



**University of Puerto Rico
Medical Sciences Campus
Institutional Animal Care and Use Committee (IACUC)
Assurance number: D16-00262 (A3421-01)**

Animal Welfare Assurance for Domestic Institutions

I, Ramon F. Gonzalez, Interim Chancellor as named Institutional Official for animal care and use at the University of Puerto Rico, Medical Sciences Campus, 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 and invertebrate animals supported by the PHS, DHHS, and/or NSF. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
 - i. Animal Resources Center (ARC) and its satellites
 - ii. Caribbean Primate Research Center (Sabana Seca)
 - iii. Caribbean Primate Research Center (Cayo Santiago)
 - iv. Institute of Neurobiology

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the ["U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."](#)
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).

- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub award) 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: See Addendum #1-Institutional Animal Care and Use Committee's Lines of Authority and Responsibility.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: Idia Vanessa Rodríguez, DVM

Authority: Dr. Rodríguez has direct program authority and responsibility for the Institution's animal care and use program including access to all animals as the **Institutional Veterinarian and the ARC's Full time Attending Veterinarian.**

Dr. Rodríguez, obtained a BSc. in Agriculture at Kansas State University in 1996. She completed her Doctor of Veterinary Medicine Degree in May, 2001 also at Kansas State University. In July 2001 she was hired at the ARC as the clinical veterinarian. She is currently an active member of the, PRVMA, AALAS, AALAS-CB, ASLAP and APV. She is licensed to practice veterinary medicine in PR and Kansas. She participated in the APV and AALAS 2001, 2004 and 2007 annual meetings and more recently attended the AALAS 2015 annual meeting in Phoenix. On April 2003 attended the Workshop and Symposium on Laboratory animal diseases offered by The Midwest Div. of the Charles Louis Davis, D.V.M. Foundation in Co-Sponsorship with The Biologic Resources Laboratory (BRL), of The University of Illinois at Chicago. On March 2004, she assisted to the PRIME Arena & IACUC 101 in Boston, MA. On October 2004 she took a course on swine anesthesia at Ethicon, Co. facilities at Cincinnati, Ohio. In 2005 she participated in POLA and CLASS at Walter Reeds, Maryland. On November 2005 participated in a two day seminar related to Biocontainment and BL-3 facilities offered by Dr. James Swearengen at the Medical Sciences Campus. In May 2006, participated in an Amphibian Husbandry and Care seminar at the Medical Sciences Campus given by Dr. Larry Capitini, DVM from The Ohio State University. On September 2008, she took a course on MRI principles and use, in Tampa Florida and participated in a rodent colony management course offered by Jackson Labs in November 2008 at Bar Harbor, Maine. She also attended ultrasound cardiac and abdominal training workshops offered in Bedford, NY on September 2008 and January 2009. In 2010 participated on a weeklong seminar on laboratory animal pathology offered by Dr. Rao Srini and another on NHP pathology offered by Dr. Keith Mansfield from the NEPRC. On recent years she has attended continuing education seminars offered by the PR Veterinary Medical Association. Attended, several webinars related to the lab animal field as well as and Caribbean Branch educational seminars. She also participates along with the other veterinarians in the unit in the journal club and study discussions. She is the Institutional Veterinarian and an active member of the Medical Sciences Campus IACUC and an alternate member of the Institutional Biosafety Committee. She also collaborates with researchers working with SIV, and dengue in rhesus macaques, and collaborates in research projects with North Carolina/Global Vaccine, Wistar Institute, BD Bioscience and University of PR. Over the years she has taken an active supporting role in the management and direction of the Animal Resources Center facility and currently serves in the capacity of Associate Director.

The Animal Care Program in the Medical Sciences Campus oversees two major areas; the first is primates, and the second, general laboratory animal, under the Directorship of Dr. Idia Vanessa Rodríguez. Due to the complexity of each area, the facilities' Attending Veterinarian is in charge of the Animal Care Program in their area and responds directly to

the Institutional Official. The Veterinarians have full responsibility for implementing the PHS Policy and the recommendations of the Guide.

She dedicates 80% of the time to oversee the institutional animal care program and the Animal Resources Center Animal care program.

2) Name: Melween I. Martínez, DVM

Authority: Dr. Martínez has direct program authority and responsibility for the Institution's animal care and use program including access to all animals as **Director of the Animal Resources Center** and **Director of the Caribbean Primate Center**.

