TABLE OF CONTENTS

I. APPLICABILITY OF ASSURANCE

II. INSTITUTIONAL COMMITMENT

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. LINES OF AUTHORITY AND RESPONSIBILITY FOR ADMINISTERING THE PROGRAM AND ENSURING COMPLIANCE

B. VETERINARIAN

1. Name, Qualifications
2. Degrees
3. Training and/or Experience in Laboratory Animal Medicine
4. Authority
5. Time Contributed to Program

C. INSTITUTIONAL ANIMAL CARE & USE COMMITTEE CONSTITUTED IN ACCORDANCE WITH PHS POLICY

D. RESPONSIBILITIES OF THE INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

1. Review Program at Least Semiannually
2. Inspect Facilities at Least Semiannually
3. Provide Reports to Institutional Official
4. Review of Concerns involving Use of Animals
5. Make Written Recommendations to Institutional Official
6. Process for IACUC to Review, Approve, Require Modifications for Protocol Approval

a. Principal Investigator Prepares and Submits Protocol

1) Protocol Application
2) Statement of Work or Project Description
3) Required Training
4) Enroll In Occupational Health Program
5) Protocol Departmental Sign Off
6) Preliminary Protocol Submission
7) Final Protocol Submission
8) Other Institutional Review Required
b. Administrative Processing of Protocols

1) Protocol Tracking
2) Initial Review
3) Veterinary Consultation
4) Protocol Distribution to Committee

c. Committee Review Process

1) Full Committee Review at Convened Meeting of Committee
2) IACUC Meetings
   a) Meeting Schedule
   b) Quorum
   c) Use of Telecommunications for IACUC Meetings
      i) Criteria for Meeting by Telecommunication
3) Determinations Made by Majority Vote at Convened Meeting with Quorum
   a) Approval
   b) Request Modification to Secure Approval
   c) Withhold Approval
4) Protocol Review by Designated Member Review Process
   a) Distribution to All Committee Members
   b) Designated Member Reviewer(s) Assigned
   c) Reviewer Determination
   d) Communication with Principal Investigator

7. Proposed Changes Regarding the Use of Animals in Ongoing Activities

a. Significant Changes or Modifications
b. Minor Changes or Modifications

8. Notifying Investigators of IACUC Determinations

9. Continuing Review

a. Annual Review
b. Three Year Renewal
c. Post Approval Monitoring

  1) Consistency between Funding Proposal and IACUC Protocol
  2) The Post Approval Monitoring Visit
  3) Sharing Information about the Review
  4) Post Approval Monitoring Follow-Up
  5) Post Approval Monitoring Appeal Process

10. Procedures Used to Suspend an Activity involving Animals

E. OCCUPATIONAL HEALTH PROGRAM

1. Description of Occupational Health Program
2. Enrollment Required for Certain Employees and Students
3. Opting Out or Declining Participation
4. Point of Contact for Occupational Health Program

F. FACILITY AND SPECIES INVENTORY

GEORGIA INSTITUTE OF TECHNOLOGY
ANIMAL WELFARE ASSURANCE: A-3622-01

Expires September 30, 2016
G. TRAINING AVAILABLE TO SCIENTISTS, ANIMAL TECHNICIANS, AND OTHER PERSONNEL INVOLVED IN ANIMAL CARE, TREATMENT, OR USE

1. Training by Veterinarian and Animal Facility Manager
2. Online Module Completion Required
3. Graduate Level Special Topics Course
5. Training Required for Non-Georgia Tech Personnel
6. Frequency of Retraining

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

V. RECORDKEEPING REQUIREMENTS

A. Records Maintained at Least Three Years
B. Additional Records Maintenance
C. Availability of Records for Inspection and Copying

VI. REPORTING REQUIREMENTS

A. Institution's Reporting Period
B. Reporting Noncompliance, Serious Deviations, and Suspension of Activities

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official
B. PHS Approving Official
C. Effective Date of Assurance
D. Expiration Date of Assurance

VIII. APPENDICES

A. Membership of the Institutional Animal Care and Use Committee
B. Facilities and Species Inventory
C. Semiannual Report of Program and Facilities

EXPIRES SEPTEMBER 30, 2016
Georgia Institute of Technology

A-3822-01

Animal Welfare Assurance
in Accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, Jilda Diehl Garton, as named Institutional Official for animal care and use at Georgia Institute of Technology, hereinafter referred to as Institution, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live vertebrate animals supported by the Public Health Service (PHS) and conducted at this Institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or -supported activity by this Institution.

Institution includes the following branches and major components of Georgia Institute of Technology:
- Georgia Tech Research Corporation
- Georgia Tech Applied Research Corporation

II. INSTITUTIONAL COMMITMENT

This Institution will comply with all applicable provisions of the Animal Welfare Act and other state and federal statutes and regulations relating to animals.

This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

This Institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. LINES OF AUTHORITY AND RESPONSIBILITY FOR ADMINISTERING THE PROGRAM AND ENSURING COMPLIANCE WITH THIS POLICY
The President (CEO) of the Georgia Institute of Technology delegated authority through the
Executive Vice President to the Vice President for Research (VPR) to serve as the Institutional
Official. The Institutional Official/VPR reports directly to the Executive Vice President and
regularly attends IACUC meetings and participates actively in policy discussions with the
Chair, Veterinarian, other IACUC members, and Office of Research Integrity Assurance staff.
The Chair of the IACUC is directly responsible to the Institutional Official/VPR for ensuring the
proper execution of the responsibilities of the Committee. He is assisted by the Office of
Research Integrity Assurance, which provides program administration. The Executive
Director of Research Integrity Assurance reports to the Institutional Official/VPR and is
responsible for coordinating activities of the Georgia Institute of Technology Institutional
Animal Care and Use Committee (IACUC) and for providing administrative support to the
committee. The Associate Director of Research Integrity Assurance reports to the Executive
Director of Research Integrity Assurance and is responsible for coordinating activities of the
Georgia Institute of Technology Institutional Animal Care and Use Committee (IACUC) and for
providing administrative support to the committee. The Veterinarian reports to the
Institutional Official/Vice President for Research; the facility manager reports to the
Veterinarian.

