WVU IACUC POLICY:
Amendments: Significant and Minor Modifications to IACUC protocols

Purpose

As described in the PHS Policy and the Animal Welfare Regulations, the IACUC is responsible for reviewing and approving proposed changes (amendments) to animal activities. Changes must be conducted in accordance with the University’s Animal Welfare Assurance and be consistent with the Guide for the Care and Use of Laboratory Animals, the requirements in the PHS Policy, and the Animal Welfare Regulations. The purpose of this policy is to define minor changes to animal care and use protocols that can be approved administratively and significant changes to animal care and use protocols that must be reviewed and approved by the IACUC.

Definitions

Amendment – An amendment is any modification to an IACUC-approved animal care and use protocol. Amendments may be classified by the IACUC as minor or significant.

Minor Amendment – A minor amendment is one that has minimal to no effect on personnel safety, animal welfare or animal use. The scope of minor amendments is very narrow and its use is limited.

Significant Amendment – A significant amendment is a proposed significant alteration to an approved protocol that proposes an evolution to the study design often based on new information or animal welfare. It is one which substantially alters animal use from that originally approved in the protocol, negatively impacts or has the potential to negatively impact animal welfare, or which impacts personnel safety.

Designated Member Review (DMR) – Once a proposed amendment is made available to all IACUC members, and no member calls for full committee review, the IACUC Chairperson will designate at least one qualified person to conduct the review, who shall have the authority to approve, require modifications (to secure approval), or request full committee review of any proposed activities.

Full Committee Review (FCR) – A review which is conducted by a quorum of the IACUC at a regularly scheduled or specially convened meeting.

Scope

During the course of a three-year term of protocol approval, circumstances may dictate changes in personnel and/or procedures. Under these circumstances, it is the PI’s responsibility to submit a protocol amendment for review and consideration by the IACUC. Approval must be granted prior to implementing the change.

Policy

This policy is to facilitate review and approval of amendments. At any time, one or more Committee members may call for Full Committee Review (FCR), in which the amendment will follow the review and subsequent approval process to occur in a convened IACUC meeting. The IACUC staff in the Office of Research Integrity and Compliance (ORIC) will apprise the IACUC of all amendments which are reviewed and approved via DMR.
in between meetings. All amendment proposals are submitted to the IACUC and the process of approval of all amendments will be documented by the IACUC. Protocols may be re-reviewed at any time by the IACUC if any member determines it to be necessary.

Following the initial submission of an amendment, the IACUC staff will determine the type of amendment and the appropriate route of review to begin the review/approval process. Note that all amendment submissions that contain the addition of a procedure that would be categorized as D or E automatically get assigned to FCR.

**Minor Amendments**

Minor amendments are administratively handled by the Animal Compliance and Training Officer (ACTO) in ORIC. Principal Investigators will be notified of any minor amendment approvals and the ACTO will document the approvals in the agenda of the next IACUC meeting, during which any member can call for a discussion of any of the minor amendment approvals. The following changes are considered minor amendments:

1. Addition or deletion of personnel other than the PI on the protocol (provided that the individual is adequately trained and qualified to work with the species on the protocol);
2. Addition or change in vivarium housing or procedure/use rooms (changes to rooms used for surgery of non-regulated species must be first inspected by the veterinary staff, if they have not already been approved for surgery);
3. Addition or deletion of a common strain of rats (e.g., Sprague Dawley, Wistar, etc.) or mice (C57/B6, CD-1, FVB, etc.) as long as there is no change in the number of animals;
4. Changes or updates in contact information;
5. Some changes in sponsor or funding information; and
6. Changes of typographical or grammatical errors.

**Significant Amendments**

For the purposes of review, any significant amendment will require IACUC review and approval; however, if the Committee is in agreement, significant amendments that do not involve adding a new procedure that would be categorized as D or E may go through the DMR process. Alternatively, if one or more Committee members call for Full Committee Review (FCR) or the amendment involves the addition of a procedure that is categorized as D or E, the amendment will follow the review and subsequent approval process to occur in a convened meeting. Note that FCR may be requested by any committee member for any reason. The following changes are considered examples of significant amendments:

1. Changes in study objectives;
2. A change from non-survival surgery to survival surgery;
3. Addition of surgical procedures;
4. Change to multiple major procedures;
5. Protocol changes that may escalate the previously approved USDA Pain Category and/or increase the duration of pain, discomfort, or distress of the animal;
6. Addition or change in experimental substances/drugs or hazardous agents;
7. Change in euthanasia method;
8. Changes that impact personnel safety;
9. Changes in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC (i.e. satellite housing);
10. Increases in animal numbers;
11. Change in species or addition of a regulated species; or
12. Change in PI.
References

1. NIH Guidelines on Significant Changes to Animal Activities, NOT-OD-14-126