

**GEORGIA INSTITUTE OF TECHNOLOGY  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE  
POLICIES AND PROCEDURES**

**March 2017**



## Policies & Procedures Revisions and Updates

- March 2017
  - Update links within document.
- March 2016
  - Revises annual renewal and progress report to lessen administrative burden on PIs and their staff
  - Umbrella forms no longer in use. All funds to be treated the same and added to protocols receiving funding through the amendment process
- July 2015
  - Assigning reviewers
  - Closeout reports removed
- August 2014
  - Update form links
  - Clarify requirements for Umbrella form usage
- July 2013
  - Deletes incorrect statement about required training for non-Georgia Tech personnel from VII. “REQUIRED TRAINING FOR RESEARCH PERSONNEL”
- June 2013
  - Updated the Compliance Officer position to Research Associate
  - Corrected links for the Office of Research Integrity Assurance
- December 2012
  - Updated eligibility requirements for Principal Investigator
- June 2012
  - Updated the Office of Research Compliance to the Office of Research Integrity Assurance
  - Added page numbers to Table of Contents
- April 2012:
  - Updated Training Requirements for individuals working with vertebrate animals. Add Section Number.
  - Updated Post Approval Monitoring. Add Section Number
  - Updated Agreements with Other Institutions. Add Section Number
  - Updates title of Vice President for Research/Institutional Official throughout
- March 2012:
  - Clarifies Occupational Health and Safety for visitors.
  - Update Procedures for Applying for IACUC Approval as it relates to visitors.
- January 2012:
  - Clarifies eligibility for title of Principal Investigator. IV.
- November 2011:

- Reduces protocol application requirements for researchers conducting vertebrate animal research at off-campus sites. V.B.
- Updates eligibility for title of Principal Investigator. IV.
- October 2011:
  - Adds Cooperative Agreement with St. Joseph’s Translational Research Institute for deferral of IACUC review. V.C.2.
- July 2011:
  - Updates animal procurement process to require that the protocol application indicate whether personnel are authorized to place animal orders. Authorization to procure animals must also be indicated when adding personnel by amendment. VIII.
  - Updates title of Associate Vice President for Research to Vice President for Research throughout policies and procedures
- April 2011:
  - Establishing process for handling extraordinary calls for full committee review. VI.C.
- March 2011:
  - Clarification of guidance on use of embryonic eggs, Appendix C.
  - Update to add title of Associate Director of Research Integrity Assurance throughout policies and procedures
- August 2010: Revisions include:
  - Clarification of how visitors and volunteers are cleared to participate in animal research at Georgia Tech. Removes references to “affiliates.” IV.F.
  - Updates titles of Assistant Vice President for Research to Associate Vice President for Research and other institutional officials throughout document.
  - Clarification of whether IACUC review is required for use of by-products such as discarded tissues or carcasses. Appendix B.
  - Addition of “Expectations of IACUC Members.” III.C.2.
- October 2009: Adds “Access to PRL.” Appendix J.
- January 2009: Revises Designated Member Reviewer process, following determination by full committee that substantive modifications are required for approval. VI.B.2.
- October 2008: Adds “Prohibition Against Pets In Animal Research Laboratories and Animal Housing Facilities.” Appendix I.
- July 2008: CITI modules replace LATA for required IACUC training; Occupational Health Program announced; exceptions to training and Occupational Health Program requirements; Post Approval Monitoring undertaken; umbrella form clarified; reorganization and general updates to policies & procedures.
- March 2008: Further clarification of designated review process, describing the procedure for assigning designated reviewers.
- November 2007: Clarifications regarding process of activities requiring IACUC approval.
- September 2007: Policy Update: Procurement of Vertebrate Animals.
- June 2007: Exception for Role of Principal Investigator for Georgia Tech Students Named on Emory Protocols and Those Receiving Fellowship Funds in Certain Circumstances. Adds IV.B.1. and IV.B.2.

- June 2007: Numerous minor corrections, clarifications, and updates. Renumbering of policies.
- January 2007: Adds Umbrella Notification form to facilitate tracking of multiple faculty members' activities under separate animal protocols (or sub-studies) funded by a large Program or Center grant ("umbrella") to a single Principal Investigator.
- October 2006: Adds clarifying language regarding training requirements for non-Georgia Tech personnel.
- September 2006: Revisions include:
  - Clarification of procedure for animal procurement and approved animal vendors.
  - Clarification of categories of biomedical research.
  - Clarification of roles and responsibilities.
  - Release of Policy on Adoption of Animals Used in Research and Teaching,
- March 2006: Clarification of procedure for revisions made to existing protocols.
- November 2005: Clarifications: Meeting dates, Pain classifications sections, Procedures for Applying for IACUC Approval, Protocol Review Criteria.
- July 2005: Several revisions:
  - Clarifies regulatory authorities governing animal use.
  - Adds information regarding activities involving study of vertebrate animals in their natural habitat.
  - Adds language regarding activities involving the study of animals in zoos, petting zoos, wild animal parks, or similar habitats.
- March 2005: Clarification of procedure for designated review to clarify that Chair appoints IACUC members to conduct designated review if full-committee review is not called.
- November 2004: Clarification of procedure to secure continuing approval for projects conducted entirely off campus.
- September 2004: Deletion of requirement for signature on application form from PRL when animals to be housed there.
- July 2004: Release of the Occupational Health & Safety Program document, with requirement for enrollment by everyone named on a protocol.
- June 2004: Revised form to be utilized as Annual/Final progress report & continuation application.
- May 2004: Office of Laboratory Animal Welfare (OLAW) approves Georgia Tech's continuing Assurance for another five years, expiring February 28, 2009.
- May 2004: Non-Georgia Tech Personnel Participating in Protocols at Georgia Tech. Sets forth requirements for non-Georgia Tech personnel to participate in Georgia Tech Protocols.
- May 2004: Procurement of Laboratory Animals consolidated into GTRC/Office of Research Integrity Assurance.
- April 2004: Eligibility for status of PI established in accordance with campus policy.

**GEORGIA INSTITUTE OF TECHNOLOGY  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

**POLICIES AND PROCEDURES**

Table of Contents

<b>I. OUR MISSION AND ASSURANCE</b>	<b>11</b>
<b>II. REGULATORY AUTHORITIES GOVERNING ANIMAL USE</b>	<b>12</b>
<b>A. U.S. Department of Agriculture (USDA)</b>	<b>12</b>
<b>B. Public Health Service (PHS), National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW)</b>	<b>12</b>
<b>III. ADMINISTRATIVE ORGANIZATION OF GEORGIA INSTITUTE OF TECHNOLOGY'S ANIMAL CARE AND USE PROGRAM</b>	<b>13</b>
<b>A. Institutional Official</b>	<b>13</b>
<b>B. Institutional Attending Veterinarian</b>	<b>13</b>
<b>C. Institutional Animal Care and Use Committee (IACUC)</b>	<b>13</b>
1. IACUC Membership	13
a) Alternate Members	14
2. Expectations of IACUC Members	14
a) Education Provided for IACUC Members	14
b) Attendance at Committee Meetings	14
c) Serving As Primary or Secondary Protocol Reviewer or As Designated Reviewer	15
d) Participation in Semiannual Program Reviews and Facilities Inspections	15
e) Member and Alternate Member Conflicts of Interest	15
f) Confidentiality	15
g) Failure to Meet Membership Expectations	16
3. Meeting and Quorum Requirements	16
a) IACUC Meetings	16
b) Use of Telecommunications for IACUC Meetings	16
c) Quorum Defined	16
<b>D. Office of Research Integrity Assurance</b>	<b>17</b>
1. Committee Support	17
2. Semiannual Self-Evaluations of the Animal Care and Use Program and Facilities at Georgia Institute of Technology	17
a) Review of the Animal Care and Use Program	17
b) Review and Inspection of Animal Facilities	17
3. Federally Required Reports	18
a) USDA Registration and PHS Assurance	18
b) Annual and Semiannual Reports	18
i. USDA	18

ii. PHS, NIH Office of Laboratory Animal Welfare	18
iii. Semiannual Reports to the Institutional Official	18
iv. Other Reporting Requirements	19
4. Record Keeping	19
<b>IV. PRINCIPAL INVESTIGATOR ELIGIBILITY REQUIREMENTS</b>	<b>20</b>
<b>A. Eligibility for Title of Principal Investigator</b>	<b>20</b>
<b>B. Exceptions Requiring Approval by Executive Vice President for Research</b>	<b>20</b>
<b>C. Graduate and Undergraduate Student Research Projects</b>	<b>20</b>
1. Exception for Georgia Tech Students Receiving Stipends and Tuition in Support of Their Work on Emory Protocols	20
2. Exception for Georgia Tech Students Receiving Fellowships Supporting Their Work on Emory IACUC Protocols	21
<b>D. Non-Georgia Tech Personnel Participating in Protocols at Georgia Tech (Visitors and Volunteers)</b>	<b>21</b>
<b>E. Definitions</b>	<b>22</b>
1. Principal Investigator	22
2. Co-Principal Investigator	22
3. Co-Investigator	22
<b>V. WHEN AND HOW PRINCIPAL INVESTIGATORS SHOULD SECURE IACUC APPROVAL</b>	<b>23</b>
<b>A. Activities Requiring IACUC Approval</b>	<b>23</b>
<b>B. Off-Campus Activities Requiring IACUC Approval</b>	<b>23</b>
1. Georgia Tech Personnel Working at Off-Campus Site with PHS-Approved IACUC	23
2. Non-Georgia Tech Personnel Working at Off-Campus Site with PHS-Approved IACUC	23
3. Georgia Tech Personnel Working at Off-Campus Site with No PHS-Approved IACUC	23
<b>C. Agreements with Other PHS-Assured IACUCs</b>	<b>23</b>
1. Emory University and Georgia Institute of Technology	24
2. St. Joseph’s Translational Research Institute, Inc. and Georgia Institute of Technology	24
<b>D. Activities Involving the Study of Animals in Zoos, Petting Zoos, Wild Animal Park, or Similar Habitats</b>	<b>25</b>
1. Collaborative Research Agreement between Zoo Atlanta and Georgia Tech	25
<b>E. Activities Involving the Study of Vertebrate Animals in Their Natural Habitat (“Field Studies”)</b>	<b>26</b>
1. Field Activities Exempt under USDA Regulations	26
2. Field Activities Not Exempt under PHS Regulations	26
3. Field Studies involving Capture and/or Invasive Measures	26
4. IACUC Inspection Required for Certain Facilities	26
<b>F. Procedures for Applying for IACUC Approval</b>	<b>26</b>
1. NEW PROTOCOL APPLICATION	27

2.	ATTACHMENT: SOW or PD	27
3.	REQUIRED TRAINING	27
4.	ENROLL IN OCCUPATIONAL HEALTH PROGRAM	27
5.	DEPARTMENTAL SIGN OFF	27
6.	PRELIMINARY PROTOCOL SUBMISSION	27
7.	INITIAL REVIEW PROCESS	27
8.	FINAL PROTOCOL SUBMISSION	28
9.	COMMITTEE REVIEW	28
<b>G.</b>	<b>Protocol Amendments</b>	<b>28</b>
<b>H.</b>	<b>IACUC Forms</b>	<b>28</b>
1.	Protocol Application for Animal Use	28
2.	Protocol Amendments	28
3.	Program or Center Grants	27
<b>I.</b>	<b>Categories of Biomedical Research</b>	<b>29</b>
1.	Category A: No Direct Contact with Live Animals	29
2.	Category B: No Research, Testing or Teaching Procedures Are Performed	29
3.	Category C: Non-Painful/Non-Stressful	29
4.	Category D: Painful/Stressful WITH Analgesia / Anesthesia / Tranquilizers	29
5.	Category E: Painful/Stressful WITHOUT Pain and Stress Relieving Measures	29
<b>J.</b>	<b>Protocol Review Criteria</b>	<b>29</b>
1.	Potential Value of the Study.	29
2.	Selection of Vertebrate Animal Species.	30
3.	Justification of Animal Numbers.	30
4.	Minimization of Pain/Distress.	30
5.	Alternatives	30
6.	Duplication	30
7.	Living Conditions/Housing	30
8.	Personnel	30
9.	Surgery	31
10.	Euthanasia	31
11.	Adoption as Alternative to Euthanasia	31
<b>VI.</b>	<b>ADMINISTRATIVE AND COMMITTEE REVIEW OF THE PROTOCOL OR AMENDMENT APPLICATION</b>	<b>32</b>
<b>A.</b>	<b>Administrative Processing</b>	<b>32</b>
<b>B.</b>	<b>Committee Review Process</b>	<b>32</b>
1.	Full Committee Review at a Convened Meeting	32
a)	Protocol Approved	32
b)	Protocol Returned for Modifications	33
c)	Protocol Disapproved	33
2.	Designated Member Review When Full Committee Review Is Not Called	33
a)	Designated Member Reviewer Assignments	34
3.	Revisions to an Existing Protocol (Amendments)	34
4.	Annual Continuing Review	35
5.	Three Year Renewal	35
<b>C.</b>	<b>Process for Handling Extraordinary Calls for Full Committee Review</b>	<b>35</b>



