NU–IACUC POLICY

Northeastern University Institutional Animal Care and Use Committee

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| Policy on IACUC Review Procedures  |

Approval Date: October 14, 2021

The Institutional Animal Care and Use Committee (IACUC) must conduct a review of the components related to the care and use of animals and determine if they are in accordance with Public Health Service (PHS) Policy, the Animal Welfare Act/Regulations, and other local, state, and federal laws or regulations relating to animals.

**Policy**

There are two valid methods of IACUC review (1) Full Committee Review (FCR) by a convened quorum of the members of the IACUC, or (2) Expedited Review (ER) by the Designated Review Committee (DRC), subcommittee of the IACUC. ER is employed only after all voting members have been provided an opportunity to call for Full Committee Review.

**Full Committee Review**

Documents submitted for Full Committee Review are distributed to the members well enough in advance of the meeting to allow for an adequate review. Full Committee Review must occur during a convened meeting with a quorum of the IACUC members present. No member may participate in the IACUC review or approval if they have a conflict of interest, except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. Abstentions from voting (for reasons *other* than conflict of interest) do not alter the quorum and do not change the number of votes required for approval.

FCR requires a majority vote of the quorum present to approve, require modifications to secure approval, or withhold approval. These specific categories are explained below. If additional modifications are requested, the list is agreed upon by the Full Committee and a vote for either substantive or non-substantive is taken to determine the next review designation.

* If non-substantive modifications are required to secure approval, a revision can be submitted for Designated Member Review (DMR) by the DRC as described below.
* If substantive modifications are required, the revision must be submitted back to Full Committee Review.

**Expedited Review**

Documents submitted for Expedited Review are sent electronically to all members for a specific duration that enables enough time to perform an adequate review. The members are instructed to review the submissions and are given a deadline by which to respond. Members may vote for either a Full Committee Review (FCR) or Designated Member Review (DMR). Calls for FCR are kept as part of the review documentation.

* If anyone calls for Full Committee Review during this timeframe, the document must then be submitted to a convened IACUC meeting for FCR, as described above.
* If no member calls for FCR, the submission continues to DMR by the DRC as described below.

**Designated Member Review**

The DRC, a subcommittee of the IACUC is designated by the Chair or Vice-Chair (in the Chair’s absence) to act as the Designated Member Reviewers (DMR’s) either after Full Committee Review or after receiving no vote for FCR through the Expedited Review process.

- For use of DMR after a Full Committee Review, the Designated Member subcommittee or DRC is made up of the IACUC Chair, the veterinarian and the DLAM Director. Additional members may be selected, if deemed appropriate.

- For use of DMR after Expedited Review, the Designated Member subcommittee or DRC is made up of the IACUC Chair, the veterinarian and the DLAM Director. Again, additional members may be selected if deemed appropriate.

The Designated Member Reviewers (DMR’s) or DRC must be unanimous in any decision. They must all review identical versions of the submission. If modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications. DMRs have the authority to approve, require modifications to secure approval, or request Full Committee Review. If a Designated Member calls for a Full Committee Review, then approval may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. The Designated Member(s) cannot disapprove a submission.

**Notification of the Investigators**

Regardless of the method of review, the IACUC will notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of any modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond.

**Voting Categories**

* APPROVAL – no additional changes are required, and approval can be granted.
* DISAPPROVAL– the research cannot be conducted at this time.
* MODIFICATIONS TO SECURE APPROVAL:
* NON-SUBSTANTIVE ISSUES– non-substantive modifications are required to secure approval. The revision is submitted to Designated Member Review**\***. If all required modifications are made, the subcommittee can approve or require additional modifications to secure approval by selecting either Designated Member or Full Committee Review of the required modifications. The designated reviewers cannot disapprove.
* SUBSTANTIVE ISSUES*-* If a protocol requires substantive modifications, the revised protocol or amendment must be submitted back to a Full Committee Review. The revision can either be approved or the committee can require further modifications to secure approval by selecting either Designated Member\* or Full Committee Review of the required modifications.

**References:**

1. Public Health Service Policy, 2002. NIH OLAW. Section IV, B. Functions of the Institutional Animal Care and Use Committee. P.13-15.
2. Animal Welfare Act and Animal Welfare Regulations, 2002. USDA APHIS. Subpart C. 2.31. Institutional Animal Care and Use Committee. P.34
3. Office of Extramural Research Revised Guidance Regarding IACUC Approval of Changes in Personnel Involved in Animal Activities, 2003. NIH OLAW. NOT-OD-03-046.
4. Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR), 2009. NIH OLAW. NOT-OD-09-035
5. Modified from Tuft’s Policy

**\*** The IACUC members, by signing below, have agreed that the quorum of members present at a convened meeting may decide by unanimous vote to use Designated Member Review after Full Committee Review, when modifications are needed to secure approval. All members understand that he/she can request to see the revised research proposal or may call for Full Committee Review of the revision, at any time, prior to Approval.

# **IACUC Members Date:**

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Dr. James Monaghan - Chair

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Dr. Richard Melloni - Vice Chair

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Dr. Scott E. Perkins, VMD -Veterinarian

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Mr. Sean M. Sullivan

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Dr. Abbas Yasseen

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Dr. Jon Grabowski

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Dr. Abigail Koppes

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Dr. Chiara Bellini

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Mr. Matthew Fisher, Non-affiliated/Outside Member

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Ms. Nan C. Regina

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Mr. Jeff Seo