Dr. Martínez completed her BSc. in Animal Health Technology in 1984 at the University of Puerto Rico. In 1991 received her Doctorate Degree in Veterinary Medicine at Tuskegee University. In 1992, she completed an Internship in Internal Medicine and Surgery at the School of Veterinary Medicine, University of Tennessee. Since then, she has been a professor at the Veterinary Technology Program of the Medical Sciences Campus. As part of her duties at the program, she worked for 8 years at the San Juan and Carolina's Municipal Animal Shelters as a staff veterinarian. In 1996 was elected President of the Puerto Rico Veterinary Medical Association. In this position she developed, organized and participated in various educative community programs related to animal care. On February 2000 was appointed by the Chancellor as Director of the Animal Resources Center at the Medical Sciences Campus. Also, she was appointed as Vice-Director of the Unit of Comparative Medicine of the MSC. She was an active member of the IACUC and the Institutional Veterinarian for six year, and is an active member of the Institutional Biosafety Committee, and an alternate member of the IACUC. She is a member of, PRVMA, APV, AALAS, ASLAP and licensed to practice veterinary medicine in Puerto Rico. She is one of the resources at the IACUC training sessions and participates in several continuing education activities related to veterinary medicine yearly. Has received training related to the management of an animal facility at the New England Regional Primate Center and at the Animal Facilities of the School of Medicine in Harvard 2,000. She has attended several Annual APV and AALAS conferences. (At the San Antonio AALAS conference she was one of the speakers in "Meeting Las Americas" session.), Workshop and Symposium on Laboratory animal diseases offered by The Midwest Div. of the Charles Louis Davis, D.V.M. Foundation in Co-Sponsorship with The Biologic Resources Laboratory (BRL) of The University of Illinois at Chicago. Has participated of: National Symposium on Biosafety, a visit to the CDC and Emory animal facilities in Atlanta, the Charles Rivers Short Course on Animal Care and Use, the IACUC 101 Course, Basic Surgical Skills Workshop, the Workshop & Symposium on Laboratory Animal Diseases of the Charles River Davis Foundation, Annual Retreat of the Northeast Biosafety Consortium, Biocontainment Laboratory Biosafety and Biocontainment Training, PR Veterinary Medical Association Meetings and completed ILAM Course (RILAM) among others. In November 2005 coordinated and participated in a two day seminar related to Biocontainment and BL-3 facilities offered by Dr. James Swearengen at the Medical Sciences Campus. In May 2006, organized and participated in an Amphibian Husbandry and Care seminar at the Medical Sciences Campus given by Dr. Larry Capitini, DVM from The Ohio State University. In 2009, organized and participated on Jackson Lab teleconference on rodent colony management. In 2010 organized and participated on a weeklong seminar on laboratory animal pathology offered by Dr. Rao Srin and another on NHP pathology offered by Dr. Keith Mansfield from the NEPRC. In 2012 participated in PRIMER meeting in Boston, attended several webinars, helped organize the AALAS Caribbean Branch educational seminar, and visited the Yerkes National Primate Center. She has participated in NIH proposal peer review and also collaborates and coordinates research projects with Wistar Institute, North Carolina Global Vaccine, BD Bioscience and UPR, in where agents like SIV and Dengue and others are studied. In 2012 Dr. Martínez was appointed Director of the Caribbean Primate Research Center-UPR and is PI of the CPRC P40 Core Grant. She is a past President of the AALAS Caribbean Branch and has served as reviewer of several NIH study sessions. She is also part of the PRVMA "One Health Committee".

Dr. Melween Martinez dedicates 20% time effort to the Institutional Animal Care Program.

3) Name: José Vientós, DVM

Authority: Dr. Vientós has *direct* program authority and responsibility for the Institution's animal care and use program including access to all animals as **Attending Veterinarian at Institute of Neurobiology and its satellites.**

Dr. Vientós obtained his Doctorate Degree In Veterinary Medicine in 1979 from Kansas State University. He has been a Professor at the Veterinary Technology Program at the MSC since 1983. He is well recognized for his extensive experience in birds and exotic medicine. From 1992-1996, he was the veterinarian in charge of the animal exhibition at *El Parque de las Ciencias in Bayamón, P.R.*

He was also a consultant for the Department of Natural Resources of PR and for the US Fish and Wildlife Dept. at the P.R. Parrot, and also at the PR Parrot Project at Utuado. Dr. Vientós also works at the Animal Emergency Clinic and owns a clinic specialized in avian and exotic medicine in San Juan, PR. He is a member of the AVMA, AAV, PRVMA, and Association of Zoo Veterinarians. He has been the veterinarian in charge of the Animal Facility at the Institute of Neurobiology for over 15 years. In May 2006, Dr. Vientós participated in an Amphibian Husbandry and Care seminar at the Medical Sciences Campus given by Dr. Larry Capitini, DVM from The Ohio State University.

Since the Animal Facility at the Institute of Neurobiology is smaller Dr. Vientós works part time, 4 to 5 hours per week. He dedicates 80% of those hours to the animal care and use program.

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7) Name: **Olga González, DVM, Diplomate ACVP**

Authority: Dr. González has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals as **Director of Comparative Medicine and Veterinary Pathology at CPRC**

Dr. González obtained her Bachelor's degree in Biology from the University of Puerto Rico – Rio Piedras Campus in 2001 and obtained her Veterinary Degree from the University of Wisconsin-Madison in 2005. After graduating from veterinary school, she completed a three year residency program in Veterinary Anatomic Pathology from the University of Wisconsin-Madison in 2008, and achieved board certification that same year. After working 1.5 years at the Wisconsin Veterinary Diagnostic Laboratory, she moved to Puerto Rico. She worked as an Assistant Professor in the Animal Science Department of the University of Puerto Rico - Mayaguez until being hired by the CPRC in 2011 as Director of Comparative Medicine and Veterinary Pathology at the CPRC and is the current President of the AALAS Caribbean Branch.

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of more than the least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

Name of Member	Degree/ Credentials	Position Title	PHS Policy Membership Requirements****
Elizabeth Rivera	DVM	Chairperson Professor	Veterinarian
Idia V. Rodriguez	DVM	Institutional Vet	Veterinarian
José A. Vientós	DVM	Associate Professor	Veterinarian
(b) (6)			Scientific
			Scientific
			Scientific
			Non-Scientific
			Non-Affiliated (Community)
			Scientific
			Scientific
			Scientific

D. The IACUC will:

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

At least once every six months, the Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Animal Welfare Act, as a basis for the review. To facilitate the evaluation, the Committee follows the OLAW Program and Facility Review Checklist from OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following:

- IACUC Membership and Functions;
- IACUC Records and Reporting Requirements;
- Husbandry and Veterinary Care (all aspects);
- Personnel Qualifications (Experience and Training);
- Occupational Health and Safety; and
- Emergency and Disaster Plans

In addition, the evaluation will include a review of the elements in the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

In an IACUC convened meeting the Chair will select the subcommittees (inspection teams) comprise of at least a minimum of 2 voting members, with at least a veterinarian. In the event that the Veterinarian in charge of the Animal Care Program cannot participate in the evaluation, his/her alternate in the IACUC will take his/her place. If any member of the Committee desires to evaluate a specific area he/she may join the designated subcommittee. These procedures are established for PHS and USDA covered species.

