

**UNIVERSITY OF MARYLAND CENTER FOR ENVIRONMENTAL SCIENCE  
ASSURANCE NUMBER D16-00606****Animal Welfare Assurance for Domestic Institutions**

I, *Dr. Peter Goodwin*, as named Institutional Official for animal care and use at *University of Maryland Center for Environmental Science (UMCES)*, 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 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 and/or the NSF. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:  
UMCES-Appalachian Laboratory (AL), Frostburg, Maryland; UMCES-Chesapeake Biological Laboratory (CBL), Solomons, Maryland; and UMCES-Horn Point Laboratory (HPL), Cambridge, Maryland.
- B. The following are other institution(s), or branches and components of another institution: UMCES-Institution for Marine and Environmental Research (IMET) is under auspice of the IACUC of the University of Maryland – Baltimore County (UMBC).

**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), Eighth Edition.
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub-awards) 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: a diagram, "Organizational Flow Chart" is appended as an attachment.

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

1) Name: Dr. Brent R. Whitaker

#### Qualifications:

- Degrees: M.V.S. University of Florida College of Veterinarian Medicine, and the Institute of Food and Agricultural Sciences, Gainesville, Florida; D.V.M. University of Florida, College of Veterinary Medicine, Gainesville, Florida

*Training and/or experience in laboratory medicine: Dr. Brent Whitaker is a Research Associate Professor – Veterinarian at the University of Maryland, Baltimore County, and an independent contractor. Dr. Whitaker is veterinarian of record for the University of Maryland's Center of Marine Biotechnology- COMB (now Institute of Marine and Environmental Technology- IMET) from 1991 to present. Dr. Whitaker was an IACUC member for COMB from 1992- 2004 at which time the committee transitioned under the watch of the IACUC of UMBC. He currently serves as a content expert for University of Maryland's School of Medicine IACUC. In 2010, Dr. Whitaker chaired the first ever Aquatic Animal Care & Use workshop at NIH- What You Need to Know About Research & Management of Zebrafish & Xenopus Frogs at NIH. He has also provided many lectures on fish welfare, as well as interpretation of the guide as it applies to aquatics. Dr. Whitaker provided service to the National Aquarium for 28 years in various capacities from veterinarian to Senior Vice President of Biological Programs where he oversaw the care and welfare of over 20,000 animals representing more than 700 different species. Dr. Whitaker is licensed in Maryland and Pennsylvania.*

Authority: Dr. Brent Whitaker has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals.

The Veterinarian will advise the Institutional Animal Care and Use Committee, the Laboratory Directors, and the UMCES President (IO), on appropriate procedures for use of vertebrates in research as set forth in the *Guide* and other applicable documents as identified at III.D.1. below. The veterinarian may advise the IACUC to require specific changes in research protocol before faculty or student research is initiated. Further, the veterinarian has the authority to suspend

immediately any research found to be conducted in violation of UMCES or PHS policy until the IACUC shall advise the President (IO) of the Institution that such violation(s) have been remedied. Dr. Whitaker's authority pertains to all vertebrate animal research at UMCES, whether or not the research is funded by the PHS.

Time contributed to program: The veterinarian will contribute 5% time in direct service to IACUC for site visits, research protocol review. The veterinarian is required to attend a site visit at each laboratory at least once during each year; he is also required to be at all semiannual meetings. In addition, he will be available as needed by faculty and students for advice and consultation. Dr. Whitaker is under contract to UMCES and is paid on an hourly basis to provide the above services.

Should Dr. Whitaker not be available, the Institution will request back-up assistance from Dr. Adam Terry, DVM, All Kinds Veterinary Hospital, Callaway, MD, who is the attending veterinarian for the UMCES Chesapeake Biological Laboratory.