B. VETERINARIAN

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

1. **Name, Qualifications**

   Laura O'Farrell, DVM, Diplomate of the American College of Laboratory Animal
   Medicine (ACLAM) in 1997

2. **Degrees**

   - DVM, University of California, Davis, 1993
   - PhD in Neuroscience, University of California, Los Angeles, 1995
   - Master's Degree, Laboratory Animal Science, Pennsylvania State University,
     1995

3. **Training And/Or Experience In Laboratory Animal Medicine**

   - Residency training in Laboratory Animal Medicine, Pennsylvania State
     University, Hershey, PA.
   - Thirty two years of experience working with laboratory animals.
     Experienced with providing veterinary care, surgery and research techniques
     for rats, mice, hamsters, gerbils, wild rodents, ferrets, rabbits, cats, dogs, pigs,
     sheep, frogs, birds, lizards, zoo animals and various non-human primates
     including great apes.

4. **Authority**

   The Attending Veterinarian/Director of Animal Resources has been delegated the
   authority and responsibility to provide veterinary care for the animals utilized in the
   Institution's program and to direct operations of the central animal facility and any
   satellite housing.

5. **Time Contributed to Program**
Full time. When the Attending Veterinarian is unavailable, Veterinarians from the Emory University Department of Animal Resources provide animal care services in accordance with a formal, contractual agreement.

C. INSTITUTIONAL ANIMAL CARE & USE COMMITTEE CONSTITUTED IN ACCORDANCE WITH PHS POLICY

The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy IV.A.3.b.

1. Training for IACUC Members

All IACUC members, including alternates, shall receive initial education, including an overview of the PHS Policy, the Guide, and Animal Welfare Act requirements. Each member of the IACUC shall receive instructions on accessing the IACUC Policies and Procedures and the approved Assurance document. Continuing education sessions will be provided during IACUC meetings, and members will be afforded the opportunity to participate in professional conferences and symposia. IACUC members are expected to complete the on-line CITI training module IACUC Chairs, Members, Coordinators Basic Course and are encouraged to take other modules.

D. RESPONSIBILITIES OF THE INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

1. Review Program at Least Semiannually

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

The Office of Research Integrity Assurance (ORIA) facilitates the semiannual program review mandated by federal regulation. At least once every six months, ORIA distributes for IACUC review the current policies, committee forms (protocol, amendment, annual review), and website materials, and ORIA receives and compiles member comments for the committee's discussion. The semiannual program review also includes evaluation of the following:

- IACUC membership and functions;
- IACUC protocol review practices;
- IACUC records and reporting requirements;
- Veterinary care, including preventive medicine, animal procurement, transportation, surgery, pain, distress, analgesia and anesthesia, euthanasia, and drug storage and control;
- Research personnel qualifications and training; and
- Occupational health and safety of personnel.

The entire membership of the IACUC participates in the program review evaluation and discussion at a convened meeting of the committee. Recommended changes, if any, are passed by majority vote. The Office of Research Integrity Assurance records the matter in the meeting minutes and prepares and documents any resulting programmatic changes. In the event of a substantive programmatic change recommendation, a subcommittee of the IACUC may be appointed by the Chair to
further investigate the recommendation and report back to the full IACUC for a determination. The Institutional Official/VPR is notified in this case.

2. Inspect Facilities at Least Semiannually

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

At least once every six months, the IACUC inspects all Georgia Institute of Technology facilities where animals are housed and/or used. A minimum of two voting members of the committee participate in the inspections. The IACUC utilizes the Guide and the Animal Welfare Act as the principal guiding documents in conducting the inspections.

The Office of Research Integrity Assurance creates an inspection itinerary, schedules inspection visits to laboratories and housing areas, escorts the inspection teams, and crafts the written report. Areas inspected include the central animal housing facility and related facilities such as, but not limited to, cage wash, aseptic surgery, procedure areas, necropsy, supplies and inventory storage, controlled substance storage and records, surgical suites, and recovery areas. The OLAW Semi-Annual Inspection Checklist is used as a resource for the inspection. No IACUC member wishing to participate in any review or inspection shall be excluded. The subcommittee may invite ad hoc consultants to assist in the reviews and inspections.

3. Provide Reports to Institutional Official

The Office of Research Integrity Assurance prepares the report of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submits the reports to the Institutional Official/VPR. The IACUC procedures for developing reports and submitting them to the Institutional Official/VPR are as follows:

Upon completion of the semiannual animal program and facilities reviews, the Office of Research Integrity Assurance, with subcommittee input, prepares a written report. The report shall describe Georgia Institute of Technology's adherence to the Guide, PHS Policy, and the Animal Welfare Act. IACUC-approved departures from the Guide, or the PHS Policy shall be identified specifically and reasons for each departure will be stated and reported to the IO for each six month reporting period during which the IACUC-approved departure is in place. Following review of the report by the inspection teams, the report is distributed to all members of the IACUC for their review and discussion at a convened meeting of the committee where a quorum is present. The report must be signed by a majority of the members of the committee. Minority views, if any, are included in the semiannual report to the Institutional Official. The IACUC shall submit the signed semiannual report to the Institutional Official/VPR and shall maintain a copy in the Office of Research Integrity Assurance files. The report shall be made available to USDA, OLAW, and any federal funding agencies upon request.

