

Georgia College

IACUC Protocol Approval Criteria

NOTE: This document is meant to serve a guide for IACUC protocol reviewers and researchers. This is not an all-encompassing list of criteria but is an attempt to highlight the main criteria the IACUC reviewers look at while assessing protocols.

These criteria are compiled from rules and regulations set by the Office of Laboratory Animal Welfare, USDA, and the Public Health Service.

1. Scientific Aims

- The goal of the research is supported by key background information.
- The specific aims of the research are clear and feasible.
- There is no unnecessary duplication of experiments as attested to by the PI and explained if warranted.

2. Animal Subjects

- The specific aims of the research cannot be achieved using non-animal models.
- The required animal subjects:
 - are a scientifically appropriate species and strain.
 - possess the required biological characteristics:
 - sex, age, weight, health status, genetic background, source
- The selected species is the least sentient that is scientifically suitable.

3. Scientific Elements

- For research protocols, study design incorporates the necessary scientific elements that fit the protocol:
 - a testable hypothesis or appropriate research question
 - experimental and control groups are specified
 - statistically and scientifically justified animal numbers
 - procedures are concisely and sequentially described
 - procedures are clearly linked with the specific aims
 - minimization of bias using randomization and blinding
 - appropriate statistical analysis of resultant data leading to valid conclusions
- For teaching protocols, study design includes:
 - Justification for why animals are being used for teaching; i.e. what critical skills are students learning that cannot be used without including live animals
 - An explanation of how students will be taught regarding why and how animals will be used in class
 - A statement asserting that students will be given access to the approved protocol

4. Animal pain, distress, and discomfort

- The assigned USDA pain categories (B, C, D, E), as applicable, fit the protocol.
- The PI has provided written documentation in the form of a literature search (for categories C and D) describing the methods and sources used to determine that no

Georgia College

IACUC Protocol Approval Criteria

alternatives to procedures that may cause more than momentary or slight pain or distress were scientifically feasible:

- Literature database(s) searched (at least 2), including the date of search, years covered, and key words
 - Other sources consulted (e.g., named expert)
 - An explanation why any alternatives described in the relevant peer reviewed scientific literature cannot be used to achieve the specific aims of the research.
 - Procedures being used have the least amount of potential adverse effects (AEs). AEs are: more than momentary or slight pain or distress, more than minor discomfort, cumulative AEs, etc.
 - The nature, magnitude, and duration of any anticipated AEs are adequately described and consistent with known effects of the procedures applied to the species involved in the research.
 - The regimen to treat anticipated pain, discomfort or distress involves use of appropriate sedation, analgesics, and anesthesia administered pre-operative, intra-operative and post-operative, as necessary.
 - Any withholding of pain-relieving agents or use of neuromuscular blockers is clearly justified for compelling scientific reasons.
 - The humane endpoint is the earliest possible point at which pain and distress are prevented, terminated, or relieved.
 - The experiment is designed so that the experimental and humane endpoints are closely linked.
 - The action(s) to be taken upon reaching the humane endpoint is acceptable.
5. Altered living conditions (for animal research labs)
- Any departure from species-appropriate living conditions, as set forth in The Guide, applicable USDA Regulations, or that are medically necessary:
 - are fully justified
 - provide animals with as much choice and control over their environment as possible
 - provide as much environmental enrichment as possible
6. Euthanasia
- The method(s) of euthanasia complies with current AVMA Guidelines, based upon:
 - The specific aims of the research
 - The species, size and age of the animal
 - A minimum of pain and distress associated with the method
 - Safety of personnel
 - The method to confirm death is appropriate
7. Scientific merit (*please note: the primary focus of the IACUC is to evaluate animal welfare, but IACUC is expected to consider general scientific relevance of the proposal*)
- Procedures are designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society

Georgia College

IACUC Protocol Approval Criteria

8. Ethical Cost-benefit analysis
- The ethical cost is minimized to the greatest extent possible.
 - The research is scientifically valuable.
 - There is a valid expectation that the resultant data will be of sufficient potential benefit or improved benefit to human and/or animal health and well-being, the provision of significant new knowledge contribution to the good of society