



WHAT HAPPENS IF AN ANIMAL PROTOCOL EXPIRES?

The University signs an Assurance with the Office of Laboratory Animal Welfare (OLAW) which states that all animal research, regardless of funding source, will be conducted following the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals. This policy prohibits conducting ANY animal activities (procurement, breeding, housing, euthanasia, surgery, behavioral studies, dosing, or other) after a protocol has expired. It also prohibits the expenditure of federal funds for animal activities after a protocol has expired (including the purchase of animals and costs for breeding, housing, or other uses). Any activities with animals conducted after a protocol has expired are considered to be in serious violation of PHS Policy and reported to the RFUMS Institutional Official as well as to OLAW (and other agencies that may be relevant, such as USDA).

Failure to promptly submit and obtain approval of an annual renewal application will result in expiration of a protocol, as will failure to submit and gain approval for a new animal protocol application by the end of 3 years. No administrative extensions of expired protocols can be given by the IACUC. Thus, Principal Investigators (PIs) are strongly encouraged to attend to required paperwork in a timely manner in order to remain in compliance.

While the responsibility for compliance with requirements is ultimately upon the PI, the IACUC has measures in place to help:

- IACUC will notify a PI that a protocol is expiring. This notification will include a deadline for renewal submission and steps to remain compliant with RFUMS policy and federal regulations. For expiration at the 3 year mark (requiring a new protocol), typically 2-3 reminders are sent to the PI from the IACUC office. For annual renewals at years 1 and 2, typically 1-2 reminders are sent to the PI. If the PI does not have animals remaining on an expiring protocol, IACUC will send a simple letter stating that the protocol has expired.
- IACUC will inform the PI that the Biological Resource Facility (BRF) has an Animal Holding Protocol (AHP) specifically for the coverage of animals for which the applicable animal protocol has expired.
- IACUC will inform the PI of necessary steps to transfer naive, non-treated animals to another active animal protocol that the PI may have, if appropriate. Note that surgically treated animal or animals treated with biohazardous or chemically hazardous materials may not be transferred to a different protocol.

To Ensure Compliance, the PI:

- Must ensure that no use of the animals by his/her laboratory personnel will occur under an expired protocol status.
- If the PI's renewal / new protocol application is not likely to be approved prior to the expiration date of the protocol, the PI should definitely make further arrangements: The PI can arrange to euthanize remaining animals prior to expiration or can arrange to transfer animals to the BRF's AHP.
- Per NIH policy, no charges for animal activities (including maintenance/housing charges) conducted during lapses of IACUC approval can be made to NIH awards. Charges must be transferred to a non-federal (e.g. departmental) funding source.

Procedures for Expired Protocols with Animals Remaining:

- IACUC notifies the PI as well as the BRF Assistant Director that a protocol has expired with animals remaining in the BRF.
- The BRF staff will identify active cage cards in the BRF rooms under the expired protocol, and transfer those cages of animals to the AHP.

- Once the animals are transferred to the AHP, the cages are tagged with a clearly identifying cage card so that all staff as well as lab members will recognize that these animals may not be used in any way, except to be maintained by BRF staff. ***Any use of animals housed under the holding protocol by the PI's laboratory will be treated as serious regulatory non-compliance.***
- BRF will contact the PI for instructions as to whether they wish to maintain the animals on the AHP or have them euthanized by the BRF. If the PI has another active protocol for the same species to which untreated animals could be transferred (using an Animal Transfer Application) they can initiate this process. **NOTE: Animals that had been surgically treated or dosed with biohazardous material or chemical hazards may not be transferred to a different active protocol that the PI may have with the IACUC.** The PI should make arrangements to complete their experimental procedures on such animals and euthanize them for tissue harvest prior to expiration of the protocol.
- Animals in breeding colonies will be maintained by the BRF and any pregnant females will be allowed to complete gestation. Any breeding pairs or trios will be separated at the time of transfer to the AHP. Litters born during the holding period, or those transferred to the AHP as neonates will be weaned at appropriate times, and then added to the AHP. In limited cases, the PI or designate may be permitted to provide input (notations on cage cards) during weaning under strict BRF supervision.
- No new breeding pairs may be established under an expired animal use protocol or under the AHP.
- BRF will assess a service fee associated with keeping animals on the AHP as well as for weaning and euthanasia services; the PI is responsible for these charges.
- The BRF Assistant Director will report any required activations of the AHP to the IACUC at each convened meeting.

Conditions of the Animal Holding Program (AHP):

- **NO experimental manipulations** are allowed. Only BRF staff is permitted to do husbandry.
- **Restricted Access:** Animals housed under the BRF holding program are completely off-limits to investigators. The PI is responsible for informing his/her laboratory personnel about this. If necessary, Security will be instructed to remove BRF access from the ID cards of all personnel listed on the expired protocol.
- **Cage Labeling:** Animal cage cards are clearly marked with the BRF holding notation "BRF HOLD", along with a starting date. A "Holding" sign is also posted on the housing door. Animals may be moved to a secured housing area if this is deemed necessary.
- **Per Diem Charges:** Per diem charges for animals on a holding protocol are the responsibility of the investigator. As noted above, federal funds can not be used for per diems during the time a protocol is expired.

Retrieving Animals from the BRF's Animal Holding Protocol (AHP):

- Once a new approved animal protocol is obtained by the PI, animals will be released from the AHP to the new protocol upon the PI's request via submission of an Animal Transfer Form. The BRF will coordinate the change in cage cards.
- If a new protocol to replace the expired protocol has been submitted, or the PI notifies IACUC that one will be submitted during the current month, animals may remain on the AHP for up to two months from the expiration date of the prior protocol while awaiting IACUC review and approval.
- If this time period runs out, animals on the AHP will be humanely euthanized by BRF unless other arrangements, approved by the IACUC, have been made.