

## I. Introduction

The Animal Welfare Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals require that the Animal Care Committee (ACC) review and approve, prior to initiation, activities involving the use of animals in research, testing or teaching. In an effort to standardize this process at UIC, the ACC has developed the following guidelines.

### A. Definitions

#### 1. Animal Care Committee (ACC)

The CEO (Chancellor) of UIC has delegated responsibility for appointing the members of the Animal Care Committee to the Institutional Official (Vice Chancellor for Research). The UIC ACC composition is designed to meet the requirements set forth in the Public Health Service Policy and consists (at a minimum) of a chair, the veterinarian with programmatic responsibility, the chairs of the respective subcommittees (scientists), a non-scientist, an unaffiliated member, and an at large representative from the Health Science Center and the East Campus. The ACC is responsible for reviewing and approving, requiring modifications in (to secure approval), or withholding approval of those activities involving the use of animals in research, testing and teaching.

#### 2. Subcommittees of the ACC

The Vice Chancellor for Research will appoint three standing subcommittees for initial protocol review: Small Animal, Primate/Exotic/Large Animal and Teaching. Each subcommittee will have at least two-three voting members; at least one of whom is a member of the ACC plus one nonvoting BRL staff veterinarian.

#### 3. Conflict of Interest

The ACC may not have a member participate in the review or approval of a protocol in which the member has a conflicting interest, except to provide information requested by the ACC. A conflict of interest is defined as being directly associated with the protocol under review such as Principal Investigator, Co-investigator or other personnel employed in the laboratory of the Principal Investigator or Co-investigator. Moreover, members of the subcommittees may not participate in the initial review process of a protocol in which the member has a conflicting interest, except to provide information.

### B. Process of Review

1. At any point during the process, if questions arise, the investigator will be contacted before the next stage in the review. Also, at any point in the review process, ACC members can call for full review of any protocol in its entirety.

#### 2. Levels of Review

- a. *Administrative/Veterinary Review* is conducted by the Chair or the Chair's designee for the purpose of assigning a protocol's level of review. This individual begins the process of entering data into the OACIB and BRL databases so that procedural codes for the protocol can be generated and veterinary comments can be entered onto a comment sheet. The protocol is then assigned to a member of the veterinary staff for pre-review. Veterinary pre-review involves a member of the veterinary staff reviewing the protocol and completing the comment sheet, which then accompanies the protocol throughout the review process. During this pre-review process,

- the veterinarian is assessing the protocol for: completeness of information and conformance with UIC-ACC Policies and Procedures; the level of potential pain and distress; appropriate use of anesthetics, analgesics and tranquilizers; the appropriateness of the euthanasia method; the proper use of aseptic technique and perioperative care; and the training of those who will be participating in the protocol. The veterinarian then contacts/meets with the investigator to discuss pertinent issues related to the prereview process. The comments generated during the veterinary pre-review process should be addressed before the protocol is forwarded to the next level of review.
- b. *Designated Review/Full Committee Approval* is conducted by the Chair or the Chair's designee when the protocol involves no potential pain to animals and/or involves only euthanasia for the collection of tissues. The Chair or Chair's designee reviews the protocol and forwards a summary report of the protocol, which contains the title, number of animals, overview of project and euthanasia method, to the ACC for final review and consideration at a convened meeting. The summary report is forwarded to the ACC four days prior to a convened meeting. Any ACC member can request that any protocol in the report be reviewed in its entirety by the ACC.
  - c. *Subcommittee Review/Full Committee Approval* is conducted on all protocols that involve pain or distress to animals. This review process is performed by one of four standing subcommittees. The respective subcommittee reviews the protocol and forwards a summary of the protocol to the ACC for final review and consideration at a convened meeting. The summary of the protocol includes the title, investigator name and department, number of animals/species/sex/age, analgesics/anesthetics, euthanasia method, project overview, requested clarifications and a recommendation. If the subcommittee is not unanimous in its recommendation or if the protocol contains procedures described under item 5 below then the protocol in its entirety along with the summary report is forwarded to the ACC four days prior to a convened meeting. Any ACC member can request that any protocol in the report be reviewed in its entirety by the ACC.
  - d. *Full Committee Review and Approval* is conducted on all protocols involving the use of live vertebrate animals at UIC prior to initiation. This review process is conducted by a quorum of the ACC at a convened meeting. All protocols are reviewed and approved either based upon a summary report from a subcommittee or designated reviewer and/or as a result of a review of the entire protocol by the ACC.
  - e. *Designated Review/Designated Approval* is conducted for all protocols submitted on Form G-Umbrella protocols. The OACIB forwards a summary report of these protocols to all members of the Full Committee on a weekly basis. The report shall include the title, protocol number, investigator name, department, project overview, and requested clarifications based on initial assessment. Full Committee members will have 3 working days to request that the protocol undergo full committee consideration. If full Committee review is not requested by any member within 3 working days and, in addition, a quorum of the full ACC membership has responded to receipt of the summary report, the protocol can be reviewed and approved by the Chair or the Chair's designee. If any member of the Committee requests full Committee review, the protocol in its entirety will be reviewed at a convened meeting.
3. Protocols with no potential pain to animals and/or involving only euthanasia complete Form A.. These protocols will undergo both administrative/veterinary review and designated review by the Chairperson of the ACC or another qualified committee member designated by the Chairperson. If the designated reviewer is satisfied with the protocol, then the protocol application is recommended for approval and a summary report of the protocol is forwarded to the ACC for consideration and approval at a convened meeting. If the reviewer of the protocol application has concerns then the protocol is forwarded to an appropriate subcommittee for a second level of review (see item B, 4 below).
  4. Protocols producing only minimal or transient pain complete protocol Form B, through item 4. Protocols requiring pain control complete Form B, through item 6 or 7 depending on the nature of the work proposed. Protocols for activities involving the use of animals for instructional purposes complete Form C.

