

HOWARD UNIVERSITY
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals
(Animal Welfare Assurance No.: A3742-01)

I, Yonette F. Thomas, Ph.D., as named Institutional Official (IO) for animal care and use at Howard University, hereinafter referred to as Institution, by means of this document, 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:

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
 - 1. E.E. Just Hall, College of Arts and Sciences
 - 2. Numa P.G. Adams Building, College of Medicine

- B. The following are other institution(s), or branches and components of another institution:
 - 1. None

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, as well as all 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 in accordance with 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 (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 this Policy are described in Appendix A.
- B. Authority: Dr. Doris E. Hughes-Moore has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals. The qualifications and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1. Doris E. Hughes-Moore, D.V.M.

Dr. Hughes-Moore received her B.S. degree in 1967 from Tuskegee Institute and her D.V.M. degree in 1973 from Purdue University. Her residency training in veterinary clinical pathology and pathology occurred at Purdue University and Washington State University, respectively during the years 1974-1976. She has considerable experience in research and in writing reports of studies performed as a result of contractual agreements. Dr. Hughes-Moore is the University Veterinarian and Director of the Animal Facility in the College of Medicine and the Veterinarian for the Biology Satellite Facility and serves as a member of the IACUC. She serves as Coordinator for the Occupational Health and Safety Course. The percent of time that Dr. Hughes-Moore contributes to the animal care program is 100% time and effort.

2. Douglas S. Dobbin, D.V.M.

Dr. Douglas Dobbin, a practicing veterinarian with over 25 years of experience in emergency medicine, serves as the Relief or Back-up Veterinarian for Howard University at such times when such coverage is required by the University Veterinarian. Dr. Dobbin received his D.V.M. degree in 1985 from Virginia Maryland Regional College of Veterinary Medicine and practiced emergency medicine for 16 years at Beltway Emergency Hospital and ten years at Dover Animal Emergency Hospital.

In the matter of veterinary care, as it relates to the health of the animal, the veterinarian has the authority to exercise their professional judgment in implementing the PHS Policy and the recommendations of the Guide.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the 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 five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached, Section VIII, is a list of the chairperson and members of the IACUC and their 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 Program Review is conducted by the IACUC at least once every six months. To encourage maximum participation, the Program Review is performed during a regularly scheduled IACUC meeting with a quorum present. The full committee reviews and discusses each aspect of the animal care and use program using a checklist that follows the OLAW "Sample Semiannual Program Review Checklist". The semiannual facility inspections are conducted prior to the program review so that observations and trends can be discussed.

Each portion of the program, including IACUC functions, policies, responsibilities, reporting, and record keeping requirements; the training program; the veterinary care program, and occupational health and safety program, is thoroughly reviewed using the checklist. Deficiencies described by the Guide, PHS Policy, and/or USDA regulations are noted. Each deficiency is further identified as either a minor or a significant deficiency. Members are encouraged to identify items to be addressed and minority views are recorded.

2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

Facility inspections are performed by the IACUC at least once every six months. The semiannual facilities inspections are conducted as a group tour led by the campus veterinarian, IACUC chair, and includes the director of Environmental Health and Safety and ORRC administrative staff. The inspectors follow the "Sample Semiannual Review Checklist" provided by OLAW. All IACUC members are encouraged to participate and each member may sign up for as many dates as possible. It is required that at least three voting IACUC members perform each inspection, but all who wish to participate are included. The IO may also request the presence of additional staff.

Inspections typically involve several half-day tours, which include inspecting laboratories and meeting PIs and their staffs. Prior to the inspection, each team is provided checklists

that identify each area to be inspected, the type of area, and examples of inspection criteria. Areas reviewed include all animal housing, procedure and surgical areas, the cage-washing facility, and feed and medical storage areas. The Guide is used as a basis for the inspection; any deviations are recorded as either significant or minor and follow-up is done to assure corrective action is completed in a timely manner. Minority views on all aspects are incorporated into the review.

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

The facility inspection reports and program evaluation checklist are reviewed and signed by the members of the IACUC during the convened meeting. These are utilized as the final report which contains a description of the nature and extent of the institution's adherence to the Guide and PHS Policy and identifies specifically any deficiency described in the provisions of the Guide and PHS Policy as well as the reasons for the deficiency. Each deficiency is delineated, along with a plan of corrective action and a schedule for correcting each deficiency. Each deficiency is further identified as either a minor or significant deficiency. The IACUC considers a significant deficiency to be one which in the judgment of the IACUC and Institutional Official is or may be a threat to the health or safety of the animals. Once the IACUC signs the report, a cover letter is prepared by the Office of Regulatory Research Compliance IACUC Administrator which summarizes the findings and delineates any program recommendations and minority views. The final report, once signed by a majority of the members, and cover letter are submitted to the Institutional Official. On behalf of the IACUC, the IACUC administrator in the Office of Regulatory Research Compliance (ORRC) provides follow-up to ensure completion of required corrective action.

