

University of Maryland College Park Animal Care and Use Standard

Principal Investigator Response Time to Clarifications for Animal Use Protocols/Amendments

<u>Purpose</u>: This standard describes timelines for PI responses to IACUC clarification requests related to protocol and amendment submissions.

Background: Timely IACUC actions related to animal use activities are important to ensure protocols, amendments and other documents are managed efficiently. This allows research to begin/continue within the desired timeline, helps prevent obsolescence, and allows the IACUC office to maintain accurate records and tracking. Principal investigator (PI) responses to IACUC clarification requests are an integral part of this process.

Standards: A PI will have up to four (4) months in which to respond to IACUC clarification requests (pre-review comments, modification letters, etc.). If the PI (or designee) does not submit a response and/or revised protocol documents within the four month time period, or provide written explanation for the delay, the pending protocol action will be removed from IACUC consideration. The PI will need to resubmit the document(s) to initiate the IACUC review and approval process again.