BACKGROUND

This Standard Operating Procedure (SOP) provides a detailed description of procedures for Full Committee Review (FCR) of protocols followed by the IACUC.

IACUC Procedure

Investigators submit new protocols via email or electronically via eProtocol for pre-review. Relevant sections of all protocols that have animals in USDA category D or E are pre-reviewed by a veterinarian prior to submission to a convened IACUC meeting. Protocols that only have animals in category B or C are pre-reviewed by a senior staff member of the IACUC Office; if it is deemed necessary, these protocols may also be sent to a veterinarian for pre-review. Once the pre-review process has been completed the protocol and related documents (e.g., grants, attachments) are submitted for IACUC review. The PI is required to submit an application that is signed (electronically or physically) by the PI, Department Chairperson and all laboratory personnel.

The week prior to the monthly meeting, a primary and secondary reviewer are assigned to each protocol by the Chairperson (or designee). The protocols and grants are provided to the full IACUC.

The primary and secondary reviewers are responsible for reviewing the entire protocol along with the grant application (if applicable). All other members are expected to review each protocol and provide comments if necessary.

During the meeting

Prior to discussion of each protocol, member(s) with conflicts of interest will recuse themselves and the Chair verifies quorum.

During protocol discussion, the primary and secondary reviewers present their critiques. The Chairperson then solicits comments from the entire committee, and ensures that all opinions are heard as part of the deliberation. Once a consensus or a clear division in opinions is apparent, the Chairperson will ask the primary reviewer to make a motion. Once a motion is seconded, the Committee votes by a show of hands. The protocol may be placed in one of four categories based on the decision of the committee. They are:

- **Recommended for Approval**: The protocol complies with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines and USDA regulations and is written in such a way that only administrative questions or clarifications are required.

- **Modifications Required to Secure Approval**: The protocol complies with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines and USDA regulations, but is written in such a way that minor questions and/or clarifications must be resolved to secure approval. The committee members present at the meeting must decide by unanimous vote to use Designated Member Review (DMR) to review the protocol after it has been modified.

- **Tabled, Request for Major Revisions (Requires Full Committee Review)**: The protocol either does not comply with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines or USDA regulations or is written in such a way that there are serious questions that must be resolved to secure approval.

- **Approval Withheld**: The protocol either does not comply with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines or USDA regulations or the PI will not agree to comply with the IACUC’s requirements.
**Following the meeting**

Investigators are notified as to the outcome of the protocol reviews, and are provided with the questions and/or clarifications of the Committee. The categories are handled as follows:

- **Recommended for Approval:** The protocol can be approved as soon as all administrative IACUC requirements have been completed (see “Final Approval Requirements” below). Principal Investigators who have protocols in this category will not receive an official letter from the office until Final Approval has been granted; however, a reminder as to what IACUC requirements are still outstanding will be sent to the PI.

- **Modifications Required to Secure Approval:** The protocol must be revised per the Committee’s questions and/or requests for clarifications and resubmitted for review by Designated Member Review (DMR) as assigned by the Chairperson (or designee). The reviewer will confirm that all questions and/or requests for clarification have been resolved. Once the reviewer is satisfied with the revision, the protocol will be recommended for approval. The protocol does not need to be submitted to another convened meeting for FCR unless the reviewer determines that the changes made by the investigator constitute a substantial alteration to the protocol or are unacceptable and cannot be resolved. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

- **Tabled, Request for Major Revisions:** The protocol must be revised per the Committee’s questions and/or requests for clarifications and resubmitted for FCR at a convened meeting.

- **Approval Withheld:** The protocol is not eligible to be reviewed again by the Committee; the Institutional Official will be copied on the letter to the PI.

**IACUC Final Approval Requirements**

Once a protocol is “recommended for approval” it will receive Final Approval as soon as the Office of Environmental Health and Safety (OEHS) grants approval (i.e. Institutional Biosafety Committee, Radiation Safety, Chemical Hazards, ANICON, training courses) and all IACUC-required training (i.e. CITI online modules, Division of Laboratory Resources hands-on training) has been completed. Protocol approval is granted for a period of three years with instructions that the protocol must be reviewed on an annual basis to remain active, and any changes must be submitted for review via the amendment process.

**Annual Review and Approval**

After the first and second year, the investigator is required to submit the protocol for annual/continuing review. If the project will continue beyond the third year, a new protocol must be submitted to the Committee.