

IACUC07 TITLE: IACUC Minor Amendment Policy

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Except for changes in personnel (other than the PI), the IACUC generally will not approve minor amendments to protocols where a full submission (e.g., 3-year rewrite, major amendment) is under IACUC review. All minor amendments are reviewed on a case-by-case basis, however, and exceptions may be made in emergencies after consultation with the Attending Veterinarian, IACUC Chair, and designated reviewer for the full submission. PIs have the option to request that the IACUC office pull a pending full protocol submission from the meeting packet in order to submit a minor amendment before the IACUC reviews the full submission.

Centers, core facilities, and shared resources are permitted to submit additional types of minor amendments, such as simple requests to add drugs, cell lines, or strains, during IACUC review; however, all minor amendments approved during IACUC review of a full submission must be incorporated into that submission prior to final approval. This exemption is intended to provide centers, core facilities, and shared resources with additional flexibility so they can maintain the pace of their research.

The main reason for this policy is that a minor amendment approved while a full submission is under IACUC review would need to be incorporated into the full submission. (Otherwise, the minor amendment is effectively invalidated when the full submission is approved.) The full submission review process becomes more complicated as a result of such changes, potentially resulting in a delayed approval.

Incorporating a minor amendment into a pending full submission may also change the full submission outside the scope of the IACUC's original review of the protocol – that is, the full submission may become substantially different from the version reviewed by the IACUC. Such changes can, in certain cases, necessitate that the IACUC re-review a full submission.

Note that it is not possible to submit minor amendments for new protocol applications before they are initially approved by the IACUC.