development.

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: Hazell Reed, Ph.D. | |
| Title: Vice Chancellor, Division of Research and Economic Development | |
| Name of Institution: North Carolina Central University | |
| Address: *(street, city, state, country, postal code)*<br><br>1801 Fayetteville Street<br>Hubbard-Totton Suite 309<br>Durham, NC 27707 | |
| Phone: 919-530-6893 | Fax:919-530-6894 |
| E-mail: hreed@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: Hazell Reed | Date: January 23, 2013 |

| **B. PHS Approving Official** *(to be completed by OLAW)* | |
|---|---|
| Name/Title:<br>Office of Laboratory Animal Welfare (OLAW)<br>National Institutes of Health<br>6705 Rockledge Drive<br>RKL1, Suite 360, MSC 7982<br>Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817)<br>Phone: +1 (301) 496-7163<br>Fax: +1 (301) 915-9465 | |
| Signature: | Date: |
| Assurance Number: | |
| Effective Date: | Expiration Date: |

## VIII. Membership of the IACUC

| | |
|---|---|
| Date: December, 2012 | |
| Name of Institution: North Carolina Central University | |
| Assurance Number: A3626-01 | |
| **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)*<br>North Carolina Central University<br>Julius L. Chambers Biomedical/Biotechnology Research Institute<br>700 George Street<br>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 and Cancer Research Program | Chair, Scientist |
| Derek Norford | D.V.M., Ph.D. | University Veterinarian | Veterinarian |
| M3 | Ph.D. | Associate Professor, Biology and Cardio-Metabolic Research Program | Scientist |
| M4 | B.S., A.L.A.T., L.A.T. | Research Operations Manager | Member |
| M5 | M.S. | University Health Physicist | Member |
| M6 | Ph.D. | Associate Professor, Biology and Nutritional Research Program at Kannapolis, NC | Scientist |
| M7 | Ph.D. | Assistant Professor, Biology and Nutritional Research Program at Kannapolis, NC | Scientist |
| M8 | Ph.D. | Associate Professor, Chemistry and Neuroscience Research Program | Scientist |
| M9 | B.A. | Administrative Assistant | Nonaffiliated & Nonscientist |
| M10 | J.D. | University Attorney | Ex-officio/non-voting |
| M11 | Ph.D. | Director, Research Compliance | Ex-officio/non-voting |
| M12 | Ph.D. | Associate Professor, Pharmaceutical Sciences | 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: Undi Hoffler, Ph.D. | |
| Title: Director, Research Compliance | |
| Phone: 919-530-5140 | E-mail: uhoffler@nccu.edu |
| **Contact #2** | |
| Name: | |
| Title: | |
| Phone: | E-mail: |

## X. Facility and Species Inventory

| | | | |
|---|---|---|---|
| Date: December, 2012 | | | |
| Name of Institution: North Carolina Central University | | | |
| Assurance Number: A3626-01 | | | |
| 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 |
| Animal Resource Complex (ARC)/ JLC-Biomedical/ Biotechnology Research Institute (BBRI) | 8,000 | Mice | 1291 |
| ARC/BBRI | | Rats | 28 |
| ARC/BBRI | | Zebrafish | 1691 |
| Zebrafish Lab/BBRI | 240 | Zebrafish | 1000 |
| NCCU Kannapolis Zebrafish Facility | 230 | Zebrafish | 1200 |
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Note: Unless otherwise indicated, mice and rats means mice of the genus *mus* and rats of the genus *rattus* that are purposely bred for research.

*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.