Subject: Full Committee Review Process for Protocols

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 and amendments ("submissions") via email or eProtocol.

- 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 can be pre-reviewed by a senior staff member of the IACUC Office and may be polled to determine if Designated Member Review (DMR) or FCR is appropriate for the submission; 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.

- Amendments involving significant changes (see the Review of Significant Changes to Approved Protocols SOP) are all 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 protocol submission by the Chairperson (or designee). The protocols submissions are provided to the full IACUC.

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

Determinations

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

- Recommended for Approval: The submission 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 submission protocol complies with all requirements of the Guide for the Care and Use of Laboratory Animals, PHS guidelines and USDA regulations, but is written is 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 protocol after it has been modified.

- Tabled, Request for Major Revisions (Requires Full Committee Review): The submission 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. Subsequent approval must be decided by Full Committee Review at a convened meeting.
• **Approval Withheld:** The submission 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 submission protocol reviews process, and are provided with the questions and/or clarifications of the Committee. The categories are handled as follows:

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

• **Tabled, Request for Major Revisions:** The submission 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 submission protocol 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 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 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 the protocol for an annual/continuing review. If the project will continue beyond the third year, a new protocol must be submitted to the Committee.