C. The 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 5 members and its membership meet the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program and reviews are as follows:

The IACUC is mandated to review at least once every six months the Institution's program for the care and use of animals using the *Guide* as a basis for evaluation. All members of the IACUC are invited to participate in the Program Review via the University System of Maryland Interactive Video Network (IVN) conducted in accordance with NOT-OD-06-05, Guidance on use of Telecommunications for IACUC meetings under the PHS Policy on Humane Care and Use of Laboratory Animals with real-time voice and video conferencing. The Chair convenes a meeting with a quorum from the Full Committee. Once a quorum is established, the Chair continues by reviewing the Institutional Policies and Responsibilities, minutes from the last meeting, goes over old business, and then moves on to new business on various issues, any problems, and future plans.

The last semiannual meeting was held November 5, 2018. Reviews were performed by the IACUC as a whole over the IVN on November 5, 2018, voting as needed. The next meeting will be scheduled in six months from this date.

- 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 the primary reference when

evaluating the Institution's animal care and use program and facilities. The IACUC procedures for conducting semiannual facility inspections are as follows:

Semiannual inspections are performed by at least two members of the IACUC using the Semiannual Facility Site Visit Checklist. The veterinarian is required to be present at one of the semiannual inspections at each laboratory of the Institution (AL, HPL, or CBL) during the year. All members of the IACUC are encouraged to participate in the Facility Site Inspections. The IACUC has access to all areas within the laboratories for the purpose of verifying that activities involving animals are being conducted in accordance with the protocol approved by the IACUC. Any sites where animals are held for 12 hours or more are inspected by the IACUC. Furthermore, any satellite holding facilities or areas where surgical manipulations are done are included in the semiannual reviews. The inspection committee does a thorough walk-through of the laboratory to identify any minor or significant deficiencies and records them on the Facility Site Visit Checklist. The IACUC also monitors other areas within the laboratories where only routine immunization, dosing, and weighing take place by random site visits and evaluations.

After inspection, a letter is written to the Principal Investigator (PI) in charge of the laboratory inspected with a copy to the Director and Safety Officer. The letter consists of an explanation of the deficiency or that there are no deficiencies. If deficiencies are found, the inspection team asks the PI or Laboratory Manager to correct the deficiency by an agreed upon deadline (typically 2 weeks). A report of the semiannual inspection is then sent to the IO with an explanation of the deficiency and the schedule for completion. The IACUC Chair will then verify and record that the deficiency has been appropriately handled in the required time-frame. In the case of a significant deficiency, the PI is asked to remove vertebrates to an approved area, if this is needed, until the deficiency is corrected.

3) Prepare reports of the IACUC evaluations according to PHS IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official, which is signed by a majority of IACUC members and any minority views will also be included, are as follows:

- a) Procedures for Program Reviews: At the Semi-annual Meeting, the IACUC goes over the program review. This information is received from the semiannual site inspections done throughout the year. This report is sent to the IO along with the Semiannual Meeting report.
- b) Procedures for Facility Site Inspections: Facility site inspections occur on a semiannual basis with two members of the IACUC attending each laboratory inspection. The veterinarian is required to attend one site inspection at each laboratory at least once each year. The veterinarian can be called in at any time for special inspection, if needed.
- c) Process for Deficiency Correction: All minor or significant deficiencies resulting from any inspections are reported to the Chair of IACUC by the inspection team. A letter is sent to the PI and Director of the respective laboratory involved from the Chair of IACUC requesting a resolution of the deficiency. A date is set for completion of

correction(s) for any noted deficiencies. The IACUC requires a written response via email or otherwise from the PI and/or Director at the conclusion. If a deficiency is not completed satisfactorily, the Chair discusses with the PI what is needed, then reports to the Director of the laboratory finalizing the correction. All transactions are encompassed in the Semiannual Meeting and a separate report is sent to the IO. The IACUC will self-report to OLAW, if needed. If there are no deficiencies, it is conveyed in the Semiannual Report to the IO.

