

## ALL CAMPUS ANIMAL CARE & USE COMMITTEE POLICY

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### Designated Review of Protocols

**Purpose:** Both the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Act regulations regarding review and approval of animal activities, described in animal protocols, allow for the use of Designated Review of those activities. This policy details the circumstances under which the Designated Review process is practiced by the U.W.-Madison Animal Care and Use Committees (ACUCs), and how the Designated Review process is implemented.

#### **Policy:**

The Designated Review method of protocol review and approval is practiced in three circumstances, described below. On an annual basis each ACUC shall review and ratify this policy by signature of all appointed voting members.

**I. Designated Review can be used as an alternative to review of a protocol at a legally convened meeting.** The process described below will be used to facilitate Designated Review.

- a. All voting committee members will be provided with a full copy (electronic or hard-copy) of each protocol for which Designated Review is requested. Specific eligibility is left to the discretion of the individual school/college level ACUC.
- b. Any committee member may request that a protocol undergo a full-committee review. If such a request is made, then the protocol will be reviewed by way of the normal full committee review/approval process. Such full-committee review/approval will be conducted at a convened meeting with a constituted quorum of members present and eligible to vote.
- c. While a request for full-committee review of a protocol can be made anytime, for the purpose of keeping the review/approval timely, if the response deadline for committee members as designated by the chair has passed without a request for full-committee review, the chair will initiate the designated reviewer process.
- d. To proceed with the designated reviewer process, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review the protocol, and have the authority to approve, require modifications in (to secure approval) or request full committee review of the protocol. If the chair assigns multiple designated reviewers there must be unanimous approval by all designated reviewers. If there is not unanimous agreement the protocol

will automatically go to the full-committee for review. Disapproval of a protocol requires full-committee action.

- e. Animal use protocols that are submitted for the purpose of serving as the base for training grants will be reviewed via Designated Review by the appropriate ACUC Chair and Senior Program Veterinarian. Either may call for full committee review of such protocols, in which case the protocol will be scheduled for the next fully convened ACUC meeting.
- f. Subsequent submissions (rewrites) of protocols that are deferred at a convened ACUC meeting cannot be approved for Designated Review at that meeting unless all voting members are present and unanimously vote to approve the rewrite for Designated Review and select those Reviewers at the time of the vote.

The full ACUC shall be provided for review (at least quarterly) a copy of the log of amendments reviewed and approved by the Designated Review described above. Any ACUC member may request a full-committee review of any previously approved amendment noted on the log.

**II. Designated Review by the ACUC Chair and Senior Program Veterinarian can be used when an amendment to an ACUC-approved protocol meets the criteria below.** At their discretion, either the ACUC Chair or Senior Program Veterinarian may refer any amendment to the entire ACUC for review and approval. Any amendment not falling within the guidelines will automatically require full ACUC review.

The full ACUC shall be provided for review (at least quarterly) a copy of the log of amendments reviewed and approved by the ACUC Chair and Senior Program Veterinarian. Any ACUC member may request a full-committee review of any previously approved amendment noted on the log.

- Increase in animal numbers not to exceed 10% of originally approved numbers and species;
- Addition or modification of procedures that are within the scope of currently approved experimental or surgical procedures;
- Addition or modification of injection or blood draw that are within the scope of currently approved procedures.
- Use of an alternative drug or material, with very similar actions to the original, should the currently approved one become unavailable or as a replacement with improved efficacy.
- Qualifications and training of instructors invited by the university to teach specific procedures, generally for continuing education courses, in lieu of completing on-line animal user certification for UW-Madison

- Addition of locations where procedures on animals, or other animal activities of a duration less than 12 hours.

The addition of survival surgery, the addition of or change to a procedure likely to increase animal pain or distress, the addition of a new species, and increases of animal numbers greater than 10% require full-committee review.

**III. Designated Review can be used following an ACUC approval of a motion to approve a protocol pending satisfactory response to review questions raised during the review of that protocol.** The ACUC motion is commonly referred to as “approved pending” in committee meeting minutes and protocol review correspondence. The Designated Reviewer in this circumstances shall be the Senior Program Veterinarian or other voting committee member as determined by the ACUC Chair.

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Reference Minutes: 10/9/2009