

IACUC POLICIES AND PROCEDURES

Animal Care and Use Protocol Review Process

Purpose:

This document provides the approved practice and procedures for review of animal care and use protocol proposal by the University of Kentucky Institutional Animal Care and Use Committee (IACUC). While the criteria that must be met before an IACUC can approve a proposed research protocol is covered under Public Health Service Policy (IV, c,1,a-IV,c,1g;IV,d1,-IV,d,1e) and the Animal Welfare Act (2.31,d; 2.31,e), the method to accomplish this left up to each individual institution. This document serves to document the practice and processes performed to ensure proper reviews for each type of review.

Web-based Protocol Review Process:

The University of Kentucky uses the web-based e-Sirius® electronic protocol submission system to permit the investigator to submit their protocol to the IACUC on-line. The e-Sirius® system protocol form populates sections based upon the response to early questions by the investigator and protocols only contain sections related to the actual protocol being submitted.

The University of Kentucky reviews all protocols, regardless of funding source, on an annual basis and requires a *de novo* review of every protocol at an interval not to exceed 3 years.

New Animal Use Protocols and 3 year *de novo* Protocol reviews:

The University of Kentucky IACUC uses both the Full Committee and the Designated Reviewer methods for review and approval of new Animal Care and Use Protocols and submitted 3 year *de novo* protocol reviews. Protocols involving only breeding activities (USDA Column B) or research activities with no more than slight or momentary pain and distress (USDA Column C) are assigned as eligible for Designated Review by the IACUC office. All other protocols are automatically assigned to Full Committee Review for final approval.

Designated Member Review (DMR) Process:

Protocol submissions determined to be eligible for approval by the Designated Member Review method by the IACUC office are initially routed to the full IACUC. These protocols are available to all IACUC members for review and comment for a minimum of 5 business days.

The IACUC chairman has delegated the authority to assign the primary reviewer to the Office of Research Integrity-IACUC (ORI-IACUC) office. The veterinary reviewer role is generally assigned to the veterinarian directly overseeing the facility involved. Both the primary and veterinary reviewers may request additional reviewers be assigned by the ORI-IACUC office for specific expertise or assistance.

The IACUC members review the protocol and may request clarifications, additional information, protocol changes, modifications, etc. from the investigator. After the reviewers have completed

their review, the protocol is returned to the investigator by the IACUC office for their responses and changes. If no IACUC member requests Full Committee Review during the period of IACUC review, the review is completed by a primary and veterinary reviewer as a Designated Member Review. Complex protocols may be exchanged between the reviewers and the investigator several times for changes and clarifications prior to approval by the Designated Reviewers.

Any Designated Reviewer can call for a Full Committee review of any protocol submitted for Designated Review at any time during the review process. Once requested, the protocol must be approved by Full Committee review which occurs during the regular convened meeting of the IACUC (usually the third Wednesday of every month).

Any approval decision by the Designated Reviewers must be a consensus decision. If the Designated Reviewers cannot reach a consensus decision, the protocol is sent for Full Committee review.

Full Committee Review (FCR) Process:

Protocol submissions are initially routed to a primary reviewer and a veterinary reviewer by the ORI-IACUC office. The primary reviewer is assigned by the ORI-IACUC office while the veterinary reviewer is assigned to the veterinarian directly overseeing the facility involved. The full committee (which includes the primary and veterinary reviewers) has five days to review, comment on, make suggestions, or ask for additional information or clarifications online.

The ORI-IACUC office then routes the protocol back to the investigator with all comments for consideration, responses, and changes listed. While there is no time limitation for the investigator to respond and resubmit the protocol, reminders are sent by the IACUC office periodically. After responding to the written concerns, the investigator resubmits the protocol to the ORI-IACUC office.

The protocol is then rerouted to the primary and veterinary reviewers for additional review and to ensure the investigator has responded to the questions, requested changes, clarifications, etc. If questions or concerns remain, the primary or veterinary reviewers may return the protocol to the investigator for additional responses, information, clarification, etc. Complex protocols may be exchanged between the reviewers and the investigator several times before the protocol is considered ready for Full Committee Review and it is placed on the meeting agenda.