Deficiencies that are identified during review are categorized as either minor or significant, and they are so described in the written report. A significant deficiency is defined by USDA regulations and PHS Policy as something that is or may be a significant threat to animal health or safety; such deficiencies require immediate attention and resolution. The report shall include a plan and schedule with dates for correction of each program or facility deficiency. The Office of Research Integrity Assurance shall coordinate with the researcher or other responsible party on resolving the deficiency. Resolution may require notification of facilities management
personnel, identification of resources (i.e., funding), and follow-up by the Office of Research Integrity Assurance. These activities are reported to the IACUC at the next meeting.

Any failure to adhere to the plan and correction schedule that results in a significant deficiency remaining uncorrected shall be reported by the IACUC through the Institutional Official/VPR within 15 days, in writing and as appropriate, to the Animal and Plant Health Inspection Service (APHIS) and to the Office of Laboratory Animal Welfare. The Executive Vice President for Research shall be notified. If the activity is federally funded, the relevant agency shall also be informed.

4. Review of Concerns involving Use of Animals

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

Anyone with a concern about any aspect of animal care and use at Georgia Institute of Technology or who wants to express a complaint about how animals are being treated is encouraged to contact the Institutional Official/VPR, the IACUC Chair, any IACUC member, Research Associate, or the Associate or Executive Director of Research Integrity Assurance. Concerns may also be emailed to iacuc@gatech.edu. Detailed contact information and instructions for raising concerns are provided at http://www.researchintegrity.gatech.edu/. This information is also prominently posted in the central animal facility. The IACUC and Office of Research Integrity Assurance investigate any animal care and use concern, even if submitted anonymously. No adverse action will be taken against anyone making a good-faith report. No Institute employee, committee member, student, or other person shall be discriminated against or be subject to any reprisal for reporting, in good faith, concerns or violations of regulations or standards under the Animal Welfare Act. Persons with no formal relationship with the Georgia Institute of Technology are also encouraged to register their concerns, also without fear of reprisal or future discrimination.

The IACUC Chair, Attending Veterinarian, Research Associate, and/or Associate or Executive Director will meet with the individual(s) against whom a complaint or concern is lodged. The purpose of this discussion is to allow the researcher an opportunity to respond to the claim and to clarify any misunderstanding. If the claim is found to have merit, the IACUC Chair may further investigate and/or appoint other committee members to do so. The Office of Research Integrity Assurance participates in the fact-finding, to facilitate documentation and to ensure that the rights and reputation of the accused individuals are protected.

Such complaints and concerns are communicated immediately to the Institutional Official/VPR by the IACUC Chair, Attending Veterinarian, or Office of Research Integrity Assurance. Any suspension of an activity involving animals shall be immediately reported by the Institutional Official/VPR (or, in her absence, by the Office of Research Integrity Assurance) to the Office of Laboratory Animal Welfare and, as appropriate, to APHIS and the federal agency funding the activity. In every case the Office of Research Integrity Assurance maintains a record of the concern, the investigator, resulting recommendation and resolution, and the reports to the Institutional Official/VPR and to appropriate federal agencies.

5. Make Written Recommendations to Institutional Official
The IACUC will make written recommendations to the Institutional Official/VPR regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official/VPR are as follows:

The Institutional Official/VPR routinely attends meetings of the Institutional Animal Care and Use Committee and is well informed regarding committee activities. Recommendations are presented and deliberated during committee meetings, and the Institutional Official/VPR participates in such discussions. When a formal action is addressed, a motion is made and seconded, and then the majority vote rules. The IO is informed by the Office of Research Integrity Assurance, which provides meeting minutes; her attention is drawn to items of concern. The IACUC also utilizes the Semiannual Report to the IO for formally communicating recommendations; this document is signed by a majority of committee members.

6. Process for IACUC to Review, Approve, Require Modifications for Protocol Approval

In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals.

a. Principal Investigator Prepares and Submits protocol

1) Protocol Application: The protocol form must be fully completed and contain the required attachments. The form is in Word and is available on the Office of Research Integrity Assurance webpage at http://www.researchintegrity.gatech.edu.

2) Statement of Work or Project Description: A copy of the funding proposal or final grant pages sent to the funding agency must be attached for funded studies. Federal regulations require the IACUC to compare the protocol to the funding proposal Statement of Work or Project Description. Substantive differences must be satisfactorily addressed prior to IACUC approval. Occasionally, a large Program or Center grant to a single Principal Investigator will fund multiple faculty members' activities. In these cases, when the Program/Center grant PI is not also a member of the research team on animal protocols that the grant funds, the IACUC accepts protocols from Principal Investigators who are not PI on the supporting Program/Center grant.

3) Required Training: Everyone named on the protocol (including students, lab techs, Visiting Scholars, and others) are required to complete the online training course, "Working with the IACUC" and the other training modules appropriate for the planned work. For example, if the protocol proposes the use of mice or rats, all named personnel must complete "Post-Procedure Care of Mice and Rats in Research: Reducing Pain and Distress" and "Working with Mice (or Rats) in Research Settings."
online training is linked from the ORC website at http://www.researchintegrity.gatech.edu/.

4) **Enroll In Occupational Health Program:** Everyone named on the protocol must enroll in the Georgia Tech Occupational Health Program, managed by Environmental Health & Safety. An opt-out provision is available. Details about the Occupational Health Program are linked from www.researchintegrity.gatech.edu.

5) **Protocol Departmental Sign Off:** The prepared protocol application is to be signed by the applicant's department head or, in lieu of a written signature, department heads may send an email to iacuc@gatech.edu stating that they are aware of the proposed work and concur with its submittal to the IACUC. When the department chair is the Principal Investigator named in the protocol, no other sign-off is required.

