IACUC Standard Operating Procedure

Subject: Pre-review of Animal Protocols in eSirius

Background: The review of all full committee research and use protocols by the Institutional Animal Care and Use Committee (IACUC) is conducted at a convened meeting of the IACUC. However, reviewers often discuss issues with the Principal Investigator before the IACUC meeting and any revisions and/or modifications that the PI would like to make to the proposed research project must be incorporated into the eSirius protocol that is being reviewed by the IACUC at their next meeting. These pre-reviews are often conducted by Center for Animal Resources and Education (CARE), Animal User Health and Safety Program (AUHSP) working group, Office of Research Integrity and Assurance (ORIA), and other individuals working on behalf of the IACUC. These groups may be making recommendations for improvements, request for clarifications, and/or suggesting conditions for approval by the IACUC.

The PI’s response(s) must be incorporated into the eSirius protocol in order for this updated version to be considered by the IACUC. After IACUC review, all conditions for protocol approval will be indicated in the request for revision(s) generated in eSirius and sent to the PI via email. All conditions must be addressed and incorporated into the protocol in eSirius before the IACUC approval letter is released.

Procedures

The IACUC meetings are generally held the third Thursday of each month. Protocols to be reviewed at the following month’s meeting are due the Friday immediately following the meeting. While Principal Investigators may submit animal protocols at any time, those protocols meeting this deadline will normally be assigned for the next IACUC meeting. The Principal Investigator (PI) must create the animal protocol in eSirius. After creating the protocol, s/he must release the protocol for IACUC review by the published deadline. The administrative staff starts the pre-review process as soon as the protocol has been released by the Principal Investigator to provide a thorough evaluation by groups possessing expertise in specialized fields (veterinarians, occupational health, ORIA administrative staff, etc). These groups provide feedback to the investigator in order to enable the committee review process to operate efficiently.

The protocols undergo individual review by the CARE veterinarians and are discussed in detail at a meeting of the veterinarians and associated staff by the end of the month. The CARE veterinarians will communicate with the PI’s via phone or email regarding areas of special concern. As part of the pre-review process, the CARE veterinarians enter recommendations for improvements, request for clarifications, and suggested conditions for approval directly into the corresponding section of the eSirius protocol.

Additionally, the protocols are pre-reviewed by the AUHSP working group which also meets by the end of the month after the deadline for submission. They assign the Risk Level associated with the activities outlined in the protocol. In addition, this working
group will enter recommendations for improvements, request clarifications and suggested conditions for approval directly into the corresponding sections of the eSirius protocol. Members of the AUHSP working group will communicate with the PI’s via phone or email regarding areas of special concern. ORIA will also conduct an administrative pre-review of the animal protocol by the end of each month. By the end of each month, the IACUC Coordinator will pull back all animal protocols that are scheduled to be reviewed by the IACUC at their next meeting.

Approximately two days later the IACUC Coordinator will forward the collective pre-review comments to the PI. The PI will have the option to make any changes that he/she wishes to make to the animal protocol based upon the pre-review or they may chose not to respond. If the PIs responds to these recommendations, request for clarification, and or suggested conditions, the chance for obtaining IACUC approval is increased and the time period from creation of the protocol to approval by the IACUC has been substantially reduced. The PI will have approximately one week to provide these clarifications and/or revise his/her animal protocol.

Approximately 6 days after being given an opportunity to respond to the reviewers’ comments, the IACUC Coordinator will pull back the protocols from the investigator and any additional changes that the PI would like to make to the protocol must be submitted via an amendment to the IACUC. If the PI fails to make this deadline, the original version of the protocol will be evaluated to determine if it is adequate to allow detailed review by the IACUC. The protocol will either be returned to the Principal Investigator for substantial revision or submitted to the IACUC for review.

Approximately one week prior to the next IACUC meeting the agenda will be established and associated protocols, amendments, renewals and exemptions will be sent to IACUC committee members. Suggested conditions for approval placed on a protocol by either the CARE veterinarians, the AUHSP working group, or the ORIA administrative review that have not been incorporated into the revised animal protocol will be submitted to the IACUC for consideration as a condition on the protocol. ORIA will not release the IACUC approval memo until all conditions placed on the protocol by the IACUC have been met.

IACUC Approval Date: October 19, 2006