Guidelines for Review and Approval of Animal Activities

Background: Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy)(1) and the Animal Welfare Act and Regulations (AWAR)(2) permit two standard methods of review for animal activities:

- Full committee review by a convened quorum of the members of an IC-ACUC, and
- Designated member review by one or more qualified members.

Full Committee Review (FCR):
FCR occurs during a convened meeting of a quorum of the IC-ACUC members. OLAW defines a quorum as a majority of the total number of voting members on the committee. Prior to the convened meeting, access to descriptions of the animal activities for review must be made available to all IC-ACUC members.

IC-ACUC member(s) having a conflict of interest (e.g., Principal Investigator or animal user) *may* participate in the discussion to provide information and answer questions but *must* recuse themselves and leave the meeting during final deliberation and voting. A quorum must be maintained to render a decision, and recused members do not count toward the quorum.

FCR Dispositions:

- Approval;
- Require modifications to secure approval; or
- Withhold approval

Designated Member Review (DMR):
DMR is conducted by a subset of the IC-ACUC and occurs outside a convened meeting. DMR can be used instead of FCR or subsequent to FCR. Prior to the review, all IC-ACUC members must be provided with access to descriptions of the animal activities for review and given the opportunity to request FCR. If FCR is not requested, the Chair may designate one or more qualified members to perform the review. If more than one member is selected, the designated reviewers must all review identical versions of the animal activities. If any reviewer requests modifications, all reviewers must be informed of and agree to the request for modifications.

DMR Dispositions:

- Approval;
- Require modifications to secure approval; or
- Request FCR

The use of DMR must be agreed to by the IC-ACUC members, by unanimous consent, and in advance of its use, by one of the following:

1. Establishing and approving an IC-ACUC procedure on DMR which follows these guidelines, or
2. Documenting the acknowledgement and approval of these guidelines as the standing IC-ACUC procedure.

Once approved, the IC-ACUC does not have to re-approve the use of DMR as new members are added; however new members must be informed of this and all standing IC-ACUC procedures when they join the committee.

Require Modifications to Secure Approval:

When the IC-ACUC requires modifications to secure approval following FCR, the IC-ACUC must then make the following determination:

If **all** members of the IC-ACUC **are present** at the meeting, the IC-ACUC may:

- Vote for FCR, or
- Vote for DMR (vote must be unanimous). The Chair designates the reviewer(s). Any member of the IC-ACUC may request to review the revised materials and may request FCR at any time before approval.

If **all** members of the IC-ACUC **are not present** at the meeting, the IC-ACUC may:

- Vote for FCR, or
- Vote for DMR, provided one of the following conditions are met:
    - Option 1 – Established written agreement. All IC-ACUC members have previously agreed in writing that:
        - A quorum at a convened meeting may decide, by unanimous vote, to use DMR subsequent to FCR.
        - If DMR is used, the Chair designates the reviewer(s) and any IC-ACUC member may request to review the revised materials and may request FCR at any time before approval.
    - Option 2 – No pre-established written agreement. The revised materials must be:
        - Made available to all IC-ACUC members, including those not present, and all members must have an opportunity to request FCR. If no member requests FCR, DMR may proceed.
        - If DMR is used, the Chair designates the reviewer(s) and any IC-ACUC member may request to review the revised materials and may request FCR at any time before approval.

Administrative Corrections:

Typographical or arithmetic errors, misspellings, incorrect room or telephone numbers, etc., are not considered substantive. If these are the only corrections needed, an animal activity can be approved by the IC-ACUC. These corrections can be verified by the IC-ACUC Chair or Coordinator and additional IC-ACUC review is not required.

Review of Changes to Previously Approved Animal Activities

In accordance with OLAW guidance(3), IC-ACUCs have the option to establish and approve policies(4) for the review of proposed changes to previously approved animal activities. These policies must be reviewed by the IC-ACUC at appropriate intervals of no less than once every three years to ensure they are appropriate and accurate. Without an IC-ACUC-specific policy, significant changes can only be reviewed by FCR or DMR (as described above).

