



**Georgia State University
Institutional Animal Care and Use Program**

**Animal Care and Use Protocol / Amendment
Submission and Review Procedures**

POLICY

The Georgia State University Institutional Animal Care and Use Committee (hereinafter "the IACUC") will "...conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with this Policy" (PHS Policy IV.C.). Further, the IACUC will "...confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and that the research project is consistent with the *Guide* unless acceptable justification for a departure is presented" (USDA Animal Welfare Act 9 CFR, Subchapter A).

PROCEDURES

In accordance with PHS policy and USDA regulations, this institution provides IACUC members the opportunity to review animal care and use activities, hereinafter referred to as "protocols," provide comments, and/or request a Full-Committee Review. If, however, no request for a Full-Committee Review is made within three working days of the e-mail distribution to IACUC members (an additional three working days is added for hard copy submission), two IACUC members are selected by the Chair as "designated reviewers" and are notified by e-mail or memorandum.

The designated reviewers will then have five working days to review the protocol and return via e-mail any comments or requests for modification to the IACUC Compliance Office.

IACUC members who wish to participate as designated reviewers can contact the Chair or IACUC Compliance Officer and request to be a designated reviewer. If additional expertise is needed, an outside consultant(s) in an appropriate area of study is selected by the Chair or IACUC Compliance Officer. The consultant can provide information in his/her area of expertise but has no vote on the protocol approval.

Member participation is facilitated through the IACUC Compliance Office. Please contact the IACUC Compliance Officer at (404) 413-3508 for more information.

New Protocol Submission

Principal Investigators (PI) are required to complete and submit the Research Protocol for Animal Use application form to the IACUC for new activities involving the care and use of animals for research and teaching. In addition to the PI, all other listed personnel working on this protocol must have completed all appropriate animal care and use and species specific training. The instructions on how to complete the initial online training can be found at <http://www.gsu.edu/research/iacuc.html>.

Protocol Amendment Submission

Principal Investigators must complete and submit a Protocol Amendment form if they propose any changes in ongoing active protocols. If additional personnel are to be added, they must have completed all appropriate Safety and species specific training. This form must be approved by the IACUC prior to initiating animal related significant changes.

1. Significant vs. Minor Changes: ALL changes in ongoing active protocols must be submitted to the IACUC using the Protocol Amendment form. The IACUC Compliance Office, in coordination with the IACUC Chair and/or Attending Veterinarian, will make a determination if the changes are considered Significant or Minor using the following criteria which was compiled by the NIH Office of Laboratory Animal Welfare as examples of significant changes:
 - a) Changes in the objectives of the study;
 - b) Proposal to switch from non-survival to survival surgery;
 - c) Changes in species or in the approximate number of animals used*;
 - d) Changes in personnel involved in animal procedures**;
 - e) Changes in anesthetic agents or in the use or withholding of analgesics;
 - f) Changes in methods of euthanasia;
 - g) Changes in duration, frequency or number of procedures performed on the animal; or
 - h) Changes in the degree of invasiveness of a procedure or discomfort to an animal

This is not an exhaustive list.

* The GSU IACUC has adopted a change in the number of animals of greater than 10% to be considered "significant".

** The GSU IACUC may classify certain proposed additions and changes in personnel, other than the Principal Investigator, as "minor" provided that an appropriate administrative review mechanism is in place to ensure that all such personnel are appropriately identified, adequately trained, qualified, and meet other criteria as required by the IACUC.

Protocol amendments with changes that are deemed "significant" will follow the standard Protocol Amendment Submission and Review process.

Protocol amendments with changes that are not deemed "significant" based on a thorough evaluation by the IACUC Compliance Office, in coordination with the IACUC Chair and/or Attending Veterinarian can be approved administratively.

Category B – E (Pain or Distress) Protocols

PIs submitting Category B, or C protocols are highly encouraged to consult with the Attending Veterinarian who will guide and assist them in writing their protocol. PIs submitting Category D or E protocols **must** consult with the Attending Veterinarian to guide them in writing their protocol [AWR 2.31(2)(d)(1)(iv)(B)]. Additionally, all Category E protocols automatically go to the IACUC for Full-Committee Review. PIs should factor in adequate time (at least two months) for the protocol review and approval process.

USDA Classifications and Examples of Pain Categories:

Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

Examples:

- Breeding colonies - Includes parents and offspring.
- Animals held under proper captive conditions or wild animals that are being observed.

Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

Examples:

- Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
- Euthanasia performed in accordance with the recommendations of the most recent [AVMA Panel on Euthanasia](#), utilizing procedures that produce rapid unconsciousness and subsequent humane death.
- Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

Examples:

- Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, laparotomy or laparoscopy.
- Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus such as rats and guinea pigs.
- Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics.