d) Departures: Departures are identified as animal housing or manipulation procedures that are deviations from the Guide, PHS Policies, or AWAR. In the case that a protocol requires a departure, the procedure is reviewed by the IACUC veterinarian/committee as well as discussed at the semi-annual IACUC meetings to determine whether the departure is justified based upon a veterinary assessment of potential impacts on the health and wellbeing of the animals and the validity of the scientific question that will be addressed by the departure. If a procedure proposed in an IACUC protocol is identified as a departure during the review, the Principal Investigator will be asked to provide to the committee a written document to be appended to the IACUC protocol detailing why such procedures must be used and on what grounds (veterinary, scientific) the departure is justified. The documented procedure is reviewed by the committee. Approval of a departure is provided in writing to the Investigator. A copy of this written document must be maintained in the animal housing facility where the procedure will be conducted. Departures will be communicated to the IO in the semi-annual IACUC report.

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

Anyone at UMCES or from the public who would like to report concerns of animal care and use at UMCES is free to contact the IACUC Chair or any member of IACUC with their confidential concerns at [iacuc@umces.edu](mailto:iacuc@umces.edu). A list of the Committee members can be found on MyUMCES website at <http://www.umces.edu/animal-care-and-use-policies> under Section 2. Purpose, Membership and Activities of the UMCES IACUC. These policies can also be found at the UMCES Policies and Procedures, under Sponsored Programs / Humane Care and Use of Vertebrate Animals, VII-2- Assurance of Compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals, *Appendix VII-2.2*. The IACUC procedures for reviewing concerns, if needed, are communicated by email to the Chair and members of the IACUC, and discussed at a convened meeting via IVN (audio-visual), face-to-face conferencing or in person. The convened Committee reviews the concerns and decides what action should be taken to rectify any deficiency(s) by a majority vote of the Committee with a quorum. The Chair then notifies the UMCES President (IO) of concerns and alternative ways to correct the deficiency(s). At any time, with a majority vote of the quorum present, the Committee can suspend a previously approved or current activity. If the concerns are of a serious nature, then the Committee will forward the information and how to correct this serious deficiency to the IO and OLAW.

The reporting procedure is listed on the UMCES website at MyUMCES under Animal Care and Use Policies and Reporting Concerns found at [http://www.umces.edu/ animal-care-](http://www.umces.edu/animal-care-)



and-use-policies, and entitled "How to Report Animal Welfare Concerns". This information is also posted at each laboratory entrance, near animal holding areas, and on State/Federal bulletin board posting areas at each site.

- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

The IACUC makes recommendations to the Institutional Official via its Semiannual Report using the *Guide* as the primary reference. The report includes: the results of the facility site inspections for the prior six months; a listing of any deficiencies on the inspection forms for each laboratory facility (AL, HPL, or CBL); who was contacted about the deficiency; what suggestions were made for correcting any deficiency; and when the deficiency was resolved. A report from the respective laboratory to the Chair via email or letter describing the resolution of the deficiency is then included in the Semiannual Report to the Institutional Official. During the Semiannual Meeting, IACUC members may bring up topics for discussion concerning policies, facilities, site inspections and deficiencies (minor or major), protocols, and personnel training. The IACUC votes on recommendations when warranted and includes our recommendations to the Institutional Official in the Semiannual Report.

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

Since the Committee members are physically located hundreds of miles apart on the Western and Eastern shores of the Chesapeake Bay and in western Maryland, we use a secure open-source management system that facilitates posting, reviewing, and approving of research protocols and discussions about protocols among Committee members. The IACUC protocol management system software is on UMCES Chesapeake Biological Laboratory's secure website and only the UMCES personnel and person granted permission by IACUC committee have access to the IACUC portion of this site.

