Animal Welfare Regulations no longer require an annual review of protocols.

- PHS Policy determines the maximum interval between IACUC review and approval as 3 years, i.e., a complete review is required at least every 3 years. The review must encompass all the criteria in PHS Policy IV.C.1-4 and animal work may not be administratively extended beyond the 3-year expiration date.

- In December 2021, the USDA removed the annual review of all protocols and replaced it with a requirement to conduct a complete review of IACUC-approved protocols at 3-year intervals instead.

Therefore, effective in the new UTRMS protocol system, researchers working with non-USDA or USDA species who are not funded by the United States Department of Defense (DoD) are no longer required to complete annual reviews. Researchers who received DoD funding are required to continue with annual reviews.

Sixty (60) days before the first and second anniversary of the protocol approval, the PI is sent a notification requesting the status of the protocol (active or inactive), requesting any proposed modifications to the protocol, and asking for the number of animals the PI has used in the previous 12 months. The PI must complete the Annual Renewal Form and return it to the Office of Research Support and Compliance (RSC) at least thirty days before the first and second anniversary of the protocol approval. Review of the Annual Renewal Form is conducted as described in Procedure 4.0, “Protocol Review and Notification Procedures.” If a PI fails to submit an Annual Renewal Form by the first and second anniversary of the protocol approval, the following action is taken:

Depending on the species covered in the protocol:

- If the protocol covers species that are not regulated by the USDA, then the IACUC Chair (or in his/her absence, the Vice-Chair) may notify the PI, the Attending Veterinarian, and the Director of the Office of Sponsored Projects (if the project is externally funded), that all work under the animal protocol must cease until further notice. The Attending Veterinarian, in consultation with the IACUC Chair (or in his/her absence, the Vice-Chair), may determine if any threat to animal well-being is posed and if so will take the appropriate action.

- If the protocol includes species that are regulated by the USDA, then the action described in Policy 4.5, “Third Year Resubmission” will be followed. In summary, the protocol will be closed and
animals will be transferred to a holding protocol. The PI will need to submit a new protocol in order to restart the research.

The PI must promptly provide, in writing, a statement that he or she will not use any animals under the protocol for teaching or research until the IACUC has reviewed and approved the annual renewal. If the PI fails to promptly provide such a verification statement and continues animal work, then the University may report such incident, as described in Policy 6.0, “Reporting Welfare Concerns and Noncompliance.”

For non-USDA species, when the PI has successfully submitted and obtained approval of the annual renewal after an appropriate review method, animal work may continue.

If the PI fails to successfully renew the non-USDA species protocol within 30 days of the protocol anniversary date, the protocol will be considered to be permanently expired and the PI will be required to resubmit a new protocol in order to restart work. Additionally, the IACUC may consider suspending or terminating that PI's animal use privileges.

If a protocol is allowed to lapse while the associated vertebrate animals are still being housed on campus, they must be turned over to the custody of the Animal Resource Center (an IACUC-approved holding protocol is present to cover such situations). The ARC Director will make a determination (after possible consultation with the IACUC Chair, the relevant Dean, and/or the Vice President for Research) on whether the animals can be safely and humanely maintained temporarily by the ARC staff, or if they should instead be transferred to another study, placed with an outside agency, or euthanized.

If the animals have been used primarily for teaching or demonstration and were originally privately-held animals that were not purchased with university funds, they may be able to be returned back to the original owners or another experienced individual. Requests for such transfers can be made to the ARC Director.

<table>
<thead>
<tr>
<th>Approval Date</th>
<th>Change(s) Approved</th>
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<tbody>
<tr>
<td>08/09/2021</td>
<td>Clarified procedures for USDA and non-USDA species protocols</td>
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<tr>
<td>02/12/2024</td>
<td>Removed annual protocol review for non-DoD funded research in new UTRMS protocol system</td>
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