The Program is evaluated every six months at the following sites:

- The Animal Resource Center which includes the Experimental Surgical Laboratory, and (b) (6) Laboratory and (b) (6) laboratory.
- The Institute of Neurobiology in Old San Juan which includes (b) (6) Laboratory.
- The Caribbean Primate Research Center
 - Field Station located in Cayo Santiago Island, off the coast of Humacao
 - Field Station located in Sabana Seca, Municipality of Toa Baja.
- All laboratories where procedures with live animals are performed (survival or terminal surgeries and procedures).

Other laboratories where dead animals or their tissues are manipulated are inspected once a year.

The secretary will make the arrangements with the Occupational Health Clinic for the Tuberculin skin test for those members evaluating primates holding facilities.

Each subcommittee will select a Chair who will be responsible for the following: coordinate the site visit, present the evaluation report to IACUC in its next meeting and sign and submit the written report to the IACUC Chair.

The IACUC Secretary will prepare a package for each subcommittee member for their review prior to the site visit. The package will be delivered to each member at least five working days prior to the date of the evaluation. The packages will include the following:

- Semiannual evaluation report and the response from the facility director and/or veterinarian in charge from the previous evaluation.
- Evaluation reports related to non-compliance allegations and response from the facility director and /or veterinarian in charge during the last six months, if applicable.
- Semiannual Program and Facility Review Checklist.
- A list of the IACUC approved protocols for the area or facility.

The members of the subcommittee will use the corresponding checklist for the review of the animal care program, facility inspection and the occupational health program. The checklist is designed to assist the IACUC in conduction through semiannual evaluations. The checklist covers the major topics of the Guide, and the requirements of the PHS Policy.

At the end of the evaluation, the subcommittee will meet with the Veterinarian in charge of the Animal Care Program or facility director to inform him/her of the results of the evaluation and their recommendations.

The Subcommittee Chair in agreement with the other members for his team will prepare a report that will include a description of the nature and extent for the institution's adherence to the Guide and must identify specifically any departures from the provisions of the Guide and must state the reason for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific. If necessary, the subcommittee may invite consultants for complex issues found during the evaluation.

The report and checklist used for the evaluation are to be submitted to the IACUC Chair.

The IACUC Chair will submit a copy of the semiannual facilities evaluation report (approved by the IACUC in its meeting) to the facility director and Veterinarian in Charge of the Animal Care Program. They are requested to respond to the concerns outlined by the Subcommittee. The format used, for the Semiannual Program Review and Facility Inspection Checklist is the one recommended by OLAW's Sample Documents on their Main Page (<https://grants.nih.gov/grants/olaw/sampledoc/ccheklist.pdf>).

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

The IACUC Office will prepare a final report to Institutional Official of the Medical Sciences Campus of the University of Puerto Rico on the semiannual evaluations performed by the IACUC on the animal care program, animal facilities, occupational health program, and laboratories where survival surgery is performed. The report will include a description of the nature and extent for the institution's adherence to the Guide and must identify specifically any departures from the provisions of the Guide and must state the reason for each departure. The reports distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the report will contain a reasonable and specific plan and schedule for correcting each deficiency. Written comments from each facility directors and/or veterinarian in charge will be included in the report to the Institutional Official. The semiannual report to the Institutional Official will include:

- Evaluation reports of the Animal Care Program prepared by the Evaluation Subcommittee.
- Inspection reports of Animal Facilities prepared by the Evaluation Subcommittee.
- Responses to the program evaluation and inspection reports prepared by the Evaluation Subcommittee from animal facility directors and/or veterinarians in charge regarding any deviation from the Guide and the PHS Policy.
- Minority Views of members present in the meeting during the discussion of the report.
- Signatures of IACUC members present in the meeting during the discussion of the report.

The Chair will deliver and review the report with the Institutional Official in a scheduled meeting. Any IACUC member that desires to participate in the meeting with the Institutional Official may do so. One copy of the document is handed over to the IO for the record and further actions, and another is kept in the IACUC Office. Copies of reports shall be made available to OLAW and USDA APHIS upon request.

Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to OLAW, USDA APHIS and any agency funding the activity.

The format used, for the presentation of the report on semiannual evaluations to the Institutional Official, is the one recommended by OLAW's Sample Documents on their Main Page (<http://grants.nih.gov/grants/olaw/sampledoc/docclass60.pdf>).

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

"Whistleblower signs" that include multiple contact numbers must be placed at different areas of the animal facility and everywhere animal procedures take place. Concerns may be reported to the Chair, member of the IACUC, Institutional Compliance Officer or to the Institutional Official in writing, by electronic mail or by a phone call. The individual reporting the concern(s) must describe the noncompliance, animal facility and any perceived harm to animals. It is the policy of the Medical Sciences Campus that no facility employee, committee member, laboratory personnel or any other person shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act.

An evaluation subcommittee will be created to evaluate any concerns brought by the public, employees, students or any other persons. The evaluation subcommittee will comprise of a scientist, a veterinarian

and the IACUC Chairperson. If any other member of the Committee wishes to participate in the evaluation he/she may join the evaluation subcommittee. The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the sub-committee should interview the complainant(s), the respondent(s) and other individuals who might have information regarding aspects of the allegations and observe the animals in their environment, if applicable. During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the subcommittee will notify the Chair, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents. If the concerns involve a non-human primate holding facility, the Chair will assure that the members of the evaluation subcommittee have had a recent tuberculin skin test done. The evaluation will be performed within 48 hours of notification of the concern.