Classification E: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Examples:

- Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequelae from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Negative conditioning via electric shocks that would cause pain in humans.
- Chaining of nonhuman primates not conditioned to the procedure for the time period used.

Notification of Protocol Status

The Principal Investigator is notified by the IACUC Office:

1. If the protocol is approved. The file and database are updated to note the date of approval and both a hardcopy and an e-mail of the letter of approval is sent to the investigator.
2. If the protocol requires modification. The investigator is informed of the modifications needed via e-mail and returns a response. The response is sent via e-mail to the designated reviewers who have four (4) working days in which to determine if the investigator's response is acceptable or if further detail is necessary.
 - a. If the response is acceptable to all designated reviewers, the IACUC Compliance Office issues an approval letter.
 - b. If further detail is necessary, the investigator is notified via e-mail and returns a response. If the response is acceptable to all designated reviewers the IACUC office issues an approval letter.

At any time during this process the PI may request a Full-Committee Review (FCR) which would proceed in accordance with the procedures outlined below.

3. If the protocol will be sent for Full-Committee Review. A quorum of the IACUC reviews the protocol. The Principal Investigator (PI) may request to be present at the IACUC meeting before the discussion of their protocol to answer any questions or to make a statement. Approval of the protocol may be granted only after review is completed, and with the approval vote of a majority of the quorum present. The PI is informed in writing via e-mail by the IACUC Office of the outcome of the Full-Committee Review. If the protocol is approved, a letter of approval of protocol is sent to the investigator.

Significant Change Amendments

Significant changes will be handled using the procedures described in the Protocol Amendment Submission process above.

Notification of Protocol Approval or Approval Withheld

The IACUC Office will notify investigators in writing via e-mail and hardcopy letter of the IACUC's decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4.

If an approval is withheld, the PI may request from the IACUC Office detailed reasons for the decision.

Continuing Review (Post-Approval Monitoring)

If the submitted protocol application is associated with sponsored research, the protocol application must be consistent with the grant proposal that was submitted to the sponsoring agency. Several mechanisms are in place to ensure consistency between the various documents.

1. The grant proposal routing form requires Sponsored Programs Contract Officers to validate that IACUC approval has been obtained prior to processing;
2. The protocol application requires that every PI certify that the information provided therein is consistent with the information on the corresponding grant application; and
3. The IACUC Compliance Office conducts randomized comparisons between approved protocol applications and grant applications. This process will occur at a minimum rate of 10% of approved protocols per year and is subject to increase based on findings. All discrepancies are investigated by a subcommittee of the IACUC and may result in sanctions by the IACUC, which could include suspension of research activity.

The IACUC will conduct a continuing review of each previously approved, ongoing activity (sponsored or non-sponsored) covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4, at least once every three years. Protocol compliance and review of ongoing protocols or modification of approved protocols will be handled by: (1) requiring that PIs submit Protocol Continuation Form to the IACUC indicating the status of their research on an annual basis; (2) when placing animal orders the Animal Facilities Manager verifies that the approved number of animals has not been exceeded by more than 10%; and (3) the Attending Veterinarian and/or IACUC Compliance Officer, whenever possible, observes animal research procedures in progress.

Suspension of Research Activity

The IACUC has the authority to suspend any research activity involving animals at the institution that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, The Guide for the Care & Use of Laboratory Animals, the Public Health Service Policy on the Humane Care & Use of Laboratory Animals, the GSU Assurance or the GSU Program of Animal Care & Use.

The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. In the event of an emergency, the IACUC Chair or the University Veterinarian can suspend research activities conducted under a particular protocol immediately. If the IACUC suspends an activity involving animals, the Institutional Official (IO) in consultation with the IACUC shall review the reasons for suspension, take appropriate correction action, and report that action with a full explanation to OLAW.

Concerns or complaints regarding animal usage at GSU should be brought directly to the attention of the individuals involved whenever possible, followed by notification to the IACUC.

