



INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

POLICIES AND PROCEDURES

June 2021

Policies & Procedures

Recent Revisions and Updates

- June 2021
 - Addition of Appendix C
- March 2021
 - Updates to Occupational Health Program in line with renewed Assurance
 - Clarification of when an off-campus protocol is required
- May 2020
 - Small clarifications
- March 2020
 - Reduction of the requirement for veterinary review of IACUC protocols to those required by federal regulations/guidance
 - Clarification that veterinary and EH&S reviews can occur at any time prior to protocol approval
 - Removal of the requirement to conduct annual reviews solely because a protocol is supported by DOD
- 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

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

POLICIES AND PROCEDURES

Table of Contents

I. OUR MISSION AND ASSURANCE	8
II. REGULATORY AUTHORITIES GOVERNING ANIMAL USE	9
A. U.S. DEPARTMENT OF AGRICULTURE (USDA)	9
B. PUBLIC HEALTH SERVICE (PHS), NATIONAL INSTITUTES OF HEALTH (NIH), OFFICE OF LABORATORY ANIMAL WELFARE (OLAW)	9
III. ADMINISTRATIVE ORGANIZATION OF GEORGIA INSTITUTE OF TECHNOLOGY'S ANIMAL CARE AND USE PROGRAM	10
A. INSTITUTIONAL OFFICIAL	10
B. INSTITUTIONAL ATTENDING VETERINARIAN	10
C. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)	10
1. IACUC MEMBERSHIP	10
A) ALTERNATE MEMBERS	11
2. EXPECTATIONS OF IACUC MEMBERS	11
A) EDUCATION PROVIDED FOR IACUC MEMBERS	11
B) ATTENDANCE AT COMMITTEE MEETINGS	11
C) SERVING AS PRIMARY OR SECONDARY PROTOCOL REVIEWER OR AS DESIGNATED REVIEWER	11
D) PARTICIPATION IN SEMIANNUAL PROGRAM REVIEWS AND FACILITIES INSPECTIONS	11
E) MEMBER AND ALTERNATE MEMBER CONFLICTS OF INTEREST	12
F) CONFIDENTIALITY	12
G) FAILURE TO MEET MEMBERSHIP EXPECTATIONS	12
3. MEETING AND QUORUM REQUIREMENTS	12
A) IACUC MEETINGS	12
B) USE OF TELECOMMUNICATIONS FOR IACUC MEETINGS	12
C) QUORUM DEFINED	13
D. OFFICE OF RESEARCH INTEGRITY ASSURANCE	13
1. COMMITTEE SUPPORT	13
2. SEMIANNUAL SELF-EVALUATIONS OF THE ANIMAL CARE AND USE PROGRAM AND FACILITIES	13
A) REVIEW OF THE ANIMAL CARE AND USE PROGRAM	13
B) REVIEW AND INSPECTION OF ANIMAL FACILITIES	14
3. FEDERALLY REQUIRED REPORTS	14
A) USDA REGISTRATION AND PHS ASSURANCE	14
B) ANNUAL AND SEMIANNUAL REPORTS	14
I. USDA	14
II. PHS, NIH OFFICE OF LABORATORY ANIMAL WELFARE	14
III. SEMIANNUAL REPORTS TO THE INSTITUTIONAL OFFICIAL	15

IV. OTHER REPORTING REQUIREMENTS	15
4. RECORD KEEPING	15
IV. PRINCIPAL INVESTIGATOR ELIGIBILITY REQUIREMENTS	16
A. ELIGIBILITY FOR TITLE OF PRINCIPAL INVESTIGATOR	16
B. EXCEPTIONS REQUIRING APPROVAL BY EXECUTIVE VICE PRESIDENT FOR RESEARCH	16
C. GRADUATE AND UNDERGRADUATE STUDENT RESEARCH PROJECTS	16
1. EXCEPTION FOR STUDENTS RECEIVING STIPENDS/TUITION IN SUPPORT OF WORK ON EMORY PROTOCOLS	16
D. NON-INSTITUTE PERSONNEL PARTICIPATING IN PROTOCOLS (VISITORS AND VOLUNTEERS)	17
E. DEFINITIONS	18
1. PRINCIPAL INVESTIGATOR	18
2. CO-PRINCIPAL INVESTIGATOR	18
3. CO-INVESTIGATOR	18
V. WHEN AND HOW INVESTIGATORS SHOULD SECURE IACUC APPROVAL	19
A. ON-CAMPUS ACTIVITIES REQUIRING IACUC APPROVAL	19
1. USE OF VERTEBRATE ANIMALS SOLELY FOR INSTRUCTIONAL PURPOSES	19
B. OFF-CAMPUS ACTIVITIES REQUIRING IACUC APPROVAL	19
1. WHEN THERE IS AN AGREEMENT WITH ANOTHER PHS-ASSURED IACUC	19
A. EMORY UNIVERSITY AND GEORGIA INSTITUTE OF TECHNOLOGY	19
B. GLOBAL CENTER FOR MEDICAL INNOVATION	20
2. WHEN THERE IS NO AGREEMENT WITH ANOTHER INSTITUTION	21
A. INSTITUTE OF PERSONNEL WORKING AT OFF-CAMPUS SITE WITH PHS-APPROVED IACUC	20
B. PERSONNEL WORKING AT OFF-CAMPUS SITE WITH PHS-APPROVED IACUC	20
C. INSTITUTE PERSONNEL WORKING AT OFF-CAMPUS SITE WITH NO PHS-APPROVED IACUC	21
C. ACTIVITIES INVOLVING THE STUDY OF ANIMALS IN ZOOS, PETTING ZOOS, WILD ANIMAL PARK, OR ...	21
1. COLLABORATIVE RESEARCH AGREEMENT BETWEEN ZOO ATLANTA AND THE INSTITUTE	21
D. ACTIVITIES INVOLVING THE STUDY OF VERTEBRATE ANIMALS IN THEIR NATURAL HABITAT (“FIELD STUDIES”)	21
1. FIELD ACTIVITIES EXEMPT UNDER USDA REGULATIONS	21
2. FIELD ACTIVITIES NOT EXEMPT UNDER PHS REGULATIONS	22
3. FIELD STUDIES INVOLVING CAPTURE AND/OR INVASIVE MEASURES	22
4. IACUC INSPECTION REQUIRED FOR CERTAIN FACILITIES	22
E. ACTIVITIES THAT MAY NOT REQUIRE IACUC APPROVAL	24
1. USE BY-PRODUCTS SUCH AS DISCARDED TISSUES OR CARCASSES	24
2. USE OF EMBRYONIC EGGS	24
3. USE OF SERVICE, EMOTIONAL SUPPORT, AND THERAPY ANIMALS	24
F. PROCEDURES FOR APPLYING FOR IACUC APPROVAL	23

