

# University at Buffalo Institutional Animal Care and Use Program

## Policy on Expired Protocols

### Introduction

This policy describes the response of the IACUC and LAF when a Principal Investigator's (PI's) IACUC protocol expires, as well as the process for maintenance of animals associated with expired protocols. If the project is to be continued, a PI must submit their protocol for IACUC review and approval every three years. Protocols expire at 11:59 PM on the date of expiration.

### Policy

#### **1. Prior to protocol expiration:**

- a. Click automatically notifies PIs at 90, 60 and 30 days prior to upcoming protocol expiration and submission deadlines.
- b. The IACUC Office will send a report to the LAF by the 5<sup>th</sup> of each month, notifying the LAF of protocols that are due to expire within the next 30-60 days.
- c. After notification, the LAF will determine if there are any live animals on the animal facility census associated with the protocol.
- d. The LAF will advise the PI (and potentially the PI's Department Chair) that, *should* the protocol expire, any per diem or service charges incurred during the lapse in approval cannot be billed to Public Health Service (PHS) funds and instead will be billed to the PI's Department, or to other non-PHS funding if available.
- e. PIs should also be aware that the LAF reserves the right to discontinue UB Card access to the vivarium for personnel listed on expired protocols.

#### **2. Upon protocol expiration:**

- a. The PI will be automatically notified of the protocol's expiration by Click. The notification will inform the PI of the resulting consequences and the processes necessary for correction.
- b. The IACUC Office will send an additional notification to the PI and LAF of the protocol's expiration. The additional notification will reiterate any consequences and processes necessary for correction. A copy of the IACUC Policy on Expired Protocols will be attached to the notification.
- c. The LAF will be responsible for determining if the expired protocol is associated with animals purchased or maintained by the LAF. The location, species, and number of animals currently associated with the protocol will be determined by the LAF.
- d. The LAF will notify the IACUC Office of the presence or lack of animals currently associated with the protocol in the vivarium.
- e. The PI must submit an Animal Transfer Form to place the animals on the LAF Holding Protocol (**LAF17031N**), as per LAF SOP 5.A.22 (LAF Procedure for Protocols that are Expired or Exceed Approved Animal Numbers). The Animal Transfer Form should be completed 5 days before the lapse date.

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- f. If PIs wish to transfer animals to another approved protocol, they must consult with the IACUC Office for guidance (many factors determine this allowance).
- g. In the case of wildlife studies, disposal of the animals must be in accordance with State and Federal guidelines and regulations.
- h. LAF will post a Notice of Expired Protocol on the animal holding room door(s) and cage card notices on animal cages per LAF SOP 5.A.22.
- i. The PI is responsible for obtaining appropriate funds to cover any per diem or service charges from the LAF for the housing, care or maintenance of animals during the period the protocol is lapsed. **Financial charges cannot be made to a Public Health Service (PHS) grant during lapses in IACUC approval.** Departmental funds or other non-PHS monies must be used to cover any costs during a lapse in approval.
- j. If the expired protocol is associated with animals not purchased or maintained by the LAF (e.g., fish, amphibians, reptiles etc.), the IACUC Office will require a response from the PI as to the presence of animals on the protocol. The PI will be required to confirm that the policy will be followed regarding the maintenance of animals on expired protocols. Follow-up reports may be requested.
- k. If the expired protocol is not currently associated with any animals, the IACUC Office will follow internal procedures to document closure of the protocol *unless* the PI wishes to keep it in lapsed status (PI's responsibility to notify IACUC).
- l. If the protocol has not been reapproved within 30 days of the expiration date, the PI must submit a letter to the IACUC requesting an additional 30 day extension. Extension requests must be received by the IACUC Office 5 days prior to the 30 day deadline and will be reviewed by the IACUC Committee.
- m. If an extension is not granted, or if the PI fails to submit an extension letter within the described timeline, the LAF will assume full ownership of any animals on the Holding Protocol, and appropriate action will be taken (i.e., euthanasia). In addition, the IACUC Office will follow internal procedures to document closure of the protocol.

### 3. Maintenance of Animals Associated with Expired Protocols:

- a. **Animals may continue to be maintained on the LAF Holding protocol, but no experimental procedures can occur.**
- b. Only routine husbandry is allowable on the LAF Holding Protocol. This includes special diets required to maintain animal well-being.
- c. Any care beyond basic husbandry that is required to maintain the animals must be submitted in writing and approved via Full Committee Review (FCR) by the IACUC.
- d. Breeding pairs from protocols previously approved for breeding will be separated so no further breeding will occur. Breeding is not approved on the LAF Holding Protocol.
- e. Charges will occur as follows:
  - i. If additional care is required beyond routine husbandry and maintenance, the LAF shall establish a technical service fee associated with keeping the animals.

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- ii. Service fees and per diem fees incurred when animals are held on the LAF Holding Protocol will continue to be the responsibility of the PI.

**4. After IACUC (re)approval of the protocol, all studies may resume as described in the protocol.**

- a. A report shall be made by the LAF Director to the IACUC at each Semi-Annual Facility Inspection and Program Review, summarizing any LAF Holding protocol activity associated with expired protocols during the previous six months.

**5. Protocol Compliance:**

- a. If any experimental work or breeding is performed during the protocol's lapse in approval, it will be considered a violation of IACUC and PHS Policy (non-compliance).
- b. Such instances of non-compliance require a prompt report by the IACUC to the Office of Laboratory Animal Welfare (OLAW) and AAALAC. After completion of internal procedures, the Institutional Official (IO) will submit a written summary report to OLAW outlining the facts surrounding the violation and all corrective actions taken. AAALAC will also be notified.

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