

**University of Texas at Austin**  
**Institutional Animal Care and Use Committee**

**IACUC Policy # 4.5**

|                       |   |         |     |
|-----------------------|---|---------|-----|
| Title                 | The Third-Year Resubmission: de novo Review |         |     |
| Date of Approval      | 11-12-18                                    |         |     |
| Date of Last Revision | 07-12-21                                    | Version | 2.0 |

The PHS Policy requires that a complete IACUC review of PHS-supported protocols be conducted at least once every three years. This triennial review is interpreted by OLAW as a requirement for de novo review, meaning that the criteria and procedures for review specified in IV.C. of the PHS Policy must be applied not less than once every three years.

The three-year period begins on the actual date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. Since protocol approval period cannot be extended, investigators must be cognizant of the protocol approval period. To aid investigators, the Office of Research Support and Compliance (ORSC) shall attempt to provide adequate warning of pending protocol expiration. Although a sophisticated protocol database exists, the automatic warning system is not fail-safe. It is the responsibility of the investigator to submit the third-year resubmission by the appropriate deadline date for a scheduled Full Committee Review (FCR) prior to protocol expiration. The IACUC requires a Third Year Resubmission be submitted as a new proposal, using the most recent version of the application.

**Procedures for Conducting Triennial Reviews**

Ninety (90) days prior to the three-year anniversary of the animal protocol approval date, the PI is sent a notification requesting a resubmission of the protocol. The PI must resubmit the entire protocol to the RSC. A de novo review of the third-year resubmission is conducted. The third-year resubmission must be approved by the IACUC before the expiration date of the original protocol. If a PI fails to submit a third-year resubmission and receive approval by the expiration date of the protocol, the following action is taken:

- On the third anniversary of the protocol approval, the ORSC staff will notify the PI, the PI's dean (and/or department chair), the Attending Veterinarian, the IACUC Chair, and the Director of the Office of Sponsored Projects (if the project is externally funded), that the animal protocol has expired. The PI will be notified in writing that all activities under the protocol must cease and any ongoing work under the expired protocol is a serious and reportable violation of PHS Policy.
- The Attending Veterinarian will be notified of the expired protocol and any remaining animals under that protocol will be transferred to a holding protocol. Per diems for animal care will continue to be charged. In the event that animal care charges are being charged to a sponsored project, an alternate account must be identified for such charges.
- When the PI has successfully obtained approval of the third year resubmission protocol, animals will be transferred from the holding protocol to the new approved protocol.
- If the PI fails to successfully renew the protocol, the IACUC may consider suspension or recommending to the IO that the PI's animal use privileges should be terminated.



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| Approval Date | Major Change(s) Approved  |
|---------------|---|
| 07/12/2021    | <ul style="list-style-type: none"><li>• Minor clarification made regarding procedures for conducting triennial reviews.</li></ul> |