1.	NEW PROTOCOL APPLICATION	24
2.	ATTACHMENT: SOW OR PD	24
3.	TRAINING	24
4.	OCCUPATIONAL HEALTH PROGRAM	24
5.	DEPARTMENTAL SIGN OFF	24
6.	PRELIMINARY PROTOCOL SUBMISSION	ERROR! BOOKMARK NOT DEFINED.
7.	INITIAL REVIEW PROCESS	24
8.	FINAL PROTOCOL SUBMISSION	25
9.	COMMITTEE REVIEW	25
G. PROTOCOL AMENDMENTS		25
H. PROTOCOL REVIEW CRITERIA		25
1.	POTENTIAL VALUE OF THE STUDY.	25
2.	SELECTION OF VERTEBRATE ANIMAL SPECIES.	25
3.	JUSTIFICATION OF ANIMAL NUMBERS.	25
4.	MINIMIZATION OF PAIN/DISTRESS.	26
5.	ALTERNATIVES	26
6.	DUPLICATION	26
7.	LIVING CONDITIONS/HOUSING	26
8.	PERSONNEL	26
9.	SURGERY	26
10.	EUTHANASIA	27
11.	ALTERNATIVE ENDPOINTS	27
VI. REVIEW OF PROTOCOL OR AMENDMENT APPLICATION		29
A. ADMINISTRATIVE PROCESSING		29
B. COMMITTEE REVIEW PROCESS		29
1.	FULL COMMITTEE REVIEW AT A CONVENED MEETING	29
A)	PROTOCOL APPROVED	29
B)	PROTOCOL RETURNED FOR MODIFICATIONS	30
C)	PROTOCOL DISAPPROVED	30
2.	DESIGNATED MEMBER REVIEW WHEN FULL COMMITTEE REVIEW IS NOT CALLED	30
A)	DESIGNATED MEMBER REVIEWER ASSIGNMENTS	31
3.	REVISIONS TO AN EXISTING PROTOCOL (AMENDMENTS)	31
4.	ANNUAL CONTINUING REVIEW	30
5.	THREE YEAR RENEWAL	31
C. PROCESS FOR HANDLING EXTRAORDINARY CALLS FOR FULL COMMITTEE REVIEW		31
VII. REQUIRED TRAINING FOR RESEARCH PERSONNEL		32
A. REQUIRED TRAINING FOR ALL RESEARCH PERSONNEL NAMED ON ANIMAL PROTOCOLS		32
1.	TRAINING FOR NON-GEORGIA INSTITUTE OF TECHNOLOGY PERSONNEL	32
2.	EXCEPTION TO TRAINING REQUIREMENT	32
3.	FREQUENCY OF RETRAINING	32
B. GRADUATE LEVEL SPECIAL TOPICS COURSE		33
VIII. PROCUREMENT OF VERTEBRATE ANIMALS		34
IX. POST APPROVAL MONITORING		35

A. POST APPROVAL MONITORING IS AN IMPORTANT PART OF PROGRAM OVERSIGHT	35
B. CONSISTENCY BETWEEN FUNDING PROPOSAL AND IACUC PROTOCOL	35
C. THE POST APPROVAL MONITORING VISIT	35
D. DESCRIPTION OF POSSIBLE DISCREPANCIES	36
E. SHARING INFORMATION CONCERNING THE REVIEW	36
F. POST APPROVAL MONITORING FOLLOW-UP	36
G. APPEAL PROCESS	37
H. RECORDKEEPING	37
X. OCCUPATIONAL HEALTH PROGRAM	39
A. OCCUPATIONAL HEALTH AND SAFETY COMMITTEE (OHSC)	39
B. DESCRIPTION OF OCCUPATIONAL HEALTH PROGRAM	39
C. ENROLLMENT REQUIRED FOR CERTAIN EMPLOYEES AND STUDENTS	39
D. INDIVIDUAL ENROLLMENT AND RISK ASSESSMENT	40
E. RECOMMENDATIONS & REQUIRED TRAINING	40
F. MEDICAL CARE AND MONITORING SERVICES	40
G. ONGOING ENROLLMENT	41
H. RESEARCH PROTOCOL RISK REVIEW	41
I. ANIMAL FACILITY STAFF ACTIVITY RISK REVIEW	41
J. OPTING OUT OR DECLINING PARTICIPATION	42
K. RELATED INSTITUTIONAL SAFETY POLICIES	42
XII. REVIEW AND INVESTIGATION OF NONCOMPLIANCE	43
A. REPORTING CONCERNS ABOUT ANIMAL CARE AND USE	43
B. NONCOMPLIANCE WITH PROTOCOL, POLICIES, LAWS OR REGULATIONS	43
C. EXAMPLES OF NONCOMPLIANCE	43
D. PROCEDURE TO BE FOLLOWED IN CASES OF ALLEGED OR APPARENT NONCOMPLIANCE	43
1. THE PROCESS OF INQUIRY	44
A) INQUIRY DEFINED	44
B) PROCEDURES TO BE FOLLOWED WHEN CONDUCTING AN INQUIRY	44
C) NOTIFICATION OF GOVERNING AUTHORITIES	44
2. THE PROCESS OF INVESTIGATION	44
A) INVESTIGATION DEFINED	44

B) PROCEDURES TO BE FOLLOWED WHEN CONDUCTING AN INVESTIGATION	44
C) NOTIFICATION OF GOVERNING AUTHORITIES	44
3. POSSIBLE CONSEQUENCES OF A FINDING OF NONCOMPLIANCE	45
4. STEPS FOR REINSTATEMENT OF A PROTOCOL	45
5. THE APPEAL PROCESS	45
APPENDICES	46
APPENDIX A: PROHIBITION AGAINST PET RODENTS	48
APPENDIX B: ACCESS TO THE ANIMAL FACILITY	49
APPENDIX C: USE OF ANIMALS AS FOOD FOR PREDATORY ANIMAL SPECIES	51

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

I. OUR MISSION AND ASSURANCE

The Georgia Institute of Technology (Georgia 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 Tech or by individuals associated with the Institute. These *Policies and Procedures* are applicable to all research, teaching, training, experimentation, biological testing, breeding, and related activities, hereinafter referred to collectively as “activities,” involving vertebrate animals and conducted at this institution, or at another institution when Georgia Tech personnel are involved, or when funding flows through Georgia Tech.

