

Directions for completing UNCG IACUC application for Animal Research

The following numbered paragraphs refer to the numbered items on the applications:

1-3. Contact/general information

4. Provide a non-technical summary of the work proposed. Include the rationale, specific objectives, and expected benefits of the proposed research at a level of detail sufficient to justify the proposed use of animals. This summary should be written for the general educated public (6th - 8th grade) to understand, in a manner similar to that of a newspaper article. Please avoid cutting and pasting information from grants/proposals or journal articles.
5. Federal law states that “it shall be the responsibility of the research facility to ensure that its personnel involved in animal care, use, and treatment are qualified to perform their duties, and that partial fulfillment of this responsibility shall be through providing training and instruction to those personnel.” This requirement can be met with the online Laboratory Animal Training Association (LATA) modules. In the event that specific training is required to perform the activities outlined in the protocol, please provide us with information to make such assurances. Training experiences of the personnel should clearly be described, with specific information about experience with particular species. It is the responsibility of the faculty member to ensure that the students have received proper training, including completion of the LATA module. The LATA training modules can be found at <http://hazel.forest.net/latanet/client/uncg/introduction.htm> the user name is “uncg” (all lower case letters) and the password is “bell” (all lower case letters). If you have any difficulties with these training modules please contact Animal Facility Manager at 334-5277 or the Director for the Office of Research Compliance 256-1482.
6. This section must be completed if agents that are hazardous to humans or animals will be used in animals. Use of hazardous agents requires review by IACUC and perhaps other committees, including the Radiation Safety Committee and Institutional Biosafety Committee. Complete the chart and answer the questions by checking the appropriate boxes. Provide additional information and/or signatures as directed.
7. Legal authorization, in addition to this review process, is often needed (e.g., for use of controlled substances such as: radioisotopes or drugs, collection of certain species such as songbirds, site-specific permits for use of federal property or work with endangered species). Provide the name of any agency which regulates what you intend to do. Include the specific legal authorization that you or someone connected with your project holds the license number. State what you are authorized to do.
8. List any other state or country from which legal authorization to conduct research is required.
9. List the specific aims or hypotheses of the study. Following each statement briefly provide enough information to clearly articulate your rationale for undertaking the study. Use charts or diagrams to illustrate, if applicable.

10. The Animal Welfare Act also requires the principal investigator to provide written assurance that the proposed activities do not unnecessarily duplicate previous experiments. Research facilities will be held accountable if it is subsequently determined that an experiment is unnecessarily duplicative and that a good faith review of available sources would have indicated as much. Your response should detail your search of available sources, such as journals, conferences, and databases, (including key words used), and whether you have published a review on this subject within the past few years.
11. Where appropriate please use illustrations such as charts, time lines, and diagrams.
12. There is a significant interest in the application of alternatives to the use of animals in research, education and testing. The Public Health Services (PHS) Policy and the Animal Welfare Regulations (AWRs) require research institutions to ensure that investigators have appropriately considered alternatives to procedures that can cause more than slight or momentary pain or distress in animals, consistent with sound research design. Through U.S. Government Principle III, the PHS Policy further requires that the minimum number of animals be used and that non-animal methods be considered. Alternatives are framed within the context of the “3Rs”:
 - Replacement, or utilizing non-animal models
 - Reduction of numbers of animals used
 - Refinement of techniques to eliminate or reduce unnecessary pain and distress in animals

Investigators must thoroughly justify any use of animals that is proposed in the protocol. (IACUC Guidebook 2nd Edition 2002)

13. Consult the UNCG Attending or Consulting Veterinarian concerning the types of analgesics and anesthetics, proper dosages (in mg/kg), and routes of administration before completing this part of the application.
14. Dietary/Environmental Manipulations can be detrimental to the health of animals; however, for some studies it is mandatory. Please justify in detail any proposed manipulation and explain under what parameters it will be conducted, as outlined in sections A-C.
15. {This applies to Sections C or D} Surgical procedures (major, minor, survival, and non-survival) must be discussed in detail with the Attending or Consulting Veterinarian. When completing this section the principal investigator must thoroughly address the following:
 - Details of the procedure
 - Appropriateness of the species for the procedure proposed
 - Qualifications of the personnel performing the surgical procedures
 - Species-specific and procedure-specific facility requirements
 - Patient monitoring practices in the pre-surgical, surgical and post-surgical periods
 - Personnel occupational health and safety issues

(IACUC Guidebook 2nd Edition 2002)

16. Check the “YES” box if either of the following two statements is true:

1. Animals will be subjected to procedures or combination of procedures conditions that WILL cause the animal more than slight or momentary pain. Neither anesthesia nor analgesia will be used in this protocol.
2. Animals will be subjected to procedures or combination of procedures that WOULD cause the animal more than slight or momentary pain IF appropriate anesthesia or analgesia were not provided. Appropriate anesthesia or analgesia WILL BE USED in this study to prevent other than slight or momentary pain.

If the first statement is true, and animals will experience more than slight or momentary pain in the absence of anesthesia or analgesia, you must provide a complete and thorough justification for the use of such procedures or conditions in the absence of sedation or pain relief.

Check the “NO” box if the following statement is true:

1. Procedures and/or conditions described in this protocol will not under any circumstances cause the animals more than slight or momentary pain, and neither anesthesia nor analgesia is required.

The Animal Welfare Act also requires that alternatives to procedures that may cause more than momentary or slight pain or distress to the animals must have been considered; that the principal investigator must provide a narrative description, in writing, of the methods and sources (journal citations, personal communications, etc.) that were used to determine that alternatives were not available. Research facilities will be held responsible if it is subsequently determined that an alternative procedure was available to accomplish the objectives of the proposed experiment. Please provide specific information for the benefit of the committee and possible verification by federal inspectors. (For example, which journals do you regularly review? At which conferences have you discussed these matters?)

If you have additional questions on this topic please consult with the Attending Veterinarian.

17. One of the primary goals of the IACUC is to reduce pain and distress, including that produced by the physical restraint of animals. The need for prolonged physical restraint has been reduced by the development of harness and swivel devices that allow an animal some degree of movement, implantable telemetry devices, or ambulatory infusion systems that allow complete freedom of movement. Clearly justify the use of any physical restraint. (IACUC handbook 16:37)
18. According to Public Health Services Policy and the Animal Welfare Regulations, it is required that all procedures involving animals in research, including methods of euthanasia, be approved by the IACUC. Such approval is based on the PHS Policy which specifically states that methods of euthanasia must be consistent with the recommendations of the American

Veterinary Medical Association Panel on Euthanasia

(http://www.avma.org/issues/animal_welfare/euthanasia_report.pdf). Methods of euthanasia not specifically approved by the AVMA will not be approved by the IACUC without a complete and thorough scientific justification by the principal investigator for the use of such methods. The Office of Laboratory Animal Welfare (OLAW) in 2002 issued a Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) guidance to Assured institutions clarifying current requirements regarding the use of carbon dioxide (CO₂) as a euthanasia agent for small laboratory animals. The entire guidance can be reviewed at <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-062.html>. Most important is that death must be verified after euthanasia and prior to disposal. Please note that thoracotomy after apparent death from CO₂ is one way to ensure the irreversibility of the procedure.

The criteria used as the basis for the Panel's recommendation include:

- Minimum pain, distress, anxiety or apprehension;
- Minimum delay until unconsciousness
- Reliability and irreversibility
- Safety of personnel; emotional effect on personnel
- Compatibility with requirement and purpose, including subsequent use of tissue
- Compatibility with species, age and health status
- Drug availability and human abuse potential

19. Self explanatory