The review process begins when the PI sends a written protocol to the Chair of IACUC via email attachment and a hard copy via regular mail with original signatures on it.. The Chair pre-reviews the protocol to make sure the PI has submitted a complete protocol. Once this is done, the protocol is uploaded to the management software system as an Adobe Acrobat pdf file, and a designated review is requested by contacting all IACUC members electronically.. The Committee is thereby notified that a protocol(s) has been posted for review, are appointed Designated Reviewers by the Chair, and are given a deadline date of four (4) weeks past the submission date. Committee members may approve or require modifications to secure approval. Every member sees the comments of all other members and examines each subsequent revision. Every IACUC member must approve the final version of the protocol. There is no majority rule. Any member of the IACUC can also call for a committee meeting to discuss a protocol; the IACUC then meets via IVN and the IACUC can withhold approval or defer review of a protocol. The Chair then writes a letter informing the PI of any concerns, questions, or decision of the IACUC, who is instructed to provide any

information needed to complete the review within two (2) weeks or asked to revise and resubmit the protocol for review.

The PI's reply is then uploaded and the Committee is asked to review the additional information and approve or require modifications to secure approval. Once all Committee members have approved the protocol, and after a final check of the protocol by the Chair and Veterinarian, an approval letter is written to the PI from the Chair with an assigned protocol number. This packet includes a "Change" letter (for future changes before the protocol expires) and URL links for *Public Health Service Policy on Humane Care and Use of Laboratory Animals, 2002* and *What Investigators Need to Know about the Care and Use of Laboratory Animals, NIH Pub No. 06-6009* as a guide for each PI.

Meeting Attendance Voting: A quorum of 50% +1 is required in order to hold a meeting. Meetings are held via IVN. A majority is required for voting on items brought before the IACUC.

Designated Reviewer: When reviewing IACUC protocols, our entire Committee functions as designated reviewers.

The Chair of the Committee often submits protocols for approval and declines from doing his own review because of a conflict of interest. His protocol is then presented to the IACUC for review and treated as a regular protocol review. At these times, a member of the Committee is appointed to function as "Acting Chair" during the review process.

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:

Proposed Significant Changes: During the original assignment of a protocol number, a "Change" letter is included in the letter packet sent to the PI. This "Change" letter allows the PI to notify the IACUC of any changes during the three-year duration of the protocol. The IACUC Committee refers to the table used for determining minor or significant changes that is found in *Table 10.1 from The IACUC Handbook. Edited by Jerald Silverman, Mark A. Suckow, and Sreekant Murthy*. The change could be minor or significant. If the change is minor, such as adding a student, it can be requested through the "Change" letter and the change will be made and a review is not needed. If it is a significant change, such as change in number(s) of animals, species, etc., the PI will be requested to submit a new protocol with changes explained and included. All significant changes go through the IACUC as a regular review and must be approved by the Committee. The IACUC assigned protocol number will stay the same with the revision noted via letter to the PI and a copy put in the permanent file.

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:

**Notifying the PI:** If modifications are required, the IACUC Chair writes a letter listing concerns/questions to the PI, who is given two weeks to reply with an answer. This reply is uploaded and the Committee, as designated reviewers, is asked to review the answers and approve or require modifications to secure approval of the protocol. Once all reviews are in, if approved, a letter is written to the PI from the Chair with an assigned protocol number. This packet includes a "Change" letter (for future changes before the protocol is expired); the URL links to "*Public Health Service Policy on Humane Care and Use of Laboratory Animals*" booklet and a PDF link to the brochure "*What Investigators Need to Know About the Care and Use of Laboratory Animals*", NIH Pub. No. 06-6009.

**Notifying the Institution:** The approval letters are sent to the UMCES Grants Officer (ORAA office). This is to notify the Grants Officer that the protocol has been approved by the IACUC and a number assigned. The Grants Officer can then attach the number/letter to the grant and notify the granting agency that a protocol has been received and officially approved. The Grants Officer oversees all protocols for grants.

9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.I.-5. The IACUC procedures for conducting continuing reviews are as follows:

**Annual Reviews:** The IACUC Chair sends a letter of inquiry to the PI on an annual basis, during the duration of the protocol, asking the PI to indicate: 1) if there are no changes, 2) if changes, whether they are minor or significant, or 3) if the project has been completed. If there are significant changes, then a new protocol must be submitted and approved by the IACUC. All information is recorded and filed from the first through the third year.