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

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 Tech Institutional Animal Care & Use Committee (IACUC) 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 ORIA website [here](#). Georgia Tech Policies & Procedures are posted to the same URL. This address is provided in writing to all Principal Investigators (PI) 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 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 Tech 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 [here](#).

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 Tech, 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 Tech 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 Development and Operations (VPRDO) serves as the Institutional Official and has the authority to legally commit Georgia Tech to meet federal regulatory requirements. The Institutional Official/VPRDO is responsible for appointing members to Georgia Tech's IACUC. As Institutional Official, the VPRDO signs Georgia Tech's Institutional Assurance.

B. Institutional Attending Veterinarian

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 Tech. The Attending Veterinarian provides routine veterinary care and preventive medical care, as well as on-call emergency care and consultation for Georgia Tech'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 certain animal research protocols before they can proceed. These include Tech protocols that may cause pain or distress to animals, when these protocols will be conducted on Georgia Tech campus or at an external institution that does not hold a PHS assurance. The Attending Veterinarian has the authority to suspend any Georgia Tech protocols that do not follow the *Guide* or the Animal Welfare Act.

When the Attending Veterinarian is unavailable, another Georgia Tech laboratory animal veterinarian will act on behalf of the Attending Veterinarian.

C. Institutional Animal Care and Use Committee (IACUC)

The IACUC was established pursuant to the Animal Welfare Act and PHS Policy and reports to the Institutional Official/VPR.

1. IACUC Membership

The Institute Official/VPRDO 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 Tech in any way other than as a member of the IACUC (i.e. Non-Affiliate Member (NAM)). The NAM may be either a scientist or non-scientist. IACUC members, including the NAM, 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 Tech.

A Georgia Tech faculty member chairs the IACUC; the chair may not be the Director of Animal Resources or the Attending Veterinarian. The IACUC elects one of its members to serve as Vice Chair when the Chair is absent. 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/VPRDO and are listed on the official IACUC roster submitted to OLAW. There is a specific one-to-one designation of role of IACUC membership and alternates, to ensure that the Committee is properly constituted when alternates are participating. For example, an alternate for a NAM must also meet the NAM requirements. An alternate may only contribute to a quorum and function as a voting 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 replace.

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 ORIA 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, an IACUC member will have a commitment that conflicts with meeting times. 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 cases where the protocol will be discussed at a convened meeting of the IACUC, 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 their written protocol reviews to the ORIA IACUC team. If the primary member has an alternate, the primary shall ask the Alternate Member to attend the meeting in their 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 other materials. Unless physical limitations prevent their participation, Committee members are 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 (COI). IACUC members are responsible for disclosing any potential or perceived COI in any and all business conducted by the IACUC. A Committee member or alternate might have a COI if the individual is the 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 ORIA IACUC team 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 Tech. 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 Tech 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 ORIA.

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 ORIA 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 fourth Monday of the month, depending on the holiday schedule and whether there are matters to consider. Additional meetings will be called if necessary for the Committee to fulfill its responsibilities. A quorum is required at any meeting at which formal action is taken by the IACUC, and any formal action taken by the IACUC (i.e. approval, suspension) must be approved by majority vote at a convened meeting with a quorum of IACUC members.

b) Use of Telecommunications for IACUC Meetings

Through use of telecommunications (e.g., telephone- or video-conferencing), Georgia Tech's IACUC may conduct official business without all members physically present. In this case, the following criteria must be met:

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

A mail ballot or individual telephone polling cannot substitute for participation in a convened meeting. Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IACUC members but shall not be counted as votes.

e) 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 (ORIA)

1. Committee Support

The ORIA 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 ORIA 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 ORIA oversees the development and implementation of policies, procedures, and educational programs which satisfy the many regulations governing the conduct of such research. The ORIA 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 ORIA 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, 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 Tech's Animal Care and Use Program and inspects all Georgia Tech 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 to 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 ORIA is responsible for completing the USDA Registration and PHS Assurance. Input will be sought from the IACUC, Animal Facility Leadership including the Attending Veterinarian and others as necessary to complete these documents. The Registration and Assurance are signed by the Institutional Official/VPRDO and submitted to the appropriate agency by the ORIA.

b) Annual and Semiannual Reports

i. USDA

The ORIA shall prepare and submit the Annual Report to USDA/Animal and Plant Health Inspection Service (APHIS) for signature by the Institutional Official/VPRDO. 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

The Institutional reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year.

- The Annual Report shall include the following:
 - Any change in the accreditation status of the Institution (e.g.: if the Institution obtains accreditation by AAALAC), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
 - Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the

evaluations to the Institutional Official. Semiannual reports to the Institutional Official shall include any minority views filed by members of the IACUC.

- Reporting Noncompliance, Serious Deviations, and Suspension of Activities
The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - Any serious or continuing noncompliance with the PHS Policy.
 - Any serious deviations from the provisions of the Guide.
 - Any suspension of an activity by the IACUC.
- Reports filed above will include any minority views filed by members of the IACUC.

iii. Semiannual Reports to the Institutional Official

Upon completion of the semiannual animal program and facilities reviews, the ORIA will prepare a written report, with subcommittee input, to be reviewed by the IACUC. The report shall describe Georgia Tech'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/VPRDO 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/VPRDO 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 ORIA Director or Institutional Official to the OLAW and, as appropriate, to APHIS and the federal agency funding the activity.

4. Record Keeping

The ORIA 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 ORIA 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 or as determined by the Records Retention Policy for the University System of Georgia. 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 (PI) or co-Principal Investigator (Co-PI) 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 (EVPR) or Institutional Official/VPRDO, as described in item B., below;
- OR, the individual is a student who qualifies under C. 1 or 2, below.

