

Guideline for Review and Approval of Animal Study Proposals (ASP)

Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) and the Animal Welfare Regulations permit only two methods of Animal Study Proposal (ASP) and proposed significant changes review:

- 1) convened meeting of the ACUC
- 2) designated review in lieu of a convened meeting

Convened Meeting: The standard or default method for review and approval of ASPs by the NIH Animal Care and Use Committees (ACUC) is through the deliberative process during convened meetings of the ACUCs. For those meetings, usually held monthly, a quorum¹ must be present for the ACUC to conduct business. Copies of new or renewal ASPs or proposed significant changes are distributed to the ACUC members for their review prior to the convened meeting. All members are expected to attend and participate in the full committee reviews at the convened ACUC meeting (detailed in Appendix 1 and Figure 1). The members are asked to identify ahead of time any ASPs which they feel must be reviewed and deliberated only by the convened process. It is further understood that any ASP initially subjected to full committee review may require modification and the adequacy of that modification may be assessed by either: (1) return of the modified ASP to the full committee, or (2) in the absence of a call for full committee review, return of the modified ASP to the designated review process (detailed in Appendix 2 and Figure 1).

ACUC members having a conflict of interest² with any particular ASP (or proposed significant change) may participate in questions and answers regarding the ASP, but must recuse themselves during deliberation and voting on that action. During that deliberation, the member(s) in conflict of interest must not be counted as part of the quorum, which must still be present to render a decision.

Designated review: In lieu of a convened meeting, when an expedited review is required, at least one member of the ACUC, designated by the chairperson and qualified to conduct the review, shall review those research proposals and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research proposals.

Designated review can be proposed by the ACUC Chair and that process can proceed in the absence of a call by any ACUC member to limit the entire review process to full committee review. Implementation of this form of the designated review process is detailed in Appendix 2 and Figure 1

¹Quorum = greater than 50% of the voting members (VM), i.e. VM of 8, need 5; VM of 7, need 4

²Conflict of interest = principal investigator and animal users listed on the ASP

Appendix 1: Using a Combination of Convened Meeting and Designated Review Processes to Conduct the Approval Process for Animal Study Proposals or Proposed Significant Changes.

1. Copies of each of the proposed ASPs or proposed significant changes are distributed to the entire ACUC prior to the convened meeting. In this case, it is the 'default' understanding by that ACUC that those ASPs or proposed significant changes are intended for discussion and probable vote (unless tabled) by the convened ACUC (at least a quorum being present) at the upcoming meeting. The members are asked to identify ahead of time any ASPs or proposed significant changes which they feel must be reviewed and deliberated only by the convened process (i.e., no shift to designated review.) If any member so identifies, that ASP or proposed significant changes may not be assigned for designated review as in 2. below.
2. Following discussion by the convened quorum, the ACUC may agree to the following status for an ASP or proposed significant change not ready for final approval as presented: the convened quorum agrees it has sufficient information to judge the humane and appropriate animal use aspects of the ASP or proposed significant change, but decides additional information/clarification must be furnished before final approval can be granted (the ASP or proposed significant change is otherwise approvable). In that case, it is proposed, by the Chair, that the adequacy of the response which furnishes the additional information/clarification will be subsequently judged by the designated review process. The Chair will further identify who the designated reviewer(s) will be (unless the ACUC has pre-determined in such cases that the designated review process will always include specified ACUC members). The convened quorum is then given the opportunity to call for full committee review of the PI's response; in the absence of such a call, further processing of that ASP or proposed significant change will proceed by the designated review process. Following receipt of the additional information, the designated reviewer(s) (acting as one) can: (1) grant final approval for that ASP or proposed significant change; (2) request further information/clarification (to secure approval); or (3) return the ASP or proposed significant change back for convened ACUC deliberation.

Subsequent actions leading to final approval of ASPs or proposed significant changes:

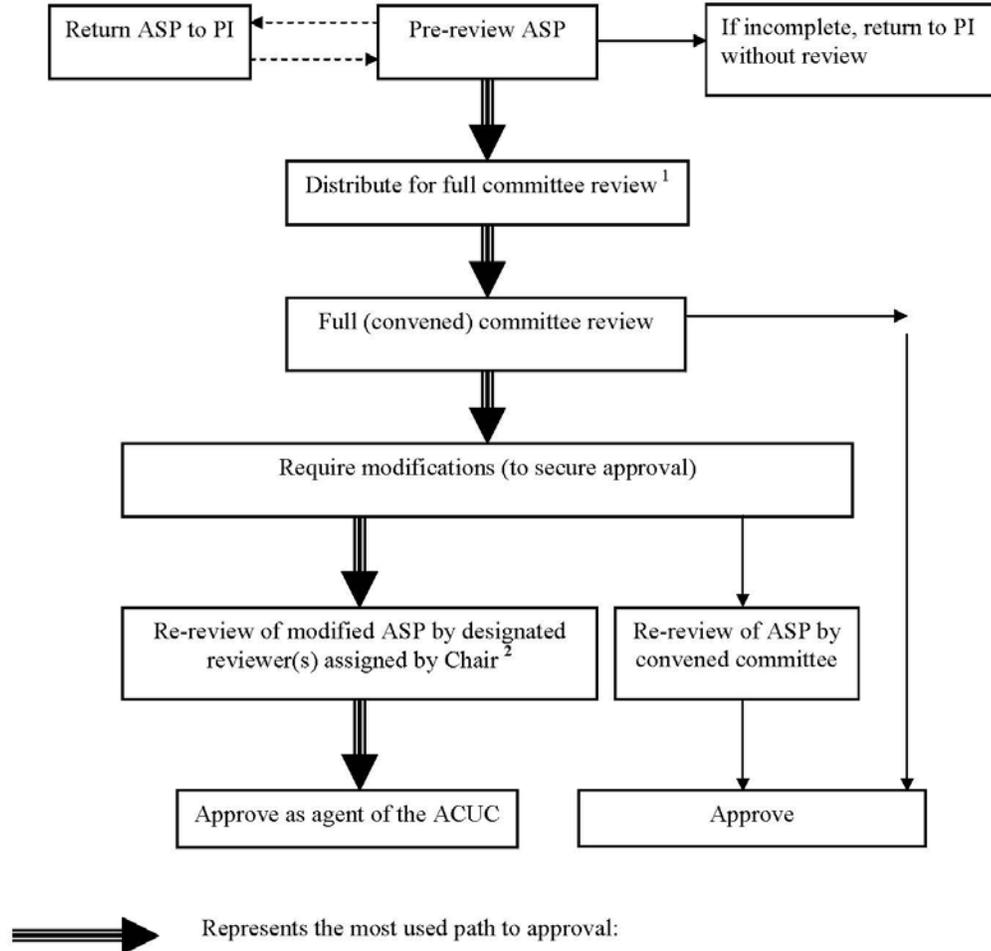
1. Chair signs and dates the ASP or proposed significant change. This denotes the date and finalization of the approval process. Animal ordering and initiation of animal activities described in that ASP/amendment can then proceed.
2. The following changes may be made to the ASP or proposed significant change immediately subsequent to the review and approval process without invoking the designated review process:
 - a. Minor administrative/typographical changes
 - b. Minor changes that were specifically stipulated by the ACUC/designated reviewer(s) (to secure approval) and agreed to by the investigator.

Appendix 2: Use of Designated Review In Lieu of a Convened Meeting

1. The submitted ASP or proposed significant change is pre-reviewed to assure it's readiness for consideration for designated review - submitted ASP determined to adequately address U.S. Government Principles.
2. The ACUC Chair decides if the ASP or proposed significant change is ready and should be proposed for review by the designated review.
3. The ACUC Chair appoints, unless pre-defined by ACUC policy, the designated reviewer(s).
4. All ACUC members then receive a copy of the ASP or proposed significant change to be reviewed, accompanied by the name(s) of the proposed designated reviewer(s).
5. The ACUC members are given five work days to respond back to the Chair/APD/ACUC Coordinator and indicate one of two dispositions for that ASP or proposed significant change:
 - a. All members or a quorum of members respond to the request and have no objections to that particular ASP or proposed significant change being reviewed and potentially approved by the designated review process.
 - Comments for the designated reviewers to consider may be provided, but they cannot be listed as contingencies for the document's approval.
 - b. One or more members call for full committee review (convened meeting) for that particular ASP or proposed significant change.
6. Following receipt of responses from the ACUC members (after five work days or prior if all members respond) and after receipt of responses from at least a quorum of the ACUC members, and in the absence of a call for full committee review, the designated reviewer(s) reviews the ASP or proposed significant change. The reviewers either approve the ASP or proposed significant change, return the ASP or proposed significant change to the PI for the purpose of obtaining further information (to secure approval), or direct the ASP or proposed significant change for full committee review. The designated reviewer(s) cannot disapprove an ASP or proposed significant change - that decision can only be rendered by the full committee at a convened meeting.
7. Chair signs and dates the ASP or proposed significant change. This denotes the date and finalization of the approval process. Animal ordering and initiation of animal activities described in that ASP or proposed significant change can then proceed.

Figure 1

**ACUC Review Process
Full Committee Review or Full Committee Review with
Follow-up Review of Modification by Designated Review**



1. It is ARAC policy that ASPs distributed for full committee review that may require modification (to secure approval) may have those modifications reviewed by a designated reviewer(s) unless any ACUC member stipulates that any specific ASPs must only be reviewed/re-reviewed by the full committee.
2. Following review by the convened committee, the modifications to the ASP are not at the level of significant change (see ARAC Guideline for Significant Changes to Animal Study Proposals.)