- The evaluation subcommittee will evaluate the particular areas of the concern or non-compliance allegations, such as but not limited to the animal facility, animal care program, occupational health program, protocol files and administrative functions that may hinder the health and welfare of animals and humans.
- The evaluation subcommittee will interview those individuals that may have some knowledge in regards to the concern reported, such as but not limited to animal caretakers, animal technologists, veterinarian in charge, scientists, laboratory manager, students and facility director.
- The Evaluation Subcommittee will meet privately to discuss their findings and reach a conclusion.
- An exit-briefing meeting will be held with the facility director and/or the veterinarian in charge to discuss any departure and reasons for the departure from the provisions in the Guide and the PHS Policy. The Evaluation Subcommittee will distinguish between significant and minor deficiencies. If deficiencies are found, a specific plan and schedule for correcting each deficiency must be developed within 48 hours from the day of the evaluation and people responsible will be identified.
- If no deficiencies are found, the Evaluation Subcommittee will inform the facility director and/or the veterinarian in charge.

The IACUC may also return the report to the investigation sub-committee with a request for further fact-finding or analysis. Upon receipt from the Chair, the institutional Official may take additional administrative actions with respect to recommendations made by the IACUC. The report prepared to the Institutional Official informing of the concern, will include the date and time of the evaluation, the composition of the evaluation subcommittee, a description of the extent and nature of the departure from the Guide and PHS Policy, if any, as well as reasons for the departure. A reasonable and specific plan of action, schedule for correcting each deficiency, and persons responsible will be included in the report. If experts were consulted, the name and field of expertise of the person will be included in the report as well as any references made. In the event that no deviation is found, this will be documented in the report.

However, the Institutional Official may not overturn the IACUC's recommendation regarding animal care and use. If the suspension of an IACUC approved activity is recommended, the procedures for the suspension of a IACUC approved activity will followed.

- 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:

It is the responsibility of the IACUC to oversee and evaluate the institution's animal care program, procedures and facilities to ensure that they are consistent with the recommendations in the Guide, the Animal Welfare Regulations and the PHS Policy.

In order to meet its responsibility the IACUC may make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.

The IACUC will determine in a convened meeting based on the majority of votes from the quorum present the needs of any aspect related to the institutional animal care program or to the needs of the IACUC itself. The IACUC may invite consultants to its meeting for advice on complex issues.

The IACUC will prepare written reports describing problems or potential for problems that may depart the program from the Guide and the PHS Policy. The IACUC will provide a reasonable and specific plan and timetable for solutions, persons responsible and a description of resource required, such as but not limited to facility, equipment, training and human resources.

The Chair will schedule a meeting with the Institutional Official to review the recommendations, and any IACUC member that desires to participate may do so.

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

The Medical Sciences Campus Community is notified during the months of January and August of each year of the schedule for the IACUC monthly meetings and the deadline dates for the submission of documents for each meeting. This allows the principal investigator adequate time to plan for his/her project and allows the IACUC members to prevent any conflict with the scheduled meetings. Prior to the meetings, the IACUC secretary will communicate with each member to confirm their participation to the meeting.

The researcher is required to complete the Animal Study Proposal Form (ASPF) in all of its parts. The researcher submits to IACUC's Office the original and 3 copies of the ASPF along with 1 copy of the grant proposal, training certificates of all personnel handling animals, two literature searches to demonstrate that the experiment will not duplicate previous work, two literature searches related to minimization of pain and distress if the experiment falls under USDA Classification of Pain And Distress category D or E, between 8 to 10 working days prior to the scheduled meeting; and evidence of compliance with the Animal Exposure Surveillance Program (AESP description in Section E) at least twelve working days prior to the scheduled meeting.

He/she then discusses the experimental procedures and the animal care with the Facility Director and/or Facility Manager and the Attending Veterinarian. If recommendations are made, the ASPF will be corrected before submission to the IACUC.

The IACUC Office ensures that the principal investigator, director or facility manager of the proposed animal holding facility and the attending veterinarian have signed the ASPF. This ensures the IACUC that the attending veterinarian was involved in the planning for the care of the animals in the proposed activity. The pre-review or initial screening process, is done to make sure that all other supporting documents like occupational health and training certifications of the personnel involved are up to date; and literature searches for non-duplicative efforts and methods to minimize pain & distress are done. The secretary will register the document and assigns a protocol number, prepares a file for the original ASPF and a copy of the proposal.

Five days prior to the meeting, the following documents will be delivered to the IACUC members: an agenda listing the protocols for review, copy of all protocol with supporting documentation, a list of suggestions of protocols to be seen during the meeting thru Designated Member Review Process (DMRP), and any issues pertaining to IACUC's responsibilities; a copy of the previous meeting's minutes for approval; the Protocol Follow Up Report.

The Chair will have available at the meeting the complete file pertaining to the protocol for those committee members who wish to review it, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act.

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.

No member may participate in the IACUC review or approval of a research project in which he/she has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may any member who has a conflicting interest contribute to the constitution of the quorum for that specific proposal.

Full Committee Review (FCR) of the protocol occurs during a convened meeting of a quorum of the IACUC members and with a formal vote. Each protocol will be assigned to a Primary and Secondary reviewer who will present the protocol to the established quorum. At the FCR, members will decide for one of the following outcomes: Approved, Pending on modifications to secure approval, Withhold approval (which may be brought back to FCR or become a DMRP) or Not Approved.