Adjunct faculty may not serve as PI or Co-PI on an IACUC protocol *unless they are also eligible to be a PI as described above*; they may hold the title of co-investigator if they sign a Visiting Scholar Agreement. (Some personnel are faculty in the Georgia Tech Research Institute (GTRI) 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 or Institutional Official

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

C. Graduate and Undergraduate Student Research Projects

Generally, the PI must be a full time faculty member who meets the definition of PI. 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 PI. Exceptions to this policy are described below.

1. Exception for Georgia Institute of Technology Students Receiving Fellowships, Stipends, and/or Tuition in Support of Their Work on Emory Protocols

In those few cases where the PI is a faculty member at Emory University, AND no Georgia Tech faculty member has any involvement in the project, AND the funding (if any) is awarded to Emory University with a subcontract to Georgia Tech solely for the student’s fellowship, stipend and/or tuition, AND a Georgia Tech student is being mentored and supervised by the Emory University PI, the Georgia Tech student will be named PI for Georgia Tech’s tracking purposes.

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

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

The Student PI must also meet with an IACUC Associate in the Georgia Tech ORIA for a brief overview of PI responsibilities.

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

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

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

- 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.
- 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.
- 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 ORIA along with documentation of satisfactory completion of the required IACUC CITI training module(s). Upon approval by the IACUC, visitors/volunteers may serve as co-investigators working with Georgia Tech PI who are responsible for conducting the research and ensuring compliance with the approved protocol.
- Environmental Health & Safety (EH&S): The volunteer/visitor must meet with EH&S regarding participation in Occupational Health. While volunteers/visitors may not enroll in Georgia Tech's Occupational Health Program, their occupational risk will be assessed, and they will be advised regarding whether to consult a private healthcare provider.

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

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 Tech IACUC permits the use of live or deceased vertebrate animals solely for instructional purposes under the following conditions:

- a. The PI determines that the educational goals can best be achieved by such usage; and
- b. 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 required 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 Georgia 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 Tech.

In particular, when Georgia Tech is the prime recipient of funding from the Public Health Service (PHS), Health and Human Services (HHS), National Science Foundation (NSF), or National Aeronautic and Space Administration (NASA), and this funding is subawarded to an external institution, an MOU is needed to document the collaboration. In these cases, the external institution must have an active PHS Animal Welfare Assurance.

When a written agreement (e.g., MOU) exists between Georgia Tech and another PHS-Assured institution, the Georgia Tech IACUC can accept the other institution’s IACUC approval. However, the Georgia 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 Georgia Tech IACUC with these materials, and give the Georgia 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 Tech governs protocols wherein investigators from either school perform the work on the other campus and the animals are housed there.

Georgia Tech defers to Emory's IACUC for the review and oversight of certain protocols when a Georgia Tech investigator is performing a research project at an Emory site. Likewise, Emory will defer to Georgia Tech's IACUC for the review and oversight of protocols when an Emory investigator is performing a research project at a Georgia Tech site. In these cases, each reviewing IACUC agrees to use the investigator's home IACUC forms. When a Georgia Tech investigator performs research at an Emory site, the Georgia Tech faculty member shall provide 1) the Georgia Tech IACUC Application for Georgia Tech Personnel Working at Off-Campus Site, 2) a copy of the final IACUC approved application from Emory, 3) a copy of the Emory IACUC approval letter, and, 4) if externally funded, a copy of the funding proposal/statement of work. Additional information may be requested if deemed necessary by the reviewing IACUC. Once this information is received, the Georgia Tech 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 Tech. Likewise, disapprovals of protocols by Georgia Tech's IACUC may not be administratively overruled (approved) by Emory. However, the investigator's home institution has the right to review and deny any protocol, prior to submission or subsequently approved by the other IACUC. Once the Emory IACUC initially approves a protocol, it is placed on the next Tech IACUC meeting agenda under "Activities Approved via MOU" for Committee notification.

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

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

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

b) Global Center for Medical Innovation (GCMI)/Translational Testing and Training Laboratories, Inc. and Georgia Institute of Technology (Georgia 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," Georgia 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 Georgia Tech and GCMI personnel from other Institutional requirements to report off-campus research activities as outlined below.

Excerpt from "Georgia Tech/GTRC/GCMI MOU"

Georgia Tech conducting Animal Subject (AS) Research at GMCI-Operated Facilities. When Georgia Tech Personnel will be engaged in AS Research at GCMI-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 GCMI procedures shall be followed including ordering / housing of animals, training, and IACUC review / approval. The GCMI 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 GCMI IACUC.

- c. When Georgia Tech personnel will be engaged in the AS Research at GCMI, the following materials must be submitted to the Georgia 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 Georgia Tech IACUC will notify the PI that the activity may proceed.
- d. While the responsibility of IACUC notification remains with the PI, to facilitate compliance, GCMI will provide the Georgia Tech IACUC with a copy of the approved protocol, SOW and any amendments. The Protocol and amendments shall be provided electronically to the Georgia Tech IACUC at IACUC@gatech.edu or uploaded in the protocol submission system (Elements) by the PI.

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

- a. Approval of Protocols, Amendments, Modifications, and Renewals for Georgia Tech activities to be conducted at GCMI by Georgia Tech personnel.
- b. Initiation of any investigation or inspection (whether by Georgia 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 Tech and the collaborating institution, the Georgia Tech IACUC must perform a review of the off-campus animal project **before** any Georgia Tech 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 Tech 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 Tech IACUC will perform its own review of the approved protocol from the other IACUC. The Georgia Tech 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 Tech IACUC Application for Georgia Tech Personnel Working at Off-Campus Site(s). If no substantive issues are raised by the Georgia Tech IACUC, the Committee will issue an approval letter for the off-campus activity. During the course of the off-campus activity, the Georgia Tech 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 Tech 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 Georgia 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 Tech faculty member shall provide for the Georgia Tech IACUC's consideration a copy of that institution's approved IACUC application and letter of approval. The Committee may request additional information or, in rare cases, require modifications. Non-substantive issues will not

be raised. If the Georgia Tech member does have direct involvement with the off-campus work, the current Georgia 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** Georgia 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 Tech personnel require prior IACUC review and approval, even if the activity is purely observational. The protocol should specify that the researchers do not own the animals or building and that the researcher has no direct control over the animal's habitat, care, feeding, husbandry, and so forth. The researcher must obtain a statement from the facility indicating that it is responsible for its animals and premises.

