



TITLE: Annual Review and Protocol Renewal

Purpose: The purpose of this procedure is to provide guidelines for the IACUC and investigators to efficiently carry out protocol renewals. This procedure will provide a uniform process for renewals and make it clear that protocols must be renewed prior to their expiration in order for research under that protocol to continue.

PROCEDURE: Public Health Service regulation mandates that the IACUC conduct 1) continuous review of each previously approved, Animal Care and Use Protocol and associated ongoing activity, and 2) a complete review of approved protocols once every 3 years. To accomplish this requirement, PIs will be notified by the IACUC email system at least 3 months before each protocol is scheduled to expire. This correspondence will advise them that they must submit 1) an **Annual Report** or 2) a renewal **Animal Care and Use Protocol** so that it can be approved prior to the expiration date. If a PI does not respond to the first notification, a second notification will be sent at least 2 months before each protocol is scheduled to expire. If a PI still does not respond, the system will notify the PI 30 days before the protocol expiration date that the protocol will expire. This will be the final notice to submit renewal documents. To guard against the chance a PI does not receive the notification due to extended absence from their office (e.g., illness, sabbatical, etc.), the Chairperson of the PI's department will be copied on this final notification.

1. The **Annual Report** form can be found on the IACUC website. Submission of the annual report requires report of the number of animals used to date, unexpected outcomes, and modifications to the approved protocol (amendment submission required). Required on or before the first and second year anniversaries of the approved protocol.
 - a) Submitted renewal reports that are received by the deadline(s) identified in the above notifications will be scheduled for review at the committee's next convened IACUC meeting or for Designated Review. Results of the IACUC review will be communicated to the PI in a timely manner to avoid protocol expiration.
 - b) If necessary, amendment(s) to approved protocols must be finalized before the annual report due date. The Protocol Modification form is available on the IACUC website.
 - c) If a PI fails to respond to amend the protocol, the protocol will be suspended. Upon suspension, the IACUC will within 24 business hours notify the PI, the responsible attending veterinarian, the Animal Facility Manager, and Department Chair. The Protocol Modification form must be submitted and approved if the investigator wishes to restart the research.
2. A 3-year renewal **Animal Care and Use Protocol** form can be found on the IACUC website. Required on or before the third year anniversary of the approved protocol.
 - a) If modifications are required by the IACUC for approval, the PI will have a maximum of 2 weeks to respond. Such response will be in the form of a protocol rewrite which incorporates and highlights (bold) the response(s).

- b) If a PI fails to respond to the IACUC's questions within the required time frame, the protocol will expire on its expiration date. Upon expiration, the IACUC will within 24 business hours notify the PI, the responsible attending veterinarian, the Animal Facility Manager, and Department Chair. An investigator wishing to restart the research will have to submit a new protocol, which will undergo the IACUC review and approval process.

Approved by the IACUC 29 June 2015

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