A quorum meeting includes half of the total members plus one. Each IACUC meeting shall have present at least one veterinarian in charge of the animal care program or designated alternate member. If all the information required to make a decision is included in the ASPF and in agreement with the proposed research proposal, but is not consistent with the provisions of the Guide or in accordance with the Animal Welfare Act and the PHS Policy, the IACUC will withhold approval after a majority vote of the quorum present.

Following FCR if substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

1. If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review, or returned for FCR at a convened meeting.
2. If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations: All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

When IACUC uses DMRP, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date will be reported to OLAW as a serious noncompliance with the PHS Policy.

The procedure that qualified for designated member review (DMR) are the following:

- ➔ Annual Renewals (excluding De Novo Review)
- ➔ Annual Renewals with Minor Modifications
- ➔ Minor Modifications
- ➔ Noninvasive Behavioral Protocols (excluding Initial Submissions and De Novo Review)
- ➔ Protocols evaluated by the IACUC in a convened meeting but deferred or pending additional information or clarification and agreed in the meeting that it can be seen as DMR.

Initial Submissions, De Novo Review and equivalents, and Major modifications to approved protocols do not qualify for the DMRP.

The IACUC Administrator or the Secretary will provide recommendations for the DMR process on the list of protocols (agenda) submitted to the members along with all required documentation prior to each meeting. They will also provide suggestions of possible reviewers to the Chair. The recommendations will be based on those protocols that meet the criteria above. These protocols will be included in the package to allow all Committee members to review the protocols and to request a full committee review, if desired. Alternatively, at any time, a Principal Investigator (PI) may submit a completed IACUC Protocol Form and a request for DMRP to the IACUC office. If the protocol meets the criteria for DMRP consideration, the IACUC Secretary or Administrator will forward this request along with the complete protocol and supporting documents to all members to review and to request a full committee review, if desired. The members' recommendations of DMRP or FCR shall be done within two days upon receipt of

the package, by e-mail, letter or phone call (if other methods are not available). The IACUC Office may consider the lack of a reply as equivalent to declining to call for full review only after the two day period has elapsed. If no member calls for full committee review, then the IACUC Administrator or Secretary will communicate the results to the IACUC Chair along with recommendations for qualified reviewers from the IACUC member roster. The IACUC Chair will then select the Subcommittee to review the protocols. The Subcommittee will have five business days to evaluate the protocols and submit their recommendations to the IACUC Administrator or Secretary. The designated reviewer may result in approve, pending modifications to secure approval, or request full committee review of the protocol. Approval may not be withheld.

If a member has a conflict of interest (e.g., personally involved in the project), he/she will be replaced by another member qualified to conduct the review (PHS Policy VI, C, 2; AWAR §2.31, d, 2).

The designated reviewers are given five working days to return their approval and/or recommendations of the standardized protocol to the IACUC Office. If they cannot perform the review within the assigned time frame, they are asked to inform the IACUC Office promptly. The IACUC Chair then reassigns the designated reviewers.

The reviewers can seek advice from consultants to clarify questions regarding any aspect of the project, but consultants may not approve or disapprove the protocol and may not vote with the IACUC unless they are a member of the IACUC. Reviewers may also contact the investigator directly or thru the IACUC Office to request written clarifications regarding any aspect of the project. Upon receipt of appropriate written responses from the Investigator and/or consultant, the designated reviewers will send their written decisions for approved, pending modifications to secure approval, or request full committee review of the protocol to the IACUC Office. Once the IACUC Office has received the IACUC member's written determinations, they are collated and either sent to the IACUC Chair for final approval or if modifications are requested, sent to the Investigator for their written response.

Designated reviewers must agree in their final decision or full committee review is required. If one of the designated reviewers requires modifications, the other designated reviewer needs to be aware of those changes and agree to them.

The IACUC Secretary will file a copy of the communication sent to the Principal Investigator and the Director of the proposed animal holding facility regarding the outcome of the review, the approved ASPF signed by the IACUC Chair and initialed on each page, and the proposal in a folder identified by the protocol number. Additional copies of the same documents will be destroyed.

- 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:

The principal investigator is required to address the proposed changes to his ongoing research project to the approved in the ASPF. The Principal Investigator will meet with the veterinarian and the director and/or Manager of the animal facility where animals will be held to discuss changes related to the animal care. If recommendations are made, the ASPF will be corrected before submission to the IACUC. The review and approval procedure used is the same proposed in previous Section III.D.6.

Protocols must be active at the time of submission to the committee. If protocol expires following submission to the committee for review, further animal use is not allowed until protocol is reviewed and final approval letter is issued by the committee.

- 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:

The IACUC Chair will notify the principal investigator (PI) and the director of the animal holding facility 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 in writing. Written notification is directed to the principal investigator and copy to the director of the proposed animal holding facility for the following:

- Notification of Approval will indicate protocol number and title, date of the IACUC meeting and the expiration date of approval. It will also contain a paragraph indicating that any changes to the protocol as described in the approved ASPF must be submitted to the IACUC for approval before its implementation.
- Written notification that the protocol is Pending on modifications to secure IACUC approval is directed to the principal investigator and a copy to the director of the animal holding facility. Notification shall contain protocol number and title, date of the IACUC meeting and a description of issues that need to be clarified, additional information needed, or modifications to those components related to the care and use of animals, and a deadline for when protocol changes are due.
- Written notification of IACUC determination to Withhold approval of those components related to the care and use of animals in a proposed research, project will include protocol number and title, date of the IACUC meeting, a statement of the reasons for its decision. The principal investigator will be given an opportunity to respond in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator.
- Written notification of IACUC determination to not approve the proposed protocol of those components related to the care and use of animals in a proposed research, project will include protocol number and title, date of the IACUC meeting, a statement of the reasons for its decision that has not addressed any of the PHS Policy and AWA requirements. The principal investigator will be given an opportunity to respond in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator.