1. Collaborative Research Agreement between Zoo Atlanta and Georgia Institute of Technology

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

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

Through a partnership with Zoo Atlanta, Georgia Tech students enrolled in the Schools of Biology and Psychology offer "Student for-credit coursework." Student for-credit coursework shall mean any project, work, observations or studies conducted at Zoo Atlanta by Georgia Tech students obtaining course credit. This includes, but is not limited to, PSYC 3031 - Experimental Analysis of Behavior, BIO 2802 Internship at Zoo Atlanta, or BIO 4590 Research Project Lab: Wildlife Conservation at Zoo Atlanta. The Georgia 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 Tech's purposes, "natural habitat" does not include a Zoo, petting zoo, fish hatchery, or other animal exhibit or man-made housing, regardless of how similar to the animals' natural environment.

1. Field Activities Exempt under USDA Regulations

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

2. Field Activities Not Exempt under PHS Regulations

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

3. Field Studies involving Capture and/or Invasive Measures

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

- a. number of animals to be utilized and the stability of the population from which the animals are to be taken,
- b. methods used for capturing, immobilizing and euthanizing the animals, and
- c. 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 a Georgia Tech Animal Facility for any purpose, prior approval must be obtained from the one of the two Animal Facility Directors to ensure that no pathogens are introduced into the animal facility.
- b. Researchers should maintain sufficient records to document the source of these discarded tissues or carcasses, and that their acquisition by Georgia Tech is proper and can be tracked.
- c. Approval from an 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:

- a. **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);
- b. **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; [Georgia Tech ADA Compliance](#));
- c. **Emotional support animal:** any animal providing emotional support, well-being, or comfort that eases one or more identified symptoms or effects of a documented disability. Emotional support animals may also be referred to as a comfort or therapy animals. Emotional support animals are not individually trained to perform specific work or tasks. ([Georgia Tech ADA Compliance](#));
- d. **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), Georgia 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 PI on an animal protocol (Section IV, of these Policies & Procedures).

The ORIA has migrated from a document- and email-based application process to an online system called TOPAZ Elements. The 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](#).

This process for obtaining IACUC approval is 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 PIs to consider submitting separate protocols for each funding agency/sponsor. This is particularly wise when PIs have numerous sponsors. Such separation facilitates project accounting and, in case of a serious non-compliance problem, the PI may not have to halt all of the research.

Occasionally, a large Program or Center grant (e.g. Training grants) to a single PI 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 PIs who are not PI on the supporting Program/Center grant.

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 Georgia 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 Georgia 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 PI 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 ORIA and then will be routed, when necessary, to a Veterinarian and EH&S for consultation (through the TOPAZ Elements system). Following ORIA pre-review and possibly, veterinary and safety consultation, the protocol will be returned to the PI for modifications, if necessary. If no modifications are required, the ORIA will distribute the protocol to the Committee.

7. FINAL PROTOCOL SUBMISSION

If modifications are required, the PI should revise the protocol in accordance with the veterinary consultation and then submit the revised protocol to the ORIA, 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. A protocol may also undergo review by a veterinarian or EH&S staff at this time, if such review was not needed/conducted along with administrative review.

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 Georgia Tech IACUC-approved protocol **before** the animal work begins. ORIA will advise the PI to initiate this process when they issue the Georgia 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 PI), addition of funding, or other minor changes as defined in IACUC Policy 003 "[Protocol Modification and Approval](#)" may be approved administratively by the ORIA.

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 Georgia 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.

3. Justification of Animal Numbers.

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

rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

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

ANIMAL CENSUS: COUNTING PUPS

It is the policy of the Georgia Tech 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. However, born pups of any age that are used in research are counted against the investigator's approved animal number.

4. Minimization of Pain/Distress.

- Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design. [9 CFR §2.31(d)(I) 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 authorized designee in planning such 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 ORIA Director 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.

1. Procedures for animal transfer to another protocol:

- a) The researcher must first obtain the Animal Transfer Form from the mailbox outside of EBB room B111.
- b) The form must be completed and submitted to the Animal Facility staff before beginning work with the transferred animal(s) on the new protocol(s).
- c) 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 Animal Facility 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 ORIA follows this process:

Protocols are assigned an IACUC reference number and logged into the database (this occurs automatically in the TOPAZ system).

The ORIA 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, when necessary, veterinary and/or EH&S 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. The application may also undergo review by a veterinarian or EH&S staff at this time, if such review was not needed/conducted along with administrative review. 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 ORIA documents all related correspondence and keeps the PI 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. Moreover, new protocols and three-year renewals considered to be pain category E must be reviewed at a convened meeting of the full IACUC (they may not be reviewed via DMR).

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 ORIA 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 involving USDA covered species, VA funding, and pain category E when animal work is occurring on-campus (or off-site without the coverage of an external PHS assured IACUC).

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 ORIA 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 ORIA 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 ORIA 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 Tech 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. As long as submission is not a new protocol or renewal involving pain category E, a designated reviewer will be assigned when sending protocol out to Committee for the initial call for Full Committee Review (FCR). 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 ORIA 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 ORIA 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 or ORIA will 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 ORIA. 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 and pain category E (all species), 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 Tech IACUC will accept as evidence of continuing approval a copy of the approved continuation letter from the off-campus institution. This policy applies in cases where Georgia Tech's IACUC approval has been granted under these policies at [V. B. Off-Campus Activities Requiring IACUC Approval](#).

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 every three years. 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 ORIA 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 ORIA 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 PI shall be informed by the ORIA that an additional Full Committee Review has been called, and the reason for the call shall be communicated to them. The member calling for extraordinary review shall present their concern at a convened meeting where a quorum has been established. The PI 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 Tech 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 “*Reducing Pain and Distress in Laboratory Mice and Rats*” 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, PIs 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 Tech, but participating in animal projects in Georgia Tech facilities, must also complete the required CITI training modules.

2. Exception to Training Requirement

Occasionally, a large Program or Center grant to a single PI 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 ORIA. The *IACUC Training Refresher* will be held in the Spring and Fall of each year and dates/times are available on the [Research Administration Training page](#).
- 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 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 PI 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 PI (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 ORIA 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
- Animal Facility 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.