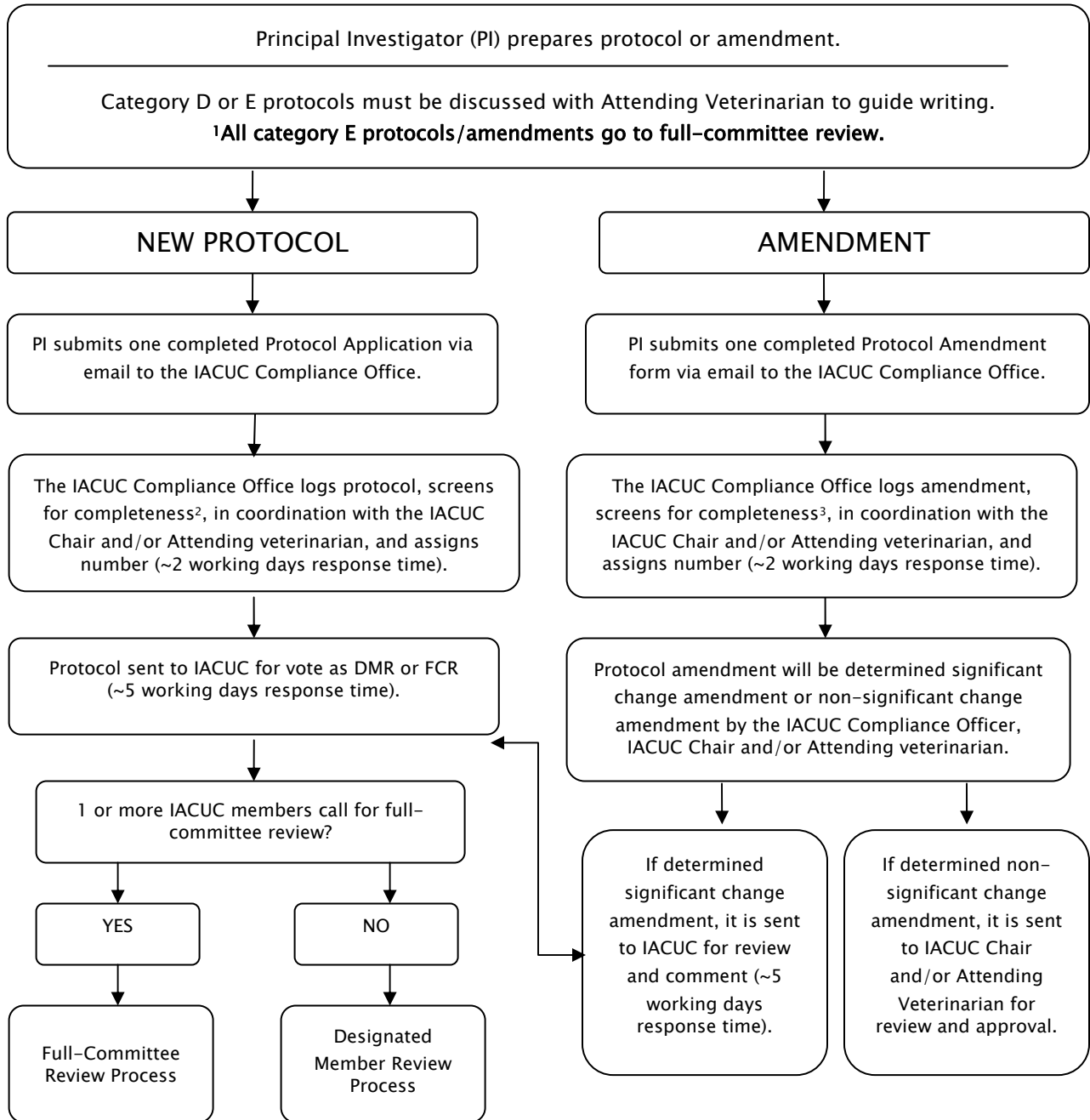
If the concern or complaint cannot be handled directly, it may be handled in one of two ways:

1. If an emergency situation exists, the Attending Veterinarian should be contacted immediately. The veterinarian will take the necessary immediate action and report such action to the IACUC.
2. If the situation is not an emergency, the concern or complaint should be relayed to the IACUC Chair and/or the IACUC Compliance Officer. The Chair will assign an ad hoc investigative committee to investigate the concern and prepare a report for the IACUC. The ad hoc committee will immediately review the concern or complaint and report back to the IACUC. The IACUC will determine what action will be taken and immediately notify the principal investigator of such action.

A written reply to those primarily involved and to the Vice President of Research (the IO) will follow each written concern or complaint submitted to the IACUC. All reports will be filed in the Office of Research Integrity for documentation of the incident and the investigation.