The IACUC will notify the principal investigator and the research facility in writing of its decisions. The PI will be given an opportunity to respond in writing. If the PI request a personal audition with the committee to further explain his/hers response, the PI will be invited to the next convened meeting. The IACUC may reconsider its decision with documentation in Committee minutes in light of the information provided by the PI.

The IACUC Office will file a copy of the communications sent to the PI and the Director of the proposed animal holding facility regarding the outcome of the review; the approved ASPF signed by the IACUC chair and initialed on each page in a folder identified by the protocol number. Additional copies of the same documents will be destroyed. The IO is notified by mean of the minutes in which it is included the decisions regarding the protocol review.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

By combining the requirements of both the PHS Policy and the USDA regulations all protocols are reviewed annually. All protocols will be renewed prior to the three-year expiration date, therefore must be completely review and approved by the IACUC. Prior to the three-year expiration date, the researcher is required to complete the Animal Study Renewal Form (ASRF) in all its parts. In other words, all approved protocols (including non USDA covered species but excluding invertebrate animal study protocols) must be renewed annually, prior to the yearly expiration date. Invertebrate animal study protocols are reviewed every three years.

After completing the ASRF in all its parts the PI submits an original with 3 copies at least 8 to 10 working days prior to the scheduled meeting. The IACUC Staff ensures that the researcher have signed the form and register the document. The ASRF will have the same protocol number as assigned in the first reversion.

Between the yearly reviews the IACUC monitors ongoing activities through a variety of mechanism during the facilities and laboratories inspections, by doing on site training, daily observation of animals by trained animal care personnel and communication to the veterinary staff for follow-up, by appropriate reporting of incidents involving occupational health and safety, and unannounced visits.

- 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:

If the IACUC determines that a previously approved activity is not being conducted in accordance with the description of that activity provided by the principal investigator, the activity will be suspended after a complete review by the IACUC in a Full Convened meeting and with the suspension vote of a majority of the quorum present.

The IACUC will inform the Institutional Official of the suspension of the activity and review with him/her the reasons for the suspension and take appropriate corrective action. Notification for project suspension is directed to the principal investigator and copy to the director of the animal facility indicating the protocol number and title, date of the IACUC meeting in which the determination was made, and a state of reasons for the suspension.

The suspension will then be reported to OLAW and USDA APHIS, the funding source, and the Financial Administration Division of the Medical Sciences Campus by the IO in a written communication send by either regular or electronic mail.

The IACUC Chair will schedule a full committee meeting to review the report. The approved activity may be suspended with a suspension vote of a majority of the quorum present at the convened meeting. The Institutional Official in consultation with the IACUC will review the reasons for the suspension and take appropriate corrective actions.

In case of a suspension due to whistleblower, the Institutional Official will issue the final outcome decision within five (5) business days of receiving the complaint. The respondent can file a written statement of appeal with that time frame. An investigation should ordinarily be completed within 90 days of its initiation, with the initiation ordinarily beginning with the first meeting of the investigation sub-committee.

OLAW and USDA APHIS will be notified within 15 business days by IACUC through the Institutional Official in the event that the following issues are not corrected within the specific time established by IACUC.

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

With the purpose of protect all personnel who handle or have contact with laboratory animals or persons who work near laboratory animals (not in direct contact with animals). The MSC has a MANDATORY Animal Exposure Surveillance Program (AESP).

These include:

- Principal Investigators on IACUC protocols
- Personnel handling animals listed on IACUC protocols
- Animal Care Staff (animal care technicians, veterinarians, veterinary technicians and veterinary technologist)
- Students using and caring for animals
- Personnel working near laboratory animals with no direct contact with animals
- Maintenance personnel
- Short term visitors, volunteers or minors who decide to participate in the Program (This Policy does not apply to them, and to independent contractors, if not wishing to participate in the AESP must sign a waiver. Short term visitors are individuals that will be present in MSC animal facilities or laboratories where animals are manipulated for the purpose of observing an animal procedure or educational activities that have been approved by the IACUC or to visit the animal facility. The activities

will not involve work with non-human primates, work in a BSL-2 or BSL-3 research facility or other high risk activity as determined by the facility manager or the facility veterinarian. Independent contractors are non-MSU personnel that are contracted to perform a duty in an animal facility or laboratory where animals are manipulated or housed.).

Current individuals covered by this policy are required to fill in a baseline health screening procedures by completing the Medical Health Screening Questionnaire. The questionnaire is reviewed by the Occupational Health Clinics (for employees and students) to determine the potential risks of working with laboratory animals. The OHC will issue a written assurance that the individual may work with laboratory animals or request further assessment.

The individual written assurance issued by the OHC must be submitted to the IACUC as part of the documentation at the time of an initial submission or renewals of an animal protocol, when new personnel are added to an approved protocol, when an individual's health status changes or when indicated by the medical reviewer. After this first step the participants are required to do an annual follow up.

The rest of this comprehensive occupational health and safety program is in place at animal facilities. This program includes participation of both the Institutional Environmental Health and Safety Office (EHSO) and the Occupational Health Clinic (OHC). A major part of the program is the continued training of all personnel in the use of protective equipment, safe practices and a thorough knowledge of the facilities SOP's. This objective is achieved through lectures, audio/video material, on-the job-training and others as required.

