

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

PROTOCOL REVIEW PROCESS

GENERAL POLICY

This policy applies to any vertebrate animal used for research, teaching, or testing, including studies that do not involve a formal grant proposal or are pilot studies.

In accordance with federal regulations and hospital policies, all animal research conducted at, or funded through, the Massachusetts General Hospital (MGH) and the Shriners Hospital for Children-Boston (SHC) must be reviewed and approved by the MGH Institutional Animal Care and Use Committee (IACUC) prior to animal procurement and initiation of the study. The IACUC has the sole authority to approve, require modifications (to secure approval), or withhold approval of research protocols involving the use of animals at MGH and SHC. Protocols are approved for a maximum of three years.

When animal research will be performed in its entirety under the institutional auspices of the MGH or SHC, an IACUC application must be reviewed and approved by the MGH IACUC.

When the animal research will be performed under the auspices of multiple institutions including the MGH or SHC, the investigator will need to submit an IACUC application, and copies of any relevant outside IACUC approvals. MGH collaborates with institutions that hold an Animal Welfare Assurance (AWA) number (or equivalent, as determined by the IACUC) and USDA registration number, if applicable. AAALAC accreditation is preferred. If the IACUC approves the collaboration, it will oversee only the research component that is performed at MGH or SHC. Any component conducted at an outside institution will be done so under the auspices of that institution's IACUC.

When the animal research will be performed in its entirety under the auspices of an outside institution but the work will be funded in part or whole by or through the MGH or SHC, the MGH IACUC will fully rely on the outside institution's IACUC. The collaboration should be documented through a contract, memorandum of understanding or other agreement. In this circumstance, there is no requirement to submit an IACUC application to the MGH IACUC. When the animal research described above is funded

through a Public Health Service (PHS) grant, the MGH will use the IACUC approval date of the institution where the research will be conducted and the MGH AWA number on the face page of the grant.

PROCEDURES

All new proposals for animal research and continuing review of projects must be reviewed by the IACUC. Complete new applications are reviewed in order of receipt at the Office of Animal Welfare Assurance (OAWA). Unless otherwise agreed to, all applications are pre-reviewed by an OAWA administrator and veterinarian. Recommendations and suggested refinements are returned to the investigator for consideration and inclusion into the IACUC protocol. Once the response to the pre-review is received, the IACUC review is conducted as either a *full committee review* (FCR) or a *designated member review* (DMR) for new protocols and triennial review applications. The determination of the level of review is made by the full committee. The MGH IACUC uses guidelines to automatically assign some studies to FCR, e.g., certain studies using USDA-regulated species, survival surgery, category E pain/distress levels, or possible animal welfare issues. All other protocols are reviewed by DMR procedure once all members of the IACUC have been provided an opportunity to call for FCR and no request for FCR has been received.

Review procedures

A. Full Committee Review (FCR): The IACUC meets as a full committee once each month. New proposals and triennial review applications are circulated to all members of the IACUC prior to the monthly meeting. Two committee members are assigned, with the IACUC Chair's approval, to serve as primary and secondary reviewers who present the proposal to the full committee for their consideration. The IACUC then discusses the proposal and acts by vote by IACUC members present at that meeting. The IACUC may 1) approve, 2) require modifications (to secure approval), 3) defer or delay decision, or 4) withhold approval/disapprove. Any such action requires a simple majority vote of a properly constituted quorum. If modifications are required to secure approval, the modified proposal may be reviewed by designated member review procedure, at the discretion of the full committee. If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications.

B. Designated Member Review (DMR): New proposals and triennial review applications that are eligible for DMR are assigned to the weekly DMR agenda. The agenda is distributed to the IACUC to provide the committee an opportunity to call for FCR. DMR agendas provide a link to the complete application for each transaction under review. The IACUC is provided 48 hours to call for FCR of an application. If no one calls for FCR, DMR of a new protocol or triennial review application is conducted by at least two members of the IACUC. The IACUC Chair approves review assignments. The reviewers must reach agreement to 1) approve, 2) require modifications (to secure approval), or 3) request full IACUC review.

Following review, the investigator is notified in writing of the action of the IACUC. If the committee action is 'Requires Modifications', the investigator is sent a list of questions and/or concerns that need to be addressed before the proposal is reconsidered for approval. The investigator is asked to submit a point-by-point written response to these questions and concerns, along with a revised IACUC application incorporating the requested modifications. The investigator's response is sent to the DMR reviewers, or FCR, as determined by the committee.