**Three-year Review:** The IACUC performs a complete *De Novo* review every three years at protocol expiration. At this time, 90-60-30-day notification letters are sent to the PI that begins 90 days before the protocol expires. This is to allow enough time for the PI to complete a new protocol, if needed, or terminate the project. The IACUC requires the PI to provide information on the status of the study protocol to date. If the PI plans to continue the protocol beyond three years, the IACUC requires that a "new" or "*De Novo*" protocol be submitted along with a brief report telling the Committee of the progress that has been made thus far. This *De Novo* review gives the PI the opportunity to modify and incorporate any changes in methodology or improvements in techniques, which is otherwise not permitted to be introduced in a current protocol without submitting a modification. The *De Novo* protocol and report is then uploaded and the Committee members are thereby notified that a protocol(s) has been posted for review, appointed Designated Reviewers by the Chair, and asked to review the *De Novo* protocol before the expiration date. Committee members may approve or require modifications to secure approval. The PI is notified of any questions, concerns, or modifications that arose during the IACUC review and is asked to respond to them before approval of the protocol. When the new three-year protocol is approved by the IACUC, a new



protocol number is then assigned to it. If further questions arise, any member can ask for a video meeting of the IACUC to discuss the protocol and, with a quorum present, could vote not to approve the protocol. If not approved, a letter will be sent to the PI stating why it was not approved. The PI would then revise the protocol and resubmit it for review.

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:

Any individual may bring or relay any concerns involving any Institute's care and use of animals to the President (IO) or to a Laboratory Director or to the IACUC Chair, Veterinarian, or any member of the IACUC. Such concerns may be raised in confidence. Upon the recommendation of the Veterinarian or as the result of majority vote of its IACUC members at a convened meeting with a quorum (not electronic discussion), the IACUC is authorized to suspend any activity involving animals. The Chair may also temporarily suspend any such activity under emergency circumstances pending further examination by the IACUC, which will decide whether to continue the suspension or to permit the activity to resume. Suspension of any activity must be justified in writing to the President (IO) of the Institution within twenty-four hours. The IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

E. The risk-based occupational health and safety program (OH&S) for personnel working in laboratory animal facilities and personnel who have frequent contact with animals are as follows:

The Institution's OH&S program is provided to ALL personnel when hired and on an as-needed basis. It covers hazardous risks, personnel training, personal protective equipment, chemicals and euthanasia procedures, vertebrate monitoring before and after procedures, field studies, zoonotic diseases, facilities, vaccinations, and husbandry. All personnel having knowledge of being pregnant or having a chronic illness or an immunodeficiency disorder should explain their job situation to their Occupational Health Professional, who can assess the risks and make recommendations concerning their health and safety. The OH&S program is not specifically represented on the IACUC and therefore is consulted on IACUC matters when employee occupational health and safety are a concern with respect to a specific protocol. There is no additional health evaluation required by the IACUC, but see #1 below.

1. At the time of hire, ALL new personnel will be asked for documentation of a tetanus/diphtheria vaccination or booster within the past 10 years and of a tuberculin skin test. If documentation is not available, a new hire will be asked to have a routine physical examination to include the tetanus/diphtheria vaccination/booster and tuberculin skin test no later than three months after health benefits become active. All employees who work with animals will be expected to have a tetanus/diphtheria booster every 10 years and a tuberculin skin test every two years.

2. Protective clothing, including uniforms, gowns, sleeve extenders, rubber boots, caps, masks, gloves, safety glasses, and respirators are provided for use in activities that involve

vertebrate animals whenever required by the work assignment.

3. The Vice President for Administration, through the Office of Human Resources, monitors the UMCES Occupational Health Program. Accidents and wounds are reported to the appropriate Laboratory Health Officer and, if deemed to warrant professional attention, the individual is sent to a health care provider for treatment. Any such referrals are reported to the UMCES Office of Human Resources.

