

SOP Number: IACUC 1.0

SOP Title: New Protocol and De-Novo Protocol Submission/Review

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	Signature	Date
Initiated by		
Reviewed by IACUC Member(s)		
Approved by IACUC (IACUC Chair/Vice-Chair)		

Effective Date :
Supersedes : 1/2006

Major Changes from Previous Version	
Sub-Section	Change Description
	Update format and process

1.0 Purpose

The purpose of this SOP is to define the process for new Animal Care and Use Protocol and De-Novo reviews by the KUMC IACUC.

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2.0 Scope

2.1 This SOP applies to the animal care and use program at the University of Kansas Medical Center, Kansas City, KS and satellite facilities.

2.2 Program will include component parts including:

2.2.1 Review Process for On Cycle and Off Cycle protocol submissions.

2.2.2 Time line for review process.

3.0 Reference

3.1 IACUC Policy: Administrative Extension of Protocols.

4.0 Responsibilities

4.1 It is the responsibility of the Principle Investigator to submit complete Animal Care and Use Proposals (ACUP) and to follow all aspects of the protocol as written.

4.2 It is the responsibility of the IACUC to review and Approve/Disapprove all ACUPs in the context of animal welfare, the PHS Policy and the Animal Welfare Act.

4.3 It is the responsibility of Office of Animal Welfare to manage the administrative processing of the protocol process.

5.0 Procedure

5.1 Review Process-On Cycle-protocol will be reviewed at the regularly scheduled monthly IACUC meeting.

5.1.1 All new ACUPs and De-novo ACUPs will go through a 3 tier review process.

5.1.1.1 A complete protocol will be submitted by the PI to the IACUC Administrator for initiation of the review process.

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- 5.1.1.2 The IACUC Administrator will forward the protocol to the regulatory veterinarian for initial review.
- 5.1.1.3 All comments will be submitted back to the IACUC Administrator and forwarded onto the PI for incorporation into the revised protocol.
- 5.1.1.4 The revised protocol is submitted back to the IACUC Administrator and reviewed by the regulatory veterinarian to assure all comments were incorporated or addressed.
- 5.1.1.5 Communication will continue as noted above until all aspects of the regulatory veterinarian review are satisfied.
- 5.1.1.6 The second tier of review will occur via the Attending Veterinarian or his/her designee.
- 5.1.1.7 The main focus of the Veterinary Review will be on the pain and distress associated with the protocol and will satisfy the regulations concerning veterinary consultation concerning all painful/distressful procedures.
- 5.1.1.8 The process for review/comments/revision of the protocol will be the same as noted above.
- 5.1.1.9 The final review will occur by an assigned member of the IACUC.
 - 5.1.1.9.1 All revised protocols will be posted for all IACUC members to review and provide comments if they so-chose.
- 5.1.1.10 The above process for review/comments/revisions will be the same as noted above.
- 5.1.1.11 **IMPORTANT: Protocol review will not progress to the next reviewer until the previous reviewer has approved all changes.**
- 5.1.1.12 The protocol will then be brought to the scheduled IACUC meeting for final vote.

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5.1.1.12.1 **Approval**-protocol is complete and letter of approval is sent as soon as all occupational health, safety committee, training, and conflict of interest requirements are complete.

5.1.1.12.2 **Modifications required to secure approval**-protocol still needs revisions prior to final approval. This vote has two possible scenarios for final approval of the protocol depending on the extent of modifications needed.

5.1.1.12.2.1.1 **Deferred to Reviewer/IACUC Chair**-once the final revisions have been completed, the final approval will be via Designated Member Review by either the assigned IACUC reviewer/IACUC Chair/Veterinary Staff or a combination thereof.

5.1.1.12.2.1.2 **Deferred to Committee**-once final revisions have been completed, the final approval will be via the full committee at the next regularly scheduled committee meeting

5.1.1.12.2.1.3 **Any IACUC member has the option to call for the protocol to be Deferred to Committee if they so-chose.**

5.1.1.12.2.2 **Withhold Approval**-protocol is determined not to meet the requirements of the KUMC IACUC, PHS Policy and/or the Animal Welfare Act.

5.2 Review Process-Off Cycle-protocol will be reviewed outside the regularly scheduled monthly IACUC meeting via Designated Member Review (DMR).

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- 5.2.1 In order for a Principle Investigator to engage the Off Cycle review process a written justification must be presented to the Office of Animal Welfare concerning the need for the review to occur prior to the regularly scheduled meeting.
 - 5.2.1.1 Justifications may include but are not limited to need of IACUC approval to release funds (Just In Time Grants), time sensitive experiments that can result in the loss of animals, or failure of the Office of Animal Welfare to notify an Investigator in a timely manner when their protocol is expiring.
 - 5.2.1.2 Justification must contain supporting documentation from the parties involved (i.e. funding agency, collaborators, etc.) to assure the validity of the request.
 - 5.2.1.3 Final approval for Off Cycle review will be via the Chair of the IACUC.
- 5.2.2 If a protocol is approved for Off Cycle review, all IACUC members are notified of the pending review and provided the protocol to be reviewed by Designated Member Review by the IACUC administrator.
 - 5.2.2.1 Two Business days are allowed for any committee member to call for full committee review.
 - 5.2.2.1.1 If called for full committee review, the process starting at 5.1 will be initiated.
 - 5.2.2.2 If no IACUC members request full committee review, then the 3 tier process will be initiated starting with the pre-review as described 5.1.2.
 - 5.2.2.3 The IACUC member that has been assigned the DMR can assign the below results for the protocol:
 - 5.2.2.3.1 **Approval**-protocol is complete and letter of approval is sent as soon as all occupational health, safety committee, training, and conflict of interest requirements are complete.

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5.2.2.3.2 **Modifications required to secure approval-**
protocol still needs revisions prior to final
approval.

5.2.2.3.3 **Full Committee Review**-reviewer feels the full
committee is needed for review of protocol.

5.3 Time lines and deadlines for the Review Process

5.3.1 On Cycle Review Process

5.3.1.1 Protocols must go through the 3 tiered review process

5.3.1.2 Submission of a protocol for review at the regularly scheduled
monthly meeting must occur 6 **weeks** prior to the meeting.

5.3.1.2.1 Protocols that are incomplete or poorly written
may not be reviewed and will be sent back to
the Principle Investigator for completion.

5.3.1.2.2 The pre-review and Veterinarian review will
take place in the initial 2 weeks-3 weeks
(depending on given month).

5.3.1.3 The revised protocol that will be presented to the IACUC reviewer
must be completed by the **1st of the Month** in which it will be
reviewed (approx. 2-2.5 weeks prior to meeting depending on the
month).

5.3.1.4 If either of the above deadlines is missed, the protocol will be
moved to the next month's agenda.

5.3.1.4.1 **De-novo expiration dates cannot be extended
per IACUC Policy: Administrative Extension
of Protocols.**

5.3.1.5 It is in the best interest of the Principle Investigator to respond in a
timely manner to the pre-review and veterinary review so that the
revised protocol can move forward in the review process.

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5.3.1.6 It is the onus of the Principle Investigator to write a good, thorough protocol to allow for quick reviews and turnarounds by the pre-review and veterinary staff.

5.3.2 Off Cycle Review Process

5.3.2.1 The time lines for review of Off Cycle protocols will be **approximately** 1 week per tier of the review process.

5.3.2.1.1 See 5.3.1.5 and 5.2.1.6