1. Sponsored Programs Contracting Officers are required to validate that IACUC approval has been obtained prior to processing sponsor awards by checking with the ORIA. 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.
2. The IACUC protocol application requires that the PI certify that the information provided therein is consistent with the information on the corresponding funding proposal.
3. The ORIA 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 PI 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 PI.

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.

- a) Lab personnel who appear to lack the necessary training to appropriately perform procedures listed in the protocol;
- b) Conditions that are not safe for humans and/or animals;
- c) Outdated materials (drugs, suture, etc.) being used; and
- d) 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 ORIA Director, and the Institutional Official/VPRDO. 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 PI and/or other lab personnel before leaving the laboratory as part of the exit interview. If the PI is unavailable, the Research Associate or IACUC Member will arrange to meet with the PI 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 ORIA. A final copy of the monitoring results will be sent by email (not campus mail) to the PI, 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 PI 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 ORIA will follow up on any issues that require protocol modifications, orientation of new personnel, or training. The ORIA 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. Occupational Health and Safety Committee (OHSC)

The OHSC develops policy recommendations and procedures to ensure Institute workplace health and safety. The OHSC is the oversight committee for the Institute Occupational Health Program, established primarily for workers engaged in research, teaching, or other activities using animal models, research using human blood, tissues, or other products, biological materials, pathogenic organisms, toxins, select agents, chemicals and other hazardous materials or specialized equipment. The OHSC advises EHS and the Institute Council on Environmental Health and Safety (IC-EHS) on the implementation and administration of the Occupational Health and Safety Program. The OHSC will periodically review the program for compliance and effectiveness and provide recommendations to the Assistant Vice President of EHS to enhance program effectiveness. The Chair of the OHSC is appointed by the Executive Vice President for Administration and Finance and the Executive Vice President for Research. OHSC members are nominated and appointed by the Chair, in consultation with the Assistant Vice President of EHS, and are selected in a manner to ensure adequate representation across schools and departments including the Stamps Student Health Services Director of Primary Care.

B. Description of Occupational Health Program

The Occupational Health and Safety Program (OHSP) as an essential part of the overall Program of Animal Care and Use. Georgia Institute of Technology is committed to providing a safe, secure and healthy environment for all faculty, staff, students, and visitors. All personnel who, based on job function and risk assessment, may be exposed to occupational health risks may participate in the Occupational Health & Safety Program (OHSP), which is administered by Environmental Health and Safety (EHS). Students not employed by Georgia Tech but who encounter health risks due to their academic or research activities at Georgia Tech shall also participate. The purpose of the OHSP is to prevent, monitor, and reduce diseases transmitted from animals to humans (zoonotic diseases) and mitigate adverse reactions from laboratory exposure associated with the animal care and use program. In addition, educational programs have been established to educate personnel about zoonotic diseases, personal hygiene, and other health related issues.

The program focuses on occupations involving exposure to animals, those who handle biological materials or chemicals or are exposed to other risks including lifting and moving or handling of equipment. The program facilitates awareness of, and appreciation for, safe conduct of work and research activities so that accidents and occupational injuries and illnesses will be minimized. EHS shall identify and control, to the extent possible, any safety, public health, and environmental hazards presented by work and research activities. The OHSP has been developed in accordance with the Occupational Health and Safety in the Care and Use of Research Animals (National Research Council (NRC)), the Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources (ILAR)), and the Biosafety in Microbiological and Biomedical Laboratories (Center for Disease Control and Prevention (CDC), National Institute of Health (NIH)).

Assessments are conducted at both the Person level and Project level to evaluate potential risks associated with research activities involving the use of animals. As risks are identified, procedures are put in place to remove, reduce or minimize risk to acceptable levels. Periodic ongoing review, as described below, identify procedures for updating risk assessments to address changes in health status including pregnancy, illness, or decreased immunocompetence.

C. Enrollment Required for Certain Employees and Students

All personnel (faculty, staff, students, visiting scholars, etc.) who are, or will be, working with animals or entering facilities where animals are housed or used are required to enroll in the BOHP. Personnel in certain roles (such as Georgia Tech Police, EHS, and Facilities Maintenance) who by virtue of their role at the Institute, may require access to the animal facilities, are required to enroll in the BOHP. Visitors that do not have frequent or substantial contact with animals are made aware of potential risk and may voluntarily elect to enroll in the BOHP.

All persons identified by EHS whose work responsibilities or academic or research environment may subject them to occupational illness or injury are required to be enrolled in the BOHP, undergo a risk assessment and complete all safety training. All persons in such positions are required to complete the Confidential Exposure/Risk Assessment Questionnaire described above and attend a training session required based on the risk assessment. Enrollment and medical monitoring services are provided at no cost to the participant. Prior to authorizing personnel to work on an IACUC protocol, ORIA will verify with EHS that the individual has completed enrollment and training required. The IACUC does not receive any medical information about the individuals and only receives confirmation that enrollment has been completed.

D. Individual Enrollment and Risk Assessment

All Georgia Tech personnel who will be working with animals or other biological materials are required to enroll in the OHSP by completing the Exposure Assessment Questionnaire (submitted to EHS). Once completed, the form is handled as Category III data as it contains non-directory data including data that may be covered under Family Educational Rights and Privacy Act (FERPA) for students. These data are not under a covered entity therefore they are not subject to Health Insurance Portability and Accountability Act (HIPAA).

Hazard identification and risk assessment are a cooperative effort involving EH&S, who administers the OHSP, the Institutional Animal Care and Use Committee ([IACUC](#)), the Institutional Biosafety Committee (IBC), the Biological Materials Safeguards Committee ([BSMC](#)), the Radiation Safety Committee (RPC), the General Safety Program ([GSP](#)), the Attending Veterinarian, and the scientists conducting animal research. As a component of enrolling in the OHSP, individuals are required to complete an [Exposure Assessment Questionnaire](#). The questionnaire requests pertinent information regarding the risks of the work/exposure. EH&S reviews the questionnaire and based upon the answers provided on the questionnaire, EH&S may contact the enrollee to request a meeting to evaluate and discuss requirements for participation.

