

## **Policy on Protocol Review Process**

This document establishes the policy of the IACUC regarding practice and procedures for review of animal care and use protocols 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 is left up to each individual institution. This document serves to describe the practice and processes performed at the University of Kentucky to ensure proper reviews for each type of review.

### **Web-based Protocol Review Process and Reviewer Assignment:**

The University of Kentucky uses a web-based Electronic Protocol Processing System to permit the investigator to submit their protocol to the IACUC on-line. The protocol form populates sections based upon the response to setup questions by the investigator and protocols only contain sections related to the actual protocol being submitted.

Each protocol/major amendment receives a primary and veterinary reviewer. The IACUC Chairperson has delegated the authority to assign the primary reviewer to the OAV-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 OAV-IACUC office staff for specific expertise or assistance. All protocols are reviewed by EHS. Protocols sent to committee status in the system remain accessible to all reviewers for 5 business days.

### **Protocol Review:**

The University of Kentucky IACUC uses both Full Committee Review (FCR) and Designated Member Review (DMR) methods to review New protocols and 3-Year *de novo* protocols. Protocols involving unalleviated pain or distress (USDA Category E) are automatically assigned to FCR for final approval. Major amendments adding these elements to a protocol previously reviewed via DMR are assigned to FCR. All other protocols and major amendments are eligible for DMR. Any protocol requesting procedures as covered under a Research Core Facility Protocol which was previously reviewed via FCR, may be reviewed DMR unless called for FCR by an IACUC member.

### **Designated Member Review (DMR) Process:**

Assigned reviewers 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 OAV-IACUC staff for their responses and revisions. If no IACUC member requests Full Committee Review during this period of IACUC review, the review is completed by the primary and veterinary reviewer as a Designated Member Review.

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.

Any member of the IACUC 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).

### **Full Committee Review (FCR) Process:**

Once the protocol has been called, the assigned reviewers continue to review the protocol until it is ready for the agenda. Complex protocols may be exchanged between the reviewers and the investigator several times before agenda placement.

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 – When items are pending (e.g. clarification of animal numbers, drug doses, etc.) the IACUC may, by a majority vote, require clarifications or modifications to secure approval by either mechanism (FCR or DMR). By unanimous agreement of all voting and alternate members, the Committee has adopted the practice of allowing DMR subsequent to FCR when substantive additional information is required to properly evaluate proposals and requires modification to secure approval. DMR subsequent to FCR 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 Chairperson and Committee generally assign the designated reviewer during the discussion of the protocol
- 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 DMR 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 Electronic Protocol Processing System.

Protocols with numerous or serious flaws requiring extensive rewriting may not be considered for review and may be deferred (tabled). 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 (FCR or DMR) before approval may be granted.

In order to facilitate protocol approval and to allow adequate time for review, it is strongly recommended that protocols submitted to the IACUC adhere to the [Guidance on Protocol Submission Deadlines](#).

### **Amendments to Animal Use Protocols:**

Amendments to protocols are submitted to the OAV-IACUC office staff. Based on the criteria listed below, amendments are classified as either major (significant) or minor. Major amendments require IACUC review as detailed in PHS Policy (IV, B,7) and AWAR (2.31, c,7). Further clarification on significant changes to animal activities is delineated in [NOT-OD-14-126](#).

Major amendments are assigned for review by the DMR method. If no IACUC member requests Full Committee Review the amendment continues the review process as described above.

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 any procedure not previously approved
- Unanticipated marked increase in clinical signs or proportion of animal deaths

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

- Correction of typographical or grammatical errors
- Changes to contact information or training updates of the PI or study personnel
- Addition or deletion of study personnel
- Decrease in the number of animals used
- Addition or deletion of animal usage location

- Changing the title of a protocol

**Veterinary Verification and Consultation (VVC)** is a method for approving significant changes to a previously approved protocol. It may not be used to add a new procedure not previously approved on the protocol. Examples of specific significant changes that may be approved administratively after consultation with an IACUC authorized veterinarian (both full and alternate veterinarian members) include the following:

- Change in anesthesia, analgesia, sedation as listed in:
  - [Non-steroidal and Opioid Analgesics for Rodents and Rabbits](#),
  - [Recommended Anesthesia for Some Laboratory Animal Species](#),
  - [Formulary for Laboratory Animals](#) (current and future editions),
  - [Handbook of Laboratory Animal Science](#) (current or future editions) and other accepted published veterinary drug formularies); or experimental substance to a substance in the same category (e.g. an antineoplastic drug to another antineoplastic drug).
- Change in euthanasia to any method acceptable/acceptable with conditions in the [AVMA Guidelines for the Euthanasia of Animals](#) (current and future editions). See [UK IACUC Policy 103](#).
- Change to the duration, frequency, type or number of procedures performed on an animal as listed in:
  - [DLAR Animal Health & Veterinary Information](#)
  - [DLAR Guidelines for Blood Collection in Laboratory Animals](#)
  - [Tumor Models in Rodents](#)
  - [DLAR Guidelines for Acclimation Periods for Newly Received Laboratory Animals](#)
  - [Implantation of Osmotic Pumps in Rodents](#)
  - [Tissue Collection \(Biopsy\) for Genetic Identification of Rodents \(Care of Weanling Mice and Rat Pups, etc.\)](#)
  - [DLAR Investigator Handbook](#)
  - <https://www.nal.usda.gov/awic/blood-collection>
  - <https://www.nc3rs.org.uk/general-principles>, and other accepted published sources.

Examples include but are not limited to: sample collection intervals, peri-mortem collection of additional tissue samples while under terminal anesthesia, behavioral tests, [food/water restriction](#), etc.

- Change of a strain generally accepted for the modeling/study of the disease/condition of interest as listed below, or change of sex of the same species:
  - [Rat Genome Database](#)
  - [Charles River Laboratories](#)
  - [Envigo](#)
  - [Jax Labs](#)

- other accepted published rodent databases
- Change (<10% increase) in animal number approved on the initial protocol and any subsequent committee reviewed amendments (see [UK IACUC Policy 101](#) for definition of animal numbers).
- Change (reducing or eliminating) previously approved water or feed restrictions.

### **Administrative Cancellation of Protocols/Amendments Pending Approval:**

This section establishes a time frame at which the OAV-IACUC staff will administratively inactivate a protocol or amendment application (pending approval) for failure to respond to IACUC requests for further clarification or additional information.

If the IACUC does not receive the pending items within a period of 6 months from the first IACUC communication, the protocol/amendment may be administratively cancelled.

### **Exemptions:**

Decisions regarding exemptions to this policy will be considered by the IACUC Chair and Attending Veterinarian (or their designated alternates).

Approved and Adopted by the IACUC:  
October 15, 2008

Last Revised:  
March 15, 2023