<b>VII. REQUIRED TRAINING FOR RESEARCH PERSONNEL</b>	<b>36</b>
<b>A. Required Training for All Research Personnel Named on Animal Protocols</b>	<b>36</b>
1. Training for Non-Georgia Tech Personnel	36
2. Exception to Training Requirement	36
3. Frequency of Retraining	36
<b>B. Graduate Level Special Topics Course</b>	<b>37</b>
<b>VIII. PROCUREMENT OF VERTEBRATE ANIMALS</b>	<b>38</b>
<b>IX. POST APPROVAL MONITORING</b>	<b>40</b>
<b>A. Post Approval Monitoring is an Important Part of Program Oversight</b>	<b>40</b>
<b>B. Consistency between Funding Proposal and IACUC Protocol</b>	<b>40</b>
<b>C. The Post Approval Monitoring Visit</b>	<b>40</b>
<b>D. Description of Possible Discrepancies</b>	<b>41</b>
<b>E. Sharing Information Concerning the Review</b>	<b>41</b>
<b>F. Post Approval Monitoring Follow-up</b>	<b>42</b>
<b>G. Appeal Process</b>	<b>42</b>
<b>H. Recordkeeping</b>	<b>42</b>
<b>X. OCCUPATIONAL HEALTH PROGRAM</b>	<b>43</b>
<b>A. Description of Occupational Health Program</b>	<b>43</b>
<b>B. Enrollment Required for Certain Employees and Students</b>	<b>43</b>
1. Opting Out or Declining Participation	43
2. Exception to Requirement to Participate in Occupational Health Program	43
<b>C. Point of Contact for Occupational Health Program</b>	<b>43</b>
<b>XI. ADOPTION OF ANIMALS USED IN RESEARCH AND TEACHING</b>	<b>44</b>
<b>A. Suitability of Specific Animals for Adoption</b>	<b>44</b>
<b>B. Responsibility for Costs Associated with Adoption of an Animal</b>	<b>44</b>
<b>C. Adoption Procedure</b>	<b>44</b>
1. IACUC Must Approve Adoption as Disposition	44
2. Assessment of the Animal's Health and Suitability for Adoption	44
3. Terms and Conditions of Adoption	45

<b>XII. REVIEW AND INVESTIGATION OF NONCOMPLIANCE</b>	<b>46</b>
<b>A. Reporting Concerns about Animal Care and Use</b>	<b>46</b>
<b>B. Noncompliance with the Approved Protocol, and/or Institute Policies, the Animal Welfare Act, PHS Policy, the <i>Guide</i>, or Georgia Tech’s Assurance</b>	<b>46</b>
<b>C. Examples of Noncompliance</b>	<b>46</b>
<b>D. Procedure to Be Followed in Cases of Alleged or Apparent Noncompliance</b>	<b>47</b>
1. The Process of Inquiry	47
a) Inquiry Defined	47
b) Procedures to Be Followed When Conducting an Inquiry	47
c) Notification of Governing Authorities	48
2. The Process of Investigation	48
a) Investigation Defined	48
b) Procedures to Be Followed When Conducting an Investigation	48
c) Notification of Governing Authorities	48
3. Possible Consequences of a Finding of Noncompliance	48
4. Steps for Reinstatement of a Protocol	49
5. The Appeal Process	49
<b>APPENDICES</b>	<b>51</b>
<b>APPENDIX A: IACUC FORMS</b>	<b>52</b>
<b>APPENDIX B: USE OF BY-PRODUCTS SUCH AS DISCARDED TISSUES OR CARCASSES</b>	<b>53</b>
<b>APPENDIX C: USE OF EMBRYONIC EGGS</b>	<b>54</b>
<b>APPENDIX D: ANIMAL CENSUS: COUNTING PUPS</b>	<b>55</b>
<b>APPENDIX E: MULTIPLE SURVIVAL SURGERIES</b>	<b>56</b>
<b>APPENDIX F: USE OF VERTEBRATE ANIMALS SOLELY FOR INSTRUCTIONAL PURPOSES</b>	<b>57</b>
<b>APPENDIX G: ADOPTION OF LABORATORY RESEARCH ANIMAL RELEASE AND WAIVER FORM</b>	<b>58</b>
<b>APPENDIX H: PROTOCOL POST APPROVAL MONITORING CHECKLIST</b>	<b>59</b>
<b>APPENDIX I: PROHIBITION AGAINST PETS IN ANIMAL RESEARCH LABORATORIES AND ANIMAL HOUSING FACILITIES</b>	<b>61</b>
<b>APPENDIX J: ACCESS TO THE PRL ANIMAL FACILITY</b>	<b>62</b>

# GEORGIA INSTITUTE OF TECHNOLOGY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POLICIES AND PROCEDURES

## I. OUR MISSION AND ASSURANCE

The Georgia Institute of Technology's Institutional Animal Care and Use Committee ([IACUC](#)) is dedicated to the humane care and use of vertebrate animals in activities related to research and teaching conducted at Georgia Institute of Technology or by individuals associated with the Institute. These *Policies and Procedures* are applicable to all research, teaching, training, experimentation, biological testing, breeding, and related activities, hereinafter referred to collectively as "activities," involving vertebrate animals and conducted at this institution, or at another institution when Georgia Tech personnel are involved, or when funding flows through Georgia Tech.

Georgia Tech's Animal Welfare Assurance, on file with the Office of Laboratory Animal Welfare ([OLAW](#)), commits the university to compliance with the Public Health Service ([PHS](#)) Policy on Humane Care and Use of Laboratory Animals, the Eighth Edition of the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)), and the Animal Welfare Act ([AWA](#)). The Assurance provides written documentation of the Institute's commitment to animal welfare and describes the university's animal care and use program.

Copies of the Assurance are available from the Office of Research Integrity Assurance (ORIA); it is posted on the ORIA website at <http://www.researchintegrity.gatech.edu>

## II. REGULATORY AUTHORITIES GOVERNING ANIMAL USE

The Georgia Institute of Technology Institutional Animal Care & Use Committee complies with U.S. Department of Agriculture (USDA) Animal Welfare Act ([AWA](#)) regulations and the National Institutes of Health Office of Laboratory Animal Welfare ([OLAW](#)) regulations governing the use of vertebrate animals.

These regulations are linked from the Office of Research Integrity Assurance website at [www.researchintegrity.gatech.edu](http://www.researchintegrity.gatech.edu). Georgia Tech Policies & Procedures are posted to the same URL. This address is provided in writing to all PIs who utilize animal models.

### A. U.S. Department of Agriculture (USDA)

The U.S. Department of Agriculture ([USDA](#)), through its division of the Animal and Plant Health Inspection Service ([APHIS](#)), administers the 1966 Animal Welfare Act ([AWA](#)) and its amendments, codified at 7 USC §2131 et. seq. and CFR Title 9. The AWA regulates the transportation, purchase, care and treatment of animals used for exhibition, sold as pets, or used in basic and biomedical research, education and product safety testing. The AWA specifically applies to the use of any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research; horses not used for research purposes; and other farm animals, such as, but not limited to, livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.

The AWA requires the establishment of an Institutional Animal Care and Use Committee (IACUC) to review all activities using animals to ensure their humane use in research activities and to conduct semiannual assessments of the institution's animal care and use program, including inspections of all animal study areas and facilities. As a research facility, Georgia Institute of Technology is subject to random inspections by the USDA and files an annual report with USDA concerning its animal care and use program.

Links to the Animal Welfare Act and related regulations are clearly present on the IACUC website at [www.researchintegrity.gatech.edu](http://www.researchintegrity.gatech.edu).

### B. Public Health Service (PHS), National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (*Policy*) was created to implement the provisions of the Health Research Extension Act of 1985. The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) administers the Policy.

The Policy applies to institutions conducting U.S. Public Health Service-supported projects involving live vertebrate animals. The *Policy* requires that the institution establish an Institutional Animal Care and Use Committee. The IACUC, using the *Guide for the Care and Use of Laboratory Animals (Guide)*, is responsible for reviewing the use of animals and conducting semiannual assessments of the institution's animal care and use program, including inspections of all animal study areas and facilities.

### III. ADMINISTRATIVE ORGANIZATION OF GEORGIA INSTITUTE OF TECHNOLOGY'S ANIMAL CARE AND USE PROGRAM

All research, teaching and biological testing involving vertebrate animals conducted by anyone at Georgia Institute of Technology, regardless of the source of funding, must be reviewed and approved in advance by the Institutional Animal Care and Use Committee (IACUC). All research, teaching and biological testing projects conducted at *another institution\* or elsewhere* by faculty, students, staff or other representatives of Georgia Institute of Technology in connection with the investigator's institutional responsibilities, regardless of the source of funding, must be reviewed in advance by the Institutional Animal Care and Use Committee. (\*See [Cooperative Agreement with Emory](#) of these policies).

#### A. Institutional Official

The Vice President for Research (VPR) serves as the Institutional Official and has the authority to legally commit Georgia Institute of Technology to meet federal regulatory requirements. The Institutional Official/VPR is responsible for appointing members to Georgia Institute of Technology's IACUC. As Institutional Official, the Vice President for Research signs Georgia Institute of Technology's Institutional Assurance.

#### B. Institutional Attending Veterinarian

The Attending Veterinarian's official position title is *Research Veterinarian and Director of Animal Resources*. The Attending Veterinarian is a voting member of the IACUC and has been delegated authority and responsibility to implement the PHS Policy and recommendations of the *Guide* and the Animal Welfare Act. The Attending Veterinarian routinely inspects the animal facilities and all animals at Georgia Institute of Technology. The Attending Veterinarian provides routine veterinary care and preventive medical care, as well as on-call emergency care and consultation for Georgia Institute of Technology's animals. The Attending Veterinarian is available to make recommendations concerning preventive health programs for animals, disease treatment, analgesia, post-operative recovery, euthanasia, general animal welfare and technical training. The Attending Veterinarian must review any animal research protocol before it can proceed and has the authority to suspend any protocols that do not follow the *Guide* or the Animal Welfare Act.

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 and Use Committee (IACUC)

The IACUC was established pursuant to the Animal Welfare Act (<http://www.nal.usda.gov/awic/legislat/awicregs.htm>) and the *Policy* and reports to the Institutional Official/VPR.

##### 1. IACUC Membership

The Institute Official/VPR appoints the members of the IACUC, typically for renewable, three-year terms. The IACUC consists of not less than five members of varying professional and personal backgrounds, including at least one veterinarian, one non-scientist, one practicing scientist, and at least one person who is not affiliated with Georgia Institute of Technology in any way other than as a member of the IACUC (i.e. community member). The community member may be either a scientist or non-scientist. IACUC members, including the community member, may be reimbursed for expenses

related to their duties on the IACUC (e.g. travel or mileage, meals, parking, IACUC seminars). No more than three members shall be from the same department within Georgia Institute of Technology.

A Georgia Tech faculty member chairs the IACUC; the chair may not be the Director of Animal Resources or the Attending Veterinarian. The IACUC elects one of its members to serve as Vice Chair in his/her absence. The Vice Chair may be the Director of Animal Resources or the Attending Veterinarian. The IACUC may, from time to time, consult with other professionals (i.e. biostatisticians, legal counsel, etc.) in fulfilling its responsibilities.

### **a) Alternate Members**

Alternates are appointed by the Institutional Official/VPR and are listed on the official IACUC rosters submitted to OLAW. There is a specific one-to-one designation of IACUC members and alternates, to ensure that the committee is properly constituted when alternates are participating. For example, an alternate for a non-affiliated IACUC member must also meet the non-affiliated member requirements. An IACUC member and his/her alternate may not contribute to a quorum at the same time or act in an official IACUC member capacity at the same time. An alternate may only contribute to a quorum and function as an IACUC member if the regular member for whom he/she serves as alternate is absent. Notwithstanding the foregoing, alternate members may attend IACUC meetings and participate in other IACUC activities even when the regular member is present. Alternates receive IACUC training or orientation similar to that provided for regular IACUC members, and they are expected to participate regularly in the IACUC's business. Alternate members are expected to "vote their conscience" as opposed to representing the position of the regular member for whom they serve.

## **2. Expectations of IACUC Members**

Members of the IACUC are expected to participate fully in the activities of the committee described below, which necessitate their completion of required education; regular attendance at committee meetings; serving as primary or secondary protocol reviewer or as designated reviewer; and participation in semiannual program reviews and facilities inspections.

### **a) Education Provided 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 a copy of these *Policies and Procedures* and will be informed about the related material posted on the Office of Research Integrity Assurance webpage. Continuing education sessions will occasionally 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.

### **b) Attendance at Committee Meetings**

Members of the committee are expected to attend a majority of meetings throughout the year. Occasionally, a faculty member will have a teaching commitment that conflicts with meeting times for an entire semester. In such cases, an Alternate Member should be appointed to perform the duties of the absent Primary Member, when possible. Members who fail to attend a majority of meetings may be removed from membership.

### **c) Serving As Primary or Secondary Protocol Reviewer or As Designated Reviewer**

The IACUC Chair will occasionally ask a committee member to conduct a primary or secondary protocol review. In such cases, the member should be prepared to provide an overview of the protocol to the rest of the committee and lead the discussion.

Primary reviewers who, at the last minute, cannot attend the meeting should email or fax their written protocol reviews to the Office of Research Integrity Assurance. If the primary member has an alternate, the primary shall ask the Alternate Member to attend the meeting in his/her absence.

### **d) Participation in Semiannual Program Reviews and Facilities Inspections**

In accordance with federal requirements, a minimum of two program reviews and facility inspections take place each year. Committee members are expected to participate in all program reviews, which involve reviewing IACUC policies and procedures, forms, webpages, meeting minutes, and so on. Unless their physical limitations prevent their participation, committee members are further expected to participate in facilities inspections at least once a year.

### **e) Member and Alternate Member Conflicts of Interest**

In order to ensure the integrity of the institute's program of animal research, members of the IACUC must remain above conflicts of interest. IACUC members are responsible for disclosing any potential or perceived conflict of interest (COI) in any and all business conducted by the IACUC. A committee member or alternate might have a conflict if he/she is the Principal Investigator (PI) or co-PI on a study being reviewed, supervises an investigator receiving funding from the study, is a family member of the investigator; has a financial interest in the study's outcome; and so on. Conflicted members and alternates must disclose their conflicts prior to deliberation of that study and leave the room during the discussion and vote. If the member/alternate becomes aware of a conflict during discussion, he/she should disclose the conflict immediately and leave the room for the remainder of the discussion and vote.

Members and alternates who are not sure whether a particular situation poses a COI may seek guidance from the Office of Research Integrity Assurance before the meeting, or they may raise their concern for consideration of the entire committee during the meeting.

### **f) Confidentiality**

Committee members and alternates review the entire program of animal research at Georgia Institute of Technology. They are privy, on occasion, to proprietary information that is the intellectual property of the institute or funding sponsors. In order to protect the confidentiality of this information and the institute and researchers, committee members and alternates shall not disclose such information to anyone who is not a committee member or alternate.

Committee members who are employees of Georgia Institute of Technology will have signed Nondisclosure Agreements at the time of employment. Community members will be asked to sign Nondisclosure Agreements when appointed. Community member/alternate Nondisclosure Agreements are maintained by the Office of Research Integrity Assurance.



## **g) Failure to Meet Membership Expectations**

Members and alternates are generally nominated to serve on the committee because they are respected and successful researchers, faculty, or other professionals; they are known to conduct their scholarly and professional activities ethically; they are knowledgeable about the types of challenges the committee encounters; and they have a history of service. Such people are extraordinarily busy and may occasionally be unable to meet the demands of committee membership. When such circumstances arise, they may request that their committee appointment be ended or temporarily interrupted, such as when a teaching schedule conflicts with meeting times.

Less often, a member or alternate may become disengaged from committee activities, such as when on an extended leave, upon retirement from the institute, or simply having no interest in further participation. In consultation with the Office of Research Integrity Assurance and IACUC Chair, the Institutional Official may elect to end the appointment of membership.

## **3. Meeting and Quorum Requirements**

### **a) IACUC Meetings**

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. A quorum is required at any meeting at which formal action is taken by the IACUC, and 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.

### **b) 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. In this case, the following criteria must be met:

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.

### **c) Quorum Defined**

A quorum constitutes a majority of the current members of the IACUC. 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.



## D. Office of Research Integrity Assurance

### 1. Committee Support

The Office of Research Integrity Assurance provides administrative support to the Institutional Animal Care and Use Committee in order to promote the ethical and responsible conduct of research and to ensure compliance with regulatory requirements relating to research involving vertebrate animals. In close coordination with the Committee, the Office of Research Integrity Assurance facilitates ethical conduct of research through advance and continuing protocol review; monitoring and reporting; convening regular meetings for review of proposed and continuing research; providing educational programs for faculty, staff, and students; maintaining the institute's federal assurance; and submitting the required federal reports in a timely manner. The Office of Research Integrity Assurance oversees the development and implementation of policies, procedures, and educational programs which satisfy the many regulations governing the conduct of such research. The Office of Research Integrity Assurance reports to the Institutional Official/Vice President for Research and to the Office of the President.

### 2. Semiannual Self-Evaluations of the Animal Care and Use Program and Facilities at Georgia Institute of Technology

The Office of Research Integrity Assurance facilitates the semiannual program and facilities self-evaluations that are mandated by federal regulation. ORIA schedules physical inspections of laboratories and housing areas, escorts the inspection teams, and drafts the written report. ORIA distributes the current policies and forms and website materials for Committee review, and ORIA receives and compiles member comments. When necessary ORIA edits and updates these documents.

#### a) Review of the Animal Care and Use Program

Twice each year the IACUC reviews Georgia Institute of Technology's Animal Care and Use Program and inspects all Georgia Institute of Technology facilities where animals are housed and/or used. The IACUC utilizes the Eighth Edition of the *Guide* ([http://www.nap.edu/catalog.php?record\\_id=12910](http://www.nap.edu/catalog.php?record_id=12910)) and the Animal Welfare Act ([http://www.aphis.usda.gov/animal\\_welfare/awa\\_info.shtml](http://www.aphis.usda.gov/animal_welfare/awa_info.shtml)) regulations as the principle documents in conducting these reviews.

A subcommittee of the IACUC, composed of at least two members, conducts these reviews and inspections. 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. This semiannual evaluation includes the following:

- IACUC membership and functions, including 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;
- Personnel qualifications and training; and
- Occupational health and safety of personnel.

#### b) Review and Inspection of Animal Facilities

The USDA regulations require inspection of the centrally designated or managed animal resource facilities as well as any other animal containment facilities in which animals are kept for more than twelve hours. PHS Policy requires inspection of all surgical facilities and areas in which animals are maintained longer than 24 hours. Thus, the IACUC inspects all facilities where animals are kept for more than twelve hours. (Locations where animals were formerly housed, *but are not currently being used and are not expected be used within the next six months*, will not be inspected). The IACUC maintains an updated list of all facilities to be inspected during its semiannual reviews, which includes the animal housing and support areas, cage wash, aseptic surgery, procedure areas, non-survival surgeries, laboratories and rodent surgeries, and inspection of local animal care records.

### **3. Federally Required Reports**

#### **a) USDA Registration and PHS Assurance**

The Office of Research Integrity Assurance is responsible for completing the USDA Registration and PHS Assurance. Input will be sought from the IACUC, Attending Veterinarian, facility oversight committee, Office of Legal Affairs, and others as necessary to complete these documents. The Registration and Assurance are signed by the Institutional Official/VPR and submitted to the appropriate agency by the Office of Research Integrity Assurance.

#### **b) Annual and Semiannual Reports**

##### **i. USDA**

The Office of Research Integrity Assurance shall prepare and submit the Annual Report to USDA/Animal and Plant Health Inspection Service (APHIS) for signature by the Institutional Official/VPR. The Annual Report shall specify the animals used or under control of the research facility, the location of all facilities where animals are housed/used and specific animal information as required by the AWA, covering the previous federal fiscal year (10/1 - 9/30).

##### **ii. PHS, NIH Office of Laboratory Animal Welfare**

At least once every 12 months the IACUC, through the Institutional Official/VPR, shall submit a report, including any minority views, to the Office of Laboratory Animal Welfare (OLAW), a unit of the Public Health Service. The report shall include the following:

- Changes to Georgia Institute of Technology's program or facilities that would place it in a different category than specified in our Assurance;
- Changes in IACUC membership and dates that the Committee conducted its semiannual evaluations and submitted its reports to the Institutional Official/VPR.
- Changes in the description of Georgia Institute of Technology's program for animal care and use as outlined in the Assurance.

If there are no changes, the report shall so state.

##### **iii. Semiannual Reports to the Institutional Official**

Upon completion of the semiannual animal program and facilities reviews, the Office of Research Integrity Assurance will prepare a written report, with subcommittee input, to be reviewed by the IACUC. The report shall describe Georgia Institute of Technology's adherence to the *Guide* and the Animal Welfare Act and deficiencies found, if any.

Deficiencies identified during the reviews are categorized as either minor or significant. 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. The report shall include a plan and schedule with dates for correction of each program or facility deficiency.

The report must be reviewed and signed by a majority of the members of the IACUC and shall include minority views, if any. The IACUC shall submit the signed evaluation report to the Institutional Official/VPR and shall maintain a copy in its files. The report shall be made available to USDA, OLAW, and any federal funding agencies upon request.

Any failure to adhere to the plan and corrective schedule resulting in a significant deficiency remaining uncorrected shall be reported, in writing, within 15 business days by the IACUC through the Institutional Official/VPR to the Animal and Plant Health Inspection Service (APHIS). If the activity is federally funded, the relevant agency shall also be informed.

#### **iv. Other Reporting Requirements**

Any suspension of an activity involving animals shall be immediately reported by the Institutional Official (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.

### **4. Record Keeping**

The Office of Research Integrity Assurance shall maintain all official institute records relating to the use of vertebrate animals. Such records include, but are not limited to, the institute's Assurance; USDA Registration; annual and semiannual reports to federal agencies and Institutional Official; minutes of IACUC meetings including attendance, deliberations, and determinations; records of proposed activities and proposed significant changes, including whether IACUC approval was given or withheld; protocol continuation applications and determinations; and records of investigations of noncompliance.

The Office of Research Integrity Assurance shall retain protocol records for at least three years after closure of the research or teaching activity involving vertebrate animals. Other records shall be retained at least five years. Records shall be accessible for inspection and copying by authorized USDA, OLAW, or other PHS representatives at reasonable times and in a reasonable manner.

## IV. PRINCIPAL INVESTIGATOR ELIGIBILITY REQUIREMENTS

### A. Eligibility for Title of Principal Investigator

The term “Principal Investigator” refers to the single individual who shall have full and final responsibility for the conduct of a research study involving vertebrate animals. Therefore, for IACUC purposes, the title of Principal Investigator (or co-Principal Investigator) will be allowed in the following cases:

- The individual is a current member of the Georgia Tech general or academic faculty as defined in the faculty handbook;
  - If retired, the individual is working on an hourly-as-needed basis, and there is at least one School, Laboratory, or Department willing to provide the necessary administrative commitment to permit the protocol to be carried out.
- OR, the individual has received an exception letter from the Executive Vice President for Research, as described in item B., below;
- OR, the individual is a student who qualifies under C. 1 or 2, below.

**Adjunct faculty** may not serve as PI or co-PI on an IACUC protocol *unless they are also eligible to be a PI as described above*; they may hold the title of co-investigator if they sign a Visiting Scholar Agreement. (Some personnel are faculty in the Georgia Tech Research Institute and also adjunct in an academic unit; some personnel may be faculty in one academic unit and adjuncts in another).

**Affiliates** may not be named as PI or co-PI.

**Non-employees** are not eligible to serve as a PI or co-PI on IACUC protocols. See [\*Section D, “Non-Georgia Tech Personnel Participating in Protocols at Georgia Tech \(Visitors and Volunteers\).”\*](#)

### B. Exceptions Requiring Approval by Executive Vice President for Research

Exceptions to the general eligibility requirements for designation as Principal Investigator will be considered upon submission of a written request to the Executive Vice President for Research. The request should justify why the individual should be designated as the Principal Investigator and must be signed by the appropriate departmental representative (Chair/Director/Department Head). A copy of the approved exception, signed by the Executive Vice President for Research and the requesting department’s head, must be provided to the Office of Research Integrity Assurance before a protocol will be approved.

### C. Graduate and Undergraduate Student Research Projects

Generally, the Principal Investigator must be a full time faculty member who meets the definition of Principal Investigator, defined in E. below. The graduate/undergraduate student may be named as Co-Investigator, as this title designates key personnel but does not have the oversight responsibilities of a Principal Investigator. Exceptions to this policy are described below.

#### 1. Exception for Georgia Tech Students Receiving Stipends and Tuition in Support of Their Work on Emory Protocols

In those few cases where the Principal Investigator is a faculty member at Emory University, AND no Georgia Tech faculty member has any involvement in the project, AND the funding (if any) is awarded to Emory University with a subcontract to Georgia Tech solely for the student’s stipend and tuition, AND a Georgia Tech student is being mentored and supervised by the Emory University Principal

Investigator, the Georgia Tech student will be named Principal Investigator (PI) for Georgia Tech's tracking purposes.

In addition to completing the required training modules in humane care and use of vertebrate animals, the student must be named in the approved Emory protocol, AND the only funding from Emory University to Georgia Tech must be for the student's stipend and tuition.

The Georgia Tech student PI must submit to the Georgia Tech Office of Research Integrity Assurance (1) a copy of the approved Emory IACUC protocol, (2) a copy of the Emory IACUC letter of approval and (3) the completed Ga Tech IACUC application for Off-Campus Animal Studies. The protocol will be distributed to the Georgia Tech IACUC in accordance with the procedures outlined herein, "[Cooperative Agreement between Emory University and Georgia Institute of Technology](#)." The Office of Research Integrity Assurance will issue a letter of approval to the student from the Georgia Tech IACUC.

The Student PI must also meet with a Research Associate in the Georgia Tech Office of Research Integrity Assurance for a brief overview of PI responsibilities.

## **2. Exception for Georgia Tech Students Receiving Fellowships Supporting Their Work on Emory IACUC Protocols**

In those few cases where the Principal Investigator is a faculty member at Emory University, AND no Georgia Tech faculty member has any involvement in the project, AND a Georgia Tech student is being mentored and supervised by the Emory University Principal Investigator, AND the funding awarded to Georgia Tech is solely for the student's fellowship, the Georgia Tech student can be named Principal Investigator (PI) for Georgia Tech's tracking purposes.

In addition to completing the required training modules in humane care and use of vertebrate animals, the student must be named in the approved Emory protocol.

The Georgia Tech student PI must submit to the Georgia Tech Office of Research Integrity Assurance (1) a copy of the approved Emory IACUC protocol, (2) a copy of the Emory IACUC letter of approval and (3) the completed Ga Tech IACUC application for Off-Campus Animal Studies. The protocol will be distributed to the Georgia Tech IACUC in accordance with the procedures outlined herein, "[Cooperative Agreement between Emory University and Georgia Institute of Technology](#)." The Office of Research Integrity Assurance will issue a letter of approval to the student from the Georgia Tech IACUC.

The Student PI must also meet with a Research Associate in the Georgia Tech Office of Research Integrity Assurance for a brief overview of PI responsibilities.

## **D. Non-Georgia Tech Personnel Participating in Protocols at Georgia Tech (Visitors and Volunteers)**

Georgia Tech seeks to foster collaborative relationships with researchers, scientists, and students who visit the Institute and who may participate in research projects involving vertebrate animals at Georgia Tech. In order to ensure appropriate protections for those visitors/volunteers and for Georgia Tech faculty and staff, this policy has been developed.

Prior to participating in animal research, non-Georgia Tech personnel must complete formal in-processing, as follows:

1. Risk Management: The host department and visitor/volunteer must complete and sign the VOLUNTEER SERVICES DESCRIPTION FORM and the VOLUNTEER SERVICES APPLICATION and return both to Risk Management.
2. Office of Legal Affairs: The host department must prepare a VOLUNTEER PROGRAM AGREEMENT FORM, obtain the signature of the visitor/volunteer, and forward the form to the Office of Legal Affairs.
3. Research Integrity Assurance: The visitor/volunteer must either be named in the original protocol application or be added in an amendment to an existing protocol prior to participating in the protocol. The volunteer/visitor's current CV or completed credentials form must be submitted to the Office of Research Integrity Assurance along with documentation of satisfactory completion of the required IACUC CITI training module(s). Upon approval by the IACUC, visitors/volunteers may serve as co-investigators working with Georgia Tech Principal Investigators who are responsible for conducting the research and ensuring compliance with the approved protocol.
4. Environmental Health & Safety: The volunteer/visitor must meet with EH&S regarding participation in Occupational Health. While volunteers/visitors may not enroll in Georgia Tech's Occupational Health Program, their occupational risk will be assessed, and they will be advised regarding whether to consult a private healthcare provider.

When visitors/volunteers are actively participating in research procedures on an approved protocol, the Georgia Tech Principal Investigator or Co-Principal Investigator must be present, in charge, and responsible. In cases where neither the PI nor co-PI is available, another Georgia Tech employee *named in the protocol* may be designated by the PI or co-PI to supervise the visitor/volunteer.

## E. Definitions

### 1. Principal Investigator

This title identifies the individual responsible for the conduct of the study. This responsibility includes the conduct of the study, all administrative aspects, and the study's adherence to relevant policies and regulations (institutional, state and federal).

### 2. Co-Principal Investigator

This designation refers to individuals who share the responsibility for the study with the Principal Investigator and therefore requires the same qualifications as for PI.

### 3. Co-Investigator

This title designates key personnel for a project, but without the oversight responsibility of a Principal Investigator. Individuals do not need to meet the qualifications of PI under this policy to be named a Co-Investigator, but should be key personnel on the project. For example, a Master's or PhD student submitting his or her dissertation for IACUC approval may be listed as the Co-investigator. The thesis or dissertation chair/advisor should be listed as the PI on the IACUC application. An undergraduate working on a senior thesis or other class research project should list him- or herself as the Co-investigator. The faculty member who is advising the student on the research should be listed as the PI for IACUC purposes.

In addition, faculty members may be listed as Co-Investigators if their role on the study is not that of PI or Co-PI.



## **V. WHEN AND HOW PRINCIPAL INVESTIGATORS SHOULD SECURE IACUC APPROVAL**

### **A. Activities Requiring IACUC Approval**

Vertebrate animal use must be approved in advance by the Institutional Animal Care and Use Committee (IACUC), regardless of funding source or status. These *Policies and Procedures* are applicable to all research, teaching, training, experimentation, biological testing, breeding, and related activities, hereinafter referred to collectively as “activities,” involving vertebrate animals and conducted at this institution, or at another institution when Georgia Tech personnel are involved, or when funding flows through Georgia Tech.

### **B. Off-Campus Activities Requiring IACUC Approval**

In accordance with NOT-OD-01-017 “Office of Extramural Research Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden,” the GT IACUC can recognize the approval from another IACUC for studies where all of the work is being conducted at a different institution.

#### **1. Georgia Tech Personnel Working at Off-Campus Site with PHS-Approved IACUC**

In cases where the Georgia Institute of Technology faculty member or student is involved in work located at an off-campus site with a PHS-approved IACUC, the Georgia Tech IACUC may accept an approval statement from that other IACUC, in lieu of performing a duplicate review. However, the Georgia Institute of Technology IACUC requires investigators to submit a copy of the IACUC approved application from the other reviewing institution, a copy of that institution’s IACUC approval letter, and the abbreviated Georgia Tech IACUC Application for Georgia Tech Personnel Working at Off-Campus Site(s). The Georgia Institute of Technology IACUC must be allowed to assess whether or not an application should be submitted to the Georgia Tech IACUC under these circumstances.

#### **2. Non-Georgia Tech Personnel Working at Off-Campus Site with PHS-Approved IACUC**

In cases where all animal work is performed off-campus by non-Georgia Tech personnel and under a PHS-approved IACUC Assurance, and where there is institutional engagement due to funding or other involvement, the Georgia Tech faculty member shall provide for the Georgia Tech IACUC's consideration a copy of that institution's approved IACUC application and letter of approval. The committee may request additional information or, in rare cases, require modifications. Non-substantive issues will not be raised. If the Georgia Tech member does have direct involvement with the off-campus work, the current GT IACUC application process must be followed.

#### **3. Georgia Tech Personnel Working at Off-Campus Site with No PHS-Approved IACUC**

In cases where all animal work is performed off-campus at an institution with no PHS-approved IACUC, the GT IACUC application process must be followed.

### **C. Agreements with Other PHS-Assured IACUCs**

## 1. Emory University and Georgia Institute of Technology

A cooperative agreement between Emory University and Georgia Institute of Technology governs protocols wherein investigators from either school perform the work on the other campus and the animals are housed there.

Georgia Tech defers to Emory's IACUC for the review and oversight of certain protocols when a Georgia Tech investigator is performing a research project at an Emory site. Likewise, Emory will defer to Georgia Tech's IACUC for the review and oversight of protocols when an Emory investigator is performing a research project at a Georgia Tech site. In these cases, each reviewing IACUC agrees to use the investigator's home IACUC forms. When a Georgia Tech investigator performs research at an Emory site, the Georgia Tech faculty member shall provide 1) the Georgia Institute of Technology IACUC Application for Georgia Tech Personnel Working at Off-Campus Site, 2) a copy of the final IACUC approved application from Emory, 3) a copy of the Emory IACUC approval letter, and, 4) if externally funded, a copy of the funding proposal/statement of work. Additional information may be requested if deemed necessary by the reviewing IACUC.

Each institution will comply with its own policies and procedures when reviewing and monitoring designated protocols. Each institution agrees to abide by the decision of the other institution's IACUC with regard to protocols reviewed by that IACUC. Disapprovals by Emory's IACUC may not be administratively overruled (approved) by Georgia Tech. Likewise, disapprovals of protocols by Georgia Tech's IACUC may not be administratively overruled (approved) by Emory. However, the investigator's home institution has the right to review and deny any protocol, prior to submission or subsequently approved by the other IACUC. Once the Emory IACUC initially approves a protocol, it is placed on the next GT IACUC meeting agenda under "Activities under Emory Cooperative Agreement" for committee notification.

Georgia Institute of Technology's investigators and faculty members must process their funding proposals through the Georgia Tech Office of Sponsored Programs. Likewise, all Emory investigators and faculty members must process their funding proposals through the Emory University Office of Sponsored Programs.

The foregoing procedures apply to all new and continuing protocols, amendments, and other activities involving the use of vertebrate animals.

See also the guidance at [IV. B., 1 and 2: Exceptions to Policy for Certain Student Research Projects](#).

## 2. St. Joseph's Translational Research Institute, Inc. and Georgia Institute of Technology

Georgia Tech and St. Joseph's Translational Research Institute, Inc. have entered into an agreement that sets forth the conditions under which the primary review and oversight of certain protocols may be deferred by one Georgia Tech to SJTRI and vice versa. Georgia Tech shall rely on SJTRI's IACUC for the primary review and oversight of certain protocols wherein a study director of Georgia Tech is performing a research project at a SJTRI site and the research animals are owned by SJTRI. SJTRI shall rely on Georgia Tech's IACUC for the primary review and oversight of certain protocols wherein a study director of SJTRI is performing a research project at a Georgia Tech site and the research animals are owned by Georgia Tech. When a Georgia Tech investigator performs research at an SJTRI, the Georgia Tech faculty member shall provide 1) the Georgia Institute of Technology IACUC Application for Georgia Tech Personnel Working at Off-Campus Site, 2) a copy of the final IACUC approved application from SJTRI, 3) a copy of the SJTRI IACUC approval letter, and, 4) if externally funded, a copy of the funding proposal/statement of work. Additional information may be requested if deemed necessary by the reviewing IACUC.



This agreement contemplates that the research animals owned by SJTRI will be housed at SJTRI where the research activities will be performed. Research animals owned by Georgia Tech will be housed at Georgia Tech where the research activities will be performed.

In the event that research animals owned by and housed at one institution or site are utilized in research or housed at the other institution or site, both parties agree to work in good faith for expeditious IACUC review by both institutions in a dual IACUC oversight role.

Each institution shall comply with its own policies and procedures when reviewing and monitoring designated protocols. Per Georgia Tech policy, GA Tech's study directors and faculty members must process their research performed at a Georgia Tech site through the Georgia Institute of Technology's Office of Sponsored Programs. Per SJTRI policy, all SJTRI faculty members must process their research performed at a SJTRI site through the SJTRI Office of Sponsored Programs.

Faculty members and study directors will be provided with copies of both institutions' policies and procedures upon request and shall abide by the appropriate policies and procedures dependent upon the research site.

Each institution agrees to abide with the decision of the other institution's IACUC with regard to protocols that receive primary or dual oversight review by that IACUC. Disapprovals of protocols by Georgia Tech's IACUC as the primary reviewer may not be administratively overruled by SJTRI IACUC. Similarly, disapprovals of protocols by SJTRI IACUC, as the primary reviewer, may not be administratively overruled by Georgia Tech. Notwithstanding the foregoing, the study director's home institution IACUC reserves the right to review and deny any protocol, prior to submission or subsequently approved by the other IACUC, upon written notice to the primary reviewing IACUC.

## **D. Activities Involving the Study of Animals in Zoos, Petting Zoos, Wild Animal Park, or Similar Habitats**

Activities conducted at a zoo, petting zoo, wild animal park, or similar habitats by Georgia Tech personnel require prior IACUC review and approval, even if the activity is purely observational. The protocol should specify that the researchers do not own the animals or building and that the researcher has no direct control over the animal's habitat, care, feeding, husbandry, and so forth. The researcher must obtain a statement from the facility indicating that it is responsible for its animals and premises.

### **1. Collaborative Research Agreement between Zoo Atlanta and Georgia Tech**

A Collaborative Research Agreement between Zoo Atlanta and Georgia Tech suffices as a statement of responsibility when work takes place at Zoo Atlanta. All animal research conducted at Zoo Atlanta or at any of their satellite locations (i.e., Chengdu Research Site) by Georgia Tech faculty, staff, or students must be reviewed and approved in advance by the Georgia Tech IACUC.

When a Georgia Tech investigator performs research at an Zoo Atlanta, the Georgia Tech faculty member shall provide 1) the Georgia Institute of Technology IACUC Application, 2) a copy of the Zoo Atlanta Scientific Review Committee (SRC) application, 3) a copy of the Zoo Atlanta SRC approval letter, and, 4) if externally funded, a copy of the funding proposal/statement of work. Additional information may be requested if deemed necessary by the reviewing IACUC.

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 GIT 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.

## **E. Activities Involving the Study of Vertebrate Animals in Their Natural Habitat (“Field Studies”)**

All activities involving the study of vertebrate animals, including those studies conducted in animals’ natural habitats and without investigator intervention, must be presented for the IACUC’s review and approval prior to being undertaken. Federal guidance is provided below.

Field studies are defined by the US Department of Agriculture (USDA) as “...any study conducted on free-living wild animals in their natural habitat, which does not involve invasive procedure, and which does not harm or materially alter the behavior of the animals under study.” For Georgia Tech’s purposes, “natural habitat” does not include a Zoo, petting zoo, fish hatchery, or other animal exhibit or man-made housing, regardless of how similar to the animals’ natural environment.

### **1. Field Activities Exempt under USDA Regulations**

The IACUC recognizes that the Department of Agriculture (USDA) regulations, as stated in the Animal Welfare Act (AWA), specifically exempt such activity, defined in the preceding paragraph, from IACUC review. However, the Georgia Tech IACUC must also comply with Public Health Service guidelines regarding vertebrate animals in their natural habitat.

### **2. Field Activities Not Exempt under PHS Regulations**

The Public Health Service (PHS) *Guide for the Care and Use of Laboratory Animals* states, "Zoonoses and occupational health and safety issues should be reviewed by the IACUC to ensure that field studies do not compromise the health and safety of other animals or persons working in the field." Therefore field studies exempted under USDA/AWA regulations must be reviewed by Georgia Tech’s IACUC.

### **3. Field Studies involving Capture and/or Invasive Measures**

Field studies involving the capture and immobilization or killing of free-living wild animals do not satisfy the USDA/AWA definition of exempt activities. These studies require IACUC review, which will focus on:

- number of animals to be utilized and the stability of the population from which the animals are to be taken,
- methods used for capturing, immobilizing and euthanizing the animals, and
- training and supervision of the personnel involved with the study.

### **4. IACUC Inspection Required for Certain Facilities**

USDA and PHS regulations require the IACUC to semiannually inspect study areas and facilities used to hold USDA-covered animals for longer than 12 hours. The Animal Welfare Act does not require inspection of animal areas containing free-living wild animals in their natural habitat.

## **F. Procedures for Applying for IACUC Approval**

Under the *Georgia Open Records Act*, protocol applications, including information incorporated by reference, may become accessible by the general public.

The following steps are required for IACUC approval:

## **1. NEW PROTOCOL APPLICATION**

The protocol form is available on the Office of Research Integrity Assurance webpage at <http://www.researchintegrity.gatech.edu/iacuc-forms>. Tips and hints on protocol preparation are provided throughout the application form.

Note the institute policy regarding eligibility for the role of Principal Investigator on an animal protocol ([Section IV](#), of these *Policies & Procedures*).

## **2. ATTACHMENT: SOW or PD**

A copy of the funding proposal or final grant pages sent to the funding agency must be attached. 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. It is prudent for Principal Investigators to consider submitting separate protocols for each funding agency/sponsor. This is particularly wise when PIs have numerous sponsors. Such separation facilitates project accounting and, in case of a serious non-compliance problem, the PI may not have to halt all of his research.

Occasionally, a large Program or Center grant (e.g. Training grants) to a single Principal Investigator will fund multiple faculty members' activities. The Program/Center grant PI may not be a member of the research team on animal protocols that the grant funds. For these programs, the IACUC may accept protocols from Principal Investigators who are not PI on the supporting Program/Center grant.

## **3. REQUIRED TRAINING**

All GIT Personnel working with vertebrate animals must complete required training as described in [Section VII. "Required Training For Research Personnel"](#) in this document.

## **4. ENROLL IN OCCUPATIONAL HEALTH PROGRAM**

All GIT personnel named on the protocol must enroll in the Georgia Tech Occupational Health Program, managed by Environmental Health & Safety and provided by contract with Concentra Health Services. An opt-out provision is available. See the link to the Occupational Health Program at [www.researchintegrity.gatech.edu](http://www.researchintegrity.gatech.edu).

## **5. DEPARTMENTAL SIGN OFF**

The prepared 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](mailto: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**

Submit the protocol application and attachments to the Office of Research Integrity Assurance via email to [iacuc@gatech.edu](mailto:iacuc@gatech.edu).

## **7. INITIAL REVIEW PROCESS**

The protocol application will be given a preliminary review by the Office of Research Integrity Assurance and then will be forwarded to the Georgia Tech Attending Veterinarian/Director of Animal Resources for veterinary consultation. The Principal Investigator may be contacted for 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.

## 8. FINAL PROTOCOL SUBMISSION

If 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](mailto:iacuc@gatech.edu) for distribution to the committee.

## 9. COMMITTEE REVIEW

All protocols are distributed to the committee in the order in which they are received. 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. In cases where other institutional reviews or approvals are required (i.e., Institutional Biosafety Committee, Material Transfer Agreement, Office of Technology Licensing, Radiation Committee), those should be sought in parallel.

## G. Protocol Amendments

Protocol amendments must be submitted for review and approval in advance of implementation. If the only change is in personnel named on the study, an *IACUC Amendment to Change Personnel* form may be submitted. To increase animal numbers, complete and submit the *Request to Increase Animal Numbers* form. All other changes should be submitted on the *IACUC Amendment Request* form. Substantive changes, such as a change in study purpose, may require an entirely new protocol application. Changes in personnel (other than in Principal Investigator), addition of funding, or other minor changes as defined in IACUC Policy 003 "Protocol Modification and Approval" may be made by the Office of Research Integrity Assurance.

## H. IACUC Forms

### 1. Protocol Application for Animal Use

The protocol application form must be used for new proposals and for continuations after the third year of a protocol. Note, a separate abbreviated IACUC application is available for Off-Campus Animal Studies conducted and approved at another Assured institution. All forms can be obtained from the Office of Research Integrity Assurance website.

### 2. Protocol Amendments

These forms are used to seek IACUC approval of modifications to previously approved protocols. Forms include:

- IACUC Amendment Request form – for all major changes
- IACUC Amendment to Change Personnel form
- Request to Increase Animal Numbers

### 3. Program or Center Grants that Fund Multiple Faculty Members' Research

Occasionally, a large Program or Center grant to a single Principal Investigator will fund multiple faculty members' activities. These faculty members will be required to amend the protocols receiving the funding in order to facilitate the IACUC's compliance with the federal regulation *requiring* that the protocol be compared to the funding proposal Statement of Work or Project Description. Completed amendment forms should be emailed to the Office of Research Integrity Assurance at [iacuc@gatech.edu](mailto:iacuc@gatech.edu).

## I. Categories of Biomedical Research

The following items describe the categories of discomfort, distress, and pain for animals used in research. Additional guidance can be found in “USDA Pain Categories\_IACUC Policy 004” on the ORIA IACUC website.

### 1. Category A: No Direct Contact with Live Animals

This includes observational field studies or use of cadavers, not euthanized specifically for this purpose.

### 2. Category B: No Research, Testing or Teaching Procedures Are Performed

This includes animals used for breeding or being held, but not directly used in research or teaching.

### 3. Category C: Non-Painful/Non-Stressful

Studies, experiments, and tests causing no pain or distress (e.g., routine procedures causing only transitory discomfort such as venipuncture, injection and the use of non-inflammatory adjuvants; cell and/or tissue harvested from euthanized animals)

### 4. Category D: Painful/Stressful WITH Analgesia / Anesthesia / Tranquilizers

Painful and/or stressful procedures carried out with the use of appropriate anesthetic (e.g., for surgery), analgesic (e.g., for inflammation), and tranquilizers (e.g., for prolonged restraint) that will prevent and alleviate pain and distress

### 5. Category E: Painful/Stressful WITHOUT Pain and Stress Relieving Measures

Painful and/or stressful procedures performed without the use of appropriate analgesic, anesthetic, and tranquilizing drugs or other measures that will prevent and/or relieve pain and distress; or those procedures not amenable to relief by therapeutic measures (e.g., infectious disease, carcinogen, or toxicity studies in which natural death is the endpoint; addictive drug withdrawal without treatment; noxious stimulation without escape). *All protocols and amendments proposing Category E procedures will be reviewed at a convened meeting of the IACUC.*

Please note: the GT IACUC generally will not allow Death as an Endpoint in any study.

## J. Protocol Review Criteria

Federal requirements state that the IACUC must review proposals for vertebrate animal use on the basis of the following:

### 1. Potential Value of the Study.

Activities involving live vertebrate animals are designed and performed with the reasonable expectation that such use of animals will contribute to the enhancement of human or animal health, the advancement of knowledge, or the good of society.

## 2. Selection of Vertebrate Animal Species.

*USGP III; USDA 9CFR 2.31; Guide pg. 25:* The vertebrate animals selected should be of an appropriate species and quality with the minimum number required to obtain valid results.

## 3. Justification of Animal Numbers.

*9 CFR §2.31, e, 1; §2.31, e, 2:* A proposal to conduct an activity involving animals must contain the following: (1) Identification of the species and the approximate number of animals to be used; (2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

*PHS Policy IV, D, 1a; IV, D, 1, b:* Applications and proposals that involve the care and use of animals shall contain the following: a) Identification of the species and the approximate number of animals to be used; b) rationale for involving animals, and the appropriateness of the species and numbers used.

## 4. Minimization of Pain/Distress.

- Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design. [9 CFR §2.31(d)(I) <http://www.gpo.gov/fdsys/pkg/CFR-2003-title9-vol1/xml/CFR-2003-title9-vol1-part2.xml#seqnum2.31> and PHS Policy IV.C.1.a <http://grants.nih.gov/grants/olaw/references/phspol.htm#review>]. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the PI justifies, in writing, the scientific reasons for the procedure. [9 CFR §2.31(d)(iv)(A) and *PHS Policy, Section IV.C.1.b*].
- The PI shall consult with the Attending Veterinarian or his/her designee in planning the use of animals. [9 CFR §2.31(d)(iv)(B)].
- Paralytics are not used without anesthesia. [9 CFR §2.31(d)(iii)].
- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure, or if appropriate, during the procedure. [9 CFR §2.31(d)(v) and *PHS Policy, Section IV.C.1.c*].

## 5. Alternatives

The PI shall consider alternatives to procedures that may cause more than momentary or slight pain and provide a written narrative description of the methods and sources used to determine that alternatives were not available. [9 CFR §2.31(d)(ii)].

## 6. Duplication

The PI shall provide written assurance that activities do not unnecessarily duplicate previous experiments. [9 CFR §2.31(d)(iii)].

## 7. Living Conditions/Housing

Living conditions of animals are appropriate for their species and contribute to their health and comfort. [9 CFR §2.31(d)(iv) and *PHS Policy Section IV.C.1.d*].

## 8. Personnel



Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures. [9 CFR §2.31(d)(viii) and PHS Policy, Section IV.C.1.f].

## 9. Surgery

Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. [9 CFR §2.31(d)(ix)]. No animal will be used in more than one major operative procedure from which it is allowed to recover unless this use is:

- a. Justified for scientific reasons in writing by the PI, or
- b. Required as routine veterinary procedure or to protect the health or well being of the animal as determined by the Attending Veterinarian. [9 CFR §2.31(d)(x)].

## 10. Euthanasia

Methods of euthanasia are consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the PI. [9 CFR §2.31(d)(xi) and PHS Policy IV.C.1.g].

## 11. Adoption as Alternative to Euthanasia

An alternative to euthanasia is the adoption of the animal which was used in the research and training program. Research animals that are naïve, were used as control animals, or were subjects in relatively benign experiments may be adopted by persons approved by the Principal Investigator or the Georgia Tech veterinarian. See [Adoption of Animals Used in Research and Teaching](#).

## VI. ADMINISTRATIVE AND COMMITTEE REVIEW OF A PROTOCOL OR AMENDMENT APPLICATION

### A. Administrative Processing

Upon receipt of the application (new protocols, annual continuing review, three-year renewals, and amendments), the Office of Research Integrity Assurance follows this process:

Protocols are assigned an IACUC number and logged into the database.

The Office of Research Integrity Assurance verifies that completion of appropriate CITI educational modules is documented for each named member of the research team. All personnel must be enrolled in the Occupational Health Program; enrollment will be verified. *Final IACUC approval will be withheld until these requirements are satisfied.*

After the protocol application has undergone administrative and veterinary review, it is returned to the PI for revisions or other response if required. Once revised and resubmitted by the PI via email to [iacuc@gatech.edu](mailto:iacuc@gatech.edu), the application is distributed to all members of the IACUC and a designated reviewer is assigned. IACUC members must respond within a certain number of days regarding their call for full committee review or their recommendation of approval. Should no member call for full committee review, designated review procedures will be followed,

When full committee review is called, the proposal is placed on the agenda for consideration at the next IACUC meeting, providing sufficient lead time. If it is past the deadline for the next meeting, the protocol will go on the agenda for the following month's meeting. When a protocol is approved via designated review, the IACUC is so informed by the listing of the protocol on the next meeting agenda and in the minutes.

The Office of Research Integrity Assurance documents all related correspondence and keeps the Principal Investigator and IACUC informed.

### B. Committee Review Process

#### 1. Full Committee Review at a Convened Meeting

Except for applications undergoing designated member reviewer procedures, applications (new protocols, annual continuing review, three-year renewals, or amendments) are considered for approval during regularly scheduled meetings of the full IACUC.

Occasionally, PIs will be invited to take questions from the IACUC at a convened meeting. The PI will leave the room during deliberations and vote. The IACUC's determination is generally communicated by email or letter to the PI after the meeting. When circumstances warrant, the Chair, Veterinarian, or Research Associate may call the PI to discuss a review.

IACUC determinations by the convened committee will result in the application being assigned to one of the following categories:

##### a) Protocol Approved

The proposed work 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 if required. While protocols may be valid for three years, annual review will be required on protocols with USDA covered species, DoD funding and for any protocol involving pain category E on at least an annual basis, and always at the end of years one and two.

## **b) Protocol Returned for Modifications**

In accordance with OLAW Guidance Notice Number: NOT-OD-09-035 dated January 8, 2009, the following procedure will be followed when the full committee determines that substantive information is lacking from a protocol that was reviewed at a convened meeting.

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 a designated member reviewer subsequent to full committee review, 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 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 full committee review of the protocol.

When the IACUC requires substantial additional information and/or has concerns, the Office of Research Integrity Assurance shall notify the PI in writing, either by email or letter, of the decision and will offer the PI an opportunity to discuss the protocol. When circumstances warrant, the Chair or Research Associate 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.

Upon resubmission, the designated IACUC member(s) will review the response to determine whether it is satisfactory; if so, the Office of Research Integrity Assurance will issue the approval letter. If the designated member review process is used, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date must be reported to OLAW as a serious noncompliance with the PHS Policy.

## **c) Protocol Disapproved**

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 or Research Associate 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.

## **2. Designated Member Review When Full Committee Review Is Not Called**

New and continuation protocols, and amendments are distributed to all members of the IACUC. Designated reviewer will be assigned when sending protocol out to committee for the initial call for

Full Committee Review. This will allow the DMR to begin the review at that time. If no member calls for full committee deliberation, the reviewer may approve the protocol outright, require modifications to secure approval, or recommend deferring for clarification or even withholding of approval. If the reviewer recommends approval of an application likely to produce no pain or distress, or only minor and transient pain or distress, the approval process is completed without convened committee review. If a reviewer *requires clarification*, 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 reviewing member may approve the application.

No individual IACUC designated member reviewer may disapprove a protocol, continuation application, or amendment, but any member may request that the full committee perform a review, which may result in disapproval. When full committee review is called, designated member review does not occur. In these cases, the Office of Research Integrity Assurance informs the PI, who may be invited to discuss the proposed work at the convened meeting of the IACUC. The PI may also choose to have the unaltered protocol or amendment reviewed by the convened committee or may submit modifications prior to the full committee's review.

Upon Committee approval, the Office of Research Integrity Assurance notifies the PI that review and approval are complete.

#### **a) Designated Member Reviewer Assignments**

Designated member reviewer assignments are made on a rotational basis as instructed by the Chair who will be copied on all designated member 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.

### **3. Revisions to an Existing Protocol (Amendments)**

Changes to an existing protocol are categorized as either *significant* or *minor*. The table below is based on guidance from DHHS/Office of Laboratory Animal Welfare. **Inconsequential changes not appearing in the chart do not require review or approval.** Questions regarding whether a formal amendment is required should be directed to the Veterinarian. *All* amendments must be approved before the changes are implemented. Amendments do not extend approval period. Additional guidance on protocol modifications can be found on the ORIA IACUC website under guidance document: "Protocol Modification and Approval IACUC Guidance 003."

## 4. Annual Continuing Review

The purpose of continuing review is to inform the IACUC of the current status of the project; to ensure continued compliance with PHS, USDA and institutional requirements; and to provide for re-evaluation of the animal activities at appropriate intervals. For protocols involving USDA covered species, DoD funding (all species) and pain category E (all species), ORIA will initiate annual reviews for the PI. Personnel training and funding status will be updated if needed and sent to the IACUC for review. PI will receive an approval letter once the IACUC review is complete.

USDA covered species, DoD funding (all species) and pain category E (all species) protocols 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 off-campus institution. This policy applies in cases where Georgia Tech's IACUC approval has been granted under these policies at [V. B. Off-Campus Activities Requiring IACUC Approval](#).

The IACUC will no longer require the formal submission, by the PI, of an annual continuation / progress report on protocols using non-USDA covered species, pain category B-D animals. Rather, ORIA will review these protocols using alternate methods such as Post-Approval Monitoring and through other protocol assistance programs and compliance monitoring.

Note: Institutional Animal Care and Use Committee protocols must, by federal regulation, undergo a complete de novo rewrite and review. As such, all protocols must be closed at the end of the third year. If the work is to continue beyond the third year, an entirely new protocol—with veterinary consultation—must be submitted for IACUC approval.

## 5. 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.

## C. Process for Handling Extraordinary Calls for Full Committee Review

An extraordinary call for review occurs when any member of the IACUC requests re-review of an approved study at a time other than continuing review, amendment, or receipt of a report of non-compliance or adverse event. Any member of the IACUC may call for review of an approved protocol at any time. Such calls shall be communicated to the Office of Research Integrity Assurance and to the IACUC Chair for placement on the next available meeting agenda. The reason for requesting additional review must be provided in writing when the request is made. The Principal Investigator shall be informed by the Office of Research Integrity Assurance that an additional full committee review has been called, and the reason for the call shall be communicated to him. The member calling for extraordinary review shall present his concern at a convened meeting where a quorum has been established. The Principal Investigator and/or members of the research team shall be afforded the opportunity to address any such concerns at that same meeting. All other procedures governing full committee review shall be followed.

## VII. REQUIRED TRAINING FOR RESEARCH PERSONNEL

Georgia Institute of Technology is required by federal regulations to provide training for all personnel involved in the use and/or care of vertebrate animals in research, testing and teaching. PHS Policy and USDA regulations require that training be made available in the following areas:

Humane methods of animal maintenance and experimentation, including the basic needs of each species of animal, proper handling and care for the various species of each animal used by the facility and proper pre-procedural and post-procedural care of animals.

Research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress.

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

Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility.

### A. Required Training for All Research Personnel Named on Animal Protocols

Everyone named on the protocol—including students, lab techs, and visiting scholars—are *required* to complete the online CITI training course, “*Working with the IACUC*” and the other CITI 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.*” CITI modules are available through a link on the Office of Research Integrity Assurance website at <http://www.researchintegrity.gatech.edu>.

CITI training 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.

In addition, Principal Investigators are responsible for providing adequate and appropriate training to team members (students, co-PIs, lab techs). Training is also provided in animal handling, manipulation, and techniques by the animal facility manager and the Attending Veterinarian.

#### 1. Training for Non-Georgia Tech Personnel

Visiting Scholars, other visitors, volunteers, and others not employed by or enrolled at Georgia Tech, but participating in animal projects in Georgia Tech facilities, must also complete the required CITI training modules.

#### 2. Exception to Training Requirement

Occasionally, a large Program or Center grant to a single Principal Investigator will fund multiple faculty members’ activities. In many, if not all of these cases, the Program/Center grant PI is not a member of the research team on animal protocols that the grant funds. In these situations, the requirement to complete CITI training is waived for the Program/Center grant PI *if he/she has absolutely no involvement in the animal work.*

This exception shall not apply for studies funded by the Department of Defense.

#### 3. 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](mailto:iacuc@gatech.edu) via email.

Deadline for retraining is July 1, 2013.

## **B. Graduate Level Special Topics Course**

A graduate level special topics course, entitled *Living System Modeling and Analysis* is available for graduate students. This course covers selection of animal models, alternatives, experimental design, laws and regulations, safety, anesthesia and analgesia, euthanasia, aseptic surgical methodology and pre- and post-procedural care. It includes hands-on laboratory sessions.

## VIII. PROCUREMENT OF VERTEBRATE ANIMALS

Faculty using vertebrate animals in research and teaching are responsible for complying with applicable regulations and institute policies governing procurement and use of animals. The Principal Investigator is responsible to ensure that the animals ordered do not exceed the number approved, that the charges are allocable to the funding source whose PeopleSoft # is specified in the Request for Animal Procurement, and that the funding source matches the source cited in the IACUC approved protocol.

Procurement of vertebrate animals is centralized in GTRC. Independent ordering of vertebrate animals by Principal Investigators, students, or departmental personnel is specifically prohibited. The procurement of vertebrate animals without an approved protocol is a violation of institute policies. No animal purchases shall be made until the proposed protocol has received IACUC approval.

Faculty should prepare a Request for Animal Procurement (RAP) form and follow the procedures set forth in the boxes below, relative to where animals will be housed. The RAP must be signed by the person placing the order. Generally, this person will be the Principal Investigator (PI), Co-PI, Lab Manager, or other official designee. The protocol application must indicate which members of the research team or laboratory staff are authorized to place animal orders.

### Important telephone numbers:

Primary Number: 404.894.9035	Research Integrity: 404.385.7316
Back-up Number: 404.894.6958	Assurance: 404.894.6949
GTRC Fax: 404.385.2078	404.894.6944

Once an order has been placed by GTRC, changes with the vendor may not be made by PIs, students, or department personnel. Instead, changes must be handled through GTRC. Cancellations of animal orders must be called to GTRC as soon as possible and must be followed up with a FAXED cancellation notice. Incorrectly ordered animals cannot be returned, so great care must be taken in completing the Request for Animal Procurement. GTRC will charge the PeopleSoft Number provided on the Request for Vertebrate Animal Procurement form. DO NOT ENTER P-CARD INFORMATION ON ORDER FORM.

A list of approved animal vendors is available from ORIA. Every effort is made to accommodate the investigator's request relative to sources of animals. If no specific vendor is indicated, selection will be made on the basis of animal quality, vendor reliability and ease of shipping, as known to GTRC at the time of placing the order. If it is necessary to receive animals from a previously unapproved source, such as from another university, approval of the Director of Animal Resources is required in advance.

<i>Orders will not be taken by phone. Orders must be faxed.</i>	
<b>Vertebrate Animals to be Housed in PRL</b>	<b>Vertebrate Animals to be Housed Elsewhere</b>
Purchase requests for animals to be housed at PRL must be received by the PRL manager by 12:00 Noon on Wednesday for delivery the following week.	Purchase requests for animals to be housed elsewhere, and NOT in PRL, must be received in GTRC by 3PM on Wednesday for delivery the following week.
Secure IACUC approval. For assistance, contact Office of Research Integrity Assurance at <a href="mailto:iacuc@gatech.edu">iacuc@gatech.edu</a> .	Secure IACUC approval. For assistance, contact Office of Research Integrity Assurance at <a href="mailto:iacuc@gatech.edu">iacuc@gatech.edu</a> .
Complete Request for Animal Procurement (RAP) form.	Complete Request for Animal Procurement (RAP) form. Specify the physical delivery location. The name of the person to accept the shipment delivery must be provided. Orders lacking this information will not be placed.
Complete the Animal Housing Space Request form.	

<i>Orders will not be taken by phone. Orders must be faxed.</i>	
<b>Vertebrate Animals to be Housed in PRL</b>	<b>Vertebrate Animals to be Housed Elsewhere</b>
Attach the departmental purchase order and deliver all documents to PRL Manager for signature and submittal to GTRC.	Attach departmental purchase order.
	Fax the RAP and attachments to GTRC at 404-385-2078. <b>DO NOT EMAIL.</b>
GTRC will verify that an approved, current IACUC protocol is in place. The Principal Investigator is responsible to ensure that the animals ordered do not exceed the number approved.	



## **IX. POST APPROVAL MONITORING**

### **A. Post Approval Monitoring is an Important Part of Program Oversight**

As regulations governing the use of vertebrate animals in research have increased in complexity and detail over the years, so have the regulatory obligations of investigators and the Institutional Animal Care and Use Committee. 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. Post approval monitoring is not an enforcement activity.

The Office of Research Integrity Assurance will conduct reviews of active, approved protocols throughout the year. Protocols may be selected by pain category or *for cause* monitoring at any time. PAM may be scheduled in advance or with no prior notice.

Post Approval monitoring may also be conducted in the following ways:

- Annual reviews
- Grant congruency checks
- Semi-annual reviews and inspections
- Non-Compliance reviews
- PRL visits
- Training including OHS, Bio, IACUC and RCR training
- Development and review of IACUC policies and SOPs

### **B. Consistency between Funding Proposal and IACUC Protocol**

If an IACUC protocol application is externally funded, i.e. “sponsored research”, the protocol application must be consistent with the proposal submitted to the sponsoring agency. Several mechanisms are in place to ensure consistency between the various documents.

- Sponsored Programs Contracting Officers are required to validate that IACUC approval has been obtained prior to processing sponsor awards by checking with the Office of Research Integrity Assurance. Investigators may request a deferral of IACUC approval at the time of proposal/grant submission; however, 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.
- The Office of Research Integrity Assurance conducts comparisons between approved protocol applications and grant applications during the initial protocol review process. Any differences are evaluated prior to the approval of the protocol.

### **C. The Post Approval Monitoring Visit**

Post approval monitoring is conducted by a Research Associate or IACUC 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 Research Associate or IACUC Member will generally schedule a post approval monitoring visit with the Principal Investigator and describes what to expect during the visit. However, the IACUC or other personnel conducting PAM on behalf of the IACUC may inspect any procedures at any time. The IACUC Research Associate or IACUC Member will respect the research environment and will not interfere with the conduct of any procedures. The Research Associate or IACUC Member shall wear the personal protection equipment (PPE) prescribed for the specific activity or laboratory. For example, if gloves or a face mask are required



when working in the PIs lab being visited, the Research Associate or IACUC Member will coordinate with the lab staff to obtain the appropriate PPE before entering the laboratory. The Research Associate or IACUC Member will work with the PI and laboratory staff to observe research activity, prepare accurate reports, provide recommendations for maintaining compliance, and provide training opportunities. The Research Associate or IACUC Member shall use the Protocol Post Approval Monitoring Checklist for the routine post process protocol reviews (Appendix H). The Research Associate or IACUC Member will also 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 Research Associate or IACUC Member 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.

## D. Description of Possible Discrepancies

The following is a list of some possible discrepancies that a Research Associate or IACUC Member might note during a post approval monitoring visit.

- Change in apparent objectives of the study from those approved in the protocol;
- Increase in degree of invasiveness from those approved in the protocol;
- Increases in duration, frequency or number of procedures from those approved in the protocol;
- Performing survival surgery when only non-survival surgery was approved in the protocol;
- Performance of procedures by personnel who are not listed in the approved protocol;
- Anesthetics, analgesics, tranquilizers, euthanasia agents antibiotics or other medications used but that are not noted in the protocol, or different from those listed in the protocol, or not used in accordance with the protocol and not prescribed by a veterinarian;
- Procedures listed in the protocol to promote animal welfare (e.g. post-op monitoring procedures) that are not being performed as approved in the protocol; and
- Survival surgery that is not performed aseptically.

The following issues, while not anticipated, will raise concern if noted during the post approval monitoring visit.

- Lab personnel who appear to lack the necessary training to appropriately perform procedures listed in the protocol;
- Conditions that are not safe for humans and/or animals;
- Outdated materials (drugs, suture, etc.) being used; and
- Animal misuse, mistreatment or neglect (welfare issues), or discrepancies which result in animal welfare concerns. *Deliberate* animal misuse, mistreatment, or neglect, or those which involve willful disregard for appropriate animal care will be immediately reported to the IACUC, the Attending Veterinarian, the Director and Associate Director of Research Integrity Assurance, and the Vice President for Research. The report will be investigated by the IACUC following their procedures for handling non-compliance.

## E. Sharing Information Concerning the Review

The Research Associate or IACUC Member 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 Research Associate or IACUC Member 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 Research Associate or IACUC Member 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 by email (not campus mail) to the Principal Investigator, IACUC Chair, Vice President for Research/Institutional Official, and Attending Veterinarian. A copy of the report will be made available to the IACUC at their next, regularly scheduled meeting and the 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 if she/he wishes to do so.

## **F. 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.

## **G. Appeal Process**

Investigators who disagree with post approval monitoring results and/or recommendations may appeal to the IACUC.

## **H. Recordkeeping**

A copy of the final compliance post approval monitoring report shall be kept in the protocol file.

## **X. OCCUPATIONAL HEALTH PROGRAM**

### **A. 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. 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.

### **B. 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. 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.

#### **1. 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.

#### **2. Exception to Requirement to Participate in Occupational Health Program**

Occasionally, a large Program or Center grant to a single Principal Investigator will fund multiple faculty members' activities. In many, if not all of these cases, the Program/Center grant PI is not a member of the research team on animal protocols that the grant funds. In these situations, the requirement to enroll in the Occupational Health Program is waived for the Program/Center grant PI *if he/she has absolutely no involvement in the animal work.*

### **C. Point of Contact for Occupational Health Program**

The Occupational Health Program is administered by the Office of Environmental Health and Safety (EHS). The OHP facilitates awareness of, and appreciation for, safe conduct of work and research activities so that accidents and occupational injuries and illnesses will be minimized. OHP 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 the EHS and, when indicated, medical surveillance and certain immunizations are provided.

Follow the link to Occupational Health from [www.researchintegrity.gatech.edu](http://www.researchintegrity.gatech.edu).

## **XI. ADOPTION OF ANIMALS USED IN RESEARCH AND TEACHING**

Research animals that are naïve were used as control animals, or were subjects in relatively benign experiments may be adopted by Georgia Tech employees, research staff, or someone else approved by the Principal Investigator or the Georgia Tech Attending Veterinarian.

### **A. Suitability of Specific Animals for Adoption**

Some animals are not suitable for adoption. Prior to being released into the custody of the adopter, the Attending Veterinarian, designee, or subcommittee must make a determination that the animal is suitable for adoption. Animals used for noninvasive experimental procedures that, to the IACUC's reasonable knowledge, have not resulted in any physiologic or physical damages may be adopted if they are determined to be in good health; have a suitable temperament as a companion animal; have an expectation for a normal quality of life and with no known current or future risks to itself or the new owner; and the new owner accepts full responsibility for the animal's care, well-being and welfare, accepts the animal as a test subject, and releases Georgia Tech from liability.

### **B. Responsibility for Costs Associated with Adoption of an Animal**

There is no university budget for this program and no adoption fee will be collected. Persons adopting a mammal are expected to have it spayed or neutered. The prospective owner is responsible for all charges related to the spay/neuter surgery and initial vaccination series as well as any other costs associated with ownership of the animal.

### **C. Adoption Procedure**

The following procedures shall be followed when an animal is being considered for placement into an adoptive home.

#### **1. IACUC Must Approve Adoption as Disposition**

If adoption is a possible disposition of animals at the end of a research study, the protocol application for IACUC review should so indicate. Principal Investigators may indicate on the original protocol that they believe the nature of the study will not interfere with the potential for adoption for the animals once the study is complete. This proposed disposition of animals will be subject to IACUC approval. The PI's indication on the protocol does not guarantee that all animals in the study will make good adoption candidates or that any particular animal will be approved for adoption by the IACUC. *This policy does not preclude the adoption of animals if that becomes a viable option in protocols not originally including adoption as a suitable disposition of animals. Such protocols should be amended to add adoption.*

When a research animal is to be placed in an adoptive home, the IACUC will be so informed at the next convened meeting. Individual adoptions do not require a vote of approval by the Committee, as this requirement could necessitate the delay of an adoption for several weeks.

#### **2. Assessment of the Animal's Health and Suitability for Adoption**

When an animal is identified for possible placement in an adoptive home, the Attending Veterinarian will review the history of the animal's use in research or teaching. Physical and behavioral exams will be conducted and the animal's suitability for adoption will be determined by the veterinarian, who will

consider its temperament, health, and research manipulations performed, and whether the animal has any future laboratory or other experimental use.

### **3. Terms and Conditions of Adoption**

Persons seeking to adopt a former research or teaching animal, cleared by the Attending Veterinarian, must complete an [Adoption Release and Waiver form](#). Once executed, the Adoption Release and Waiver will be filed in the Office of Research Integrity Assurance.

The person adopting any animal from Georgia Tech agrees not to hold the university liable for any actions or circumstances arising from the adoption or the costs, damages, potential injuries including but not limited to death, associated with the ownership of the animal. Adopted animals may not be returned to Georgia Tech, nor may they be sold for personal profit or gain to other individuals or commercial businesses.

## **XII. REVIEW AND INVESTIGATION OF NONCOMPLIANCE**

One of the basic functions of the IACUC, as specified in the USDA Regulations, is to review and, if warranted, investigate concerns involving the care and use of animals at the facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees. *9 CFR Part 2, Subpart C, Section 2.31 (c)(4)*.

*The Institutional Animal Care and Use Committee will strive to ensure that persons against whom complaints are alleged receive due process. Despite the severity of the noncompliance policy, the IACUC recognizes that the Principal Investigator is entitled to fair and just treatment and to a presumption that a reasonable explanation can be made for the appearance of noncompliance. Every effort will be made to maintain confidentiality and to protect the reputation and research of the Principal Investigator throughout the inquiry and investigation process.*

### **A. Reporting Concerns about Animal Care and Use**

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, a Research Associate, or the Director or Associate Director of Research Integrity Assurance. Concerns may also be emailed to [iacuc@gatech.edu](mailto:iacuc@gatech.edu). Detailed contact information can be found at <http://www.researchintegrity.gatech.edu>.

Reports through the Office of Research Integrity Assurance will be delivered to the IACUC Chair and the Institutional Official/VPR for further action. 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.

### **B. Noncompliance with the Approved Protocol, and/or Institute Policies, the Animal Welfare Act, PHS Policy, the *Guide*, or Georgia Tech's Assurance**

The Georgia Institute of Technology Animal Care and Use Program requires that all animal usage be conducted in a humane and appropriate manner, in accordance with guidance from the AWA, PHS Policy, the *Guide*, and Georgia Institute of Technology's Assurance and policies. Any failure to comply with these policies and regulations jeopardizes all use of animals in research at Georgia Tech.

### **C. Examples of Noncompliance**

Some examples of situations that may constitute noncompliance include, but are not limited to, the following:

1. Use of animals without first obtaining IACUC approval
2. Procurement of animals without an approved protocol in place
3. Failure to use aseptic procedures during survival surgery on USDA-covered animals
4. Neglecting or providing inadequate care for animals
5. Using procedures not approved by the IACUC
6. Using more animals than approved by the IACUC
7. Failure to obtain continuing review of a protocol
8. Failure to correct a previous non-compliant situation
9. Housing animals for more than 12 hours outside of the PRL without IACUC approval
10. Allowing untrained personnel to perform procedures or surgeries without direct supervision

11. Failure to inform the IACUC of an unexpected outcome that affects the welfare of animals
12. Failure to alleviate pain or distress of an animal when the exception has not been approved by the IACUC
13. Failure to confirm death of euthanized animals

## **D. Procedure to Be Followed in Cases of Alleged or Apparent Noncompliance**

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.

**Exception:** The requirement for IACUC approval of suspension is waived in cases where the Attending Veterinarian suspends a protocol on an emergency basis. The Attending Veterinarian has the authority to suspend any protocol that does not follow the *Guide*, Animal Welfare Act, PHS Policy, or Georgia Institute of Technology's Assurance or policies. The Attending Veterinarian is authorized, in extreme situations, 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 suspension will immediately be reported to the Office of Research Integrity Assurance and IACUC and will be the subject of a called, convened meeting with a quorum of committee members. The IACUC may additionally impose a period of suspension 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.

### **1. The Process of Inquiry**

#### **a) Inquiry Defined**

An inquiry is defined as *information-gathering and preliminary fact-finding* to determine whether the potential noncompliance warrants an investigation.

#### **b) Procedures to Be Followed When Conducting an Inquiry**

Once advised of an alleged noncompliance matter, the IACUC Chair or Vice Chair or other designated IACUC member and the Director or Associate Director of Research Integrity Assurance will conduct an inquiry. Should the inquiry result in a determination that further investigation is warranted, the Chair of the IACUC or the Director or Associate Director of Research Integrity Assurance will:

1. Notify the Principal Investigator in writing that an allegation of noncompliance has been made. Specific deviations/claims are cited, and the PI is instructed to adhere to the approved protocol until otherwise instructed by the IACUC or Attending Veterinarian. A copy of this letter is sent to the Institutional Official/VPR and the PI's department chair.
2. Notify the Institutional Official/VPR and the PI's department head of the allegations.
3. Call a meeting of the IACUC as quickly as possible to conduct an investigation of the alleged noncompliance.



### **c) Notification of Governing Authorities**

Following completion of the inquiry, the Office of Research Integrity Assurance will advise the Office of Laboratory Animal Welfare (OLAW) and, if deemed necessary, the Animal and Plant Health Inspection Service of the Department of Agriculture (APHIS/USDA).

In cases where allegations of serious noncompliance are alleged, OLAW requires immediate reporting, even before the inquiry is complete. Such initial reports to OLAW do not necessarily require identification of the person(s) against whom allegations are made.

## **2. The Process of Investigation**

### **a) Investigation Defined**

An investigation is defined as *a formal examination and evaluation of relevant facts to determine whether noncompliance has taken place or, if noncompliance has already been confirmed, to assess its extent and consequences and determine appropriate action.*

### **b) Procedures to Be Followed When Conducting an Investigation**

The Principal Investigator will be asked to meet with the IACUC in a called meeting to respond to the allegations. Other faculty, research technicians, animal care staff, and/or students may be asked to provide additional information. Animal care records and other documents related to the protocol may be reviewed by the IACUC.

Once the IACUC has completed the investigation and made a determination, the Principal Investigator will be advised in writing, with copies to the Institutional Official/VPR, the PI's department head, and the Vice President for Research.

In the event of a finding of noncompliance, sanctions imposed by the IACUC will be stated, and the notice will include guidance on the appeal process.

### **c) Notification of Governing Authorities**

Following completion of the investigation, the Office of Research Integrity Assurance will advise OLAW, APHIS (if applicable), and the federal funding agency, if any, in cases where:

1. The protocol is suspended;
2. A determination is made that there has been serious or continuing noncompliance or;
3. It is determined that there has been serious deviation from the provisions of the *Guide*.

## **3. Possible Consequences of a Finding of Noncompliance**

Depending on the seriousness of the noncompliance, the IACUC may take the following actions:

- a. Require, and provide, appropriate ethics or technical training for the individual.
- b. Impose a period of suspension 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 laws and policies.
- c. Notify OLAW (and APHIS if animals regulated by that agency are involved) and any related funding sponsor/agency. Such notification is mandatory for any suspended protocol.

- d. Lodge a charge of scholarly or scientific misconduct. Such charges are deferred for handling in accordance with Georgia Tech's *Policy for Responding to Allegations of Scientific or Other Scholarly Misconduct*, posted at <http://www.researchintegrity.gatech.edu/policy-for-responding-to-allegations-of-scientific-or-other-scholarly-misconduct>.
- e. Should noncompliance continue, the individual may permanently lose the privilege of utilizing vertebrate animals in research and teaching at the Georgia Institute of Technology.

#### **4. Steps for Reinstatement of a Protocol**

- a. The Office of Research Integrity Assurance will schedule a follow-up inspection by at least two members of the IACUC. This subcommittee will determine whether sufficient action has been taken by the PI to correct the cited deficiencies. The results of this inspection are submitted in writing to the PI, Institutional Official/VPR, and department chair.
- b. Should the follow-up inspection be unsatisfactory, the IACUC will require appropriate action ranging from extension of the schedule for correcting the deficiencies to permanent suspension of the activity. This determination will be made by a quorum of the IACUC and will include consideration of the effect the deficiencies have on the welfare of the animals.

#### **5. The Appeal Process**

In the event an individual wishes to appeal a finding of noncompliance, the following process is available.

- a. The PI may request an appeal hearing by contacting the IACUC Chair or the Director or Associate Director of Research Integrity Assurance prior to the deadline stated in the letter of noncompliance.
- b. The IACUC Chair and Institutional Official will determine whether an appeal will be allowed. If so, an IACUC meeting, in which a quorum is attained, will be convened so that the PI can provide any information that may be helpful.
- c. A majority vote of the members attending the convened meeting is required to overturn a finding of noncompliance.
- d. The PI, Institutional Official/VPR, and department chair will be notified in writing of the IACUC's final decision.



## APPENDICES

- Appendix A: IACUC Forms
- Appendix B: Use of By-Products Such as Discarded Tissues or Carcasses
- Appendix C: Use of Embryonic Eggs
- Appendix D: Animal Census: Counting Pups
- Appendix E: Multiple Survival Surgeries
- Appendix F: Use of Vertebrate Animals Solely for Instructional Purposes
- Appendix G: Adoption of Laboratory Research Animal Release & Waiver Form
- Appendix H: Protocol Post Approval Monitoring Checklist

## APPENDIX A: IACUC FORMS

The current forms may be found on the Office of Research Integrity Assurance website at <http://www.researchintegrity.gatech.edu/iacuc-forms>.

Completed forms should be submitted via email to [iacuc@gatech.edu](mailto:iacuc@gatech.edu).

Forms include:

[IACUC Application](#)

[IACUC Amendment Request form](#)

[IACUC Amendment to Increase Animal Numbers](#)

[IACUC Amendment to Change Personnel form](#)

[IACUC Application for Off-Campus Animal Studies](#)

[IACUC Amendment form for Off-Campus Animal Studies](#)

Submitting signature pages:

IACUC applications submitted to [IACUC@gatech.edu](mailto:IACUC@gatech.edu) from the PIs GIT email account are considered electronically signed and do not require an “ink” signature.

## APPENDIX B: USE OF BY-PRODUCTS SUCH AS DISCARDED TISSUES OR CARCASSES

There is no requirement for IACUC notification or review for use of whole animals that are dead at the time of acquisition, or for use of cells, blood, serum, organs, tissues, eggs or any other part of animals that were euthanized for another purpose or died spontaneously. *IACUC review is necessary when euthanasia or procedures on a live animal are initiated to obtain the needed materials.*

Even though IACUC review is unnecessary:

1. If tissues or other materials will be brought to the PRL for any purpose, prior approval must be obtained from the PRL manager or director to ensure that no pathogens are introduced into the central animal facility.
2. Researchers should maintain sufficient records to document the source of these discarded tissues or carcasses, and that their acquisition by Georgia Tech is proper and can be tracked.
3. Approval from a university safety committee will be required if materials are obtained from animals exposed to hazardous materials or agents. Consult Environmental Health & Safety for guidance. 404-894-6120.
4. Disposal of such materials must be in accordance with institute policy. Consult Environmental Health & Safety for guidance. 404-894-6120.
5. Use of such materials may require a Materials Transfer Agreement to protect intellectual property. For guidance, contact the IC3 office at 404-894-6287 or [www.industry.gatech.edu](http://www.industry.gatech.edu).

