



Institutional Animal Care and Use Committee (IACUC)

Policy #4: Policy for IACUC Review and Approval of Animal Protocols

I. Purpose

The Villanova University (VU) Institutional Animal Care and Use Committee (IACUC) is responsible for reviewing and approving the use of live vertebrate animals in research and teaching at VU. This policy establishes the requirement and processes for IACUC review and approval and animal protocols for such use, in accordance with Villanova's Assurance and Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals.

II. Principle

The PHS Policy sets forth specific methods and requirements for the review of animal protocols ([PHS Policy IV.C](#)): Full Committee Review (FCR) by a convened quorum of the IACUC, or Designated Member Review (DMR) by one or more IACUC members. These review methods pertain to review of initial protocols as well as to review of proposed significant changes requiring FCR in previously approved protocols. The IACUC will review and approve, require modifications (to secure approval), or withhold approval of activities related to the care and use of animals, as outlined below.

III. Submission and Pre-Review

- A. All protocols must be submitted to ORP via the electronic protocol management platform and are pre-reviewed by ORP.
- B. If the protocol is incomplete, it will be returned to the Principal Investigator with guidance and instruction for revision and completion.
- C. If the protocol does not require FCR, the DMR process will be initiated.

IV. Full Committee Review (FCR)

- A. All members of the IACUC are given the opportunity to review and discuss any protocol submission at a fully convened meeting (in person or virtual).
- B. Review outcomes are determined by a majority vote of IACUC voting members at an IACUC meeting with a quorum of members in attendance. Any objections or abstentions to a protocol are recorded in the IACUC meeting minutes.
 - 1. If a member has a conflict of interest with any protocol under review, they are excused from the meeting during proposal review (except to provide information requested by the IACUC) and are not permitted to cast a vote or contribute to the constitution of a quorum.
 - 2. When a member recuses themselves from the voting process, the outcome of the review is decided by vote of a quorum of members that remain present at the meeting.
- C. Initial review of protocols with Pain and Distress procedures at E-level (per [Guidelines for Assigning Pain and Distress Categories](#)), modifications to E-level procedures, requesting additional E-level procedures, or an increase in animal use for E-level procedures will be reviewed by FCR.

D. FCR may result in approval, a requirement for modifications (to secure approval), or withholding of approval.

1. When requiring modifications to secure approval, the IACUC will determine the review method for the modifications as either: FCR, DMR or DMR subsequent to FCR. See section VI for DMR subsequent to FCR requirements.
2. If approval is withheld, the PI will be notified in writing via email by ORP that no animal work is permitted as approval has been withheld. Under these circumstances, the PI will be asked to consult with the Veterinarian and/or the IACUC Chair, or specifically designated IACUC members to refine the protocol which may then be submitted for IACUC review at a future regularly scheduled meeting.

V. Designated Member Review (DMR)

- A. All members of the IACUC must be given an opportunity to call for FCR, for each protocol prior to the initiation of DMR.
- B. If no member requests FCR, the protocol may be reviewed by one or more qualified members appointed by the IACUC Chair (at least one of the reviewers must be a veterinarian). Each DMR reviewer acts on behalf of the IACUC to review and evaluate the protocol.
- C. Initial review of protocols with Pain and Distress procedures at E-level (per [Guidelines for Assigning Pain and Distress Categories](#)) will be reviewed by FCR *however*, subsequent amendments can be reviewed by DMR as long as the amendment doesn't fall under items classified in section IV.C. and at least one of the assigned reviewers is a veterinarian.
- D. If a protocol is assigned to more than one designated reviewer, the reviewers must review identical versions of the protocol and be unanimous in any decision, including agreement on modifications requested by any one of the reviewers.
- E. DMR review outcomes may include approval, a requirement for modifications (to secure approval), or referral to FCR. DMR cannot result in withholding of approval. If the DMR reviewer(s) determine to send the protocol to FCR, the ORP will notify the PI in writing (via the electronic protocol management platform or email) that the protocol will be reviewed via FCR at the next scheduled convened meeting.
- F. When DMR is conducted, the approval date is the date that the designated member(s) approve the study. Following DMR, any member of the IACUC may, at any time, request to see the protocol and/or request FCR of the protocol.

VI. DMR Subsequent to FCR

When substantive information is lacking from a protocol during FCR and modification is needed to secure approval the IACUC may take the following actions as agreed upon in advance and documented below:

- A. When all members of the IACUC are PRESENT at a convened meeting (in person or virtual):
 1. All the members may unanimously vote to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR.
- B. When all members of the IACUC are NOT PRESENT at a convened meeting (in person or virtual):
 1. The quorum of members present may decide by unanimous vote to employ DMR subsequent to FCR. All IACUC members must have the revised research protocol available to them and

must have the opportunity to call for FCR. DMR may only be conducted if all members of the committee have had the opportunity to request FCR and none have done so. ([PHS Policy IV.C.2](#))

- C. The approval date for the protocol is the date that the designated member(s) approve the study. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

VII. Review Documentation

- A. The specific method of review for each protocol will be documented, along with the outcome of the review in the IACUC meeting minutes. ([PHS Policy IV.E.1b-c](#))

VIII. Non-Compliance/Sanctions

- A. Animal work conducted before the protocol approval date must be reported to OLAW as a serious noncompliance with the PHS Policy. ([PHS Policy IV.F.3](#))
- B. Investigators who conduct animal work in the absence of IACUC approval may be subject to disciplinary action (see the [Guidelines for Resolving Issues of Non-Compliance](#)).

IX. References

1. OLAW notice # <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-035.html>
2. OLAW FAQs
 - a. <https://grants.nih.gov/grants/olaw/faqs.htm#615>
3. Policy #3 - [Determination and Approval of Amendments to Animal Activities Previously Approved by the IACUC](#), for more information on VU IACUC amendment review procedures.