Subject: Full Committee Review

BACKGROUND

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

IACUC Procedure

Investigators submit new protocols and amendments (“submissions”) via eProtocol.

- Protocols that have animals in USDA category D or E are pre-reviewed by a veterinarian prior to review by the IACUC. Protocols are polled to determine if Designated Member Review (DMR) or FCR is appropriate for the submission.

- Amendments involving significant changes (see the Review of Significant Changes to Approved Protocols SOP) are polled to determine if DMR or FCR is appropriate for the submission.

Prior to the monthly meeting, at least one reviewer is assigned to each FCR submission by the Chairperson (or designee). The submissions are provided to the full IACUC.

The reviewer(s) is responsible for reviewing the entire submission along with any grant applications (if applicable) to ensure congruency. All other members are expected to review each submission and provide comments if necessary.

Determinations

The IACUC reviews protocols and amendments per the Conducting IACUC Business During a Convened Meeting SOP. The submission will be placed in one of four categories based on the decision of the committee. They are:

- **Recommended for Approval**: The submission 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 submission 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 submission after it has been modified.

- **Tabled, Request for Major Revisions**: The submission 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. Subsequent approval must be decided by Full Committee Review at a convened meeting.

- **Approval Withheld**: The submission 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 submission review process, and are provided with the questions and/or clarifications of the Committee. The categories are handled as follows:

- **Recommended for Approval**: The submission can be approved as soon as all administrative IACUC requirements have been completed (see “Final Approval Requirements” below). Principal Investigators who have submissions 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 submission 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 submission will be recommended for approval. The submission 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 submission and/or request FCR.

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

- **Approval Withheld**: The submission is not eligible to be reviewed again by the Committee. The Institutional Official will be copied on the letter to the PI for any protocol where approval has been withheld.

**IACUC Final Approval Requirements**

Once a submission 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. Approval of new protocols is granted for a period of no more than 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. Amendment submissions expire at the end of the original protocol approval period.

**Annual Review and Approval of Protocols**

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