Title: **Protocol Review and Approval**
Effective Date: **October 21, 2010** Revision # **09**
Standard Operation Procedure Number: **IACUC-RVW-002** Last Committee Review: **September 21, 2018**

Purpose/Scope

The purpose of this Standard Operating Procedure (SOP) is to outline the IACUC's procedure regarding protocol review and approval.

References

PHS policy IV,C,2
AWAR §2.31,d,2

Approval methods:

Full Committee Review:

- Convened quorum of the members of the IACUC

- Protocols with animals in pain categories D or E will generally be sent to the full committee unless the PI requests Designated Review and the Chair approves.
  - For pain category E protocols, special consideration by the IACUC is required due to their potential for unrelieved pain or distress or other animal welfare concerns.
  - Further, the IACUC is obliged to weigh the objectives of category E studies against animal welfare concerns in accordance with the tenants of the Three R's. This in turn ensures that both the institution and the principal investigator share the same obligations for humane care and use.

Designated Member Review:

- Protocols are made available to all IACUC members via email and any member may request a full committee review within the given timeframe (usually one week).

- If full committee review is not requested, at least one member of the IACUC, designated by the Chair and qualified to conduct the review, shall serve as the reviewer and have the authority to approve, require modifications in (to secure approval), or request full committee review.

- A protocol may not be disapproved via designated review. Disapprovals must be issued by a convened quorum.

- Protocols with animals in pain categories B or C will generally be sent Designated Review unless a committee member calls for full committee review.

Designated Member Review Subsequent to Full Committee Review:

The IACUC reviews and may approve, require modifications (to secure approval), or disapprove ("return" or "table") protocols based on a majority vote of the quorum present at the meeting. If modifications are needed to secure approval, a "sub-committee" may be used (as a Designated Member Review) to grant final approval of the protocol. The subcommittee consists of the Chair and the ULAV, as standing members, and additional IACUC members as specific issues or expertise may require. The reviewers must be unanimous in any decision. They all review identical versions of the protocol and if additional modifications are requested by any one of the reviewers then the other

reviewers are aware of and agree to the modifications. If the reviewers are not unanimous in their decision, the protocol returns to the full committee. In order for this designated member review subsequent to full-committee review process to continue, annually, the IACUC must unanimously vote to continue this practice, and each member signs a statement indicating their knowledge and agreement of this practice. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request full committee review of the protocol.

Responses (When Full Committee reviewed):
Approved: No changes or clarifications are required.

Modifications required for approval:

1. The IACUC may withhold approval pending satisfactory completion of modifications to secure approval when those modifications involve matters unrelated to the substantive deliberations and judgments of the IACUC OR when more substantive conditions of approval may be so clear-cut as to require only verification that they have been met. Responses to requests for such information or verification may be handled by the IACUC Chair and the ULAV. Approval of these modifications to secure approval must be received before any work on the project can begin.

   Examples include but are not limited to:
   - Typographical errors, general
   - Obviously incorrect numerals (e.g., extra zeros, arithmetic errors, decimal placement, dates of study)
   - Obviously incorrect measurement units
   - Minor change in title
   - Unintentional placement of animals in incorrect pain/distress category if other sections relating to pain/distress are answered appropriately
   - Failure of the principal investigator(s) listed on the first page to sign on the signature line
   - Failure to complete all relevant sections of Annual Update/Amendment Form (depending on nature of omission)

2. The IACUC may also withhold approval pending approval from another regulatory committee. Neither an IACUC approval letter nor number will be released until proof is provided that approval has been obtained from that particular regulatory committee. During this period no animal work may be conducted on the project.

In either case above, six months is given from the date of committee review to address the modifications. If the modifications are not addressed in the required time allowed, the protocol will be returned and submission of a new protocol will be required to conduct the animal work.

Returned: Substantive information is required that necessitates further deliberation or IACUC judgment.

Examples include but are not limited to:
- Principal investigator is not an MSU faculty member

- Absence of critical personnel (e.g., veterinarian to oversee surgery, adequate technical assistance, etc.)
- Failure to complete all relevant sections of Protocol Review Form (depending on nature of omission)
- A "lay description" that cannot be understood by non-scientific IACUC members or that does not describe well what will actually be done in the study
- Failure to employ personnel with appropriate training and/or supervision
- Use of animals from inappropriate source (defined by AWA, by health condition of animals, or by public relations aspects).
- Failure to obtain animals legally (e.g., health permits, private individuals)
- Inappropriate husbandry/veterinary care without scientific justification
- Use of wire bottom cages for rodents without scientific justification
- Euthanasia of animals with conspecifics without scientific justification
- Any deviation from animal care environmental standards without scientific justification
- Use of inappropriate animal or animal numbers for study intended
- Use of animal species that cannot be housed suitably at MSU
- Group housing of conspecifics or of different species if pain and/or distress is a likely consequence of such housing without scientific justification
- Housing vertebrate animals on AAALAC-accredited facility projects outside an IACUC approved facility, or conduct of biomedical research outside facilities approved by the IACUC
- Conducting major surgery in an area not visited by the IACUC or in an area not IACUC-designated as a surgical facility
- Failure to justify species used
- Failure to describe experimental design clearly and accurately and/or failure to have a reasonable experimental design
- Failure to clearly justify, using reasonable methods, the number of animals to be used in the study
- Inadequate, incomplete, or inappropriate description of technical procedures, including restraint, methods to reduce pain and/or distress, including drug names, routes of administration, and dosages
- Failure to describe substances to be given to animals and the possible or probable consequences of the administration of those substances
- Failure to describe nutrient deprivation or to deprive animals of water and nutritious and adequate food without scientific justification
- Failure to describe surgical procedures, especially qualifications of personnel, perioperative care, and drugs used
- Inappropriate use of any drug or substance in an animal
- Failure to justify excessive multiuse of animals
- Failure to justify conduct of study with high likelihood of unrelieved pain and/or distress
- Failure to adhere to appropriate euthanasia guidelines without scientific guidelines
- Failure to justify use of endpoints with high probability of resulting in animal pain and/or distress (e.g. LD50 tests)
- Failure to provide for adequate veterinary care or participation
- Failure to do adequate literature search to:
    - Ensure there is no "excessive duplication" in conducting the study

- Ensure that non-animal or less sentient animals or microorganisms are unsuitable models
- Ensure that less painful and/or distressful procedures do not exist

- Failure to document appropriateness of qualifications or experience of all participants listed
- Failure to complete items prescribed on first page of protocol form before submission excluding documentation of pre-review by departmental representative

Approval withheld (Disapproved): The PI and the IACUC cannot agree on fundamental aspects of the proposed study such as the protocol design, animal welfare issues, or the PI will not agree to comply with the IACUC's requirements. If protocol approval is withheld by the committee, the PI is notified in writing with an explanation of the reasons the approval is being withheld. The letter is signed by the Chair and invites the PI to contact him for additional clarification. The PI is asked to revise the protocol according to the reasons listed and resubmit. The PI is always invited to attend the IACUC meeting when his/her protocol is being reviewed.

Reviewed:

IACUC Chairperson Date

Research Compliance Director Date