At the IACUC meeting the primary reviewer presents a synopsis of the protocol along with any comments and concerns that have not been resolved as of the meeting date. The IACUC discusses the protocol and related issues during the meeting. All protocol discussions are considered potentially confidential and are considered in an executive session. The final recommendations of the IACUC are voted upon in open session.

IACUC actions include:

- Approval
- Require Clarifications/Modifications to Secure Approval - By unanimous agreement of all voting and alternate members, the Committee has adopted the practice of allowing DMR

following FCR when substantive additional information is required to properly evaluate proposals and requires modification to secure approval. DMR can only occur in these situations by the unanimous vote of the members present at a properly convened meeting. Committee member signatures are on file authorizing this practice. If this method is chosen, the IACUC chairman and Committee generally assign the designated reviewer during the discussion of the protocol.

- Deferral (Tabled) - Protocols deferred at the meeting generally have numerous or serious flaws requiring extensive rewriting. Investigators are provided with a list of concerns, comments, and questions for response and guidance in resubmitting the protocol for consideration. Deferred protocols must be reviewed at another full IACUC meeting before approval may be granted.
- Withhold Approval – The IACUC may, by a majority vote, withhold approval for a protocol. In these cases the investigator is notified in writing of the IACUC’s decision and the reasons for such a decision. The investigator is provided the opportunity to respond to the IACUC’s decision either in person or in writing. The IACUC may reconsider its decision following the investigator’s response.

Due to the extensive pre-review process, most protocols are either approved as written or require some minor clarifications or modifications to secure approval and are assigned to designated member review for final review and approval. While the IACUC generally strives for consensus, in cases where disagreements exist the majority vote determines outcome. The IACUC decision and any requested clarifications or changes are communicated to the investigator via e-mail and the web-based e-Sirius® electronic protocol submission system.

Annual Animal Use Protocol Reviews:

The University of Kentucky uses the Designated Member Review method of protocol review for annual protocol reviews. The investigator completes a short questionnaire concerning any changes in the protocol and provides a brief progress report, which is distributed for review and consideration by all IACUC members. If no IACUC member requests Full Committee Review during the period of IACUC review, the review is completed by an IACUC reviewer as a Designated Member Review.

Amendments to Animal Use Protocols:

Amendments to protocols are submitted to the ORI-IACUC office. Based on the criteria listed below, amendments are classified as either minor or major (significant). Major amendments require IACUC review as detailed in PHS Policy (IV,B,7) and AWAR (2.31,c,7).

Significant protocol amendments are reviewed by the Designated Member Review method. Amendments are completed by the investigator within the original protocol format with changes clearly delineated by changes in text color to the reviewer. After submission to the ORI-IACUC office, the amendment request is available to all IACUC members for review and comment. If no IACUC member requests Full Committee Review during the period of IACUC review, the review is completed by an IACUC member and a veterinarian as a Designated Member Review.

Examples of major amendments include the following:

- Change in purpose or specific aim of study
- Change of principal investigator
- Change of species
- Addition of species
- 10% or more increase in animal numbers over the number approved on the initial protocol and any subsequent committee reviewed amendments
- Addition of a survival surgery
- Addition of a painful procedure
- Unanticipated marked increase in clinical signs or proportion of animal deaths
- Addition or change of anesthetic or analgesic agent or a change in dosage

Minor amendments are processed through the ORI-IACUC office as administrative changes. Minor amendments include the following:

- Changes to contact information or training updates of the PI or study personnel
- Addition or deletion of study personnel
- Addition of faculty collaborator
- Addition of another strain of the same species
- Change of sex in the animal to be used
- <10% increase in animal numbers over the number approved on the initial protocol and any subsequent committee reviewed amendments
- Need to repeat an experiment
- Addition of a minor surgery (requires ORI-Office staff with veterinary consult as needed)
- Addition of sample collection times (if not exceeding standard limits - with veterinary consult as needed)
- Additional non-invasive sampling (if not exceeding standard limits - with veterinary consult as needed)
- Reducing or eliminating previously approved water or feed restrictions
- Addition of or change in dosage of an experimental drug in the same class as one previously approved
- Addition or deletion of animal usage location
- Changing the title of a protocol

Approved and Adopted by the
Institutional Animal Care and Use Committee
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Amended and Approved by the
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November 19, 2008

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