

IACUC Review and Approval of Amendments

1.0 Purpose

All proposed changes to an approved Animal Care and Use protocol must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) before they occur (PHS Policy IV.C.1., and AWR §2.31[d][1]). The purpose of this policy is to define the review process and determination of significance for amendments to existing approved IACUC protocols.

2.0 Applicability

This policy is applicable to all persons responsible for conducting animal research, teaching, training, breeding, and related activities involving live vertebrate animals and conducted at or under the auspices of USA.

3.0 Definitions

None

4.0 Policy

All amendments to IACUC protocols must be reviewed by the IACUC prior to implementation. Amendments are reviewed through one of the following methods: (i) administrative review, (ii) designated member review, or (iii) full committee review.

4.1 Significant Changes

Significant changes include those that do or have the potential to have a negative impact on animal welfare or personnel safety. Any protocol change resulting in increased pain or distress, invasiveness, or a change in PI are considered a significant change. Any protocol change requesting a $\geq 10\%$ change in a non-USDA species or any change in the number of a USDA species requires full committee review.

Significant changes are reviewed by Full Committee Review (FCR). This review is conducted at a convened meeting by a quorum of IACUC members present.

4.2 Non-significant (Minor) Changes

The IACUC views minor changes as those that fall under the “three R’s”: replacement, reduction and refinement of procedures. As examples, moving to an AVMA approved method of euthanasia or changing a cell line or study compound, assuming the new cell line or compound is expected to behave similarly to that in the approved IACUC protocol, are considered a minor change. Minor changes are primarily reviewed by Designated Member Review (DMR) through the IACUC Chair, or an assigned IACUC member. The IACUC Chair or Vice-Chair if the chair is not available, determines if the proposed change is minor or significant.

The IACUC also authorizes the IACUC/IBC Administrator to review and approve updates to IACUC approved protocols such as changes in funding sources, locations, personnel excluding the PI, grammatical and typographical changes. This is “administrative review” and differs from DMR. An increase of $\leq 10\%$ of the originally approved IACUC number in non-USDA species may be approved administratively if the request does not alter procedures or breeding phenotype. The request must be accompanied by rationale for the increase in numbers.

5.0 Procedures

5.1 Amendment Submission

An amendment is required when an Investigator wants to initiate a change to an approved IACUC protocol. An IACUC Amendment form must be submitted via IRBNet. Based on the significance of the amendment, the review is conducted as noted in Section 4.

6.0 Enforcement

This policy is under the authority of the IACUC and communicated through the Office of Research Compliance and Assurance. The IACUC has the authority to enforce the provisions of this policy, and if necessary suspend research, or implement appropriate sanctions.

7.0 Related Documents

[PHS OLAW notice NOT-OD-14-126 Guidance on Significant Changes to Animal Activities](#)

Examples: [OLAW Webpage Significant Changes to Animal Activities](#)