



## Animal Facility SOP 42.2 Post-Approval Monitoring and Protocol Renewal

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<b>Prepared by</b>	Ingrid Tulloch
<b>Reviewed by</b>	Edited by Matt Terzi, Julie Watson Edited By Ingrid Tulloch 9/1/2021

### Purpose

This document details the policies and procedures that will be followed in order to complete the post-approval monitoring and renewal process for approved IACUC protocols.

### II. Scope

This document is intended as a guide for all Principal Investigators, Animal Facility Personnel and IACUC members to detail how Annual Review by IACUC is conducted.

Standards and requirements for the use of laboratory animal use are outlined in the [Guide](#). A requirement for maintaining compliance is the ability for IACUC to evaluate animal care use programs at Morgan State and enforce the Office of Laboratory Animal Welfare standards for laboratory animal use. Within this capacity, the IACUC will meet 4 times a year to review and approve Institutional Animal Care and Use Protocols, conduct an inspection of the animal facility and review documentation and protocol adherence two times a year.

### III. Annual Procedures

#### A. Annual Review Post Approval

- a. IACUC administrator sends to the PI an [Annual Review form](#) one month prior to the first and second anniversaries of the protocol approval date. The form includes information for animals used to date and any unexpected adverse events (not foreseen/described in protocol)
- b. The PI completes the form and sends it to the IACUC prior to the anniversary of the initial protocol approval date.
- c. If no adverse events occurred, the protocol continues for another two years.
- d. If there are adverse events, then the IACUC undertakes [post-approval monitoring procedures](#)
  - i. [Schedule](#) meeting with PI to discuss research/observe animal use.
  - ii. Determine if any adjustments are needed to avoid further adverse events.
  - iii. At the end of three years, if a new protocol must be written, take into consideration experiences with the previous protocol while writing.

#### B. Final Report after 3rd year of protocol life

- i. The administrator sends out the post-approval monitoring form together with a blank protocol form.
- ii. If the protocol is to be continued, the post approval monitoring form is submitted together with a new protocol. Protocols must be rewritten, reviewed, and approved de novo every 3 years.
- iii. All protocol amendments must be integrated into the new protocol.
- iv. If the protocol is not continued, then submit just the post-approval monitoring form