



University of Maryland College Park Animal Care and Use Standard

Animal Study Protocol Review

Purpose: This standard defines procedures used for annual and triennial reviews, including procedures to approve continuing activities for a limited time beyond the original three-year term of approval.

Background: Per the PHS policy Section IV. C. 5: “The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.” Furthermore, the Animal Welfare Regulations, 9 CFR, Part 2, Subpart C, Sections 2.31 requires that: “The IACUC shall conduct reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC but not less than annually.”

Standards: IACUC approvals of all Animal Study Protocols (ASPs) have a term limit of no more than three years. At the end of this term, a triennial review must be performed for all activities that are ongoing and continuing, and investigators may apply for a subsequent three-year term, or “triennial renewal,” of the ASP. Renewals are subject to *de novo* review by the IACUC and must include all required information and applicable signatures (department chair, facility manager, etc). The PI must also provide a rationale for continuing, and an explanation of how the activities described in the renewal do not constitute duplicative work. The IACUC may approve the renewal of an ASP for a limited term.

Activities regulated under the Animal Welfare Act Regulations (i.e., involve USDA-covered species/activities) are reviewed no less than annually irrespective of the intent of the investigator to continue the activities. Other activities may be subject to annual IACUC review under the terms and conditions of outside funding agencies.

Methodology:

Annual Review

Annual reviews of applicable activities (see above) are submitted for Full Committee Review (FCR) and approved via a majority vote of a convened quorum of the IACUC. The annual review is facilitated through the use of an annual review form, which must be completed by the PI and submitted to the UMD IACUC through the online protocol management system as an attachment to the core protocol. Annual reviews are conducted beginning in the first January following the initial approval of the ASP, and once each calendar year thereafter, unless more frequent review is requested by the IACUC. Each annual review submission is pre-reviewed for completeness by the IACUC office, which may request follow-up information or clarification of any content. The IACUC office then places the review on the next meeting agenda and the submission is made available to all IACUC members prior to the meeting.

Triennial Renewal

Triennial reviews must be performed for all activities that are ongoing and continuing, and investigators may apply for a subsequent three-year term, or “triennial renewal,” of the ASP. Renewals are subject to *de novo* review by the IACUC and must be updated with any revisions to the experimental design and procedures, animal numbers, justifications, hazards, personnel, training, emergency procedures and contacts, exceptions, and all other applicable components of the protocol. Renewals must also include all additional required information (including rationale

to continue and duplication information described above) and applicable signatures (department chair, facility manager, etc.). For those ASPs with animals in USDA Pain Categories D and E, a new search for alternatives to painful procedures must be performed.

Renewal submissions are assigned a new internal reference number and a new expiration date set upon final approval. A renewal protocol must be approved prior to expiration for the work to continue uninterrupted. If no renewal protocol is in place, the work must stop and animals must either 1) be transferred to another, appropriate protocol, or 2) be placed onto a veterinary holding protocol until such time as the renewal has been approved by the IACUC. In the case that animals are transferred to a holding protocol, no experimental procedures may be conducted. In special circumstances, the IACUC may consider allowing the continuation of breeding.

Limited-term Triennial Renewal

In extraordinary circumstances, the IACUC may elect to perform a triennial review and approve the renewal for a limited time period (e.g., six months). Review of activities under limited-term triennial renewal is conducted by one of the authorized methods (described below). However, eligible protocols should have no, or only minor, changes from the previously approved activities, thus facilitating the review process. Any subsequent changes to the protocol must be submitted by amendment and reviewed and approved by the IACUC. Activities approved under a limited-term triennial renewal will generally be completed by the end of the term, which is not to exceed one year. In order to continue activities beyond the limited term, a *de novo* review must be completed (as above, Triennial Review and Renewal).

Review Process

The review procedure may take place through either Full Committee Review (FCR) or Designated Member Review (DMR) as follows:

FCR

The ASP is completed by the investigator and forwarded to the IACUC office via the electronic submission system IRBNet. Upon receipt by the IACUC office, the application for protocol review is numbered, catalogued, and pre-reviewed. All protocols for the coming meeting are placed on the next meeting agenda and made available to the entire committee. The review cycle generally begins on the first of each month. A minimum of two (2) committee members are designated by the Chair to review each protocol in detail. Each reviewer is asked to prepare a review of their assigned protocols for the meeting. The UAV (or designee) also reviews all protocols. Reviewer comments are available to the entire committee (online) to assist in discussing the protocols. At a convened meeting of a quorum of the IACUC, each protocol is summarized by the committee reviewers. The committee at that time may approve, require modifications to secure approval, or withhold approval for the protocol. Any of these actions must be made with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an application or proposal in which the member has a conflicting interest (i.e., is personally involved in the project), except to provide information requested by the IACUC. A member who has a conflicting interest may not contribute to the constitution of a quorum.

DMR

An ASP may undergo DMR at the UAV's or the IACUC Administrator's recommendation and the IACUC Chair's discretion. The use of DMR to review full ASPs may occur under extenuating circumstances that may warrant review and approval prior to the next convened meeting or under other circumstances deemed appropriate by the IACUC Chair. The IACUC Chair will appoint one or more qualified reviewer(s) for DMR.

Use of DMR for ASPs

IACUC staff will send a list of all proposed animal use activities identified for DMR and the corresponding reviewer(s) to the entire IACUC. Full written descriptions are submitted by the PI through IRBnet, where they may be accessed by all committee members (thereby ensuring that all members of the committee have access to identical copies of the protocol). The message will include a reasonable date by which IACUC members should request FCR if desired. Generally, IACUC members have three (3) calendar days in which to respond with a request for FCR.

- If a member requests FCR, the ASP will be reviewed at the next convened IACUC meeting.
- If there are no requests for FCR, review and approval proceeds by DMR.—
- Possible outcomes of DMR include unanimous approval by all designated reviewers; request for modifications to secure approval (all reviewers must agree on the required modifications); or request for FCR.
- If modifications are required to secure approval, the original designated reviewers will review the modified document.
- If FCR is requested for any ASP, that ASP may only be approved after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

Once an ASP is approved, animal use may begin consistent with the approved activity.

Use of DMR subsequent to FCR

Following discussion of an ASP at a convened meeting of quorum of the IACUC, the committee may vote to review the modified ASP by DMR if modifications are required to secure approval.

- If the IACUC determines that modifications are required to secure approval, the committee may, by unanimous vote of the quorum present, agree to send the revised protocol to DMR for final review and approval.
- The DMR subsequent to FCR will be conducted as described for DMRs above; however, any member may request to see the revised document and/or request FCR.

Once an ASP is approved, animal use may begin consistent with the approved activity.