TITLE: IACUC Approval of Protocols or Amendments

PURPOSE: To describe the procedures for IACUC approval of protocols or amendments during Full Committee Review.

REVIEW/REVISIONS: IACUC Office staff will review and revise this SOP on advice from the IACUC.

PROCEDURES:

When a protocol or amendment undergoes Full Committee Review (FCR) at a convened IACUC meeting, the following voting procedures will be used:

The IACUC will review the protocol or amendment and discuss any issues identified.

At the conclusion of the discussion, the Chair or their designee will ask the members present if any modifications required to secure approval must be reviewed by FCR.

In the absence of a call for further FCR, the Chair or their designee will ask the members present to vote on the protocol or amendment. The following voting options are available:

- Approval
- Require modifications to secure approval – final approval by Designated Member Review (DMR)
- Withhold approval

A Committee member may also abstain from voting.

The votes will be tallied and the Committee’s decision will be determined by a simple majority vote. In the event that a majority decision is not obtained, the Committee will further discuss the issues and revote as above.

When the majority decision is to “Require modifications to secure approval – final approval by DMR”, the Committee will revote to “Require modifications to secure approval – final approval by DMR”, identifying the designated reviewer(s). This must be a unanimous vote.

As a requirement for this, all IACUC members have agreed to the following in writing:

In instances when a protocol goes to FCR and the quorum of members present determine that modifications are needed to secure approval, the members present may vote for additional review of the revised protocol via either subsequent FCR or a DMR. In order to continue with additional review and final approval via DMR:

- If all IACUC members are present at the meeting, the Committee may vote to ask for additional information and/or modifications to the protocol and have the revised protocol reviewed by a DMR(s).

- If all IACUC members are not present at the FCR meeting, all IACUC members must have agreed in advance, in writing, that the quorum of members who are present at a Full Committee Meeting may decide by unanimous vote to use DMR for the revised protocol.