



Institutional Animal Care and Use Committee Guidelines and Policies

THE PROCESS OF ANIMAL PROTOCOL REVIEW BY THE IACUC:

I. PI initiates the Protocol. The PI obtains current forms from IACUC web site, completes and submits both an electronic copy to the IACUC coordinator and a hard copy with signature by the deadline for that month.

II. Administrative Review. The protocol is checked over by IACUC coordinator to determine if veterinary pre-review is needed or not.

A. Vet pre-review IS indicated if Any animals fall into pain category D or E.

1) If this is the case,

- Did all personnel listed complete the “Post-procedural care” training module IN ADDITION to completing other training that is needed?
- Is the Institutional Safety Form completed if needed?

(if NO, the PI is contacted and informed that these are required before final approval letters will be issued, regardless of the review outcome)

2) If all of the above are in order, the protocol is emailed to the assigned veterinarian for that month to be reviewed for veterinary concerns.

3) The comments from the veterinarian’s review are emailed to the PI. If necessary (e.g. substantial changes needed), the PI must revise and resubmit the protocol until the veterinarian is satisfied. If only minor changes are required,

4) The protocol and vet comments are emailed out for Designated Review by an IACUC member assigned by the IACUC Chair.

B. Vet pre-review is NOT NEEDED for protocols that only have animals in category C, or for breeding protocols.

1) In such cases, the protocol is emailed out for Designated Review by an IACUC member assigned by the IACUC Chair.

III. Designated Review:

A. The designated reviewer (DR) assigned by the Chair reviews the protocol and communicates any comments directly to the PI via email, phone or in person. This can require several “back and forths” until the DR is satisfied (or an impasse occurs).

- DR uses the review checklist as a guide during the review.



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- DR confirms that the pain categories which the PI has assigned are, in fact, appropriate.
- DR ascertains that safety concerns have been addressed (e.g. did the PI identify biohazards and note special instructions when needed? Any doubts trigger a call to EHS and IACUC Chair).

B. The PI makes necessary changes, prepares a fresh “final” revised version of the protocol containing the changes, and emails a copy to the DR and the IACUC coordinator.

C. The DR evaluates the final revision and sends the IACUC coordinator his/her decision in writing/email, *along with copies of all pertinent review notes/correspondence and a copy of the signed review sheet.*

1) The DR’s decision is EITHER:

- Protocol Approved
- Protocol Referred to Full Committee

NOTE: Designated Reviewers can NOT disapprove a protocol – they can only refer it to full committee for additional consideration if they are not satisfied that all concerns have been addressed.

2) If the protocol is APPROVED by Designated Review:

The IACUC coordinator prepares a letter of approval that is signed by the Chair and sent to the PI; copies are sent to the Institutional Official (Dr.Sarras) and the Office of Sponsored Research.

Note: A final letter of approval will NOT be issued until all training modules for personnel are complete, a signature copy of the protocol is submitted by the PI, and any additional forms that are needed are signed and submitted (e.g. Institutional Research Safety Report signed by EHS, if needed)

3) If the protocol is Referred to Full Committee (e.g. The DR is NOT satisfied):

The IACUC Coordinator informs the PI and the Chair that the protocol will undergo further review during the next convened session of the full IACUC.

Approximately one week before a scheduled full IACUC meeting, the IACUC Coordinator emails out a list of all protocols (with abstracts) that are in review that month to the membership. Members are asked if 1) they wish a copy of any protocol to examine and 2) if they wish to refer/move any protocol into Full Committee Review. Any member can move a protocol into full committee review for any reason (see * below for typical reasons).



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IV. Full Committee Review

- *A. Often done for category E protocols.
- *B. Often done for protocols involving multiple major survival surgeries.
- *C. Typically done if PI proposes to use death as an endpoint.
- D. Will be done for any protocol that failed to satisfy the designated reviewer or that was referred to full committee for any reason.

1) During full committee review (at a convened meeting with a quorum present):

- A primary reviewer is assigned by the Chair to present the protocol to the members.
- The reviewer's checklist is used as a guide by everyone present.
- After discussion, the convened IACUC votes to either Approve or Disapprove the protocol; approval occurs by a simple majority vote of the quorum present.
- In some cases, a protocol can be "Tabled" until additional information and changes are obtained from the PI.

2) If the IACUC votes to APPROVE the protocol, the IACUC coordinator prepares the letter of approval that is signed by the Chair and sent to the PI; copies are sent to the Institutional Official (Dr.Sarras) and the Office of Sponsored Research.

Note: A final letter of approval will NOT be issued until all training modules for personnel are complete, a signature copy of the protocol is submitted by the PI, and any additional forms that are needed are signed and submitted (e.g. Institutional Research Safety Report signed by EHS, if needed)

3) IF the IACUC votes to DISAPPROVE, the IACUC coordinator informs the PI of the decision. In this case, the Chair will prepare a letter detailing the reasons that led to this decision and send this to the PI.

SIGNIFICANT AMENDMENTS TO APPROVED PROTOCOLS ARE REVIEWED IN THE SAME MANNER AS NEW PROTOCOLS

ANNUAL RENEWALS WITHOUT PROPOSED CHANGES ARE REVIEWED BY A DESIGNATED REVIEWER OR BY THE IACUC CHAIR