6) **Preliminary Protocol Submission:** The protocol application and attachments are to be submitted to the Office of Research Integrity Assurance via email to iacuc@gatech.edu.

7) **Final Protocol Submission:** If protocol modifications are required, the Principal Investigator should revise the protocol in accordance with the veterinary consultation and then submit the revised protocol to the Office of Research Integrity Assurance via email to iacuc@gatech.edu for distribution to the committee.

8) **Other Institutional Review Required:** In cases where other institutional reviews or approvals are required (i.e., Institutional Biosafety Committee, Material Transfer Agreement, Office of Technology Licensing, Radiation Safety Committee), those should be sought in parallel.

**b. Administrative Processing of Protocols**

The Office of Research Integrity Assurance provides administrative support to the Institutional Animal Care & Use Committee. Upon receipt of a protocol application, the office follows this process to facilitate IACUC review (if the submission is an amendment, three-year renewal, or annual continuation application for an existing protocol, virtually the same steps are followed).

1) **Protocol Tracking:** Applications are assigned an IACUC number and logged into a spreadsheet. Amendments and continuing review applications are linked to the relevant protocol and logged into the spreadsheet.

2) **Initial Review:** The application will be given a preliminary review. The Office of Research Integrity Assurance confirms that applications are complete and compares the proposed research procedures to those
described in the funding proposal, if any. Research Integrity Assurance also verifies completion of appropriate educational modules for each named member of the research team. All personnel must be enrolled in the Occupational Health Program; enrollment is verified. Final IACUC approval will be withheld until these requirements are satisfied.

3) **Initial Review:** The application will be given a preliminary review by Veterinary Consultation. If compliant with initial review, the protocol is then forwarded to the Georgia Tech Attending Veterinarian/Director of Animal Resources for veterinary consultation. The Veterinarian will contact the Principal Investigator for discussion, clarification, or additional information. Following veterinary consultation, the protocol will be returned to the Principal Investigator for modifications, if necessary. If none are needed, the protocol will be forwarded by the Veterinarian to the Office of Research Integrity Assurance for distribution to the committee.

4) **Protocol Distribution to Committee:** After the protocol application has undergone administrative and veterinary review and has been revised and resubmitted by the PI, it is distributed to all members of the IACUC. IACUC members must respond within a certain number of days regarding their call for review by the full committee or their recommendation for review under Designated Member Review procedures. When approval is accomplished via Designated Member Review, the IACUC is so informed by the listing of the protocol on the next meeting agenda and in the minutes. If a committee member calls for full committee review, the protocol will be placed on the agenda for that month’s meeting, unless it was received without sufficient lead time. Generally, protocols requiring full committee review should be submitted no later than the first week of the month for review at that month’s meeting.

c. **Committee Review Process**

1) **Full Committee Review at Convened Meeting of Committee:** Except for applications undergoing designated member review procedures, all applications (new protocols, annual continuing review, three-year renewals, and amendments) are considered for approval during regularly scheduled meetings of the full IACUC with a quorum present. Occasionally, the Principal Investigator (PI) will be invited to take questions from the IACUC at a convened meeting. The PI will leave the room during deliberations and vote.
2) **IACUC Meetings:** Institutional Animal Care and Use Committee meetings are conducted in the manner described here.

   a) **Meeting Schedule:** The IACUC generally meets monthly on the third Wednesday of the month, depending on the holiday schedule and whether there are matters to consider. Additional meetings will be called if necessary for the Committee to fulfill its responsibilities.

   b) **Quorum:** A simple majority of the current members of the IACUC constitutes a quorum. A quorum is required at any meeting at which formal action is taken by the IACUC. Any formal action taken by the IACUC (i.e., approval, suspension) must be approved by majority vote at a convened meeting with a quorum of IACUC members. If a quorum is lost at any time during the meeting, no further formal action will be taken until a quorum is attained. Any member who has a conflict of interest in a matter under consideration by the IACUC shall not be counted for establishing a quorum for that portion of the meeting.

   c) **Use of Telecommunications for IACUC Meetings:** Through use of telecommunications (e.g., telephone- or video-conferencing), Georgia Tech’s IACUC may conduct official business without all members physically present, although physically-convened meetings are the norm.

   i) **Criteria for Meeting by Telecommunication:** All members are given advance notice of the meeting; documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting; all absent members must have access to the documents and the technology necessary to fully participate; a quorum of voting members is convened when required by PHS Policy; and the forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate, and there is simultaneous communication). If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. Written minutes of the meeting are maintained in accordance with the PHS Policy.
A mail ballot or individual telephone polling cannot substitute for participation in a convened meeting. Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IACUC members but shall not be counted as votes.

3) **Determinations Made by Majority Vote at Convened Meeting with Quorum:** When full committee review of a protocol is undertaken, a meeting will be held with attendance by a quorum of voting members. Although the committee strives for consensus, majority rule will apply. IACUC determinations, reached by the full committee, shall result in the protocol application (or other action) being assigned to one of the following outcome categories:

   a) **Approval:** The application is approved as presented with no modifications required. The Office of Research Integrity Assurance will issue an IACUC approval letter to the PI. If the project is funded by an external agency, a copy of the approval letter will be provided to the Office of Sponsored Programs (OSP). OSP bears the responsibility for forwarding the IACUC approval information to the sponsor when required. While protocols may be valid for three years, continuing review is required on at least an annual basis, and always at the end of years one and two.

   b) **Request Modifications to Secure Approval:** The IACUC requires additional information or modifications before it can approve the study. 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 Full Committee Review at a convened meeting. If all members of the IACUC are not present at a meeting, the committee may use Designated Member Review subsequent to Full Committee Review according to the following stipulations: The Office of Research Integrity Assurance shall notify the PI in writing, either by email or letter, of the modifications required for approval and will offer the PI an opportunity to discuss the protocol. When circumstances warrant, the Chair, Research Associate, Associate or Executive Director may call the PI to discuss the review. Before IACUC review will continue, the PI must submit a revised application clearly identifying changes from the tabled application. There is no conditional...
approval, provisional approval, or approval pending clarification.