4. Animal care and use protocols involving the use of hazardous agents (pathogens, carcinogens, other hazardous chemicals, recombinant, or radioisotopes) must be reviewed and approved by the appropriate Laboratory Safety Committee and the IACUC before the activity can be initiated. The UMCES Office of Sponsored Programs and the PI(s) are informed of approvals that involve research proposals. The UMCES Radiation Safety Officer monitors all areas where radioisotopes are used, disposed of, and/or stored. Each Laboratory Safety Officer monitors the use, storage, and disposal of other hazardous materials.

5. The institutional on line training program also known as, CITI (Collaborative Institutional Training Initiative) includes information on zoonosis, personal hygiene, use of hazardous materials, and other considerations regarding occupational health and safety practices that relate to activities involving the care and use of vertebrate animals at UMCES. Personnel must be fully trained in both the care and use of animals and in the use of hazardous materials before they will be permitted to undertake such activities.

6. Eating, drinking, and smoking are strictly prohibited in areas where vertebrate animals are being kept or used. Smoking is prohibited in all state buildings and vehicles owned and operated by the state. Signs to this effect are prominently posted in all such areas.

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

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

Training: A notice is submitted quarterly to all employees of UMCES (AL, CBL, and HPL) stating that if they have need for a protocol, then they must take the IACUC Training Class if they have not done so. They apply via email notifying the IACUC Assistant that they need the class. The applicant is then provided instructions for completing the training course online through CITI (Collaborative Institutional Training Initiative). The class training consists of General Information, including OSHA instruction, pain and distress, sampling, hazardous and toxic agents, personnel training, surgery, veterinary consultation, and considerations for social animals. It includes discussion of the three "Rs" -- refinement, reduction, and replacement -- to insure that vertebrate research protocols keep pain and distress to a minimum, that numbers are only sufficient to answer the research question, and that non-animal (particularly non-vertebrate) models have been considered by the PI. Upon

completion of the training module, the applicant forwards the record of completion to the IACUC Assistant. As new techniques arise of which IACUC is aware or that are listed in a new protocol, the IACUC requires that the PI demonstrate proficiency in the practice. If proficiency cannot be demonstrated, the IACUC via the Chair requires that training be sought by the PI and be completed to its satisfaction before proceeding with the practice. The IACUC can delay approval of a protocol until the required training is complete. The IACUC keeps abreast of changes in practices and regulations via periodicals and publications, the OLAW website, various guides from professional societies and communication with other institutions. These changes are made known to UMCES employees via IACUC communications from the IACUC Assistant and IACUC members.

Training for IACUC Members: New IACUC members are mentored by current members on the issues faced by the IACUC; members have attended IACUC workshops and conferences offered by OLAW. All IACUC members are encouraged to go to the training sessions of OLAW on an "if/when" basis as budgets permit. New members also complete on line training through CITI specifically directed to IACUC Chairs, members, and coordinators.

#### **IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION**

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according 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 OLAW upon request.

This Institution is Category Two (2) -not 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. The report of the most recent evaluations (program review and facility inspection) is attached.

#### **V. RECORD KEEPING 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 IACUC Semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Peter Goodwin, President.
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. This Institution's reporting period is the calendar year (January 1-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).
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, Dr. Peter Goodwin, President.
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 sections 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: Dr. Peter Goodwin  
Title: President

Name of Institution: University of Maryland Center for Environmental Science

Address: P.O. Box 775, 2020 Horns Point Road, Cambridge, MD 21613-0775

Phone: 410-221-2001

Fax: 410-228-3843

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E-mail: pgoodwin@umces.edu

Signature: 

Date: April 15, 2019

B. PHS Approving Official

Dr. Brent C. Morse-Animal Welfare Program Specialist  
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Fax: +1 (301) 915-9465  
Email: morseb@mail.nih.gov

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Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Assurance Number: \_\_\_\_\_

C. Effective Date: \_\_\_\_\_

D. Expiration Date: \_\_\_\_\_