Hazard Identification and Risk Assessment is conducted using CDC's "Biosafety in Microbiological and Biomedical Laboratories," the materials data safety sheet and the recommendations of both Environmental Health and Safety Office (EHSO) and the Institutional Biosafety Committee. Specific instructions outside those included in the Standard Operating Procedure's (SOP's) suggested by the EHSO, the Institutional Biosafety Committee or the IACUC are incorporated into the research protocol by the Principal Investigator, and into the routine animal care by the 'Animal Facilities' staff (SOP's are modified if required). Before submitting a proposal for IACUC review, the veterinarian and the facility's Director need to read the Animal Study Proposal Form. At this point they also can identify potential hazards and will discuss them with the principal investigator to assure a good procedure to manage the risks. In turn, the veterinarian will instruct the facility's personnel about the risk management. The EHSO as well as the IACUC can assess risks through their facilities' semiannual evaluations.

All protocols using hazardous agents must be approved by the Institutional Biosafety Committee and the IACUC of the MSU. The COC-NIH recommendations, as stated in the "Biosafety in Microbiological and Biomedical Laboratories" publication, are strictly followed.

The IACUC performs semi-annual inspections that include biohazard containment areas. The veterinarian and the supervisor oversee procedures, husbandry practices and personal protective equipment while employees are working with any hazardous agent. They correct any improper procedure immediately. After the work is finished, proper measurements are reviewed with the employee to assure its correction.

The Continuing Education and on-the-job-training programs are designed to make personnel knowledgeable on the potential hazard of chemicals and disinfectants used in the facility, of the risk of physical harm and zoonotic diseases arising from contact with animals, especially non-human primates, and of the precautions necessary to minimize exposure to allergens.

Physical examinations, inoculations, TB tests, Measles titers, X-rays and blood withdrawals for the serum bank are conducted at the MSU Occupational Health Clinic. All personnel working at the animal facilities are included in this program. All non-animal facilities related personnel coming in contact with non-human primates (researchers, technicians, maintenance personnel, etc.) are required to undergo the same TB screening required of animal facilities personnel. This procedure involves the intradermal inoculation of 0.1-ml mammalian PPD, which is read after 48-72 hours. This test is repeated with a minimum frequency of six months. Positive or suspect reactors, as well as BCG vaccinated individuals,

are given thoracic radiographs, which are checked professionally for evidence of pulmonary tuberculosis. X-ray examinations are repeated yearly if needed.

Procedures performed routinely include:

<u>Procedure</u>	<u>Frequency</u>
TB Test	Semi-annual
Serum collection	As assessed
Tetanus toxoid	10 Years
X-ray examination	Yearly (if needed)
Hepatitis B	3 doses
Spirometry	As necessary
Fitting Test	Annually if necessary
Measles Titers	Once
Fecal sampling	When physician recommend (GI Symptoms)

Rabies vaccination/ titers can be required based on risk assessment and recommendations of the Occupational Health Clinic.

Complete physical exams are required when hiring new personnel, along with a TB negative status. Health logs records are kept on file on the centralized Occupational Health Clinic.

As part of the continuing education program, lectures and audiovisual presentations on personal hygiene, the use of protective equipment, sanitation and zoonosis control are given routinely. Emphasis is given to procedures to be followed in case of monkey bites or scratches, with discussion of SOP's addressing this eventuality. Other zoonoses common to laboratory animal facilities are also discussed. All personnel are trained on hazards of B virus and SIV, bites/scratches and on the procedures to follow after exposure. A demonstration is periodically performed. All personnel are provided with protective clothing like long sleeve coveralls, masks, gowns, double gloves (with the first one taped at the wrist), goggles, boots and/or face shields designed to minimize exposure to the hazards of working with non-human primates.

All veterinary, technical and animal care personnel are provided with protective work clothing. This clothing consists of scrub suits in conventional and BL-1 areas, and of coveralls in the containment areas. Additional protective items required in selected areas include laboratories coats, sleeve, covers, facemasks, head covers, shoe covers, latex gloves and goggles or face shields and rubber boots.

Shower and changing facilities are provided for all animal care personnel. Facilities for the animal caretakers, including lockers and showers are provided. Additional shower and locker facilities are provided in the ABSL-3 facility for workers laboring in this area. Workers inside the facility use provided scrub suits. For duties outside the facility, specially identified coveralls are provided. Personnel working with nonhuman primates are required to shower prior to dressing in "street" uniforms.

Uniforms and scrub suits are laundered in-house. Under no circumstance (outside of an outright emergency) may an employee wear work clothes outside the unit.

Workers are required to shower prior to changing into street clothes before leaving the premises. Everyone is required to wash their hand with a disinfectant after removing the gloves used to manipulate any animal.

All personnel are trained to know the potential for injury associated with working with different species and/or equipment, as well as the use of personal protection equipment. Personal protection equipment is provided as needed, including lab coats, scrub suits, coveralls, shoe-covers, shoes, boots, dust respirators, respirators, gloves, cut proof gloves, goggles, face shields, hair-covers, etc.

Equipment to handle animals such as catch poles, nets, heavy leather gloves and squeeze cages are provided.

Eating, drinking and smoking are forbidden in animal areas. Eating and drinking is only allowed in the cafeteria and some office areas. Smoking is only allowed in the outside corridor designated for this purpose. Personnel working in the bio-containment areas will wear protective clothing provided. Clothing will not be worn outside of the designated areas. Animal caretakers will launder this clothing at the laundry facility. Lockers and change facilities are provided. All clothing and protection devices are available at the entrance of the area. Showers are provided in the ABSL-3 and conventional areas. It is required that all personnel shower at the end of the work period.

Appropriate eye protection, shoe covers, double gloves, coveralls and head covers must be worn in the ABSL2/3 area if the personnel are in contact with the animals or cages. Rubber boots will be used when wet conditions are encountered. Shoe covers, mask, gloves, goggles and a lab coat/scrub will suffice when the personnel is not in direct contact with the animals or contaminated cages. All procedures performed on or using animals in the ABSL-3 area will be done under a safety hood.