The use of hazardous materials, such as isotopes, toxic chemicals, biological agents, etc. in animals is allowed only after a thorough review by the IACUC, IBC, BSMC, GSP, and/or RPC, as appropriate, with subsequent provisions being established which must be followed. The IACUC protocol inquires about the use of such materials and assures that the appropriate approvals are in place prior to the IACUC protocol being approved. Studies involving hazardous materials are conducted under the direction of a Principal Investigator (PI) who is responsible for ensuring the safety of the operation, and for following established policies and procedures for the use of these materials. The Animal Facility associates and the PI and their research laboratory members work closely in this respect to assure that the appropriate signage, training, and procedures are in place and that all relevant personnel are informed of such.

Each enrollee receives a detailed letter that discusses any hazards found during the risk assessment and requirements for participation. The letter will include recommendations to protect the worker's health, including any recommended or required training on appropriate safety equipment, personal protective equipment (PPE), and/or Medical Services required (as described below).

Completion of the risk assessment, all identified training or monitoring requirements identified by EH&S is required to finalize enrollment in OHSP.

E. Recommendations & Required Training

As part of the risk assessment review, EH&S will determine what training is required to protect the health and safety of all parties. Required training may range from online self-paced training to in-person hands on training. A number of training programs are provided by EHS and can be found at this [link](#).

F. Medical Care and Monitoring Services

Personnel requiring or requesting medical services are referred to an external contracted medical provider located near campus. All medical services including collection of personal health information, medical care, testing, vaccinations, or other services and records related to these services are maintained at Concentra in compliance with HIPAA policy procedures. No personally identifiable health information will be accessed by

EHS, ORIA or anyone at the Institution. The following are examples of medical monitoring services provided (other services may be also be provided based on need or individual circumstances):

- Physical Exams
- Urinalysis
- Electrocardiogram
- Pulmonary Function Test
- Base-line Chest X-Ray
- Certification of Fitness to Wear a Respirator
- Complete Blood Analysis
- Audiogram
- Vaccinations
- Assessment and Treatment for Animal Bites or Scratches
- Allergy Tests
- Tuberculin Skin Test

G. Ongoing Enrollment

Upon initial enrollment in the OHSP, all personnel notified of the requirement to update their Exposure Assessment Questionnaire anytime there is a change in risk or status including species handled, materials used, and/or change in health status including pregnancy or decreased immunocompetence. Enrollment shall be updated as frequently as needed to ensure personnel safety but no less than every three years. Upon submission of an updated questionnaire, EHS will conduct an updated risk assessment to review any new risks and identify any new precautions are required for the employee.

As part of Continuing Review processes (e.g., Annual Protocol Review, Lab Inspections, and/or Post Approval Monitoring (PAM)), EHS is consulted to ensure that all project personnel have renewed all applicable safety trainings, and that all applicable safety precautions are in line with current standards. Further, EHS personnel join the IACUC for semi-annual inspection of animal facilities and labs to identify potential new protocol and occupational risks and to advise researchers on existing risks. Personnel are trained on the necessity to update the Exposure Assessment anytime there is a change in health status including pregnancy, illness, or decreased immunocompetence. Upon receipt of an updated Exposure Assessment, a new Risk Assessment will be conducted to provide any additional training and/or services required. The new Risk Assessment may include a review of work activities and may result in recommendation for alternate accommodations. For example, during pregnancy, illness, or decreased immunocompetence, personnel would receive material-specific training if any type of modification was required for their condition. Training would include PPE modifications, procedural modifications, or other health recommendations as necessary.

H. Research Protocol Risk Review

In addition to the individual risk assessment, as part of the IACUC protocol review, EHS reviews the proposed activities for potential hazards and updates the risk assessment for protocol personnel as appropriate. EHS reviews the types of work conducted, the protocols for work, hazards associated with the work, safety precautions taken during work, and the amount of time spent conducting work activities. Based on the review of the protocol, personnel may be required to update their Exposure Assessment Questionnaire.

I. Animal Facility Staff Activity Risk Review

In addition to the individual risk assessment, activities and duties performed by animal care personnel are reevaluated as job duties change. EHS reviews the workplace activities for potential hazards (including allergens, lifting, slip, trip and fall risk). EHS reviews the types of work conducted, the Standard Operating Procedures (SOP), hazards associated with the work, safety precautions taken during work, and the amount of time spent conducting work activities. Based on the review of the activity, personnel may be required to update their Exposure Assessment Questionnaire and/or require additional medical services.

J. Opting Out or Declining Participation

While enrollment in the OSHP and completion of the Confidential Exposure Questionnaire are mandatory, personnel may request to opt out of specific medical services offered through the program. After completing the enrollment process, risk assessment and all required training, participants may decline specific medical services or vaccinations by completing the Waiver of Selected Medical Services form. The requirement to complete the OSHP enrollment process, including all training, 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.

K. Related Institutional Safety Policies

EHS has several safety and protection policies and training available on their [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 PI 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 PI throughout the inquiry and investigation process.

A. Reporting Concerns about Animal Care and Use

The IACUC will review concerns involving the care and use of animals at the Institution.

The IACUC procedures for reviewing concerns are as follows:

Anyone with a concern about any aspect of animal care and use at the Institution or who wants to express a concern about how animals are being treated is encouraged to contact the IO, AV, IACUC Chair, any IACUC member, the Director of ORIA or any IACUC Professionals in ORIA.

Mechanisms for reporting concerns are communicated in a number of ways including signage posted in prominent locations in the animal facility, digitally posted on the IACUC website ([Concerns Regarding Animal Care and Use](#)), and are provided to all personnel during training prior to gaining access to the animal facility. Multiple points of contact are identified within the animal facility with contact information for the Animal Facility Managers, AV, IACUC Chair, ORIA Director, IO, as well as an anonymous reporting system [EthicsPoint](#). Likewise, the IACUC website reporting concerns page includes contact information for the IO, IACUC Chair, ORIA Director, anonymous reporting via [Secure EthicsPoint reporting](#), with links to [Georgia Tech Department of Internal Auditing](#) and [Georgia Tech Accountability](#) programs. Detailed information can be found in the [IACUC Website](#). All reporting communications note that any person with concerns regarding animal care, use, and/or treatment may report those concerns without the fear of reprisal or future discrimination.

