

IACUC07 TITLE: IACUC Review of Amendments to Protocols Undergoing 3-Year Rewrite

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Purpose

This policy describes the process for handling amendments to protocols that are undergoing a 3-year rewrite.

An amendment approved while a rewrite is under review must be incorporated into that rewrite prior to approval. Otherwise, the amendment is effectively invalidated when the rewrite is approved – the rewrite supersedes all previous versions of the protocol. If a rewrite is approved while work from a recent amendment is ongoing *and* the details of that amendment were not incorporated into the rewrite, noncompliance can result.

Further, incorporating an amendment into a pending rewrite may change that submission in ways that are beyond the scope of the IACUC’s initial review. Such changes may, in some cases, require that the full protocol submission return to the IACUC for re-review.

Policy

The IACUC generally will not review amendments to protocols undergoing a 3-year rewrite. There are two exceptions:

1. Changes in personnel (other than the PI)
2. Addition of a funding source

Exemptions may be granted on a case-by-case basis for urgent amendments that do not fit into these categories. The process for requesting an exemption follows.

- The PI or lab member responsible for the amendment notifies the IACUC Office (dfci_iacuc@dfci.harvard.edu) that the amendment is urgent.
- The IACUC Office submits the amendment to a subcommittee comprised of the Attending Veterinarian, IACUC Chair, and designated IACUC reviewer(s) for the 3-year rewrite.
- The subcommittee discusses the amendment and decides if it may proceed.
- The IACUC Office communicates the subcommittee’s decision to the PI or lab member.
- If the subcommittee decides that the amendment **can** proceed, the IACUC Office will start the amendment review process. When the amendment is approved, the PI/lab member **must** incorporate the details of the amendment into the rewrite.

Centers, core facilities, and shared resources are permitted to submit additional types of amendments during 3-year rewrite review, especially amendments eligible for Veterinary Verification and Consultation (VVC). These include simple requests to add drugs, cell lines, or strains. This is intended to help centers, core facilities, and shared resources maintain the pace of their research.

In all cases, amendments approved during IACUC review of a rewrite must be incorporated into that submission before it is approved.

Alternative Approaches

There are three alternative ways to handle amendments while a 3-year rewrite is under review:

1. If the urgent need for an amendment is envisioned *before* a rewrite is submitted, the lab can include the amendment details in the rewrite and then submit both the rewrite and an amendment form for IACUC review. IACUC review of the amendment form can then proceed because the amendments details are included in the rewrite.
2. The PI may request that a rewrite be withdrawn from IACUC consideration in order to make an urgent amendment. When the rewrite is resubmitted, the IACUC review process starts over.
3. The lab can proceed with an amendment to the current version of the protocol while a rewrite is under review. When the rewrite is approved, the lab can then resubmit the amendment for a fresh IACUC review. The major caveat with this approach is that noncompliance can result if animal work from the original amendment is ongoing when the rewrite is approved and *before* the amendment is re-approved.

Questions

Please contact the IACUC Office (dfci_iacuc@dfci.harvard.edu) with any questions about this policy.