TITLE: Protocol and Amendment Review Process

PURPOSE: To outline the IACUC protocol and amendment review process

REVIEW/REVISIONS: IACUC will review and revise this SOP as needed.

DATE OF LAST REVISION: 08/14/2017

PROCEDURES:

Notification of Committee:
The IACUC receives a list of all protocol and amendment submissions with the following information: Principal investigator name, protocol number, title, species, pain category (if applicable) and a summary of the research procedures. The list is sent out via email. IACUC members are given 2 business days to respond with a request to see the full protocol or amendment or to call for full committee review.

Assignment of Reviewers:
The primary (designated) reviewer is assigned according to IACUC SOP 123 Protocol, Amendment or Annual Reviewer Assignment. The primary reviewer is an IACUC member with appropriate expertise. The reviewer is also charged with conducting a side-by-side comparison of the protocol to the PI's grant (for PHS or NSF funded grants) and reporting any discrepancies. In addition, the protocol is sent to a veterinary reviewer, if the primary reviewer is not a veterinarian. Amendments that do not affect animal welfare may not be sent to a veterinary reviewer.

Designated Member Review:
In the absence of a call for full committee review, all protocols and amendments, with the exception of protocols involving primates, are eligible for Designated Member Review. Upon review, a designated reviewer can vote to:

- Approve
- Require modifications to secure approval

A designated reviewer may also call for full committee review. In this case, the designated reviewer will act as the primary reviewer. A designated reviewer may not vote to withhold approval.

Full Committee Review:
Following a request for full committee review, the IACUC reviews the protocol or amendment, with the primary reviewer leading the discussion. The committee can vote to:

- Approve
- Require modifications to secure approval
- Withhold approval

If the committee requires modifications to secure approval, the IACUC can vote for the protocol or amendment to be reviewed and approved by:

- The full committee
- A named designated reviewer

This process was previously agreed to, in writing, by all IACUC members.

Approval:
The approval date is the date that either the designated reviewer or the full committee approved the protocol or amendment.