

**IACUC13 TITLE: IACUC Annual Progress Report Policy**

<b>Prepared by:</b> James Folcram, CPIA	<b>Approved by:</b> DFCI IACUC	<b>Effective date:</b> 10/1/2021 <b>Revision date:</b> N/A
--	-----------------------------------	---

- 1. Purpose
- 2. Policy
- 3. Outcomes for Noncompliance
- 4. References

**1. Purpose**

Federal regulations differ on the frequency of IACUC consideration of approved, ongoing activities depending on the species of animals used. The Animal Welfare Act Regulations (AWAR §2.31,d,5) states that all active protocols are reviewed no less than annually (USDA/APHIS). PHS Policy (IV,C,5) states that “the IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including complete review in accordance with IV,C,1-IV,C,4 at least once every three years (PHS/OLAW).

The Institutional Animal Care and Use Committee (IACUC) at Dana-Farber Cancer Institute requires that Principal Investigators (PIs) submit an annual progress report for all animal protocols, including those that do not involve a USDA-covered species (a species covered by the Animal Welfare Act). The annual progress report is intended to provide an update on the status of the protocol, confirm that no changes have been made to the protocol without IACUC approval, and capture detail on the number of animals used under the protocol in the past year.

**2. Policy**

The IACUC reviews animal protocols on a three-year cycle to comply with PHS Policy. Annual progress reports must be reviewed and approved by the IACUC one and two years from the date of the last-approved full protocol submission (i.e., initial protocol submission or 3-year rewrite) for each protocol.

To help ensure animal protocols remain in compliance with this policy, annual progress reports are due two months prior to the anniversary of the last full protocol approval. For example, a protocol approved in March 2021 would have a three-year expiration date of March 2024 and would have progress reports due in January 2022 and January 2023.

When an annual progress report is due, reminders are sent automatically by the animal protocol database as a courtesy to the Principal Investigator (PI); however, it is ultimately the PI’s responsibility to submit the progress reports in a timely manner. At minimum, reminders that paperwork is due are sent to the PI approximately 60 days, 30 days, and 7 days before the due date. (This is approximately 74, 44, and 21 days before the progress report needs to be reviewed.) The IACUC Office may send additional reminders as time permits and if circumstances warrant it.

The IACUC review process for annual progress reports is described in section 3.0, part E, of IACUC policy IACUC04, “Policy on Designated Member Review and Full Committee Review” ([https://iacuc.dana-farber.org/uploads/1/3/0/7/130725597/iacuc04\\_dmr\\_and\\_fcr\\_9.14.18\\_.pdf](https://iacuc.dana-farber.org/uploads/1/3/0/7/130725597/iacuc04_dmr_and_fcr_9.14.18_.pdf)).

### 3. Outcomes for Noncompliance

PIs are strongly advised to submit annual progress reports by the date they are due. A protocol is non-compliant if an annual progress report is not submitted and approved by the one- and two-year anniversary of the last full protocol approval.

#### a. Animal Protocols **Not** Approved for USDA-Covered Species

- This category covers all animal protocols at DFCI at present. Mice, rats, and zebrafish are not USDA-covered species.
- If an annual progress report is **not submitted** by the one- and two-year anniversary of the last full protocol approval, the PI has 60 days to submit the progress report. The IACUC Office will report the matter to the IACUC and to the Senior Manager of Compliance. During the 60-day period, it is up to the IACUC to determine whether animal work on the protocol can continue. If the IACUC determines that animal work cannot continue, the animals are moved to the ARF's holding protocol. While animals remain on the holding protocol, the PI is still responsible for per diems, but may not use federal funds (grants) during this time frame. If a progress report is not submitted within the 60-day period, the PI will be required to meet with the IACUC chair and/or AV to complete the report.
- If a progress report has been submitted but is **not approved** by the one- and two-year anniversary of the last full protocol approval (e.g., if there are unresolved IACUC comments on the progress report and the lab has not responded), the protocol does not need to be closed.

Animal work can continue if time remains before the three-year expiration date. The IACUC Office will work with the lab and IACUC reviewer to resolve all outstanding issues and secure progress report approval within 30 days. If approval cannot be secured within 30 days, the PI will be required to meet with the AV and IACUC Chair to finalize the report.

#### b. Animal Protocols Approved for USDA-Covered Species

- When there are USDA-covered species housed at DFCI, annual renewals are required for protocols using these species. This section sets forth noncompliance outcomes in this event.
- If an annual renewal is **not submitted** by the one- and two-year anniversary of the last full protocol approval, the IACUC will close the protocol following the vote of a majority of a quorum of IACUC members at a convened IACUC meeting.
- If a renewal has been submitted but is **not approved** by the one- and two-year anniversary of the last full protocol approval (e.g., if there are unresolved IACUC comments on the renewal), the IACUC will close the protocol following the vote of a majority of a quorum of IACUC members at a convened IACUC meeting.

### 4. References

- Public Health Service Policy for the Humane Care and Use of Laboratory Animals. Bethesda, MD: Office of Laboratory Animal Welfare, 2002.  
(<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>)

- United States Department of Agriculture Animal Welfare Act and Animal Welfare Regulations. 9 CFR 2.31. 1985. (<https://www.nal.usda.gov/awic/animal-welfare-act>)