These protocols will undergo administrative/veterinary review. Following this review the protocol application is forwarded to an appropriate subcommittee for review. The respective subcommittee reviews the protocol and forwards a summary of the protocol to the ACC for consideration and approval at a convened meeting. The summary of the protocol includes the title, investigator name and department, number of animals, species, sex, age or weight, analgesics/anesthetics, euthanasia method, project overview, requested clarifications and recommendation. If the subcommittee is not unanimous in its recommendation then the protocol in its entirety along with the summary report is sent to the ACC for review and consideration at a convened meeting.

5. Protocols requesting exemption/partial exemption from the UIC Environment Enrichment Program for Nonhuman Primates, the UIC Exercise Plan for Dogs, unusual methods of euthanasia, multiple major operative surgeries, prolonged discomfort, and/or unalleviated pain will undergo multiple levels of review (administrative/veterinary and subcommittee) prior to final review and consideration of these protocols in their entirety by the ACC at a convened meeting.
6. Protocols submitted on Form G-Umbrella Protocols for the following purposes are eligible for designated review/designated approval: 1) to link multiple UIC protocols covering the scope of work with vertebrate animals for a single funding source with all work conducted at UIC (e.g. individual RO1 grants with multiple protocols, program project grants, center grants, etc.); 2) to link either single or multiple protocols in which either all or a portion of the working involving live vertebrate animals for a single funding source will be subcontracted/outsourced to another institution; 3) for institutional training or travel grants in which the work and trainees are approved under mentor protocols; or 4) work conducted at Hines VA.

#### **C. Definition of “Full Committee Review”**

“Full Committee Review” refers to a convened meeting of a quorum of the full membership of the ACC. A quorum is defined as a majority of the membership of the ACC. For approval, all protocols require a majority vote of the quorum present. Four days prior to review, each member of the ACC shall be provided with a summary report of all protocol applications or the protocol application in its entirety. Any member of the ACC may request to review, in its entirety, any protocol listed in a summary report. Investigators have the right to appear before the ACC to present their protocols. If substantive corrections are required, the committee may vote to require revisions to secure approval and whether or not the revisions can be reviewed and approved by designated member review or need to be returned to the full committee for review and approval. All members of the committee and all alternative members must have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use designated member review if revisions to secure approval are requested. At any time, any member of the committee may request to see the revised protocol and/or request full committee review of the revised protocol.

#### **D. Corrections**

Corrections include additions, deletions or clarifications that may be required at any step in the review process. Corrections should be made by resubmitting appropriate pages or the protocol in its entirety if the corrections are not an exact page-for-page exchange. To assist the Committee in their review, corrections should be highlighted in a manner that separates them from the original submission.

#### **E. Appeal**

Appeals of ACC decisions should be directed to the Vice Chancellor for Research, to whom the ACC is responsible.

#### **F. Approval**

A protocol is approved for one year from the date of approval and that approval can be continued for an additional two years. At the end of three years, a new protocol must be submitted for de novo review (see

items G and H).

#### **G. Continuation of Approval**

Annual continuation of approval will be handled by the ACC, which will send each investigator a notice of annual continuation and a request for updating, including an inquiry as to whether the changes are minor or substantive. Substantive changes in the protocol may require submission of a new protocol application, which will be subjected to the review process as set out in item B in this document.

*Note: The continuation date will be the anniversary of the meeting date in which the protocol was approved or approved for designated member review of clarifications.*

#### **H. Resubmission**

Three-year resubmission of all approved, active protocols is required to assure compliance with the PHS policy. One hundred twenty days prior to the three-year anniversary date, the ACC will send each investigator a notice of expiration/resubmission and a sign-off sheet in which the investigator is to indicate that the protocol in question will be resubmitted or allowed to expire. Resubmissions are treated as new protocols.

#### **I. Prompt Review**

In order to avoid unnecessary delays in the initiation of protocols, the review process should be accomplished within 30-60 days of the timely receipt of a properly completed protocol application. At any stage of the review process, if an investigator does not submit corrections/clarifications within 60 days of notification the protocol application may be terminated.