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

All concerns involving animal care and use are to be reported to the IO, the Associate Vice President for Research Compliance. Concerns may also be reported directly to members of the IACUC, who will then report them directly to the IO. Posted at the entrance of the Animal Facilities is a sign that provides anyone with animal welfare concerns the name and phone number of the Veterinarian, the IACUC Chair and ORRC contact information. All animal welfare concerns reported to the IACUC are treated confidentially. Reports may also be made anonymously. This information is also posted on the IACUC website. If the IO or IACUC or veterinarian is suspected of a conflict of interest, the reports are to be made directly to the University Internal Auditor or Provost.

Reports of concerns involving the care and use of animals will be forwarded to the IACUC and the Office of Regulatory Research Compliance (ORRC). The IACUC may request the investigation be led by the Office of Regulatory Research Compliance (ORRC) or may create a subcommittee of the IACUC to lead the investigation. The PI is also notified of the content of the allegations. If the animal welfare allegation includes concern for biological,

chemical, or radiological safety, the appropriate safety office is consulted. The attending veterinarian, or designee, assesses the reported animal's condition to ensure the immediate health and well-being of the animal. Following assessment of the animal's welfare, investigation of all aspects of the allegation is conducted as soon as possible.

The findings are presented to the IACUC for full committee review and discussion to determine if the allegation is substantiated. The IACUC carefully reviews any concern which is reported and takes corrective actions as appropriate. Reports of the results of investigations and corrective actions are provided to the Institutional Official and reported externally (e.g., OLAW, USDA) as appropriate.

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:

Written reports and IACUC recommendations are submitted to the IO through the semiannual review and reporting mechanism. Other written reports are prepared on an as-needed basis, such as reporting on a specific compliance or facility issue; these are presented to and discussed with the IO as described above.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

Animal Use Protocols are submitted to the Office of Regulatory Research Compliance (ORRC). Projects involving animal subjects may not begin until approved by the Committee, regardless of the type of the project or its source of funding. Prior to IACUC review, each protocol is reviewed by a veterinarian, the IACUC chair, and IACUC administrator. Questions raised by these reviews are sent to the PI via email. The PI is required to respond and make changes before the IACUC review.

In addition to the veterinarian, two members of the IACUC are assigned as a primary reviewer and secondary reviewer and present their reviews at the meeting. However, all protocol materials are available to all IACUC members for review. The IACUC reviews each submission at a convened meeting of the full committee at which a quorum is present. IACUC decisions are made by a voice vote requiring a simple majority (51%) of the quorum present to approve or move actions forward. Any member may abstain from participating in a protocol review.

Members must recuse themselves (i.e., abstain from voting and be absent from the room during deliberation and vote) if there is a conflict of interest. The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity and may not vote with the IACUC unless they are also members of the IACUC and there is no perceived conflict of interest.

The IACUC will determine through deliberation whether the research project conforms with the institution's assurance and meets the following requirements: a) Procedures with animals will 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 will be 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 will be painlessly sacrificed at the end of the procedure or, if appropriate, during the procedure. An oral vote is taken following the discussion of the protocol.

The vote will indicate the IACUC's decision to approve, require modifications to secure approval, defer or withhold approval. Protocols that are deferred are generally missing key information for the IACUC to assess the application and will be reviewed as a new submission at the next convened meeting. Following the IACUC meeting, the PI is notified in writing (via email) of the IACUC's decision and if approval is withheld, the PI is informed of the reasons for its decision. When substantive information is lacking from a protocol, and the committee has questions requiring a response from the PI, the IACUC may use designated member review (DMR) subsequent to full committee review (FCR). All IACUC members have consented 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. In certain circumstances DMR alone may be utilized. In this case, the application is made available to each member of the Committee with an opportunity, generally 5 business days, for any member to call for a full Committee review. If any member requests FCR the application is held for the next scheduled meeting with a full quorum. If no member requests a FCR, the DMR process may commence.

In either case, the Chair and the IACUC administrator assign at least two IACUC member as a designated reviewer for any proposal reviewed by DMR. Veterinary review and compliance pre-review is conducted and any questions or comments are forwarded to the principal investigator. Once the PI has satisfactorily responded to the veterinarian's concerns, then the research project will advance for further review. DMR may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications.

Whether in full-committee review or designated member review, the IACUC or designated member reviewer(s) shall evaluate all components related to the care and use of animals to determine that the proposed research and/or teaching protocols will be conducted in accordance with institutional policies. In making this determination, the IACUC shall confirm that the research project will be conducted in accordance with the PHS Policy and

the Animal Welfare Act insofar as it applies to the research project, and the research protocol is consistent with the "Guide," unless an unacceptable justification for a departure is presented in writing.