All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use a Designated Member Reviewer subsequent to full committee review 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 review of the protocol.

c) Withhold Approval: The Office of Research Integrity Assurance will notify the PI in writing when an application is disapproved and will provide the basis for the IACUC’s decision. When circumstances warrant, the Chair, Research Associate, Associate or Executive Director may call the PI to discuss the review. If a protocol is disapproved, the PI has the right of appeal to the IACUC. The IACUC may, at its discretion, obtain external review of the application by a PHS-approved IACUC of an equivalent institution and/or by expert consultants in the field of that research. The Georgia Institute of Technology IACUC, however, shall be the final authority in determining the acceptability of the protocol. A disapproval determination by the IACUC may not be overruled by any officer or employee.

4) Protocol Review by Designated Member Review Process:

a) Distribution to All Committee Members: New protocols, annual continuation applications, three-year renewals, and amendments are distributed via email to all members of the IACUC, thus affording all members the opportunity to call for review by the full committee.

b) Designated Member Reviewer Assigned: If no member calls for full committee deliberation, an IACUC member is designated by the Chair to perform the formal review. Designated Member Reviewer assignments are made on a rotational basis as instructed by the Chair who will be copied on all designated review protocol distributions and will reassign reviewers as he deems necessary. In cases where committee members are also investigators on the protocol, the Chair will designate another IACUC member to do the review. When the Chair is absent or is PI or co-PI on the protocol, the Vice-Chair will accomplish or assign the review.
c) Reviewer Determination: The Designated Member Reviewer may approve the protocol outright, require modifications to secure approval or call for full committee review. If a reviewer requires modifications, the PI is given an opportunity to respond and may confer with the reviewer, Attending Veterinarian, or Research Associate. Assuming a satisfactory response is received, the Designated Member Reviewer may approve the application. No individual IACUC member may disapprove a protocol or amendment, but any member may request that the full committee perform a review, which may result in approval being withheld. If Designated Member Review is used, the approval date is the date that the Designated Member Reviewer(s) approve the study. Animal work conducted before this date must be reported to OLAW as a serious noncompliance with the PHS Policy.

d) Communication with Principal Investigator: Designated Member Reviewer approvals are communicated in writing to the applicant by the Office of Research Integrity Assurance, which adds the item to the next IACUC meeting agenda and documents the official records.

7. Proposed changes regarding the use of animals in ongoing activities

Amendments to an existing protocol must be reviewed and approved by the Institutional Animal Care & Use Committee before the changes are implemented. The administrative and committee review process is virtually identical to that for new protocols, described above. Changes made to a protocol may be categorized as one of two types, significant or minor.

a. Significant Changes or Modifications

Significant changes are reviewed either by the full committee at a convened meeting or by the Designated Member Reviewer process. While the Designated Member Reviewer process may be followed for review of some significant changes, the following actions (identified by the Office of Laboratory Animal Welfare as significant) generally require approval by the full committee as described in IACUC Policy Protocol Modification and Approval which includes:

- change in objectives of a study;
- proposals to switch from non-survival to survival surgery;
- change in degree of invasiveness of a procedure or discomfort to an animal;
- change in species or in the approximate number of animals used;
- change in anesthetic agent(s) or in the withholding of analgesics;
- change in methods of euthanasia;
- change in Principal Investigator (PI).
b. Minor Changes or Modifications

Some very minor administrative actions that have no effect on the humane care and use of laboratory animals may be administratively reviewed and approved by the Office of Research Integrity Assurance. These include changes in personnel (other than the PI or co-PI), change in protocol title, and change in funding source. (If the change in funding source includes any additional or different procedures, the amendment shall be distributed to the full committee for consideration). Revisions to an existing protocol do not extend the current approval period.

8. Notifying Investigators of IACUC Determinations

The Office of Research Integrity Assurance, on behalf of the IACUC, will notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

When a determination is made by the IACUC regarding an activity, the Office of Research Integrity Assurance prepares a letter that is sent to the Principal Investigator, with a copy to the IACUC Chair. When circumstances warrant, the Chair, Research Associate, Associate or Executive Director may call the PI to discuss a determination.

A record of such actions is made in the next IACUC meeting's agenda, which is distributed to the Institutional Official/VPR and all IACUC members.

9. Continuing Review

The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

a. Annual Review

All continuing protocols are reviewed by the IACUC at least annually. The purpose of continuing review is to inform the IACUC of the current status of the project; to ensure continued compliance with USDA and institutional requirements; and to provide for reevaluation of the animal activities at appropriate intervals.

As time permits, the Office of Research Integrity Assurance emails expiration reminders to the PI at least two months prior to the protocol anniversary date, requesting timely submission of the Continuing Review/Progress Report form. Regardless of this reminder service, it is the responsibility of the PI to ensure that continuation documents are submitted in sufficient time for review prior to protocol approval expiration. The PI must complete and return the Continuing Review/Progress Report form to the Office of Research Integrity Assurance at least one month prior to expiration.
If the PI fails to timely complete and return the Continuing Review form, IACUC approval expires on the anniversary date, and no further activities can be conducted with animals until the IACUC reinstates the protocol.