If the IACUC initially withheld approval, the investigator's written response will be reviewed by the full committee, unless otherwise agreed to by a majority of the quorum of the IACUC, at the next monthly meeting scheduled after the response is received by the Office of Animal Welfare Assurance.

All actions taken outside of the convened meeting are reported back to the full committee each month.

Upon approval, the investigator is notified in writing of the action of the IACUC.

Continuing Research

A triennial review application must be reviewed by the IACUC using DMR or FCR every three years. Failure to submit and obtain approval for continuing work prior to the expiration date of the original proposal will result in the automatic inactivation and expiration of the original protocol. Any animals that remain after the expiration date will

be reassigned to the institutional holding protocol, an appropriate experimental protocol, or euthanized.

Urgent Situations

MGH Center for Comparative Medicine (CCM) Veterinary Staff may perform emergency veterinary medical procedures to alleviate unnecessary pain or distress and/or prevent the loss of life or limb without prior IACUC approval. The CCM Veterinary Staff are available for direct consultation 24 hours a day, 7 days per week.

IACUC Member Responsibilities

IACUC members are required to attend regularly convened meetings to provide the optimal forum to conduct protocol review and to consider compliance reports or potential suspensions. The committee members are expected to meet the following protocol review responsibilities:

- Act as a voting member of the IACUC
- Participate as a protocol reviewer and inform the Office of Animal Welfare Assurance (OAWA) promptly if unable to meet review assignment responsibilities
- Participate in all convened monthly meetings, to the extent possible; inform the OAWA of all planned absences in sufficient time so that steps can be taken to ensure quorum
- Be familiar with IACUC policies, procedures and standards and support the Chair and Vice Chair in their application in an equitable and consistent manner as part of protocol review; support the Chair and Vice Chair to ensure the committee are making decisions consistent with all regulations, policies, and standards.
- Maintain committee business and proceedings as confidential

Protocol Review by Videoconference

Videoconferencing will be used for monthly full committee review meetings and ad hoc IACUC meetings. Videoconference meetings proceed as for in-person meetings (attendance is documented, quorum is ensured, etc.). If a member has a conflict of interest with a study under review, the member is placed in a virtual waiting room and the administrative staff re-admits the member to the main meeting room after the study has been reviewed and a decision made by the committee. Meeting materials are

distributed and accessed using Insight, our electronic submission and review system, as before.

Emergency/Ad Hoc Committee Meetings

The Chair may convene an ad hoc meeting to review compliance concerns, considerations for protocol suspension, and conduct protocol review when needed, provided the following can be met:

- All members are given notice that the meeting will be conducted by video conference
- Documents are provided to all members in advance of the meeting
- All members have access to the documents and can participate fully
- A quorum of voting members is convened
- The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting
- If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote
- Opinions of absent members that are transmitted by mail, telephone, or e-mail may be considered by the convened IACUC members but will not be counted as votes or considered as part of the quorum
- Written minutes of the meeting will be maintained

Requests to Use Animal Tissue and/or Products

An application (“tissue protocol”) must be submitted in the Insight system to obtain animal tissues, products, or blood, including whole dead animals and eggs or embryos from egg-laying species, not otherwise approved as part of the investigator’s own animal research protocol. Refer to the [IACUC Policy on Use and Sharing of Animal Tissues and Products](#) for more information.

Tissue protocols are reviewed administratively by the Office of Animal Welfare Assurance

REFERENCES

Bartlett, D.H.; Silk, S.B. [Office of Laboratory Animal Welfare Comments](#). *Zebrafish*. **2016**, 13(6), 1-2.

U.S. Department of Agriculture. [Animal Welfare Act and Animal Welfare Regulations](#). (Animal Care Blue Book). Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Part 2, Subpart C, §2.31. 2020.

U.S. Department of Health and Human Services. [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#). Office of Laboratory Animal Welfare, National Institutes of Health: Bethesda, MD, 2015.

v1.1, March 2003

v1.2, May 2004

v1.3, August 2006

v1.4, 15 October 2014

v1.5, 18 October 2017

v1.6, 15 November 2017

v1.7, 19 April 2019

v1.8, 17 August 2022