The PHS Policy requires that a complete IACUC review of PHS-supported protocols be conducted at least once every three years. This triennial review is interpreted by OLAW as a requirement for de novo review, meaning that the criteria and procedures for review specified in IV.C. of the PHS Policy must be applied not less than once every three years. The three-year period must begin on the actual date of IACUC approval; the IACUC is not allowed to administratively extend approval beyond the three years. To assist investigators, the ORRC should attempt to provide adequate warning of pending protocol expiration (via email). It is the responsibility of the investigator to submit the third-year resubmission by the appropriate deadline date for a scheduled Full Committee Review (FCR) prior to protocol expiration. Third Year Resubmission must be submitted as a new proposal, using the most recent version of the application.

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 as set forth in the PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

The IACUC handles proposed significant changes in previously approved activities in the same manner as new protocol applications, including the methods used for submission, review and approval. Written notification by the investigator to the IACUC for approval is required before significant changes can be made to an approved protocol. Evaluation of amendments to protocols originally subjected to full-committee review are handled in the same way as new protocols (described under part III.D.6) and may be subjected to designated review if no committee member requests full review. Amendment applications for protocols originally subjected to designated review for which no member calls for full-committee review are assigned to the member(s) that originally conducted the designated member review where possible.

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 as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

Formal notification is sent via email to the Principal Investigator outlining the Committee's decisions. The notification is prepared by the IACUC administrator on behalf of the IACUC chair. A full copy of the minutes is sent to the Institutional Official.

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 in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

The committee reviews at least once annually all continuing animal care and use proposals; and progress reports, including the number of animals used in the prior approval period and the number to be used for each year of research. IACUC approval is for one year only, and all continuing proposals are given a complete review every three years as mandated by the PHS policy.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC will suspend an activity involving animals set forth in the PHS Policy, if it is determined that the activity is not being conducted in accordance with the provisions of the Animal Welfare Act, the Guide, and this Institution's Assurance. The issue will be reviewed at a specifically convened meeting of the IACUC, and a majority vote of the quorum present will be required for suspension. The Committee chairperson will report the vote to the Institutional Official, who will consult with the IACUC regarding the suspension. If suspension is upheld, the IO will determine and take appropriate corrective action and a full report of that action with an explanation will be made to OLAW and/or APHIS. Additional review may occur if warranted as outlined in the institution's "Scientific Research Misconduct Policy."

E. The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows:

Howard University's Occupational Health and Safety Program is administered by the Department of Environmental Health and Safety (EHS). The ORRC in collaboration with EHS and the Employee Health Center promote a safe work environment by minimizing the risk of illness or injury associated with working with or around research animals and research-related hazards. The program covers all individuals who work with animals directly as well as those who may be exposed to animals or animal dander in common areas or laboratories. All animal caregivers and users must take the online LATA occupational safety module and enroll in the occupational health program. The Department of Environmental Health and Safety and the Employee Health Center have the responsibility for individual risk assessment of as well as design of the appropriate health assessment, preventive medicine and health monitoring program. The following elements of the program exist:

1. Hazard Identification and Risk Assessment

The Institutional Animal Care and Use Committee have previously identified risks associated with the care and use of laboratory animals in its training program entitled Occupational Safety for Animal Caregivers and Users. A brief summary of the assessment and its scope is as follows:

Risk of Injury or Illness (A Brief Summary)

Note: All animal caregivers and users must take the online LATA occupational safety module and enroll in the occupational health program.

A. Risk Identification

a.) Nature of Risks of Animal Care and Use Associated Hazards:

i. Bite or Scratch-Associated Hazards

- (1) Superficial wound with no notable infection or subsequent scarring.
- (2) Painful, infected wound of an acute (short duration) or chronic (long duration) nature. *Pasteurella multocida* is frequently cultured from such wounds. Other possible consequences of an animal scratch, bite or lick are Rat Bite Disease and Cat Scratch Fever.
- (3) Nerve damage resulting in minor or major disability
- (4) Serious life threatening injury or infection (loss of function, significant loss of blood, rabies).

ii. Zoonotic Hazards

Species –associated zoonotic illness (viruses, bacteria, ricketisial, parasitic and fungal agents): Ex.: Lyme disease, rabies, salmonella, scabies, flea mites, etc, with inapparent to serious injury.

iii. Animal Allergy Hazards

Animal associated allergy seen in one-third of animal care personnel expressed as eye, nose and throat irritation, skin reaction such as hives, serious respiratory illness such as asthma and potential in highly reactive people for circulatory collapse and death.

