

IACUC04 TITLE: Policy on Designated Member Review and Full Committee Review

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1.0 Purpose:

This policy describes when Full Committee Review (FCR) and Designated Member Review (DMR) are used in review of DFCI animal protocols and related submissions (e.g., annual progress reports, amendments), memoranda of understanding, and full animal protocols from animal facilities outside the U.S.

2.0 Submission and Pre-review:

New animal protocols, triennial protocol rewrites (hereafter called 3-year rewrites), and annual progress reports are submitted electronically via the IACUC’s animal protocol database. Amendments are submitted electronically via the IACUC’s web-based amendment submission portal. Exemption requests, memoranda of understanding (MOUs), and requests to perform animal work outside the U.S. (including full animal protocols from foreign animal facilities, when required for review by DFCI’s IACUC) are submitted via email.

The submission deadline for new protocols, 3-year rewrites, and annual progress reports is the third Friday of each month. There is no set deadline for other types of submissions.

Each submission undergoes pre-review by the IACUC office and the Attending Veterinarian. Other IACUC members, including the Chair, may also be consulted during pre-review, particularly when there is a question about whether a submission is too poorly written to undergo IACUC review.

3.0 Designated Member Review (DMR):

A. Applicability

DMR is employed for the following submissions:

- 3-year rewrites
- New protocols – **emergency review only**, determined case-by-case in consultation with the IACUC Chair
- Amendments to make significant changes when not eligible for VVC or administrative review
- Exemption requests
- Memoranda of understanding (MOUs) as determined in consultation with the Attending Veterinarian or IACUC Chair (see policy [IACUC12](#)) when animal work involves USDA-covered species (except rabbits), Pain/Distress Category E procedures, and/or the performance site does not maintain applicable regulatory documentation (e.g., animals

- used in the project are owned by DFCI, but performance site is not AAALAC accredited)
- Requests to perform animal work at sites outside the United States when animal use will be paid for with federal funding awarded to DFCI, which would include review of the full animal protocol from the site doing the animal work, and/or involves USDA-covered species

B. Designated Reviewer Assignment

Reviewers are designated for DMR as follows:

- I. 3-year rewrites and new protocols: The IACUC Chair designates two appropriately qualified reviewers – one primary and one secondary.
- II. Exemption requests and MOUs: The IACUC Chair designates one or more appropriately qualified reviewers.
- III. Amendments to make significant changes: The IACUC Chair is the designated reviewer. In case the Chair is unavailable or has a conflict of interest, the Chair will designate two appropriately qualified IACUC reviewers in advance – one primary and one back-up reviewer, in case the primary is unavailable or has a conflict of interest – to review such amendments. The IACUC Office will keep a record of the IACUC reviewers currently designated as the primary and back-up amendment reviewers. If the Chair, primary reviewer, and back-up reviewer are all unavailable or have a conflict of interest, the Chair may designate another appropriately-qualified reviewer.
- IV. Requests to perform animal work outside the U.S. including if protocol review is required: The IACUC Chair, Attending Veterinarian, and Associate Director of IACUC and Compliance are the designated reviewers.

In the Chair's absence, the Vice Chair designates reviewers as described above.

In all cases, IACUC members cannot be designated as reviewers for submissions where they have a conflict of interest (e.g., are personally involved in the activity).

C. DMR Notification

After reviewer assignment, the IACUC Office notifies the IACUC of the proposed DMR by email and the DMR notification period begins. During this period, all IACUC members may read the submission and request Full Committee Review (FCR). The time frame for the DMR notification period depends on the type of submission:

- 5 business days – 3-year rewrite, new protocol, or request to perform animal work outside the U.S. (including if protocol review needed)
- 3 business days – amendment to make significant change, annual progress report, MOU, or exemption request

DMR Process

If no IACUC member requests FCR during the DMR notification period, the submission proceeds to DMR. If more than one designated reviewer is assigned to a submission, all reviewers are given identical versions of the submission and must be unanimous in any decision. If modifications are requested by one reviewer, the requested modifications are shared with the other reviewers. Comments are only sent to the Principal Investigator for revision once all reviewers are in agreement about the requested modifications.

Designated reviewers are asked to render a review decision within 3 business days for amendments to make significant changes and 10 business days for all other submissions. Reviewers may be asked to respond in a shorter period in some cases (e.g., protocol imminently expiring). Regardless, designated reviewers may take more time to render a decision if needed.

Designated reviewers can take the following actions:

- **Approve:** The submission is unconditionally approved.
- **Modifications Required:** Modifications are required to secure IACUC approval. The revised submission and PI's response are returned to the designated reviewer(s).
- **FCR:** The submission must be reviewed by a quorum of the IACUC at a convened IACUC meeting.

In all cases, the decision of the designated reviewer(s) and any modifications requested are communicated to the Principal Investigator as soon as possible and in writing.

4.0 Full Committee Review (FCR):

A. Applicability

FCR is employed for new protocols, except when there is an emergency (see section 3.A). FCR is employed for other submissions when there is a request for FCR during the DMR notification period. Rarely, the IACUC Office may add submissions to the agenda of an upcoming meeting for FCR when DMR may result in a longer review process.

B. Reviewer Assignment

Reviewers are assigned for FCR as follows:

- I. **3-year rewrites, new protocols, and amendments to make significant changes:** The IACUC Chair assigns two appropriately qualified reviewers – one primary and one secondary.
- II. **Exemption requests and MOUs:** No reviewer is assigned. Instead, deliberation on these types of submissions occurs during discussion of each meeting's administrative items. (Note: MOUs are handled administratively except when they meet the DMR criteria in section 3.B. Thus, MOUs generally undergo FCR only when submitted for DMR and a request for FCR is made during the DMR notification period.)
- III. **Animal protocols from foreign animal facilities:** The IACUC Chair assigns at least two appropriately qualified reviewers – one primary and one secondary.

