Guidance to Reduce Regulatory Burden for IACUC Administration Regarding Alternate Members and Approval Dates

Notice Number: NOT-OD-11-053

Key Dates

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Related Notices

[NOT-OD-01-017](#): Office of Extramural Research Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden

Issued by

National Institutes of Health ([NIH](#))

Purpose

This notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) concerning the following two administrative IACUC issues: use of alternate IACUC members and date of IACUC approval.

Background

The Office of Laboratory Animal Welfare (OLAW), NIH, the USDA Animal and Plant Health Inspection Service (APHIS) and the Food and Drug Administration operate under a [Memorandum of Understanding](#) (MOU) that provides for enhanced communication and allows common concerns of the agencies to be managed in a consistent manner in spite of differing statutory or regulatory mandates. The MOU ensures that the differing approaches of the agencies are harmonized without unnecessarily increasing regulatory burden. As a result of ongoing discussions about administrative issues dealing with the ways that IACUCs function and efforts by IACUCs to conduct business more efficiently, OLAW is issuing the following guidance. The purpose of the guidance is to ensure that IACUC policies and procedures are in accordance with the [PHS Policy on Humane Care and Use of Laboratory Animals](#) (Policy) and, as applicable, the USDA Animal Welfare Regulations (AWRs). The USDA Animal and Plant Health Inspection Service (APHIS) has reviewed and concurs with the guidance provided in this notice.
Use of Alternate IACUC Members

Service by alternate IACUC members offers an effective management practice to ensure timely review and approval of animal activities. This guidance by OLAW and APHIS updates the provisions for the use of alternates from 2001 guidance [NOT-OD-01-017].

Although PHS Policy and the USDA AWRs are silent on the use of alternate IACUC members, OLAW and APHIS agree that alternates may be utilized if the following provisions are met:

- The Chief Executive Officer, or designee, must appoint alternates to the IACUC in writing. Appointment of the IACUC is described in the PHS Policy at IV.A.3.a and the AWRs at 2.31(b). This procedure applies to appointment of both regular members and alternates.
- Alternates may only serve as an alternate in the membership category(s) for which they are qualified. Membership categories are described in the PHS Policy at IV.A.3.b and the AWRs at 2.31(b). The specific name(s) of the regular member(s) for whom the alternate serves are not required in the appointment letter.
  - If the regular member fulfills a specific membership requirement, his or her alternate must also fulfill that requirement. If the regular member fulfills more than one membership requirement, the alternate must meet the same membership requirements.
  - One alternate may be appointed to serve for multiple regular members provided the alternate fulfills the specific membership requirement of the members for whom he or she is substituting. However, an alternate may not represent more than one member at any one time.
  - Multiple alternates may be appointed to represent one regular member.
- IACUCs must be properly constituted to conduct official business.
  - An IACUC member and his/her alternate may not contribute to a quorum at the same time or act in an official IACUC capacity at the same time.
  - An alternate may only contribute to a quorum and function as an IACUC member if the regular member for whom they serve as alternate is unavailable to participate in IACUC business, whether it is because that member is unable to attend the meeting, has to leave the meeting early or arrive late, or is recused from participating due to a real or potential conflict of interest.
  - Alternate members are expected to vote their conscience and not represent the position of the regular member for whom they serve.
- Alternate members are permitted and encouraged to attend IACUC meetings and
other IACUC activities even when the regular member is present.

- Alternates should receive IACUC training and orientation identical to that which is provided to regular members.
- Alternates must be listed as alternates on the IACUC roster submitted to OLAW as part of the Animal Welfare Assurance and annual reports. Institutions may, at their discretion, represent the names of alternates by using numbers or other symbols in submissions to OLAW. Sufficient information for OLAW to determine that alternates are appropriately qualified must be provided including the alternate’s degree(s)/credentials, position title, and membership category as described in the PHS Policy at IV.A.3.b. The identity of alternates must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

Date of IACUC Approval

The PHS Policy and USDA AWRs are silent regarding the date of approval of an animal activity. OLAW and APHIS offer the following guidance on this topic. The date of approval is the date that appears in the written notification of approval to the principal investigator. IACUCs have flexibility to develop a system that functions well for their institution, provided that the approval date occurs within a reasonable period of time after review and approval [see AWR 2.31(d), PHS Policy IV.C.]. For example, the IACUC may designate an approval date as the last working day of the month in which the proposal was reviewed, allowing time to make minor corrections or confirm other activities which may affect the approval (e.g., safety committee review, research staff training).

Inquiries

For questions or further information, contact:

Office of Laboratory Animal Welfare
National Institutes of Health
Phone: 301-496-7163
e-mail: olaw@mail.nih.gov
web: http://olaw.nih.gov/

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