iv. Needle Stick Hazards

Needle sticks with consequences dependent on syringe-needle contents:

a.) Chemical, Drug and Latex (Glove) Allergy and Toxicity Hazards

Allergy can result from exposure to drugs or chemicals or foods or other materials used for research or for animal care or equipment or facility cleaning. Allergy may be expressed as eye, nose and throat irritation, skin reaction such as dermatitis and hives, serious respiratory illness such as asthma and potential in highly reactive people for circulatory collapse and death. Toxicity as a result of exposure to chemicals or drugs used in the performance of duties can lead to inapparent illness to acute or chronic illness and cancer.

b.) Toxic, Biohazardous or Radioactive Hazards

Research or work associated with use of chemicals, drugs, radioactive or biohazardous agents in animals can vary from inapparent illness to acute or chronic illness, cancer and death.

c.) Physical Hazards

- i. Physical injury resulting from cuts and bruised associated with the use or handling of animal caging, equipment, feed bags, supplies, etc. Injuries may be minor or serious.
- ii. Thermal injuries or burns from equipment-associated duties (cage washer, autoclave, dryers, hot water, etc.) can vary from first degree to third degree, resulting in minor discomfort to serious life-threatening injury and disfigurement.
- iii. Slip, trip, fall accidents associated with the work on wet or damp surfaces or obstructed pathways or inadequate lighting can vary from simple bruises to fractures and possible disability.
- iv. Acute musculoskeletal injuries as a result of work.
- v. Musculoskeletal injuries associated with repetitive stress of awkward movement or poor posture over a period of years can result in nagging aches and pains to chronic painful injury such as backache, carpal tunnel syndrome and disability.
- vi. Hearing loss resulting from routine exposure to 85 decibel noise levels generated by animals (swine, dogs) or equipment can lead to hearing loss.

B. Means of Minimizing Risk of Injury

a.) Engineering Controls:

- i. Assure that appropriate animal restraint aids including leashes, cat and rabbit bags, muzzles, collars, snares and species holders are on hand and in good working order.
- ii. Assure that animal transports and housing (cages or enclosures) have properly working latches and are escape proof.
- iii. Assure the availability of sharps containers for all needles and syringes, glass, sharp or pointed items. Assure the availability of biohazardous nonsharps containers with bags for animal blood-contaminated nonsharps waste or animal-related laboratory or treatment generated waste.
- iv. Assure the availability of rodent change stations for cage changing.
- v. Provide heat mitts and aids for handing excessively hot or autoclaved items.

- vi. Provide a “Wet Floor” signs as required for wet floor conditions.
- vii. Assure adequate lighting

b.) Work Practices

- i. Employ appropriate animal handling and restraint techniques for animal species.
- ii. Be competent in sample acquisition procedures with species used.
- iii. Be alert to signs of fear or aggression in animals and get assistance if needed.
- iv. Get appropriate assistance when required in handling an intractable or uncontrollable animal.
- v. Assure that all animals are properly immunized and socialized.
- vi. Wear personal protective equipment as appropriate to avoid exposure to animal, drug, chemical, food or materials allergies.
- vii. Never recap needles.
- viii. Dispose of all needles, needle or syringes, wooden cotton-tipped applicators, glass, sharps, pipettes of all types in a biohazardous sharps container.
- ix. Dispose of all animal blood contaminated nonsharps or animal-related laboratory or treatment generated waste in a biohazardous nonsharps container.
- x. Avoid skin contact with hot surfaces and use hot mitts or heat aids to handle hot materials.
- xi. Avoid respiration of or skin or eye or mucous membrane contact with agents to which you are allergic or to which you suspect you are allergic.
- xii. Adhere to study related special standard operating procedures intended to protect personnel from research-associated use of chemicals, drugs, radioactive or biohazardous agents in animals.
- xiii. Use care to prevent physical injury resulting from cuts and bruises associated with the use or handling of animal caging, equipment, feed bags, supplies, etc.
- xiv. Report malfunctions posing injury and remove such items from service immediately. Use care to prevent physical injury from slip, trip, fall accidents associated with work on wet or damp surfaces, obstructed pathways or inadequate lighting.
- xv. Post wet areas. Keep pathways clear.
- xvi. Report inadequate lighting.
- xvii. Follow good ergonomic practices. Avoid straining, excess weight lifting, improper lifting, repetitive stress without breaks, etc.
- xviii. Protect hearing with ear plugs when required and use hearing preservation on or off the job. Attend the occupational safety seminar when offered:
Occupational Safety for Animal Caregivers and Users

c.) Personal Protective Equipment:

- i. Wear proper personal protective equipment when working with animals.
- ii. Use specialized gloves and other gear when needed to afford protection against fractious animals.

