



Animal Program Policy

Title: Protocol Approval Levels
Date Created: 01/29/2012
Date Reviewed: 09/22/2021

1. Full Approval

The submitted protocol is found to be satisfactory, thorough, complete, justifiable, and appropriate for the involvement of animals. The Principal Investigator has appropriately described the rationale for the use of animals, provided a clear description of the procedures to be used, addressed any alternative procedures, justified the number of animals to be used and addressed other issues as described in the Guide. All described conditions are acceptable. Some changes may be requested by the IACUC to complete the information in the protocol, or to comply with IACUC policies, but those elements are not substantive, and include changes mandated by the committee that do not require additional review: verification by the Chair that the changes have been made is all that is needed for approval. In such cases, the chair communicates the requested changes to the PI, and the Approval Date is the date that the Chair receives the revised protocol and confirms that the changes have been made. If no changes are requested, the Approval date is the date of the IACUC meeting.

2. Requirement for Modifications to Secure Approval

a. Refer to Designated Member Review (DMR)

The submitted protocol is found to be generally satisfactory, with most conditions adequately specified. However, there are deficiencies in the description of procedures, justification of animal numbers or other areas that require additional information that must be evaluated by the IACUC upon receipt. At its discretion the IACUC, by unanimous vote, may refer the protocol to the Designated Review Committee or any other members of the IACUC with a list of concerns that must be addressed. If all members of the IACUC are not present, the committee has agreed in advance that the protocol can be reviewed by DMR without approval of the absent members. The Chair conveys the concerns to the PI, and disseminates the responses to the designated reviewers, who then follows the procedures described in the Policy "Designated Member Review of Protocols". If there are additional concerns, these are again conveyed to the PI by the Chair. Once all concerns have been addressed, the protocol can be approved by unanimous consent of the DMR, and the Approval Date is the date that this unanimous consent is conveyed to the Chair. If unanimous consent of the DMR cannot be reached, the DMR will defer the protocol for re-review by the Full Committee at its next meeting. Any member of the committee may, at any time, request to see the revised protocol and/or request Full Committee Review of the protocol.

Please note: the requested revisions must be submitted and approved by the following Full Committee meeting or the protocol will be dismissed. On average, this is a 60-day period.

b. Defer

Decision on approving a protocol may be deferred to the next regularly scheduled IACUC meeting. This may happen if the committee feels that the modifications requested will require review by the whole committee, or if additional information is required for approval, and that information will not be available until the next meeting. In addition, if modifications are requested to secure approval and there is no time constraint, a revised protocol can be reviewed at the next Full Committee meeting. The Chair will submit the requested changes to the PI together with an explanation of why the protocol is being deferred to the next meeting. In the case of deferred protocols, the approval date will be determined at the next IACUC meeting.

3. Withhold Approval

The scope and aim of the submitted protocol is found to be less than acceptable in terms of animal welfare, scientific rigor, animal justification, available facilities, or other factors such that the IACUC determines the protocol should not be carried out at all unless major changes are made. The IACUC identifies the areas of concern and the Chair communicates the concerns to the Principal Investigator. Either the Chair or a member of the IACUC meets with the Principal Investigator to discuss reasons for the disapproval and subsequent action that the PI may take, which include submission of a totally new protocol on the topic, responding to all of the expressed concerns. Such submission will be considered a new protocol.