In the Chair's absence, the Vice Chair assigns reviewers as described above.

In all cases, IACUC members are not assigned as reviewers for and do not participate in FCR or approval of submissions in which they have a conflict of interest. During deliberations, members

who have a conflict of interest will leave the meeting unless asked by the committee to provide information about the submission.

C. FCR Schedule and Meeting Materials

IACUC meetings are held on the first Friday of every month (or second Friday if there is a holiday conflict) with a quorum of members in attendance.

Meeting materials are distributed electronically to all members of the committee at least one week in advance of each meeting. Paper copies of meeting materials are distributed to those committee members who request them. Meeting materials include reviewer assignments for and complete copies of all submissions to be reviewed.

D. FCR Process

For 3-year rewrites, new protocols, amendments to make significant changes, and animal protocols from foreign animal facilities, the primary scientific reviewer presents a summary of the proposed research and then provides feedback on the submission. The secondary reviewer then provides feedback on the submission. All other committee members are then encouraged to provide feedback on the submission.

For exemption requests and MOUs, an IACUC Office staff member or ARF staff member introduces the submission and provides background information. Committee members then discuss the submission.

When deliberations are complete, the IACUC Chair (or the Vice Chair in the Chair's absence) calls for a vote. For 3-year rewrites, new protocols, amendments to make significant changes, and animal protocols from foreign animal facilities, the primary and secondary reviewer recommend a review decision to the IACUC in consideration of all IACUC members' feedback. The Chair then calls on IACUC members to indicate whether they are for that decision, against that decision, or abstaining from the vote.

For FCR, a majority of the quorum of IACUC members present may vote for the following actions:

- Approve: The submission is unconditionally approved.
- Administrative Modifications Required: Only minor/administrative modifications are required to secure IACUC approval. The revised submission and the PI's response are handled by DMR-subsequent-to-FCR and the IACUC Chair is the designated reviewer.
- Modifications Required: Modifications are required to secure IACUC approval. The revised submission and PI's response are handled by DMR-subsequent-to-FCR and the primary scientific reviewer is the designated reviewer.
- Defer: Substantial modifications are required to secure IACUC approval. The revised submission and PI's response must undergo FCR at a future IACUC meeting and cannot be handled by DMR-subsequent-to-FCR.
- Disapprove: The IACUC is withholding approval for the submission. The PI is provided with IACUC feedback on the submission and may respond in person or in writing to the IACUC's decision. The PI can write a new protocol and would be expected to address all concerns that led to the Disapproval before submitting that new protocol for review.

The IACUC's review decision and any modifications requested by the IACUC are communicated to the Principal Investigator in writing as soon as possible.

E. DMR Subsequent to FCR

The IACUC permits DMR subsequent to FCR with the unanimous vote of a quorum of members present at a convened meeting.

This policy was originally established to comply with OLAW notice [NOT-OD-09-035](#). All IACUC members at the time signed a copy of the policy to acknowledge agreement. Further, it was originally required that all new IACUC members review and sign the policy during training. The policy is now incorporated here and IACUC members will no longer be required to sign the policy. New IACUC members will still be advised of this policy when they are trained.

Following a unanimous vote of Administrative Modifications Required or Modifications Required by a quorum of members at a convened meeting, revisions to the submission are handled by DMR as described in “DMR Process” in section 3.C above. Any IACUC member may, at any time, request to see the revised submission and/or request FCR of the submission. Determining whether the conditions for approval have been met is designated to the IACUC Chair following a vote of Administrative Modifications Required and to the primary reviewer following a vote of Modifications Required. The IACUC may designate additional reviewers, such as the Attending Veterinarian, during a vote at a convened meeting.

If the IACUC designates multiple reviewers for DMR subsequent to FCR, all reviewers are given identical versions of the submission and must be unanimous in any decision. If modifications are requested by one reviewer, the requested modifications are shared with the other reviewers. Comments are only sent to the Principal Investigator for revision once all reviewers are in agreement about the requested modifications.

For DMR subsequent to FCR, every effort is made to ensure that DMR is completed by the designated reviewer(s) first assigned to each submission (typically the primary reviewer); however, a new designated reviewer may be assigned in the rare case where an original designated reviewer cannot complete a review, such as if the reviewer steps down from the IACUC or is unavailable for a prolonged period of time. In such cases, the IACUC Chair (or the Vice Chair in the Chair's absence) may designate a new, appropriately qualified reviewer for the submission.

F. Review of Annual Progress Reports

After IACUC Office pre-review, the Attending Veterinarian (or the IACUC Chair or Chair's assignee if the Attending Veterinarian is unavailable or has a conflict of interest) reviews each annual progress report. If concerns are identified, the IACUC Office works with the PI to address those concerns and then returns the progress report to the Attending Veterinarian for review. If no concerns are identified or when no concerns remain, the Attending Veterinarian may administratively approve the progress report.

During each IACUC meeting, the IACUC receives a list of annual progress reports approved after the previous IACUC meeting – any IACUC member may ask to see a copy of any annual progress report on the list prior to the meeting.

When the Attending Veterinarian approves a progress report, the approval becomes effective on the protocol's annual expiration date and is communicated by email to the PI on that date.

References:

- Public Health Service Policy for the Humane Care and Use of Laboratory Animals. Bethesda, MD: Office of Laboratory Animal Welfare, 2002. (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>)
- United States Department of Agriculture Animal Welfare Act and Animal Welfare Regulations. 9 CFR 2.31. 1985. (<https://www.nal.usda.gov/awic/animal-welfare-act>)