d.) Participate in Preventative Medicine Program:

- i. Annual physical examinations are required and can be performed by the Employee Health Center or designated specialist (in case of referrals).
- ii. Get rabies immunization at frequency recommended by EHS

- iii. Assure that tetanus immunization is current (every 10 years or per EHS).
- iv. Report occupational injuries, illnesses or concerns to the EHS.

e.) Procedures for Personnel Bitten or Scratched by an Animal

- i. Immediately following any animal scratch or bite, the wound is washed with soap and water and flushed with an antiseptic (butadiene, alcohol) and water or at least cold water alone, and apply first aid measures.
- ii. The injury is reported to the supervisor. Emergency medical care can be obtained from Howard University Hospital or from the Employees Health Service.
- iii. Identify the animal and notify the veterinarian. If at all possible, preserve the life of the animals life (Do not kill the animal).
- iv. The biting animal is caged separately and if the animal is a large carnivore, is kept in quarantine for 14 days. Experimental procedures are not allowed on this animal during this period. Place the following or comparable information on the cage card in large contrasting or bold font: CAUTION: Biting Animal Under Quarantine Handle With Care. Extra care is taken when performing routine husbandry for this animal.
- v. The veterinarian must be informed if signs of sickness or altered behavior are observed during the quarantine period.
- vi. The veterinarian must be notified immediately if animal dies during quarantine period.
- vii. Note: No nonhuman primates (NHPs) are housed at the University.
- viii. Procedures to follow for other injury or illness or expected hazard exposure:
 - 1) Perform first aid if appropriate based on nature of illness and inform supervisor of situation if able to do so.
 - 2) Seek or summon medical attention for illness or injury if appropriate

2. Medical Evaluation and Preventive Medicine for Staff

- a.) Occupational Health and Safety Program and categories of personnel included in the program and the individual and office responsible for monitoring the program: Personnel covered include animal care personnel, research personnel, IACUC members, and housekeeping and facility personnel. Howard University Hospital Employee Health and Emergency Services are available for emergency treatment. The Compliance Office dually serves as the Administrative Assistant for the Institutional Animal Care and Use Committee (IACUC). The IACUC will also work hand-in-hand with the EHS to implement measures recommended for minimization of risks associated with the field of laboratory animal research, care and support services. To this end proposals for animal use must comply with this objective. Medical evaluations as a part of the annual physical examination are required by all personnel who will have contact with the animal program. The medical evaluation will further ascertain any risks associated with handling animals. Procedures for reporting exposure and potential hazards: Actual or suspected exposures are reported to the EHS and as appropriate to the Office of Total Compensation, Human Resources.
- b.) **Personnel who work with nonhuman primates:** There is no approved protocol for work with nonhuman primates at the University.

- c.) **Personnel who are pregnant, ill, or have decreased immunocompetence:** Precautions must be taken during personal pregnancy, illness or decreased immunocompetence to ensure that all risks are mitigated and no further harm or bodily injury will result from contact with the animal program. Training will be made available through the Employee Health Center as a part of the annual

3. **Personal Hygiene and Protection:**

- a.) **Personnel protective equipment and work clothes:** All animal care personnel are provided work uniforms and/or laboratory coats, work shoes, and personnel protective equipment consisting of head covers, boots, goggles, hearing protection (plugs), gloves (dust-free latex, nit rile, heavy cloth and steel mesh) and masks (N95) and arm protection.
- b.) **Laundering work clothes:** A washer and dryer are provided in the surgery suite for the onsite cleaning of uniforms and laboratory coats.
- c.) **Provisions for washing hands, showering and changing clothes:** All animal holding rooms except for the large animal holding area are equipped with hand washing sinks. Large animal rooms are equipped with bib-hose style water supply for run wash down and technicians and animal users may also wash their hands in the adjacent utility room. Three restrooms are available with showers and are located in the woman's restroom, the men's restroom and the technicians lounge. Because the loading dock and adjacent trash refuse dumpster are located on the first floor and the laboratory animal facility is located on the fifth floor of the Adams Building, technicians do wear their uniforms to pick up animal deliveries and to dispose of bulk waste. Technicians are otherwise discouraged from **wearing unclean work clothes outside of the facility** and routinely change their clothes before eating.

d.) Procedures (equipment and instructional) that reduce potential for Physical injury

Hazard postings such as "wet floor", "trip hazard" and "Hearing Protection Needed in this Area" are also used to advantage to prevent accidents or exposure. Injury from improper use of mechanical equipment is also minimized by training of personnel new to equipment by experienced personnel or by the equipment vendor representative.

