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4.4240 Institutional Animal Care and Use

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The IACUC does not review minor changes by FOR or DMR and instead uses an administrative review. In an administrative review, the IACUC chair and another member of the IACUC committee selected by the chair review and approve the amendment.

The IACUC chair must communicate all decisions on an amendment to an ACUP to the respective principal investigator and institutional official. Under no circumstance may investigators execute proposed significant or minor changes before approval.

ACUP must be emailed or mailed to the IACUC chair. Upon receipt of a request for a significant amendment, the IACUC chair must communicate the submission to all IACUC members no later than (10) business days from when the submission was received. Upon receiving a request for a minor amendment, the IACUC chair must communicate the submission no later than (10) business days to a committee member of their choice for administrative review.

The lists of significant and minor changes provided above should not be considered all-encompassing. Other significant and minor changes beyond the ones noted may exist. Investigators uncertain whether a particular amendment constitutes a significant or minor change should consult the IACUC chair or attending veterinarian.

The IACUC must perform a comprehensive self-evaluation of the institutional animal care and use program and any animal facilities under its oversight. All semiannual assessments for regulatory compliance of the program and facilities must use the *Guide* as the standard for evaluation. These evaluations must be performed by no fewer than two voting members of the IACUC, there is no requirement for any specific member to participate. All members are strongly encouraged to participate in semiannual evaluations. At no time may any member be excluded from participating in a semiannual evaluation if they so desire. After a semiannual review, the IACUC must draft a semiannual report and communicate it to the IO.

As part of the semiannual evaluations, the IACUC must perform a comprehensive assessment of all animal facilities with reference to the *Guide*

animal facility is any site that is compliant with the definition outlined in PHSPolicy (III.B). Some, but not all, examples of facilities falling within this definition are:

Locations where animals are housed or used regularly Locations where animals are housed or used less frequently but for a duration no less than 24 hours Locations where invasive procedures such as surgery or chemical administration occur Locations where administration of anesthesia, analgesia, or euthanasia occur Locations where animal care items are stored Animal transports or transport containers

The IACUC must use the OLAW Semiannual Evaluation Checklist (found on IACUC website) when assessing animal facilities for regulatory compliance. The use of this standardized checklist minimizes the risks of omitting components of the facility evaluation.



Guide and PHSPolicy.

A description of any specific departures from the provisions set forth in the *Guide* and PHSPolicy and the stated reasons for each departure.

Differentiation of all identified deficiencies as significant or minor. A significant deficiency is defined as any noncompliance that is or may be a threat to animal health and safety. A minor deficiency is defined as any noncompliance that is not a threat to animal health and safety.

A description of a reasonable and specific plan with an appropriate schedule for correcting all identified deficiencies, regardless of minor or significant categorization

Identification of the presence or absence of minority opinions of IACUC members accompanied by a

A description of the progress of approved activities

A description of any difficulties or unexpected events encountered in the one-year reporting period A description of any minor changes made to the originally approved protocol; If no changes exist, a description of the absence of changes must be included.

Investigators may describe any significant changes that obtained IACUC approval during the annual reporting period if they desire but may not use the annual report to convey a request for a significant change. All requests for significant changes must follow the procedures outlined in section *IACUC Review: Procedures from Submission to Final Decision, subsection D. Amendments to Approved Protocols.* Any identification of a significant change implemented without IACUC approval may necessitate immediate suspension or termination of animal activities.

Upon completing the annual report, investigators must sign and communicate the report to the IACUC chair within the 30-day allotment. The IACUC chair must then perform an administrative review of the annual report.

In accordance with PHSPolicy (IV.C.5), the IACUC must conduct a triennial de novo review (3-year) of any IACUC three-y@ear)(feer)n3(ani)10((th))e(ari)0(al))adto tommunic

approval. The triennial review requires investigators to submit a new ACUP for review and approval of a new three-year term.

The IACUC chair must inform investigators with an active protocol of the requirement for triennial review within two weeks following the second-

from the IACUC chair serves as the official reminder of the need for a triennial review of any continuing animal activities; the chair is not required to provide further reminders beyond this official communication but may choose to do so at their discretion.

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implementing corrections, the investigators must create a report that outlines how each correction was made, sign the report as verification that corrections were made, and communicate the report to the IACUC. The IACUC response and, if satisfactory, communicate to the IO that all corrections were

completed.

If the investigation results reveal the concerns to be invalid and not of merit, the IACUC chair must communicate that the concerns are not valid, and no further action is required to all committee members, the IO, and the respective investigators.

All documentation including submitted protocols, meeting minutes, reports of unethical treatment etc. are stored and backed up on an IACUC Microsoft Teams shared website managed by the IACUC Committee Chair. Access to the folder is restricted to IACUC members. This site also serves as a repository for animal husbandry daily checklists.

The Institutional officer, all members if IACUC, and investigators are required to undergo training administered by the Collaborative Institutional Training Initiative (CTI Program). The CTI Program provides learning modules and tests designed to teach the current best practices in ethical research. Trainees are required to download a record

Team shared folder. Below is a list of required Cl