

**POLICY REGARDING THE CLOSURE OF ACTIVE IACUC
PROTOCOLS BY PI REQUEST OR EXPIRATION**

PURPOSE:

This policy provides guidance on the process of closing an active IACUC research protocol, either by expiration or voluntarily by PI request (no more animal work will be performed).

POLICY:

Protocols must be closed out properly at the conclusion of their three-year approval period or at the conclusion of all animal work. Unless a protocol has been previously closed out, it will be considered closed upon the third anniversary of its approval date. Researchers who wish to continue protocols beyond this initial three-year period must submit a new protocol to the IACUC for approval. Protocols must be closed by notifying the IACUC and other appropriate parties, whether the decision is voluntary or not.

RIGHTS

The PI has the right to close out an IACUC protocol at any time during the period in which it is approved. If a protocol is voluntarily closed, but a PI wishes to restart animal work, a new protocol must be submitted to the IACUC for approval. All protocol closeouts must be consistent with applicable laws and policies. Failure on the part of a PI to adequately close out a protocol may result in non-compliance.

PROCESS & GUIDELINES

The process of closing a protocol allows the IACUC to fulfill its regulatory obligations to the federal agencies. Following the procedures for closing a protocol ensures that:

- The protocol has been conducted in accordance with the approved protocol
- Modifications received IACUC approval prior to implementation
- No unanticipated or adverse events were experienced, or such events were documented

Being that the process of closing out an IACUC protocol is a federally mandated activity, the following guidelines are in place:

- 90 days prior to protocol expiration, a letter will be sent to the Principal Investigator notifying them of the upcoming expiration.
- 45 days prior to protocol expiration, a notification will be sent to the PI alerting them of the impending annual review.
 - If a protocol is closed outside of its anniversary date, an annual review form will be sent to the PI. This form must be filled out and returned within 30 days of the protocol closing.
- The annual review reports will be reviewed appropriately. Any protocols with potential compliance issues will be further investigated by the IACUC.