Preventative maintenance and inspection of equipment is also carried out to assure safe and proper equipment operation. Malfunctions of equipment are reported to the supervisor of animal care for resolution or referral for repair. All technicians receive instructions on prevention of physical injury and chemical and thermal injury.

- e.) **Policies regarding eating, drinking and smoking in animal facilities:** Technicians and other University employees are prohibited from smoking in or near University buildings. Technicians are able to eat in the Technicians Lounge (Room 5419), the conference room (Room 5503) in their office (5510, 5420 and 5423). These rooms are set apart in clusters away from animal holding rooms and in close proximity to hand washing facilities. No eating, drinking, smoking or application of cosmetics is permitted in the animal rooms or in animal use areas.

- f.) **Procedures for reporting exposure and potential hazards:** Report of life-threatening exposure or potential thereof is immediately reported to 911 Emergency. The Office of Environmental Health and Safety and the relevant college or departmental safety committees provide a means for reporting non-emergency exposure and potential hazards. Following such notification, incident response is affected with incident investigation, documentation and follow-up or implementation of hazard minimization or elimination. Injury reports are made to the University Office of Total Compensation by the supervisor and Employee Health or both. Medical treatment is also sought if warranted or advised OSHA, compliance reporting is also carried out centrally via telephone if applicable to the Office of Total Compensation, Human Resources. Howard University Security may also implement investigation if warranted based on the circumstances.

3) Oversight Process and Husbandry Practices and Personal Protective Equipment (PPE)

Provision of PPE when work involves hazardous agents that pose an unacceptable risk to personnel: As previously stated that the IACUC established safeguards for experimental use and handling of hazardous agents with applicable approval of work by the requisite safety committee (Biosafety, Radiation Safety). Restricted access, posting and a monitoring system are put into place in keeping with occupational safety guidelines applicable for the works being carried out. Safeguards prescribe the *area* of authorized use and animal housing, experimentation safety and responsibility for husbandry. Safety procedures require that the researcher and his/her trained staff take responsibility for husbandry including initial removal and decontamination of contaminated waste, animal carcasses and equipment; assuring containment of same in the process. Research and animal care staff entering such animal rooms must wear appropriate personal protective equipment prescribed for use with the hazardous agent; including a disposable gown or coverall, head and feet covers, latex or nit rile gloves (or gloves of other appropriate material based on the hazard), mask or face shield and eye protection. In the instance of biohazardous waste, the cage is double-bagged with waster and autoclaved prior to waste disposal and cage washing. (Alternatively, if efficacious, chemical decontamination may be carried out). Other equipment and the room are appropriated disinfected at the prescribed interval or at the conclusion of the study. Hazardous material waster must also be double-bagged for disposal. If cage residue is felt to serve as a risk to personnel, chemical inactivation or neutralization may be required. Animals are double red-bagged and boxed for biohazardous waste service pick-up and disposal in a manner that assures that the outside of the box is not contaminated. Radiation safety prescribed procedures are followed for conduct of studies resulting in dually approved studies involving radioactive contamination or animals, their waste or cages. Cages may be appropriately lined to contain radioactive emissions and wastes and containerized in approved containers for pick-up and disposal by Radiation Safety. Animals are similarly frozen, labeled and containerized for pick-up and disposal by Radiation Safety. Technical limits prohibit the approval of work in animal rooms resulting in the generation of volatile or expired radioactive byproducts.

(4) **How Hazardous Agents are Contained**

Hazardous agents are contained within the study environment: Hazardous agents are contained through confinement, in the micro-and/or macro-environment and in accordance with mandated safety requirements. Appropriate warning posting and restricted room access are implemented in either case.

(5) **Safety Procedures for Using Volatile Anesthetics and How Anesthetic Gases are Scavenged**

Volatile anesthetics are stored and used in compliance with the Material Safety Data Sheet. One agent, isoflurane, is currently used (halothane was also previously used). Gloves, lab attire and safety glasses are used when dispensing these agents. Anesthetic gases are scavenged using the Flair Absorption System. Isoflurane regulators in use are appropriately certified. Conditional approval category anesthetics urethane and choral hydrate are now only approved for acute or terminal procedures and MSDS safety requirements apply.

(6) **Program for Housing and Caring of Animals Exposed Experimentally to Potentially Hazardous:**

Research and animal care staff observe Material Safety Data Sheet safety measures include donning PPE (disposable gown or coveralls, head and feet covers, mask and latex or nit rile gloves) upon entering the room with removal upon room egress and treating all room refuse and animal carcasses appropriately as hazardous or biohazardous waste if study management is so designated by the facility Director. Applicable biohazardous refuse and waste are placed in double biohazardous red-bags and autoclaved prior to disposal. Animal carcasses are double biohazardous red-bagged and containerized for disposal by a licensed biohazardous waste disposal service. Room equipment and surfaces are appropriately disinfected. There are no special facilities for use with hazardous agents. The Veterinary Services clinical laboratory is equipped with a chemical fume hood. Portable changing stations are available for staff use to decrease animal facility allergen load by reducing air contamination during rodent cage changing.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached table. See Section X.