In the rare event that a continuing review application documents no animal usage in the past twelve months and no change in the protocol since its most recent approval, the Chair shall have the authority to review and grant continuing approval. In this case, animals must not have been procured, and there can be no proposed deviations from the original protocol. In no case shall such approval extend the protocol past the three year expiration date.

Projects conducted entirely off-campus are also required to undergo continuing review at least annually. The Georgia Tech IACUC will accept as evidence of continuing approval a copy of the approved continuation letter from the Assured off-campus institution.

Federal regulations require that Institutional Animal Care and Use Committee protocols be closed at the end of three years. If the work is to continue beyond the third year, an entirely new protocol—with veterinary consultation—must be submitted for IACUC approval.

b. Three Year Renewal

If a protocol will continue beyond the third year, the PI must submit a complete new application, including a veterinary consultation, to the Office of Research Integrity Assurance prior to the three year anniversary date. The IACUC will conduct a review as for any new application and following the process described herein.

c. Post Approval Monitoring

The Post Approval Monitoring (PAM) program assists the IACUC in its role in monitoring the conduct of animal-based research and, with the cooperation of the Principal Investigator (PI), provides assurance to regulatory agencies and to the IACUC that animal experiments are performed in accordance with federal, state, local and institutional guidelines. The Office of Research Integrity Assurance or IACUC Member conducts reviews of active, approved protocols. Protocols may be selected at random, by area, category or for cause monitoring at any time. Elements of the Post Approval Monitoring program include:

1) Consistency between Funding Proposal and IACUC Protocol: An IACUC protocol application, if externally funded, i.e. sponsored research, must be consistent with the proposal submitted to the sponsoring agency. Several mechanisms are in place to ensure consistency between the various documents. Prior to processing sponsored awards, Sponsored Programs Contracting Officers are required to confirm with the Office of Research Integrity Assurance that IACUC approval has been obtained. While researchers may request a deferral of IACUC approval at the time of proposal submission, IACUC review and approval must be obtained prior to release of funds and initiation of work involving
animals. The IACUC protocol application requires that the PI certify that the information provided therein is consistent with the information on the corresponding funding proposal, and the Research Associate compares protocol applications with funding proposals during the initial and amendment review process. Any differences are reconciled prior to the approval of the protocol.

2) The Post Approval Monitoring Visit: Post approval monitoring is conducted by a PAM liaison - an IACUC member or Office of Research Integrity Assurance team member sufficiently trained and knowledgeable with regard to regulations and the protocol to easily evaluate the consistency between the procedures described in the protocol and those conducted in the laboratory. The PAM liaison schedules a post approval monitoring visit with the Principal Investigator and describes what to expect during the visit. The PAM liaison will respect the research environment and will not interfere with the conduct of any procedures. The PAM liaison shall wear the personal protection equipment prescribed for the specific activity or laboratory. The PAM liaison will work with the PI and laboratory staff, observe research activity, prepare accurate reports, provide recommendations for maintaining compliance, and provide training opportunities. The PAM liaison shall use the Protocol Post Approval Monitoring Checklist for the routine post process protocol reviews and will provide written documentation of the status of the post approval monitoring process to the PI and to the IACUC. During each post approval monitoring session, the PAM liaison will compare procedures conducted in the laboratory with those listed in the approved protocol and any approved amendments. Documented differences between the procedures performed in the lab and those listed in the protocol will be brought to the attention of the Principal Investigator.

3) Sharing Information about the Review: The PAM liaison shall discuss monitoring results with the Principal Investigator and/or other lab personnel before leaving the laboratory as part of the exit interview. If the Principal Investigator is unavailable, the PAM liaison will arrange to meet with the Principal Investigator to discuss results at another time. While Post Approval Monitoring visits are not policing activities, issues that pose an immediate threat to animal welfare shall be referred to the Attending Veterinarian for immediate resolution. Issues that pose an immediate threat to human safety shall be referred to Environmental Health and Safety. The PAM liaison will prepare a written report of the monitoring results which will be reviewed internally by the Office of Research Integrity Assurance. A final copy of the monitoring results will be sent to the Principal Investigator, IACUC Chair, Institutional Official/VPR, and Attending Veterinarian. A copy of the report will be made available to the IACUC at the
next meeting, and the meeting minutes will reflect the discussion of the results of the Post Approval Monitoring. The Principal Investigator will have an opportunity to respond to the report in writing and/or at the IACUC meeting.

4) Post Approval Monitoring Follow-Up: In most cases, issues can be readily and satisfactorily addressed by amending an existing protocol, or reverting to the procedures which are already listed in the approved protocol. The Office of Research Integrity Assurance will follow up on any issues that require protocol modifications, orientation of new personnel, or training. The Office of Research Integrity Assurance will support the laboratory corrective action by facilitating access to the required training and/or providing guidance for the revision of the protocol to bring it into current compliance. On occasion, additional monitoring sessions may be part of the follow-up to assist with proper corrective actions.

5) Post Approval Monitoring Appeal Process: Investigators who disagree with post approval monitoring results and/or recommendations may appeal to the IACUC.

10. Procedures Used to Suspend an Activity Involving Animals

The Institutional Animal Care & Use Committee is authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend a protocol at any time if it determines that the activity is not being conducted in accordance with the protocol approved by the IACUC or not in accordance with guidance from the AWA, PHS Policy, the Guide, or Georgia Institute of Technology’s Assurance or policies. Suspension of a protocol requires a majority vote taken at a convened IACUC meeting with a quorum of members attending. To ensure a swift and appropriate committee response, such called meetings may be held by teleconference.

If a called meeting is to be conducted by teleconference, all members are given advance notice of the meeting; documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting; all absent members must have access to the documents and the technology necessary to fully participate; a quorum of voting members is convened when required by PHS Policy; and the forum allows for real-time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate, and there is simultaneous communication). If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. Written minutes of the meeting are maintained in accordance with the PHS Policy IV.E.1.b.

