

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

AMENDMENT REVIEW PROCESS

GENERAL POLICY

As required by federal regulations and hospital policies, the IACUC must review and approve any changes or modifications to previously approved protocols in advance of implementation.

In August 2014 OLAW released a notice entitled “Guidance on Significant Changes to Animal Activities” ([NOT-OD-14-126](#)) that provided direction to the IACUC regarding review of significant changes which are defined as those modifications that have, or have the potential to have, a negative impact on animal welfare.

PROCEDURES

In accordance with this notice, submitted amendments will be assigned to one of three review paths outlined below. The specific assignment will be determined by the Office of Animal Welfare Assurance based on the nature of the revisions proposed in each amendment submission. IACUC members may call for Full Committee Review of any amendment at any time. Each review process and examples of the protocol modifications that will be evaluated via that process are as follows:

A. Designated Member Review (DMR)

Amendments requesting significant modifications must receive review by the IACUC through the DMR process as outlined in the approved MGH IACUC Protocol Review Process policy. Such amendments will be reviewed by at least one appropriately qualified IACUC member, assigned by the IACUC Chairperson, who can take one of three actions:

1. Approval
2. Requires modifications to secure approval; the Principal Investigator (PI) is provided with the reasons for this action and must respond to the feedback to secure approval

3. Call for Full Committee Review (FCR); the amendment will be reviewed through the FCR procedure as detailed in the MGH IACUC Protocol Review Process

Modifications requiring Designated Member Review

- Greater than 20% increase in animal numbers
- Addition of animals to Pain Category E
- Reassignment of animals among pain categories
- Modification of humane endpoints including description of phenotype impacting animal health and care
- Addition of non-standard housing or husbandry practices
- Addition of any new procedure except for animal identification by ear tagging/notching
- Changes that could result in potentially more severe adverse consequences
 - ◆ Changing from non-survival to survival surgery
 - ◆ Reduction in analgesics
- Addition of different classes of experimental drugs/substances
- Addition of new research objectives
- Any modification that impacts personnel safety
- Change of PI
- Other modifications that represent a significant change to the approved protocol as determined by the Office of Animal Welfare Assurance

B. Veterinary Verification and Consultation (VVC)

Some specific significant changes may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian reviewer is not required to be an IACUC member but must be familiar with approved IACUC policies. The veterinarian is not conducting Designated Member Review but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and approved policy is appropriate for the animals in this circumstance. Specific reference documents available to the veterinarian including guidelines, formularies and policies are included in this policy. Consultation with the veterinarian must be documented via the protocol review process.

The VVC process will be used to make significant modifications to procedures that are already part of the approved protocol and do not increase pain, distress or degree of invasiveness. The veterinarian reviewer should consider the overall

welfare of the animals and call for Designated Member Review if the proposed changes will compromise animal welfare. The veterinarian must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies to Designated Member Review. The veterinarian reviewer can take one of three actions:

1. Accept VVC
2. Decline; the Principal Investigator (PI) is provided with the reasons for this action and must respond to the feedback to secure approval
3. Accept No VVC; the amendment is assigned for Designated Member Review

Modifications that may be reviewed by VVC

- Change in route of substance administration or sample collection
- Addition of a new administered agent that is in the same class as already approved agents
- Change in anesthesia, analgesia or sedation that is consistent with CCM recommendations
- Change to timeline or approach of previously approved surgeries
- Modifications of pre- and post-operative/procedural care
- Change in frequency of approved procedure
- Change in euthanasia to any AVMA approved method (acceptable or conditionally acceptable).
- Increase in frequency of experimental agent administration or sample collection
- Change to timeline of any previously approved experiment
- Addition of IACUC/CCM-approved ear tagging/notching identification procedures
- Addition of any new strain
- Change of sex of animals to be used in approved experiments

C. Administrative Review

Revisions that are considered non-significant in accordance with this policy may be administratively reviewed and approved by an Office of Animal Welfare Assurance representative. The proposed change may be referred for VVC or committee review at the representative's discretion.

Modifications appropriate for Administrative Review

- Less than 20% increase in animal numbers
- Addition or change in funding/sponsor requiring congruency review
- Change/addition of study staff
- Change in performance or housing site involving CCM space or an already approved MGH location
- Change in title of proposal
- Correction of grammatical or typographical errors

REFERENCES

American Veterinary Medical Association. [AVMA Guidelines for the Euthanasia of Animals](#). American Veterinary Medical Association: Schaumburg, IL, 2020.

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[Pain Management Regimens for Mice and Rats](#)

v1.1, 19 April 2019
v1.2, 19 February 2020
v1.3, 18 March 2020
v1.4, 20 January 2021