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

The training or instruction available to scientists, animal technicians, IACUC committee members and other personnel involved in animal care, treatment, or use will be provided by the Laboratory Animal Training Association (L.A.T.A.). There are four interactive modules: The Base Module which includes laws, regulations, ethics, alternatives, IACUC and staff responsibilities; The Species Modules which include housing, social needs, nutrition, health considerations, handling, restraint, experimental techniques, environment practices and euthanasia; and The Techniques Module, which demonstrate current acceptable practices and techniques. The Occupational Health Training Module is also a part of the L.A.T.A. In addition, a copy of the complete Occupational Health Program Guidelines is given to each person with continued animal contact. Training and instruction is also offered to scientists, animal technicians, and other personnel involved in animal care, treatment or use, on research or testing methods that minimize the number of animals required to obtain valid results and minimization of stress. Webinars and seminars through OLAW and other animal care organizations will be made available to the research community. The Institution will ensure that access to a training session related to the aforementioned topic is available at least annually. New IACUC members receive orientation to the Committee where they are provided with background materials and resources. The members are provided with copies of the PHS Policy, Guide for the Care and Use of Laboratory Animals, OLAW/ARENA IACUC Guidebook, and a copy of the approved Animal Welfare Assurance. Additionally, IACUC members are provided continuing education annually by attending seminars and workshops conducted by PRIM&R, ARENA, ALAS, and SCAW.

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 six 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 in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

- (1) This Institution is Category One (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 thereto, 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 given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Yonette F. Thomas, 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 three 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. This Institution's reporting period is January 1 through December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The 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), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
2. 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, Yonette F. Thomas, Ph.D..

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 sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

| | |
|---|-------------------|
| A. Authorized Institutional Official | |
| Name: Yonette F. Thomas, PhD | |
| Title: Associate Vice President for Research Compliance | |
| Name of Institution: Howard University | |
| Address: <i>(street, city, state, country, postal code)</i> Office of Regulatory Research Compliance 1840 7th Street NW HURB-1, Suite 309 Washington, DC 20001 | |
| Phone: 202-865-8597 | Fax: 202-232-5286 |
| E-mail: ythomas@howard.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: 02/17/2012 |
| B. PHS Approving Official <i>(to be completed by OLAW)</i> | |
| Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465 | |
| Signature: | Date: |
| Assurance Number: | |
| Effective Date: | Expiration Date: |

VIII. Membership of the IACUC

| Date: January 17, 2012 | | | |
|--|------------------------|---|---|
| Name of Institution: Howard University | | | |
| Assurance Number: A3742-01 | | | |
| IACUC Chairperson | | | |
| Name*: Thomas Heinbockel | | | |
| Title*: Associate Professor | | | Degree/Credentials*: PhD |
| Address*: (street, city, state, zip code) Office of Regulatory Research Compliance 1840 7th Street NW HURB-1, Suite 309 Washington, DC 20001 | | | |
| E-mail*: theinbockel@howard.edu | | | |
| Phone*: 202-865-8597 | | Fax*: 202-232-5286 | |
| IACUC Roster | | | |
| Name of Member/ Code** | Degree/ Credentials | Position Title*** | PHS Policy Membership Requirements**** |
| Doris Hughes-Moore | DVM | Director Veterinary Services | Veterinarian |
| Jesse Jones | MSc | Businessman/Community Representative | Non-affiliated Community Member/Non Scientist |
| George Middendorf | Ph.D. | Professor of Biology | Scientist |
| Paul Wang | Ph.D. | Director of NMR Imaging Center | Scientist |
| Xinbin Gu | MD, Ph.D. | Professor of Oral Pathology | Scientist |
| Emmanuel Akala | Ph.D. | Professor of Pharmacy | Scientist |
| Dexter Lee | Ph.D. | Assistant Professor of Physiology & Biophysics | Scientist |
| Marjorie Gondre-Lewis | Ph.D. | Assistant Professor of Anatomy | Scientist |