The [EthicsPoint](#) system allows for anonymous reporting, in compliance with applicable whistleblower policies, nondiscrimination against the concerned/reporting party, and protection from reprisals. EthicsPoint enables anyone to anonymously report a concern of fraud, waste or abuse at Georgia Tech through a third party. In addition to fulfilling Southern Association of Colleges and Schools (SACS) accreditation standards and Department of Defense regulations, the system complies with the Gramm-Leach-Bliley Act and the Sarbanes-Oxley Act, federal statutes requiring enterprise-wide reporting mechanisms for the protection of businesses' private information.

Reports through ORIA will be delivered to the IACUC Chair and the IO for further action and may be redirected to [Georgia Tech Department of Internal Auditing](#). 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 Institution are also encouraged to register any concern, also without fear of reprisal or future discrimination.

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

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

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 Tech 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 Tech's Assurance and policies. Any failure to comply with these policies and regulations jeopardizes all use of animals in research at Georgia Tech.

C. Examples of Noncompliance

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

1. Use of animals without first obtaining IACUC approval
2. Procurement of animals without an approved protocol in place
3. Failure to use aseptic procedures during survival surgery on USDA-covered animals
4. Neglecting or providing inadequate care for animals
5. Using procedures not approved by the IACUC
6. Using more animals than approved by the IACUC
7. Failure to obtain continuing review of a protocol
8. Failure to correct a previous non-compliant situation
9. Housing animals for more than 12 hours outside of the central animal facility 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 Tech'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 Tech's Assurance or policies. The Attending Veterinarian is authorized, in extreme situations, to confiscate animals, remove them from the control of the PI, treat the animals, and/or euthanize them, pending an inquiry or investigation.

Any such suspension will immediately be reported to the ORIA 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 ORIA Director or designee will conduct an inquiry. Should the inquiry result in a determination that further investigation is warranted, the Chair of the IACUC or the ORIA Director or designee will:

1. Notify the PI 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/VPRDO and the PI's department chair.
2. Notify the Institutional Official/VPRDO 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 ORIA 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 serious noncompliance is 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 PI 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 PI will be advised in writing, with copies to the Institutional Official/VPRDO, 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 ORIA will advise OLAW, APHIS (if applicable), and the federal funding agency, if any, in cases where:

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

3. Possible Consequences of a Finding of Noncompliance

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

- a. Require, and provide, appropriate ethics or technical training for the individual.
- b. Impose a period of suspension for some or all of an individual's ability to use animals until it is clear that the personnel and procedures have been brought into compliance with federal laws and policies.
- c. Notify OLAW (and APHIS if animals regulated by that agency are involved) and any related funding sponsor/agency. Such notification is mandatory for any suspended protocol.
- d. Lodge a charge of scholarly or scientific misconduct. Such charges are deferred for handling in accordance with Georgia Tech's *Policy for Responding to Allegations of Scientific or Other Scholarly Misconduct*, posted [here](#).
- e. Should noncompliance continue, the individual may permanently lose the privilege of utilizing vertebrate animals in research and teaching at the Georgia Tech.

4. Steps for Reinstatement of a Protocol

- a. The ORIA 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/VPRDO, 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 ORIA Director 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/VPRDO, 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 Animal Facility
[Appendix C:](#) Use of Animals as Food for Predatory Animal Species

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 Tech. An animal research laboratory is any space listed on an animal protocol as a site where animal research is conducted; animal housing facilities are those spaces where laboratory animals reside.

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

- a) 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.
- b) Living conditions for pet animals should meet the standard generally accepted for the species.
- c) Good hygienic practices, such as routinely washing hands after handling pets, should be followed.
- d) 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.
- e) 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 ANIMAL FACILITY

Prior to being granted independent Buzz Card access to any of the Animal Facilities, all personnel must:

- a) 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.
- b) Enroll in the campus wide Occupational Health Program administered by Environmental Health & Safety.
- c) Be approved on any and all IACUC protocols under which the individual will conduct research.
- d) Undergo an Orientation session with the Animal Facility and complete the access request form.

A. Undergraduate Student Access to the 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, Animal Facility Directors, Animal Facility Managers, or PI at all times while in the Animal Facility*. Undergraduate students (such as those at Georgia Tech for a summer learning experience) and other student visitors will not be allowed independent Buzz Card access to the Animal Facility and must be accompanied by a mentor while in the facility.

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

The Animal Facility Lab Managers can grant or remove access to Animal Facilities. Any proposed change in access level must be cleared with one of the Animal Facility Lab Managers.

B. Visitors, Observers and Guest Researchers

1. Animal Facility Visitors

Short-term visitors to the Animal Facility must have prior approval from an Animal Facility Manager and/or one of the Animal Facility Directors and must be escorted by someone listed on an approved protocol (other than an undergraduate) or an ORIA or Animal Facility 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 Animal Facility. 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 Animal Facility.

2. Research Observers

Anyone on an approved protocol, *except an undergraduate student*, may bring people with a scientific interest in the Animal Facility to observe procedures, on a short-term basis, without addition to the protocol. The Animal Facility staff must be told in advance to expect observers, and observers must check in with the Animal Facility Lab 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 Animal Facility.

3. Guest Researchers

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

4. Others

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

To ensure security and safety, proof of identification and verification of access will be requested by Animal Facility team member. A record/log of entry and exit of all persons must be maintained in the Animal Facility.

APPENDIX C: USE OF ANIMALS AS FOOD FOR PREDATORY ANIMAL SPECIES

According to [OLAW guidance](#), the feeding of live vertebrate animals to other animals is subject to IACUC oversight and may be permitted (i) as a part of the protocol review process or (ii) as a covered component of the institutional program of animal care and use when PHS Policy is applicable. This IACUC oversight needs to address the care of these “feeder animals” and (i) should minimize the amount of stress experienced by the feeder animal while being fed to predatory animals and (ii) the feeder animal’s pain/distress should be kept to the amount necessary for the successful feeding of the predatory animals.

Feeder animals are needed at the Georgia Tech as its research includes predatory animal species that may only eat other live vertebrate animals. To address this need, Georgia Tech has developed a program to breed/raise feeder animals. When applicable, these SOPs are available upon request from PRL or ORIA management. These SOPs and this policy only apply to animals not covered by USDA regulations. During rearing and later housing, such feeder animals are kept separately from predatory species and receive the same quality care as like animals kept for research. As part of this care and eventual feeding to the predatory animals, steps will be taken to minimize the pain/distress experienced by feeder animals.