If the IACUC suspends a previously approved activity, the Institutional Official in consultation with the IACUC shall review the reasons for the suspensions, take appropriate corrective action, and report that action with a full explanation to OLAW. The Institutional Official/VPR or, in her absence, the Office of Research Integrity Assurance will notify the Office of Laboratory Animal Welfare (OLAW) immediately.
by telephone or email. The Office of Research Integrity Assurance will then prepare for the Institutional Official/VPR's signature a written notification to OLAW and any other appropriate federal agency.

The Attending Veterinarian is authorized to temporarily halt a protocol on an emergency basis if she reasonably believes that the protocol activities do not follow the Guide, Animal Welfare Act, PHS Policy, or Georgia Institute of Technology's Assurance or policies. The Attending Veterinarian is authorized to confiscate animals, remove them from the control of the Principal Investigator, treat the animals, and/or euthanize them, pending an inquiry or investigation.

Any such temporary halt will immediately be reported to the Institutional Official/VPR, other IACUC members, and the Office of Research Integrity Assurance and will be the subject of a called meeting with a quorum of committee members. The IACUC may, in a convened meeting with quorum, additionally impose a period of restriction for some or all of an individual's ability to use animals until it is clear that the personnel and procedures have been brought into compliance with federal and institute policies and guidance. The individuals involved may be subject to further disciplinary action by this institution. The IACUC shall oversee or monitor the areas and/or activities that are under suspension or are restricted, in the event that the entire protocol is not under suspension. Such oversight or monitoring may be accomplished by the Attending Veterinarian or a member of the IACUC and shall be reported in writing to the IACUC.

E. OCCUPATIONAL HEALTH PROGRAM

1. Description of Occupational Health Program

The Georgia Institute of Technology is committed to providing a safe, secure and healthy environment for all faculty, staff, students, and visitors. Any employee who, based on job function and risk assessment, may be exposed to occupational health risks, may participate in the Occupational Health Program, which is administered by Environmental Health & Safety (EHS) in collaboration with an off-campus healthcare organization. Students not employed by Georgia Tech but who encounter health risks due to their academic or research activities are also eligible to participate.

The program focuses on occupations involving exposure to animals and those who handle biological materials or chemicals or are exposed to other health risks. The program facilitates awareness of, and appreciation for, safe conduct of work and research activities so that accidents and occupational injuries and illnesses will be minimized. EHS shall identify and control, to the extent possible, any safety, public health, and environmental hazards presented by work and research activities. Risk assessments are conducted by trained personnel from EHS and, when indicated, medical surveillance and certain immunizations such as tetanus or hepatitis B are provided by the off-campus healthcare organization.

2. Enrollment Required for Certain Employees and Students

All faculty and staff (including stipend students) who are, or will be, working with animals are required to enroll in the Occupational Health Program. Medical monitoring is not mandatory, but all persons identified by EHS whose work responsibilities or academic research environment may subject them to occupational illness or injury are required to be enrolled in the Occupational Health Program. All persons in such positions are required to complete the Confidential Exposure/Risk Assessment Questionnaire and attend a training session. Training includes a
discussion of zoonoses, allergies and other hazards. When indicated, personnel may meet with an Occupational Health physician to discuss additional precautions that may arise due to pregnancy, illness, or decreased immunocompetence.

Georgia Institute of Technology does not own or house non-human primates. Those personnel who will work with non-human primates at another site must enroll in that site’s Occupational Health Program and complete that site’s training; accomplishment of these requirements shall be documented in writing to the Georgia Tech IACUC. If required immunizations are not provided by the other site to Georgia Tech personnel, they should consult Georgia Tech’s Occupational Health Program to arrange for such immunizations.

In the event of animal bites, scratches, or other injury, personnel will be offered treatment by the Occupational Health Program’s healthcare provider. All such events must be reported as soon as practicable to the supervisor. If medical attention is required, the injury must be reported by the supervisor to the State of Georgia Department of Administrative Services (http://ohr.gatech.edu/Workers%20Comp) and to the Georgia Tech Occupational Health Program.

Enrollment in the Occupational Health Program is provided at no cost to the participant. Through communication with Environmental Health and Safety, the Office of Research Integrity Assurance will verify enrollment of all personnel named in IACUC protocols. No personally identifiable health information will be accessed by Research Integrity Assurance or anyone else at Georgia Tech.

3. Opting Out or Declining Participation

After completing the enrollment process through Environmental Health & Safety, individuals may elect to opt out or decline the medical surveillance portion of the program by signing a Waiver of Medical Screening form. The requirement to complete the enrollment process prior to declination is to ensure that employees are fully informed about risks associated with their work activities and with the consequences of declining medical surveillance. Those who opt out of the medical monitoring component, or portions thereof, must submit a signed waiver form to EHS.

4. Point of Contact for Occupational Health Program

The Office of Environmental Health and Safety is Georgia Tech’s primary contact for the Occupational Health Program.

F. FACILITIES AND SPECIES INVENTORY

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

G. TRAINING AVAILABLE TO SCIENTISTS, ANIMAL TECHNICIANS, AND OTHER PERSONNEL INVOLVED IN ANIMAL CARE, TREATMENT, OR USE

The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is listed below. In addition, Principal Investigators are responsible for providing adequate and appropriate training to research team members, including students, co-PIs, lab techs, and others.