| | | | |
|------------------------|-------|---|--|
| Mark Burke | Ph.D. | Assistant Professor of Physiology & Biophysics | Scientist |
| John Kwagyan | Ph.D. | Biostatistician | Nonscientist |
| Kathleen Johnson | BS | Teacher/Community Representative | ALTERNATE Non-affiliated Community Member/Non Scientist/ |
| Marline Brown-Walthall | MPH | Senior Compliance Administrator (<i>ex officio</i>) | Nonscientist |
| Jamie Rotimi | MS | Compliance Officer (<i>ex officio</i>) | Nonscientist |
| Claude W. Williams | BS | Director of Environmental Health & Safety (<i>ex officio</i>) | Nonscientist |
| Arvinda Nandekhar | PhD | Biosafety Officer (<i>ex officio</i>) | Scientist |
| Elizabeth Nolte | MD | Director, Employee Health (<i>ex officio</i>) | Nonscientist |
| Sheree M. Johnson | PhD | Institutional Biosafety Committee (IBC) Liaison; Ex-Officio; Non-Voting | 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: | Marline Borwn-Walthall, MPH |
| Title: | Senior Compliance Administrator |
| Phone: | 202-865-8597 |
| E-mail: | marline.brownwalthall@howard.edu |
| Contact #2 | |
| Name: | Jamie Rotimi, MS |
| Title: | Compliance Officer |
| Phone: | 202-865-8597 |
| E-mail: | jrotimi@howard.edu |

X. Facility and Species Inventory

| Date: 1/31/12 | | | |
|--|--|--|-------------------------------------|
| Name of Institution: Howard University | | | |
| Assurance Number: A3742-01 | | | |
| Laboratory, Unit, or Building* | Gross Square Feet [<i>include service areas</i>] | Species Housed [<i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i>] | Approximate Average Daily Inventory |
| Veterinary Services Core Laboratory Animal Facility, Numa P.G. Adams Bldg | 13,777 | Rats and Mice | Rats: 122 Mice: 340 |
| E.E. Just Hall | Approximately 4,800 | Rats and Mice | Rats: 13 Mice: 2 |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

*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.

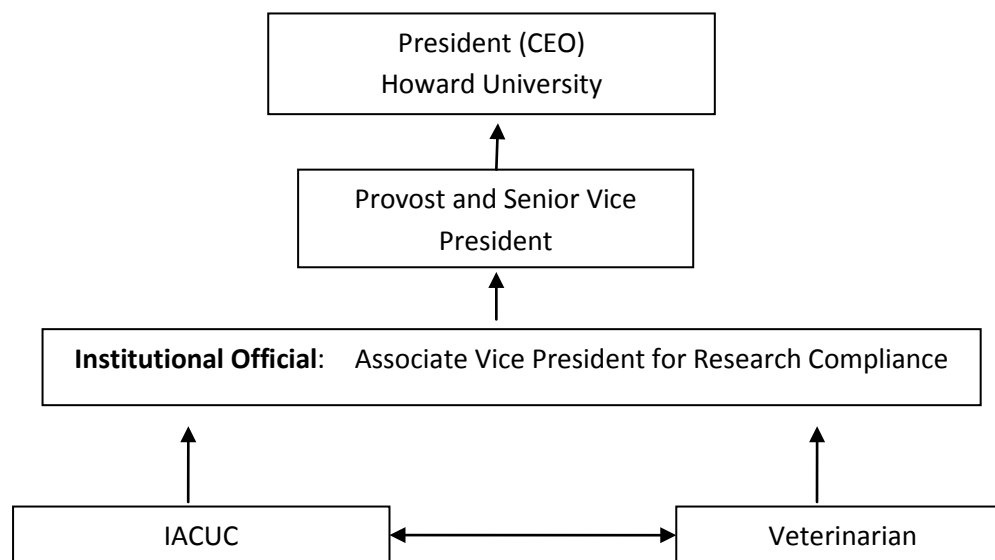
APPENDIX A

HOWARD UNIVERSITY ANIMAL WELFARE ASSURANCE (Animal Welfare Assurance No.: A3742-01)

I. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with the Policy are: The Institutional Animal Care and Use Committee (IACUC) evaluates the institution's animal program, procedures, and facilities, to ensure that they are consistent with the recommendations in the Guide, the Animal Welfare Regulations (AWR) and the PHS Policy. The IACUC reports to the Institutional Official, the Associate Vice President for Research Compliance, who is designated by the President for administering Howard's animal welfare assurance. This letter is on file with OLAW. The Associate Vice President for Research Compliance reports to the Provost and Chief Academic Officer, who in turn reports to the President (see chart below). The University will provide adequate resources for the operation of the animal care and use program. Dr. Doris E. Hughes-Moore, the current University Veterinarian and Director of Veterinary Services in the College of Medicine, has responsibility for both Animal Facilities. Dr. Hughes-Moore as the Veterinarian-IACUC member, reports directly to the IO. In her administrative role as the Director of Veterinary Services, she reports to the Dean, College of Medicine, who reports to the Provost and Chief Academic Officer, who reports to the President.

HOWARD UNIVERSITY INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE



Appendix A, Figure 1. Lines of Authority