Non-human primates will be handled under an appropriate anesthesia (example: Ketamine injection). All sharp objects will be discarded in the appropriate containers and disposed as biohazardous waste. Needles will never be recapped, removed from disposable syringes, or otherwise manipulated by hand. They should immediately be disposed of in the sharp containers. Surface and equipment must be disinfected after each use.

Personnel will instruct visitors (researchers, technicians, maintenance personnel, etc.) on biohazard and safety. Visitors must dress appropriately as the visited area requires. Physical examinations, negative TB tests and/or immunizations may be required to visit these areas depending on the species being housed and the nature of the agent under study.

If any accident occurs, personnel are instructed to stop work immediately and to report the incidence to the Director, Veterinarian or Supervisor which will refer the person to the Occupational Health Clinic. The occupational nurse in charge will evaluate the situation and will fill out a referral to the State Insurance Fund Offices (SIFO) for follow up. A copy of the list of "Zoonotic Potential According to Species", is on hand at the Occupational Health Clinic, and will be sent to the SIFO.

- 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 (*see Part 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 Animal Care and Use Committee Training Sessions are offered minimum twice a year or more as needed or requested. These sessions are designed to provide investigators and research staff with the information and skills necessary to conduct research using animals. All scientists, animal technicians, and other personnel involved in animal care, treatment, or use utilizing animals are required to attend the IACUC training sessions. These sessions will cover topics including ethics, legislation, guidelines, institutional policies, biohazards, alternate methodologies, the 3R's emphasizing in methods that minimize the number of animals required for valid results, and methods to minimize animal pain and distress. Hands on experience are done mostly with rodents (other species workshops will be offered when needed) and various animal research techniques. Animal sessions include the following objectives:

- Proper handling and restraint of animals for routine procedures.
- Observation of animals, recognition of normal and abnormal physical and behavioral changes and reporting abnormalities to the appropriate veterinary service personnel.
- Demonstrate methods of identification.
- Demonstrate methods of venipuncture and exsanguinations.
- Demonstrate sites and techniques for administration by the following routes: oral, subcutaneous, intramuscular, intraperitoneal and intravenous.
- Discuss appropriate methods to minimize animal pain and distress
- Discuss appropriate methods of environmental enrichment
- Discuss appropriate methods of anesthesia.

- Discuss appropriate indications for and methods of analgesia.
- Discuss appropriate methods of euthanasia.
- Discuss appropriate immunization protocols for antibody production/monoclonals (NIH Guidelines for adjuvants).
- Discuss aseptic technique requirements for survival surgical procedures.

IACUC members are provided one on one orientation, case study, background materials, resources, and/or training and continuing education by periodic online trainings and webinars. Also IACUC members are given access or have electronic copies provided of the PHS Policy, the OLAW/ARENA IACUC Guidebook and Animal Welfare Assurance.

IACUC also validates online courses taken thru CITI Program as part of the training program to scientists, animal technicians, other personnel involved in animal care, treatment, or use, and IACUC members.

IV. Institutional Program Evaluation and Accreditation

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

This Institution is Category 1 — accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Ramon F. Gonzalez, Interim Chancellor.
 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

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

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Ramón, F. González, DDS, MPH

Title: Interim Chancellor

Name of Institution: University of Puerto Rico's Medical Science Campus

Address: University of Puerto Rico
Medical Science Campus
PO Box 365067
San Juan, P.R. 00936

Phone: (b) (6)

Fax: (b) (6)

E-mail: rector.rcm@upr.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: (b) (6)

Date: 4/7/2017

B. PHS Approving Official (to be completed by OLAW)

Dr. Venita B. Thornton - Senior Assurance Officer
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Signature: (b) (6)

Date: April 10, 2017

Assurance Number: D16-00262 (A3421-01)

Effective Date: April 10, 2017

Expiration Date: March 31, 2021

VIII. Membership of the IACUC

Date: 2017			
Name of Institution: University of Puerto Rico's Medical Science Campus			
Assurance Number: D16-00262 (A-3421-01)			
IACUC Chairperson			
Name*: Elizabeth Rivera			
Title*: Professor, Medical Science Campus		Degree/Credentials*: DVM	
Address*: University of Puerto Rico Medical Science Campus EPS Bldg. (b) (4) PO Box 365067 San Juan, PR 00936			
E-mail*: elizabeth.rivera11@upr.edu			
Phone*: 787-758-2525 x 1836		Fax*: 787-754-0474	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Elizabeth Rivera	DVM	Chairperson Professor	Veterinarian
Idia V. Rodriguez	DVM	Institutional Vet	Veterinarian
José A. Vientós	DVM	Professor	Scientific
(b) (6)			Scientific
			Scientific
			Scientific
			Non-Scientific
			Non-Affiliated (Community)
			Scientific
			Scientific
			Scientific

* 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.

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

(b) (6)

X. Facility and Species Inventory

Date: 2017			
Name of Institution: University of Puerto Rico's <u>Medical Science Campus</u>			
Assurance Number: D16-00262 (A3421-01)			
Laboratory, Unit, or Building	Gross Square Feet	Species Housed	Approximate Average Daily Inventory
(b) (4)	32,866 sq. feet	Hamsters, Rabbits, Pigs, Gerbils, Rats, Mice, Rhesus Zebra fish Prawns	6 6 2 6 354 305 6 657 3
	3,329 sq. feet	Mice, frogs, prawns, crabs, snails	100 80 50 16 750
	17 acres	Rhesus	2,899
	38.5 acres	Rhesus	1,797

Addendum #1:

The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows

