INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

POLICIES AND PROCEDURES

February 2020
Policies & Procedures
Recent Revisions and Updates

- February 2020
  - Removal of the requirement for annual committee review of off-campus protocols

- December 2019
  - Inclusion of animal transfers between protocols
  - Addition of DOD component review
  - Policy updates
  - Clarification of off-campus protocol requirements
  - Reorganization of document
  - Inclusion of TOPAZ system for protocol submission

- March 2017
  - Updated links within document.

- March 2016
  - Revised 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
  - Updated form links
  - Clarify requirements for Umbrella form usage
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I. OUR MISSION AND ASSURANCE

The Georgia Institute of Technology’s (Tech) 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 Institute of Technology personnel are involved, or when funding flows through Georgia Institute of Technology.

Georgia Institute of Technology’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.

The Assurance is available from the Office of Research Integrity Assurance (ORIA) or by email IACUC@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 https://researchintegrity.gatech.edu/about-iacuc/iacuc-resources-regulations. Georgia Institute of Technology 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 AWA and related regulations can be found at www.researchintegrity.gatech.edu/iacuc.

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 Agreements with Emory and GCMI).

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 or their designee must review any animal research protocol before it can proceed. The Attending Veterinarian 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, another GT laboratory animal veterinarian will act as the Attending Veterinarian.

C. Institutional Animal Care and Use Committee (IACUC)

The IACUC was established pursuant to the Animal Welfare Act 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 Institute of Technology 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/role for whom the individual 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 the individual 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 Institute of Technology’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* and the *Animal Welfare Act 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 (12) hours. PHS Policy requires inspection of all surgical facilities and areas in which animals are maintained longer than twenty-four (24) hours. The IACUC inspects all facilities where animals are kept for more than twelve (12) 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 an employee of the Institute and holds a title of Academic Faculty or Research Faculty;
  - 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 Institute of Technology 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 Institute of Technology Personnel Participating in Protocols at Georgia Institute of Technology (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 Institute of Technology 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 Institute of Technology faculty member has any involvement in the project, AND the funding (if any) is awarded to Emory University with a subcontract to Georgia Institute of Technology solely for the student’s stipend and tuition, AND a Georgia Institute of Technology student is being mentored and supervised by the Emory University Principal Investigator, the Georgia Institute of Technology student will be named Principal Investigator (PI) for Georgia Institute of Technology’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 Institute of Technology must be for the student’s stipend and tuition.

The Georgia Institute of Technology student PI must submit to the Georgia Institute of Technology 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 Institute of Technology 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 Institute of Technology IACUC.

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

2. Exception for Georgia Institute of Technology 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 Institute of Technology faculty member has any involvement in the project, AND a Georgia Institute of Technology student is being mentored and supervised by the Emory University Principal Investigator, AND the funding awarded to Georgia Institute of Technology is solely for the student’s fellowship, the Georgia Institute of Technology student can be named Principal Investigator (PI) for Georgia Institute of Technology’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 Institute of Technology student PI must submit to the Georgia Institute of Technology 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 Institute of Technology 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 Institute of Technology IACUC.

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

D. Non-Georgia Institute of Technology Personnel Participating in Protocols at Georgia Institute of Technology (Visiting and Volunteer Researchers)

Georgia Institute of Technology 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 Institute of Technology. In order to ensure appropriate protections for those visitors/volunteers and for Georgia Institute of Technology faculty and staff, this policy has been developed.

Prior to participating in animal research, non-Georgia Institute of Technology 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** or **VISITING SCHOLAR AGREEMENT** 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 Institute of Technology 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 Institute of Technology’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 Institute of Technology 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 Institute of Technology 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 a 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 be listed 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. On-Campus Activities Requiring IACUC Approval

Vertebrate animal use on campus must be reviewed in-full and 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.

1. 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.

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 Tech IACUC can recognize the approval from another IACUC for studies where all of the work is being conducted at a different institution.

1. When there is an agreement with Another PHS-Assured IACUC

While OLAW and APHIS agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement, they request that institutions have a formal written understanding (e.g., memorandum of understanding, MOU) that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight (Guide page 15). Sections a) and b) outline two such agreements involving Georgia Institute of Technology.

When a written agreement (e.g., MOU) exists between Georgia Institute of Technology and another PHS-Assured institution, the Tech IACUC can accept the other institution’s IACUC approval. However, the Tech PI must provide ORIA with the other institution’s IACUC approval letter and approved protocol, as well as the funding proposal or statement of work (if applicable), and then the project may begin immediately. ORIA will provide the Tech IACUC with these materials, and give the Tech IACUC the opportunity request a discussion of any potentially substantive issues at a convened meeting of the IACUC.

a) 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 Institute of Technology defers to Emory’s IACUC for the review and oversight of certain protocols when a Georgia Institute of Technology investigator is performing a research project at an
Emory site. Likewise, Emory will defer to Georgia Institute of Technology’s IACUC for the review and oversight of protocols when an Emory investigator is performing a research project at a Georgia Institute of Technology site. In these cases, each reviewing IACUC agrees to use the investigator’s home IACUC forms. When a Georgia Institute of Technology investigator performs research at an Emory site, the Georgia Institute of Technology faculty member shall provide 1) the Georgia Institute of Technology IACUC Application for Georgia Institute of Technology 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. Once this information is received, the Georgia Institute of Technology personnel may begin work on the project.

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 Institute of Technology. Likewise, disapprovals of protocols by Georgia Institute of Technology’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 Tech 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 Institute of Technology 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.

b) Global Center for Medical Innovation (GCM)/Translational Testing and Training Laboratories, Inc. and Georgia Institute of Technology (Tech)

IACUC Reciprocity. In accordance with NOT-OD-01-017 “Office of Extramural Research Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden,” Tech and GCMI may recognize the approval from the other IACUC for studies where all of the work is being conducted at a different institution. While IACUC Reciprocity shall be recognized, this does not relieve Tech and GCMI personnel from other Institutional requirements to report off-campus research activities as outlined below.

Excerpt from “GIT/GTRC/GCMI MOU”

Tech conducting Animal Subject (AS) Research at GMCI-Operated Facilities. When Tech Personnel will be engaged in AS Research at GMCI-Operated facilities, the following procedures shall be followed to allow IACUC Reciprocity:

a. Funded Research Activities shall be routed and negotiated through the Office of Sponsored Programs (OSP) or Industry Engagement (IE) as a grant, contract, or sub-award to GCMI to support the activity.
b. All GMCI procedures shall be followed including ordering / housing of animals, training, and IACUC review / approval. The GMCI IACUC shall provide initial review and continuing oversight, including semi-annual inspections. Investigators shall utilize any forms and processes required by GCMI. Any required radiation safety, occupational health, disaster plan or Institutional biosafety review shall be provided to the GMCI IACUC.
c. When Tech personnel will be engaged in the AS Research at GCMI, the following materials must be submitted to the Tech IACUC: 1) GCMI approved IACUC protocol, 2) GCMI approval letter, 3)
Statement of Work (SOW) if sponsored research. Upon receipt of these materials, the Tech IACUC will notify the PI that the activity may proceed.

d. While the responsibility of IACUC notification remains with the Principal Investigator (PI), to facilitate compliance, GCMI will provide the Georgia Institute of Technology IACUC with a copy of the approved protocol, SOW and any amendments. The Protocol and amendments shall be provided electronically to the Tech IACUC at IACUC@gatech.edu or uploaded in the protocol submission system (Elements) by the PI.

Reporting Between Tech and GCMI IACUCs. The Tech IACUC and GCMI IACUC shall provide the other with prompt written notice of the following items regarding Collaborative AS Research being conducted at Tech or GCMI-Operated Facilities:

a. Approval of Protocols, Amendments, Modifications, and Renewals for Tech activities to be conducted at GCMI by Tech personnel.

b. Initiation of any investigation or inspection (whether by Tech, GCMI, or an oversight body/government agency or sponsor).

c. Any report of Non-compliance or suspected Non-compliance.

d. Specific complaints received regarding the research.

e. Suspension or termination of the research.

f. Reportable adverse events/deaths.

g. Reportable injury.

h. Substantive Institutional or IACUC policy changes that may affect the conduct of the research.

i. Change in status for USDA registration or OLAW Assurance.

j. Significant questions or issues raised during a semiannual program inspection.

2. When there is No Agreement with Another Institution

If there is not a written agreement between Georgia Institute of Technology and the collaborating institution, the Tech IACUC must perform a review of the off-campus animal project before any Georgia Institute of Technology personnel participate in the project and before any associated funding is released by OSP. The review process for such scenarios is described below.

a) Georgia Institute of Technology Personnel Working at an Off-Campus Site with a PHS-Approved IACUC

In cases where the Georgia Institute of Technology faculty, staff or student involved in work located at an off-campus site with a PHS-approved IACUC, and no MOU exists between the institutions, the Georgia Institute of Technology IACUC will perform its own review of the approved protocol from the other IACUC. The Georgia Institute of Technology IACUC requires investigators to submit a copy of the IACUC approved protocol from the other reviewing institution, a copy of that institution’s IACUC approval letter, and the abbreviated Georgia Institute of Technology IACUC Application for Georgia Institute of Technology Personnel Working at Off-Campus Site(s). If no substantive issues are raised by the Georgia Institute of Technology IACUC, the Committee will issue an approval letter for the off-campus activity. During the course of the off-campus activity, the Georgia Institute of Technology PI must submit any approved amendments to the protocol, any reports of adverse events, any reports of injury, and any reports of non-compliance.

b) Non-Georgia Institute of Technology Personnel Working at an Off-Campus Site with a PHS-Approved IACUC

In cases where all animal work is performed off-campus by non-Georgia Institute of Technology personnel and under a PHS-approved IACUC Assurance, but no MOU exists between the two institutions, there may still be institutional engagement due to funding or other involvement. For example, a Tech researcher is considered “engaged” in the off-campus research if s/he is involved in the design of animal studies. In this case, the Georgia Institute of Technology faculty member shall provide for the Georgia Institute of Technology 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 Institute of Technology member does have direct involvement with the off-campus work, the current Tech IACUC application process must be followed.

c) Georgia Institute of Technology Personnel Working at an 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 full Tech IACUC application process must be followed (as if the work were being performed on campus).

C. Activities Involving the Study of Animals in Zoos, Petting Zoos, Wild Animal Parks, or Similar Habitats

Activities conducted at a zoo, petting zoo, wild animal park, or similar habitat by Georgia Institute of Technology 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 Institute of Technology

A Collaborative Research Agreement between Zoo Atlanta and Georgia Institute of Technology 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 Institute of Technology faculty, staff, or students must be reviewed and approved in advance by the Georgia Institute of Technology IACUC.

When a Georgia Institute of Technology investigator performs research at Zoo Atlanta, the Georgia Institute of Technology 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 Institute of Technology 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 Tech students obtaining course credit. This includes, but is not limited to, PSYC 3031 - Experimental Analysis of Behavior, BIO 2802 Internship at Zoo Atlanta, or BIO 4590 Research Project Lab: Wildlife Conservation at Zoo Atlanta. The Tech PI is responsible for obtaining IACUC approval as noted above.

D. 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 Institute of Technology’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 Institute of Technology 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 Institute of Technology’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.

E. Activities that may not require IACUC Approval

1. 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 if IACUC review is unnecessary:

a) 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.

b) Researchers should maintain sufficient records to document the source of these discarded tissues or carcasses, and that their acquisition by Georgia Institute of Technology is proper and can be tracked.

c) 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 (https://www.ehs.gatech.edu/biosafety).

d) Disposal of such materials must be in accordance with institute policy. Consult Environmental Health & Safety for guidance (https://www.ehs.gatech.edu/biosafety).
Use of such materials may require a Materials Transfer Agreement to protect intellectual property. For guidance, contact the Office of Exchange Agreements (https://industry.gatech.edu/researcher-toolkit#exchange-agreements).

2. 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. However, please consider the following exceptions:

a) 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.

b) 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.

3. Use of Service, Emotional Support, and Therapy Animals

Definitions:

- **Assistance animal**: Any animal that works, provides assistance, or performs tasks for the benefit of a person with a disability, or provides emotional support that alleviates one or more identified symptoms or effects of a person’s disability (U.S. Department of Housing and Urban Development, FHEO-2013-01);

- **Service animal**: Any dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability (Americans with Disabilities Act 1990, Section 35.136);

- **Emotional support animal**: An animal of any species, the use of which is supported by a qualified physician, psychiatrist or other mental health professional based upon a disability-related need (Fair Housing Act, 42 U.S.C. Part 3604);

- **Therapy animal**: A type of animal-assisted intervention in which there is a “goal directed intervention in which an animal meeting specific criteria is an integral part of the treatment process” (C.F.R. Part 382).

Use of the above animals on campus does not require approval of the IACUC as long as the animal is not undergoing manipulation for research or experimentation (subject to AWA requirements), and is not being used for instruction of students (subject to OLAW requirements). However, the use of such animals in a context related to research or instruction should be communicated to the IACUC for their awareness. Further, these animals are not permitted in animal facilities or animal study areas.

F. Procedures for Applying for IACUC Approval

Under the Georgia Open Records Act (GORA), Tech records (which may include protocol applications or portions thereof) may become accessible by the general public. All GORA requests should be sent to Office of Legal Affairs (OLA) for review and response.
Note the institute policy regarding eligibility for the role of Principal Investigator on an animal protocol (Section IV, of these Policies & Procedures).

The Office of Research Integrity Assurance (ORIA) has migrated from a document- and email-based application process to an online system called TOPAZ Elements. The new online process includes separate forms for new applications, amendments, and renewals, whether the activity will occur either on- or off-campus.

- TOPAZ Elements users are directed to login to the online protocol submission system. The PI must complete the final Certification section of the form and then submit the form. This will be treated as an electronic signature. Additional guidance for the TOPAZ Elements system is available on the ORIA website.

Both processes for obtaining IACUC approval are referenced, as appropriate, in the steps below:

1. **NEW PROTOCOL APPLICATION**
   The TOPAZ Elements version of this form can be found under the Animal Protocols menu (“Create Original Protocol”) once the user is logged in to the system.

2. **ATTACHMENT: SOW or PD**
   A copy of the funding proposal sent to the funding agency or the final statement of work must accompany all externally-funded IACUC protocol applications.

   Federal regulations require the IACUC to compare the protocol to the funding proposal Statement of Work (SOW) or Project Description (PD). 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/spoonor. 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.

   When submitting a Word version of the new protocol application via email, the funding proposal or statement of work must be attached to the email.

   In TOPAZ, the funding proposal or statement of work must be attached to the online protocol form in the Accounts section.

3. **REQUIRED TRAINING**
   All Tech 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 Tech personnel named on the protocol must enroll in the Georgia Institute of Technology Occupational Health Program, managed by Environmental Health & Safety and provided by contract with Concentra Health Services. An opt-out provision is available.

5. **DEPARTMENTAL SIGN OFF**
   The prepared application is to be approved by the applicant’s department head to indicate that they are aware of and support the proposed activity and concur with its submittal to the IACUC. When the department chair is the Principal Investigator named in the protocol, no other approval is required.
For TOPAZ protocols, ORIA will route the submission electronically to the Department Chair for their approval within the system.

6. INITIAL REVIEW PROCESS
The protocol application will be given a preliminary review by the Office of Research Integrity Assurance and then will be routed to a Georgia Institute of Technology Veterinarian and Environmental Health & Safety for consultation (through the TOPAZ Elements system). Following veterinary and safety consultation, the protocol will be returned to the Principal Investigator for modifications, if necessary. If no modifications are required, the Office of Research Integrity Assurance will distribute the protocol to the Committee.

7. 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 the TOPAZ system, for distribution to the Committee.

8. 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. In cases where other Institutional reviews or approvals are required (i.e., Institutional Biosafety Committee, Radiation Committee, etc.), those should be sought in parallel.

9. DOD Component review (if applicable)
If the protocol is funded by a branch of the Department of Defense (e.g., Army), the DOD component oversight office (e.g., ACURO) must conduct an administrative and veterinary review of the Tech IACUC-approved protocol before the animal work begins. ORIA will advise the PI to initiate this process when they issue the Tech protocol approval letter through TOPAZ.

G. Protocol Amendments
Protocol amendments must be submitted for review and approval in advance of implementation.

Submission via TOPAZ:
All types of amendments (personnel, animal numbers, procedures, etc.) are submitted using the Create Amendment Protocol option under the Animal Protocols menu in TOPAZ.

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 approved administratively by the Office of Research Integrity Assurance.

As with full protocol applications, major protocol amendments funded by the Department of Defense must be approved by the DOD component office prior to beginning the new/modified animal work. ORIA will forward to the DOD component office the Tech amendment approval letter to initiate this process for the PI.

H. 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.


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.

a. 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.


- 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) and PHS Policy IV.C.1.a]. 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. Alternative Endpoints

a) Adoption: 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 have otherwise been determined to be suitable for adoption may be considered as candidates for adoption. The “Request to Adopt Vertebrate Animals” form can be obtained from the Director or Research Integrity by email request.

b) Transfer to another protocol: Another alternative endpoint for a research animal is the transfer to a different approved IACUC protocol. Animals that are qualified for adoption would generally also qualify for transfer to another protocol. However, some animals such as animals exposed to a biological hazard would not qualify for this alternative endpoint.

- Procedures for animal transfer to another protocol:
  1. The researcher must first obtain the Animal Transfer Form from the mailbox outside of EBB room B111.
  2. The form must be completed and submitted to the PRL staff before beginning work with the transferred animal(s) on the new protocol(s).
  3. Researchers must also update the protocol information on the transferred animal’s cage card.

- Note: The PI is responsible for tracking their protocol expiration dates and contact the PRL to transfer animals off of protocols before expiration.
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 reference number and logged into the database (this occurs automatically in the TOPAZ system).

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 (within the TOPAZ system), 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 Member 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 (FCR) 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.

b) Protocol Returned for Modifications

In accordance with OLAW Guidance Notice Number: NOT-OD-11-053, the following procedure will be followed when the 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 Review 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 Review 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 (DMR) When Full Committee Review (FCR) 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 or may not 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 Review.

Upon Committee approval, the Office of Research Integrity Assurance will notify 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 IACUC Chair who will be copied on all Designated Member Review protocol distributions and will reassign reviewers as appropriate. 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. Questions regarding whether a formal amendment is required should be directed to the Office of Research Integrity Assurance. All amendments must be approved before the changes are implemented. Amendments do not extend the original 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), VA funding (all species), pain category E (all species), and for off-campus protocols in which the external institution is performing annual reviews, ORIA will initiate annual reviews for the PI. For all such cases, personnel training and funding status will be checked by ORIA and updated, if needed. On-campus protocols of the types listed above will be sent to the IACUC for review. If no substantive concerns are raised by the committee, the PI will receive an approval letter once the IACUC review is complete. For off-campus protocols that involve another PHS-assured institution, duplicative review is not needed (see NOT-OD-01-017). Instead, the Georgia Institute of Technology 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 Institute of Technology’s IACUC approval has been granted under these policies at V. B. Off-Campus Activities Requiring IACUC Approval.

Annual reviews can be conducted before the anniversary of the original protocol approval (or before the anniversary the last time the protocol was reviewed). The Committee, while reviewing protocol amendments, may review the full approved protocol and will then allow for the simultaneous annual reviews of the protocol. This is true as long as the amendment approval date does not extend beyond the anniversary of the original approval or the last amendment 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 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 Institute of Technology Personnel

Visiting Scholars, other visitors, volunteers, and others not employed by or enrolled at Georgia Institute of Technology, but participating in animal projects in Georgia Institute of Technology 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 [VPR Training page](mailto:VPR.Training@gatech.edu).
• Completion of *Living System Modeling and Analysis* is available for Graduate Students.
• Attend professional IACUC training or IACUC related education meetings via AALAS, AWIC, PRIM&R, ACLAM.

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.

**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, and that the funding source matches the source cited in the IACUC approved protocol. Refer to the “Procurement of Vertebrate Animals Policy” for full details.
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 may use a Protocol Post Approval Monitoring Checklist for the routine post process protocol reviews. 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 Institute of Technology 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 Institute of Technology.

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 the IACUC website.
XI. 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. 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 Institute of Technology’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 Institute of Technology.

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 Institute of Technology's Policy for Responding to Allegations of Scientific or Other Scholarly Misconduct, posted at http://www.research.integrity.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:       Prohibition Against Pets in Animal Research Laboratories and Animal Housing Facilities
Appendix B:       Access to the PRL Animal Facility
APPENDIX A: 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 Institute of Technology. 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 Institute of Technology 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 B: 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 the individual will conduct research.
4) Undergo an Orientation session with the PRL and complete the access request form.

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. Undergraduate students (such as those at Georgia Institute of Technology 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.

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.

Only a PRL manager can grant or remove access to PRL facilities. Any proposed change in access level must be cleared with a PRL manager.

B. Visitors, Observers and Guest Researchers

1. PRL Visitors
Short-term visitors to the PRL must have prior approval from a PRL Manager and must be escorted by someone listed on an approved protocol (other than an undergraduate) or a PRL or IACUC team member. 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 and sensitivities 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.

2. Research Observers
Anyone on an approved protocol, except an undergraduate student, may bring people with a scientific interest in the PRL to observe procedures, on a short-term basis, 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 Institute of Technology researchers may enter the PRL and perform hands on work with animals if they are approved on a Georgia Institute of Technology protocol. The Georgia Institute of Technology PI, co-PI or other approved designee must be present, in charge and responsible when non-Georgia Institute of Technology 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 any PRL facility.
To ensure security and safety, proof of identification and verification of access will be requested by PRL staff. A record/log of entry and exit of all persons must be maintained in the PRL.