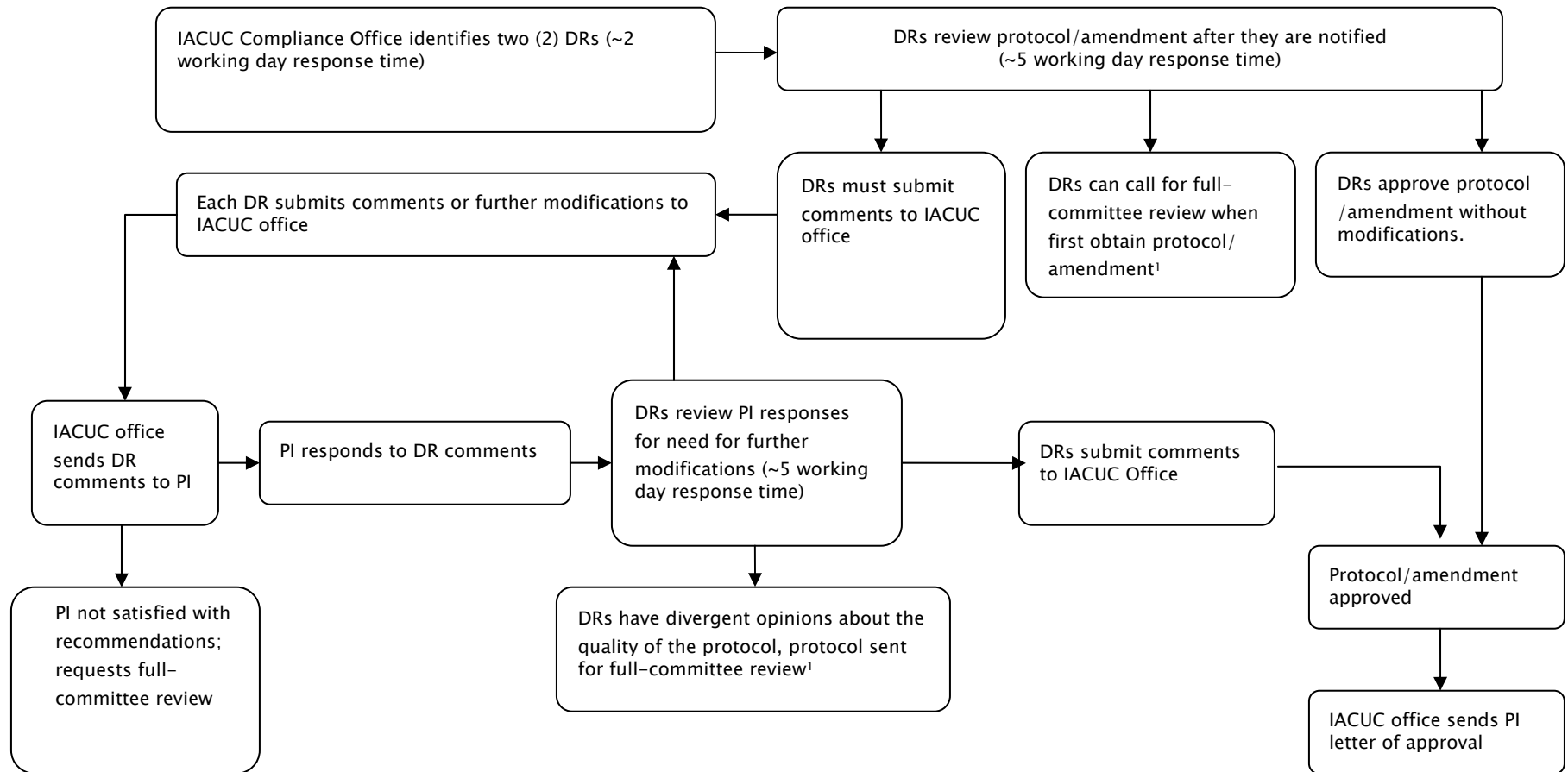
No GSU faculty, staff or student will be discriminated against, or be subject to any reprisal, for reporting noncompliance with any of the regulations or policies pertaining to animal care and treatment. The online training module that is mandatory for any individual involved with research using animals discusses this legally required reporting mechanism. In addition, the reporting policy is posted inside each animal facility.

Georgia State University Institutional Animal Care and Use Committee New Protocol or Amendment Process



²"Pre-review" procedures: if the protocol/amendment is determined to be incomplete, the IACUC Compliance Office will send the PI comments, along with comments from the IACUC Chair and/or Attending veterinarian if appropriate, and request that the changes be made and re-submitted to the IACUC Compliance Office prior to progressing to the next step in the process.

Georgia State University
Institutional Animal Care and Use Program
Designated Member Review Process



DRs at any point in the process can call for full-committee review.
¹A Full-Committee Review will result in protocol/amendment approval, request for modifications or approval withheld.

Georgia State University Institutional Animal Care and Use Program Full-Committee Review Process