1. Training by Veterinarian and Animal Facility Manager
The Attending Veterinarian is the Principal Investigator on a training protocol and
provides individual, hands-on instruction on animal handling; manipulations;
injections; anesthesia; euthanasia; aseptic surgical technique; collection of blood,
urine and feces; intubation and ventilation; perfusion; catheterization and
gonadectomy. Other topics include the minimization of numbers of animals required
for valid results and methods to minimize animal pain and distress. The central
animal facility manager instructs animal care staff and students in many of these
techniques and in other specialized procedures, as needed.

2. Online Module Completion Required

Everyone named on a protocol—including students, lab techs, visiting scholars, and
others—is required to complete the online training course, “Working with the IACUC”
and the other training modules appropriate for the planned work. For example, if the
protocol proposes the use of mice or rats, all named personnel must complete “Post-
Procedure Care of Mice and Rats in Research: Reducing Pain and Distress” and
“Working with Mice (or Rats) in Research Settings.” Modules are available through a
link on the Office of Research Integrity Assurance website at http://www.
researchintegrity.gatech.edu. Module completion is verified by the Research
Associate for all personnel proposing to work with animals, at the time of protocol
application, continuing review, and when new personnel, including students, are
added to the protocol.

3. Graduate Level Special Topics Course

A graduate level special topics course, “Living System Modeling and Analysts,” is
available for graduate students. This course contains specific lectures on alternatives,
selection of animal models, use of power analysis to determine the minimum number
of animals needed for a study, experimental design, laws and regulations, safety,
anesthesia and analgesia, euthanasia, aseptic surgical methodology and pre- and post-
procedural care. It includes five hands-on laboratory sessions.


Through a partnership with Zoo Atlanta, Georgia Tech students enrolled in the
Schools of Biology and Psychology offer “Student for-credit coursework.” Student for-
credit coursework shall mean any project, work, observations or studies conducted at
Zoo Atlanta by Georgia Tech students obtaining course credit. This includes, but is
not limited to, PSYC 3031 - Experimental Analysis of Behavior, BIO 2802 Internship at
Zoo Atlanta, or BIO 4590 Research Project Lab: Wildlife Conservation at Zoo Atlanta.
The GT PI is responsible for obtaining IACUC approval as noted above.

5. Training Required for Non-Georgia Tech Personnel

Visiting Scholars and others not employed by or enrolled at Georgia Tech, but
participating in animal projects in Georgia Tech facilities, must also complete the
required training modules. In cases where activities are funded through Georgia
Tech, but performed in a non-Georgia Tech host institution, all named personnel,
including non-Georgia Tech personnel employed at/enrolled at the host institution,
must either complete the online modules or present documentation of having
completed equivalent training through their home institution.

6. Frequency of Retraining
To ensure continuous education, all participants with a training requirement described above must complete retraining every 3 years. The continuing education can be met by completing any one of the following:

- Retaking of CITI training course, “Working with the IACUC” and the other CITI training modules appropriate for the planned work as previously described.
- Attending an “IACUC Training Refresher” hosted through the Office of Research Integrity Assurance. The IACUC Training Refresher will be held in the Spring and Fall of each year and dates/times are available on the OSP Training page at: http://training.osp.gatech.edu.
- Completion of “Living System Modeling and Analysis” with Attending Veterinarian Dr. Laura O’Farrell is available for Graduate Students.
- Attend professional IACUC training or IACUC related education meetings via AALAS, AWIC, PRIM&R, ALCAM.

Note: Documentation of completion of training requirement (other than CITI modules) should be provided by the individual to iacuc@gatech.edu via email.

**IV. INSTITUTIONAL PROGRAM EVALUATION & ACCREDITATION**

All of this Institution’s programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution’s adherence to the Guide. Any departures from PHS policy and the Guide will be identified specifically, and reasons for each departure will be stated. Reports will note and 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/VPR. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the 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. RECORDKEEPING REQUIREMENTS**

**A. Records Maintained at Least Three Years**

This Institution will maintain for at least three years:
- A copy of this Assurance and any modifications thereto, as approved by the PHS.
- Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
- Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
- Records of semiannual IACUC reports and recommendations (including minority views) forwarded to the Institutional Official/VPR.
- Records of accrediting body determinations.

**B. Additional Records Maintenance**
This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. Availability of Records for Inspection and Copying

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. Institution’s Reporting Period

This Institution’s reporting period is January 1 – December 31. The IACUC, through the Institutional Official/VPR, will submit an annual report to OLAW on January 31 of each year. The report will include:

1. Any change in the accreditation status of the Institution (e.g.: if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution’s program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution’s program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Jilda Diehl Garton, Institutional Official/VPR. Semiannual reports to the Institutional Official shall include any minority views filed by members of the IACUC.

B. Reporting Noncompliance, Serious Deviations, and Suspension of Activities

The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- Any serious or continuing noncompliance with the PHS Policy.
- Any serious deviations from the provisions of the Guide.
- Any suspension of an activity by the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Jilda Diehl Garton
Title: Vice President for Research
Name of Institution: Georgia Institute of Technology
Address: Research Administration Building
505 Tenth Street, NW
Atlanta, GA 30318
Phone: 404-894-4819
Fax: 404-385-2078
E-mail: jilda.garton@gtrc.gatech.edu
Signature: [Signature]
Date: October 1, 2012

B. PHS Approving Official

Name: Dr. Venita B. Thornton, D.V.M., M.P.H.
Title: Office of Laboratory Animal Welfare (OLAW)
National Institute of Health
Address: 6705 Rockledge Drive
RKL1, Suite 360- MSC 7982
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Phone: (301) 469-7161 Fax: (301) 915-9473
Fax: [Fax]
E-mail: thorntov@od.nih.gov
Signature: [Signature]
Date: Oct. 4, 2012

C. Effective Date of Assurance: Oct. 4, 2012

D. Expiration Date of Assurance: Sept. 30, 2016