According to OLAW, IC-ACUC-approved policies may be used for the administrative handling of some changes according to the following considerations:

1. **Significant changes** that must be approved by FCR or DMR:

a)	Changes from non-survival to survival surgery
b)	Changes resulting in greater pain, distress, or degree of invasiveness
c)	Changes in housing or use of animals to a location that is not part of the program overseen by the IC-ACUC
d)	Changes in species
e)	Changes in study objectives
f)	Changes in Principal Investigator (PI)
g)	Changes that impact personnel safety

These changes must be documented in the Animal Study Proposal (ASP), shared with the appropriate animal facility staff, and reported to the IC-ACUC.

2. **Significant changes** that may be handled *administratively* by Veterinary Verification and Consultation (VVC):

a)	Changes in anesthesia, analgesia, sedation, or experimental substances
b)	Changes in euthanasia to any method approved in the *AVMA Guidelines*(5)
c)	Changes in duration, frequency, type, or number of previously approved procedures performed on an animal

The optional process of VVC allows an IC-ACUC-authorized veterinarian to verify that a proposed significant change to a previously approved activity is within the scope of an IC-ACUC-approved policy and is appropriate for the animals and circumstance. The veterinarian is acting as a subject matter expert and may refer any significant change to the IC-ACUC for FCR or DMR for any reason.

The following are required for the use of VVC:

- An IC-ACUC-approved policy that defines the scope of each significant change by referencing an IC-ACUC-approved guidance document (e.g., SOP, formulary, guideline, etc.) that the IC-ACUC-authorized veterinarian can use to verify the change.
- Documentation of the consultation with IC-ACUC-authorized veterinarian

These changes must be documented in the ASP, shared with the appropriate animal facility staff, and reported to the IC-ACUC.

3. **Significant changes** that may be handled *administratively* without additional consultation:

a)	Increase in previously approved animal numbers
b)	Addition of stock or strain with no anticipated adverse phenotypes

An IC-ACUC-approved policy is required that defines the scope of the change (e.g., allowable number or percentage of animals to be added) and designates the individual(s) responsible for verifying the

change is within the scope of the policy.

These changes must be documented in the ASP, shared with the appropriate animal facility staff, and reported to the IC-ACUC.

4. **Other changes** that may be handled *administratively* without an IC-ACUC-approved policy, consultation, or notification:

a) Correction of typographical errors
b) Correction of grammar
c) Updates of contact information
d) Changes in personnel, other than the PI (provided all criteria required by the IC-ACUC is met)
e) Changes in housing or use of animals to a location that is part of the program overseen by the IC-ACUC

For personnel changes, there must be an administrative review to ensure personnel are adequately trained and qualified, enrolled in an occupational health and safety program, and in compliance with IC-ACUC requirements.

These changes must be documented in the ASP and shared with the appropriate animal facility staff.

PIs may use fewer animals than approved. This does not require IC-ACUC approval, notification, consultation or administrative handling.

Final Approval:
Regardless of the method used, following IC-ACUC review, written notification of approval is sent to the investigator(6). This denotes the approval date and finalization of the approval process. Animal ordering and initiation of animal activities can then proceed.

References:

1. Office of Laboratory Animal Welfare. Public Health Service Policy on Humane Care and Use of Laboratory Animals. In: National Institutes of Heath, Office of Laboratory Animal Welfare, editor. 2015.
2. United States Department of Agriculture. USDA Blue Book: Animal Welfare Act and Animal Welfare Regulations USDA2022 [Available from: https://www.aphis.usda.gov/media/document/17164/file.
3. Office of Laboratory Animal Welfare. NOT-OD-14-126: Guidance on Significant Changes to Animal Activities 2014 [Available from: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html.
4. Office of Animal Care and Use. Example/Template IC ACUC Policy: Changes to Animal Study Proposals 2023 [Available from: https://oacu.oir.nih.gov/system/files/media/file/2023-06/Example_ACUCPolicy_Changes-2023.pdf.
5. American Veterinary Medical Association. AVMA Guidelines for the Euthanasia of Animals: 2020 Edition. American Veterinary Medical Association; 2020.
6. Office of Laboratory Animal Welfare. NOT-OD-11-053: Guidance to Reduce Regulatory Burden for IACUC Adminstration Regarding Alternate Members and Approval Dates 2011 [Available from:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-053.html.

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