Hunter College
Institutional Animal Care and Use Committee
Protocol Review Form

Regulatory Requirements

Federal law requires that all use of live vertebrates by Hunter staff must be approved by the Institutional Animal Care and Use Committee (IACUC) before it can begin. The IACUC is responsible for determining that all animal use by Hunter faculty and students complies with appropriate state and federal guidelines. This includes both funded and unfunded research and the use of animals within the classroom for educational purposes even if for observation only. If preserved tissues are ordered from an outside supplier, no live animals are involved, and no IACUC review is necessary. However, if the supplier must generate tissues, antibodies, etc. to your specifications, IACUC review is necessary prior to placing the order. Observational field projects which do not involve any manipulation of animals or disrupt the living environment do not need to be reviewed; field projects which involve experimental manipulations must be reviewed.

Properly completed and approved protocol forms legally protect the interests of the researchers, instructional staff, and Hunter College. Breaches of protocol, (e.g., misinformation, research activity in the absence of or not specifically covered in an approved protocol) may result in a range of disciplinary actions, depending on the seriousness of the breach.

NIH regulations require that a documented search for alternatives to animal use must be performed. Survival surgery must be carried out under aseptic conditions at a location specifically set aside for that purpose. Methods of euthanasia must conform to the recommendations of the 2007 AVMA panel. These and other questions covered by the protocol form are often raised by state inspectors during their periodic visits.

INSTRUCTIONS: Please submit one completed, signed protocol application to Annmarie Rivera, Office of Research Administration, Room E1427 or other Research Administration staff in her absence. For your convenience, the form is available as a WordPerfect, a Word or an ASCII file. All protocol applications must use this form. In addition to the standard form, there is also a short techniques form which should prove useful for those who use the same techniques in multiple protocols. Protocols may cover a maximum period of three years of research or teaching. If approved, annual updates will be required by the anniversary of the start date. A new annual update form is available. Because of changes in the interpretation of federal regulations, annual updates now request information on the past year's animal use and the project's progress.

Incomplete or illegible applications will not be reviewed. **All questions must be answered.** If a question is not relevant to your research, please fill in "not applicable" (NA). Protocols must be signed by the appropriate department chairperson or school director prior to review. While you should add as many pages as necessary to clearly convey the experimental design and scientific justification of your project, the Committee urges you to write as clearly and concisely as possible. **Be sure that you define all abbreviations the first time they are used and write in terms understandable to a lay person, not just an expert in your field. Protocols which are written in technical jargon will be returned for revision before they will be approved.** For complex projects, tables summarizing experimental design and the type and number of animals per treatment are often useful in providing the maximum amount of information in the minimum amount of space.

Anyone who will work with animals, whether faculty, employees, teaching assistants, students, or volunteers must first complete a two-stage training and certification process, as mandated by federal regulations. Any new instructors or assistants who will be using animals in their courses must take the certification course before doing their planned animal labs. The course is offered on line and accessed by logging on to CITI (www.citiprogram.org) and selecting City University of New York as your institution. After registering, choose "I am here to take the Lab Animal Welfare

courses". Following that selection, click on the appropriate "Learner Group" ("Researchers, students, facility staff, key personnel"). The Learner Group contains the required modules. After completing all of the required modules, print the Completion Certification. For those researchers whose field of study includes animals for which there are additional "optional" modules, they may be expected to also complete those modules. The second stage of training for those who will need access to the main animal facility consists of a working tour of the facility. Contact Sonia Acevedo (sacevedo@hunter.cuny.edu) to schedule a tour. In addition, before beginning animal work, individuals must familiarize themselves with the protocol which covers the experiments or demonstrations on which they will be working. The principal investigator of the protocol then submits a request to add the person to the protocol. If the information is not already provided in the protocol, this memo must include 1) the person's qualifications/experience relevant to the procedures they will carry out, 2) a list of the specific procedures he/she will carry out, and 3) a signed statement certifying that the individual is familiar with the protocol and will not deviate from the approved procedures. Certification statements are available from Annmarie Rivera. Once the Committee approves the request and adds an individual to the list of approved personnel, he/she may begin work.

In general, the Committee meets once per month. Completed protocols submitted at least 10 days prior to the meeting will be considered at that month's meeting. About 50% of proposals are approved as submitted. In the remaining cases, the protocol is either incomplete or unclear, and the PI is asked to furnish additional information. This necessarily delays approval. **Information requested by the Committee during the initial review must be incorporated into the Protocol Review Form; it cannot be provided in memo form.** This change has been made to simplify record keeping and to avoid difficulties that have occurred in the past when a federal or state inspector reviewed protocols and could not follow the maze of memos and protocol amendments.

A request to modify your protocol must be submitted whenever you contemplate changes in an approved protocol. In other words, **you must request approval prior to initiating changes** (e.g., adding new personnel, increasing the number of animals to be used or changing the treatment of living animals). Simple requests can be handled by a short memo to the Committee.   More extensive changes or a series of small changes may require submitting a new protocol form so that your protocol does not become a maze of paperwork impossible for inspectors to follow.

Committee members are happy to assist you with your submission. If you are unsure about the nature of the information requested on the form, or if you have any questions about research techniques or animal care procedures, the Facility Manager, Barbara Wolin, and the College Veterinarian, Dr. Patricia Glennon (212-650-3981), welcome the opportunity to assist you.   If you wish, committee members can "pre-review" your protocol prior to submission. Following the Committee's review of your protocol, you are welcome to meet with the Committee to resolve any questions that may have arisen. However, protocols are approved only after submission of a written revision incorporating any requested changes. PIs who use the same techniques in several different projects may wish to have the techniques approved separately. A short technique form is available for this purpose. Approved techniques can then be referenced by descriptive title and technique approval number on regular protocol applications and do not have to be described.

When you submit a grant application involving animal use, federal agencies require that the project be reviewed by the Hunter IACUC prior to their review. Since Hunter College is being asked to certify that the IACUC has approved the proposed research, obviously all details of the protocol application you submit should be identical to the work proposed in your grant application. The new certification statement included in the protocol asks you to verify that this is the case.

Methods of euthanasia which meet American Veterinary Medical Association (AVMA) guidelines:
overdose of pentobarbital (120mg/kg body weight ip for rodents, iv for rabbits and larger animals)
CO_2 narcosis
perfusion of anesthetized animal

exsanguination of anesthetized animal
cervical dislocation of anesthetized animal
decapitation of anesthetized animal
cervical dislocation without prior anesthetization (requires justification)
decapitation without prior anesthetization (requires justification)