## APPENDIX C: USE OF EMBRYONIC EGGS

Embryonic eggs, prior to hatching, are not regulated by any federal or state guidelines or other regulations and, thus, no IACUC protocol is required.

**CHICKEN EGGS:** Although chicken embryos less than 18-days old cannot survive ex ovo, there is a possibility that, if not closely monitored, the eggs could hatch prior to use. The resulting live chicks are regulated under PHS policy. For that reason, investigators intending to use embryos beyond the 18th day must prepare a protocol which includes a plan for handling any chicks that hatch. Protocols proposing routine use of embryonic bird eggs prior to 18 days of incubation are not required to submit an IACUC protocol.

**FISH EGGS:** When using zebra fish eggs, researchers should seek IACUC approval for the first larval stage. These tiny eggs hatch into microscopic larva that appear to be two bulging eyes, an almost see-through tail and nothing else. A wide estimation of numbers is recommended, as these hatch by the thousands and would be impossible to enumerate.



## APPENDIX D: ANIMAL CENSUS: COUNTING PUPS

It is the policy of the Georgia Institute of Technology Institutional Animal Care and Use Committee that, for the purposes of maintaining an accurate animal census and per diems, rat and mice pups will not be counted until weaned. Born pups of *any age that are used in research* are counted against the investigator's approved animal number.

## APPENDIX E: MULTIPLE SURVIVAL SURGERIES

Multiple major survival surgical procedures on a single animal are strongly discouraged. However, under certain circumstances they may be permitted when they are scientifically justified by the user and with the approval of the Institutional Animal Care and Use Committee. Multiple survival surgical procedures may be justified when they are related components of a research project and are deemed essential. Cost savings alone is not an adequate reason for performing multiple survival surgical procedures.

## **APPENDIX F: USE OF VERTEBRATE ANIMALS SOLELY FOR INSTRUCTIONAL PURPOSES**

The Georgia Institute of Technology IACUC permits the use of live or deceased vertebrate animals solely for instructional purposes under these conditions:

- The Principal Investigator determines that the educational goals can best be achieved by such usage.
- The Institutional Animal Care and Use Committee has determined that the proposed usage is humane and appropriate and is consistent with the federal regulations governing utilization and care of vertebrate animals used in teaching and research. The minimum number of animals essential to instructional objectives should be used.

Any faculty member who intends to use vertebrate animals for teaching purposes must submit a protocol for IACUC review, following the process described in this document. The protocol must clearly explain why animals are needed to achieve the goals of the course and justify the species and number of animals to be used. IACUC approval must be secured before animals are ordered.

Live vertebrate animals must be cared for according to the university's policies and procedures governing the use of laboratory animals. Disposal of animal tissue must be in compliance with relevant health and safety regulations. Reuse of previously approved preserved material requires no IACUC approval.

## APPENDIX G: ADOPTION OF LABORATORY RESEARCH ANIMAL RELEASE AND WAIVER FORM

I, \_\_\_\_\_ (Name of Recipient), in consideration for the transfer of ownership of \_\_\_\_\_ (Description of Animal), receipt of which is hereby acknowledged, do hereby forever release and discharge the Georgia Institute of Technology and the Board of Regents of the University System of Georgia, its members individually, and its officers, agents and employees, of any and all liability arising out of the transfer of ownership of said animal.

I, \_\_\_\_\_ (Name of Recipient), understand and agree to the following stipulations and disclosures:

1. That said animal has, or may have been, a subject for research purposes;
2. That the recipient accepts said animal "as is" with no warranties, guarantees, or promises of any kind made to anyone with regard to said animal's physical condition or temperament;
3. That the said animal may cause harm to the recipient or other individuals including but not limited to physical injury including death, property damage, and transmitting of disease;
4. That ownership of said animal may incur costs including, but not limited to, neutering, vaccinations, licenses, and medical treatment, and that recipient shall bear sole responsibility for payment of these costs;
5. That recipient agrees that he/she is able to and will provide a good home and proper care and treatment for said animal. Further, the recipient agrees that the animal is being adopted as a personal pet to recipient and shall not be used for any other purpose including, but not limited to, commercial use or other testing;
6. That recipient agrees to hold in confidence and not to disclose any proprietary or confidential information related to the use of this animal in any research project, unless specifically authorized in writing to do so by the Vice President for Research or his/her duly authorized representative;
7. That recipients who are Georgia Tech employees remain bound by the nondisclosure agreement executed at the time of their employment. That agreement is incorporated herein by reference.
8. That I have read the above notice carefully and I hereby assume all risks of damages or injury that I may sustain as a result of adoption of said animal. Furthermore, I acknowledge that I have been given adequate opportunity to review and question the document.

I further covenant and agree that for the consideration stated above I will not seek any monies, damages, or costs of any kind from the Georgia Institute of Technology, its officers, directors, employees, trustees, or other agents and representatives for any claim for damages arising or growing out of my voluntary adoption and ownership of said animal. I have received a copy of this document and I certify that I am at least eighteen (18) years of age, am suffering under no legal disabilities, and that I have read the above carefully before signing.

\_\_\_\_\_  
Signature of Recipient

\_\_\_\_\_  
Georgia Institute of Technology  
Vice President for Research  
and General Manager, GTRC

Date \_\_\_\_\_

Date \_\_\_\_\_

## APPENDIX H: PROTOCOL POST APPROVAL MONITORING CHECKLIST

Principal Investigator:

Protocol Number:

Protocol Approval Period:

Protocol Title:

Species:

Number of animals used and approved:

Date(s) of Monitoring:

Participants:

Research Associate:

### **Grant or Contract:**

- Are the procedures in the Grant or Contract and Protocol consistent?

### **Personnel:**

- Do the PI and/or laboratory personnel have access and/or knowledge of the most recent version of the complete IACUC approved-protocol, including amendments?
- Do the PI and personnel have accurate knowledge of the protocol?
- Are the people performing the study listed on the protocol?
- Are all personnel enrolled in the Occupational Health Program (OHP)?

### **Study Procedures:**

- Does the protocol number on the cage card match approved protocol number?
- Are the procedures performed consistent with those in the approved protocol?
- Are lab personnel appropriately trained to perform these protocol procedures?
- Are investigators wearing required PPE and/or other attire (e.g. masks & gloves) for the species and procedures performed?

### **Anesthesia:**

- Are the methods of anesthesia in compliance with the protocol?
- Are anesthetized animals monitored in a manner that is consistent with IACUC policy and the approved method described in the protocol?
- Are the animals maintained at an appropriate depth of anesthesia for the procedure performed?
- If inhalant anesthetics are used, are they scavenged properly?

### **Surgery:** (if no surgical procedures check here )

- Is surgery performed in a location that has been approved by the IACUC?
- Is the individual performing surgery properly trained in anesthetic, surgical, and post-operative monitoring techniques?
- Is the individual performing surgery wearing PPE during surgery as described in the protocol?
- Is the surgical field prepared as described in the IACUC-approved protocol?
- Is the surgical field maintained as described in the IACUC-approved protocol?
- Are implanted devices sterilized before use?
- Is there an appropriate recovery area for this species?
- Are incisions closed appropriately and in accordance with the approved protocol?
- Is an appropriate heat source used to keep the animal warm throughout the procedure?

### **Post-Surgical care:** (if no surgical procedures check here )

- Are the methods of analgesia (dose, frequency, duration) consistent with the approved protocol?
- Is post surgical (post procedural) care adequately documented?
- Are surgical sutures, staples or wound clips removed at appropriate interval as described in the protocol?
- If any, were post-operative problems reported to the Attending Veterinarian?

### **Euthanasia:** (if no euthanasia procedures check here )

- Does the method of euthanasia correspond with what is written in the protocol?

### **General Record Keeping:**

- Is there an up to date and complete surgical log?
- Are animals identified by protocol number and individual numbers or cage cards?

- Are medical and post-procedure care progress notes complete and accurate?
- Is medication administration accurately documented?
- Are injections, blood collection, and fluid collection amounts dated documented?

**Animal Facility:**

- Do the animals have Environmental Enrichment provided? If not, does the PI have an exemption?
- Are there any facility concerns? If so, please list:

**Investigators Laboratory:**

- If animals are housed in the lab for greater than 12 hours, has the lab been approved by the IACUC?
- For survival procedures are drugs, suture material and other items within the noted package expiration dates? (Note: euthanasia drugs must always be in date.)
- Are controlled substances stored appropriately?
- Are there any safety issues or other concerns that pose a threat to human or animal safety, or animal welfare (biosafety, radiation safety, environmental safety concerns)? If so, please list:

**Non-Compliance:**

- Have any non-compliance issues occurred on this protocol or in the lab relating to this protocol? If so, please list and include the results from the non-compliance.

**Regulations:**

- Have there been any regulation changes (OLAW, USDA, GT, DEA, etc.) that affect this protocol? (If so, what are they specifically and attach new regulation)

**Comments / clarifications:**

## APPENDIX I: PROHIBITION AGAINST PETS IN ANIMAL RESEARCH LABORATORIES AND ANIMAL HOUSING FACILITIES

Due to concerns relating to hygiene, animal welfare and disease transmission, the Institutional Animal Care and Use Committee prohibits the housing of non-research animals (“laboratory pets”) in all animal research laboratories and animal housing facilities at Georgia Tech. An animal research laboratory is any space listed on an animal protocol as a site where animal research is conducted; animal housing facilities are those spaces where laboratory animals reside.

The IACUC acknowledges that some employees may maintain non-research animals as pets within laboratories or other Georgia Tech spaces not subject to IACUC oversight. The IACUC therefore has the following *recommendations* for maintaining laboratory pets that are outside of its purview:

- There is a real risk of disease transmission between laboratory pets and research animals *that may be located nearby*, and coworkers may suffer from allergies that are exacerbated by exposure to them. The potential for disease transmission between pets and research animals is much greater if pets are housed in close proximity to where research animals are used.
- Living conditions for pet animals should meet the standard generally accepted for the species.
- Good hygienic practices, such as routinely washing hands after handling pets, should be followed.
- Rodent colonies, in particular, are at constant risk for exposure to adventitious pathogens. Another potential source of exposure is from people who have rodents in their homes, either as pets, or as food source for pets (e.g. snakes). Prudent practices are necessary to minimize the risk of disease transmission from these unmonitored animal populations to rodent colonies. Those who have rodents at home are asked to not handle those animals prior to working with research animals that day. Clothing that comes in contact with pet rodents should be washed before being worn to work.
- Disease transmission in non-mammalian species is also possible. Personnel keeping pet birds, amphibians, reptiles, or fish should be aware that these animals may harbor pathogens that pose significant risk for research animals. While such animals may appear healthy, some carry potentially zoonotic organisms, such as *Salmonella spp.*



## APPENDIX J: ACCESS TO THE PRL ANIMAL FACILITY

Prior to being granted independent Buzz Card access to the Physiological Research Laboratory (PRL), all personnel must:

- 1) Complete the required online CITI module “Working with the IACUC” Basic Course and any other CITI module(s) applicable to the research project in which he/she will be participating.
- 2) Enroll in the campus wide Occupational Health Program administered by Environmental Health & Safety.
- 3) Be approved on any and all IACUC protocols under which he/she will conduct research.
- 4) Undergo an Orientation session with the PRL manager.

### A. Undergraduate Student Access to the PRL Animal Facility

Undergraduate students must complete the four basic steps described above *and be accompanied by a trained graduate student from an approved protocol, post-doctoral associate, laboratory technician, PRL Director, PRL Manager, or Principal Investigator at all times while in the PRL.* Short term undergraduate students (such as those at Georgia Tech for a summer learning experience) and other student visitors will not be allowed independent Buzz Card access to the PRL and must be accompanied by a mentor while in the facility.

In rare cases, undergraduate students who demonstrate advanced proficiency and are carrying out an independent project may be granted Buzz Card access to the facility and may enter unescorted. Proficiency shall be determined by the Director of Animal Resources/Attending Veterinarian.

PRL staff may inspect Buzz Cards to verify that a student’s access has been approved. Personnel who are found in the PRL without such approval may be asked to leave. Students and others who improperly admit unapproved personnel may lose their own access to PRL.

### B. Visitors, Observers and Guest Researchers

#### 1. Visitors

Visitors with a scientific interest in the PRL who are not approved on protocols may tour the PRL, but they must be escorted by a PI from an approved protocol, the IBB or PRL Director or IBB or PRL staff members. Such visitors must remain in the facility hallways; they may not enter animal rooms or procedure rooms. The escort is responsible for advising the visitor about hazards or possible disturbing sights within the PRL. The escort is also to enforce the policy that persons with pet rats or mice, or reptiles that consume rats or mice, are not allowed in the PRL. Such visits do not require advance notification.

#### 2. Observers

Anyone on an approved protocol *except an undergraduate student* may bring people with a scientific interest in the PRL to observe procedures without addition to the protocol. The PRL staff must be told in advance to expect observers, and observers must check in with the PRL manager. Observers must always be escorted, but may enter procedure, surgery and housing rooms. Observers must not touch animals. The escort is to enforce the policy that persons with pet rats or mice, or reptiles that consume rats or mice, are not allowed in the PRL.

#### 3. Guest Researchers

Non-Georgia Tech researchers may enter the PRL and perform hands on work with animals if they are approved on a Georgia Tech protocol. The Georgia Tech PI, co-PI or other approved designee must be present, in charge and responsible when non-Georgia Tech personnel are working with animals in the PRL. (See the complete IACUC policy on visiting researchers at section I.V.F, “Principal Investigator Eligibility Requirements”).

#### 4. Others

Persons without scientific, commercial, regulatory, legal or construction/repair concerns in the PRL (such as curious relatives and friends) are not allowed to enter the facility.