



IACUC FORMS AND REVIEW PROCESS

Overview/Purpose

This document describes when a protocol is required and the process for the review of protocols, amendments and continuing reviews by the IACUC members with support from ORRP, EHS, and OAV staff.

Definitions

1. **Animal** – Any animal used for research, testing or teaching that includes the following:
 - a. Live vertebrate animal
 - b. Dead vertebrate animal if it was euthanized for the sole purpose of obtaining or using their tissues or other materials in research
 - c. Dog or cat cadavers or parts
 - d. Offspring of egg-laying vertebrate species after hatching and larval forms of fish and amphibians.
 - e. *Exceptions (not requiring IACUC protocol):*
 - i. Observational studies of animals in their natural habitat as described in IACUC policy "[Vertebrate Animal Field Studies](#)".
2. **Administrative Requirements** – Documents, inspections, or non-IACUC requirements that must be completed before a protocol, amendment, or annual review can be approved. These include facility inspections and reviews by the Institutional Biosafety Committee or Radiation Safety committee.
3. **Continuing Reviews** – Review of activities on approved protocols at the following intervals:
 - a. **Annual:** A review of a protocol that occurs in years 1 and 2 of an approved protocol.
 - b. **3 Year Renewal:** A de novo review of activities that occurs during the 3rd year of an approved protocol. The 3 Year Renewal is a new protocol in the eProtocol system.
4. **Designated member review (DMR)**- a review of a protocol, amendment, or annual review outside of a convened IACUC meeting. Determination of which member will conduct the review is made by the IACUC Chair.
5. **e-Protocol**- electronic web-based system for submission and review of IACUC protocols.
6. **Major survival surgery:** Penetrates and exposes a body cavity or any procedure which produces substantial impairment of physical or physiologic functions.
7. **Quorum**- A simple majority of the regular IACUC members.
8. **Study Team Members:** PI, Co-Investigators, Key Personnel and External Personnel listed on a protocol.

Procedures

1. Once investigators submit the protocol/amendment via the eProtocol system, it is automatically routed to the staff of the Office of the Attending Veterinarian (OAV.) Veterinarians review for appropriate animal use procedures, anesthetic and analgesic, and euthanasia methods.
2. After completion of the veterinary consultation, protocols are routed to the department chair for approval prior to forwarding to the IACUC. Amendments and annual reviews are routed to the IACUC.
3. Once submitted to the IACUC, the ORRP staff will process for either Full Committee Review (FCR) or Designated Member Review (DMR), as described below. Protocols using only dog or cat cadavers will be reviewed through an administrative process by the IACUC Chair or appropriate designee.
4. ORRP will also coordinate with Environmental Health and Safety regarding biosafety and/or radiation concerns as applicable, and with the COI officer if a study team member has a potential conflict of interest.

Review Process

Full Committee Review (Convened Meeting)

1. The IACUC will review an initial protocol or an amendment at a Convened Meeting if the proposed activities involve at least one of the following:
 - a. major survival surgery on a USDA covered species and other non-rodent species,
 - b. unrelieved pain or distress (not including rodent stress models),
 - c. death as an endpoint,
 - d. multiple major survival surgeries.
2. An IACUC member may also refer any amendment or protocol* scheduled for DMR review to full committee review (this criterion also applies to Annual Reviews). An IACUC member can request a protocol be reviewed at a convened meeting at any time.

*Three year de novo reviews of protocols will be conducted by DMR unless this method is used.

3. The ORRP staff will forward the document in the electronic system to the IACUC Chair, who will assign at least two reviewers to a protocol or amendment for review at a convened meeting. These two reviewers are responsible for summarizing, providing recommendations, and initiating the general discussion by the Full Committee on the protocol or amendment. The discussion should include whether the activities as indicated in items 1. a-d above are justified for the research being conducted.
4. ORRP staff will send an email to all committee members approximately one week before the meeting with the agenda. Protocols/amendments may be added to the agenda if received by the ORRP office at least 24 hours prior to the meeting. The IACUC Chair will determine if an item will be added to the agenda during the week prior to the meeting.

5. All committee members have access to eProtocol and can add IACUC member notes for consideration at the meeting. Guidance documents on adding notes and how to view changes submitted for an amendment are available on the secure committee website.
6. Reviewers should look at previous notes from the veterinary consult to determine if any have not been adequately addressed and should be considered at the meeting.
7. ORRP staff will provide a hard copy of all IACUC member notes or unanswered vet notes listed in the protocols/amendments being reviewed at that convened meeting. IACUC members should write notes as if writing directly to the PI. ORRP staff will copy notes into another IACUC Request so the IACUC reviewer is not known to the investigator.
8. At the full committee meeting, the primary reviewer will lead the discussion of the protocol/amendment regarding the justification for the study being called to full committee review to determine if it is appropriate. It is expected that the primary and secondary reviewers will look at each other's comments prior to the meeting. The secondary reviewer will lead the discussion if the primary reviewer is not present.
9. After discussion at a convened meeting, the IACUC will vote for one of the three following options:
 - a. Approve
 - b. Requires Further Information
 - c. Disapprove(Note: The decision must be cast by a majority of the voting members who are present at the meeting)
10. If further Information is required on a protocol or amendment, the IACUC must indicate whether responses can be reviewed and approved by Full Committee Review or by Designated Member Review. Designated member review will be allowed only if all voting members at the meeting agree. If Designated Review is chosen, the specific reviewer who will act on behalf of the Committee will be identified by the IACUC Chair.
11. If a protocol is disapproved, the reason for the disapproval will be sent to the PI. The PI is given the opportunity to respond in person at the next scheduled full committee meeting or in writing. The committee could request that the protocol be reviewed again based on information provided during the appeal process. This will require the PI to submit a new protocol for consideration.
12. ORRP staff will send requests for further information to the investigator along with notice of any administrative requirements that will need to be completed before final approval is granted.
13. Responses from the PI will be forwarded to the designated reviewer. The designated reviewer has the 3 options defined under Designated member review below.
14. Administrative requirements will be determined as being complete by the ORRP staff.
15. The approval date for the protocol or amendment will be set as the date that the IACUC DMR or FCR review is completed and all administrative requirements, if applicable, are completed, whichever is later.

16. Once approved and all administrative requirements have been completed, an email will be sent notifying all study team members that the protocol or amendment has received approval.

Designated Member Review:

1. The IACUC will review initial and renewal protocols and amendments that do not need to be reviewed at a convened meeting through the Designated Member Review process. Annual Reviews involving USDA covered species or if required by a funding agency are also reviewed by Designated Member Review.
2. The ORRP staff will forward all items for designated member review to the IACUC Chair, who will assign one Designated Reviewer to Protocols, Amendments, and Annual Reviews for protocols involving USDA species. An IACUC subcommittee may also be contacted for review of specific activities such as satellite housing requests and use of privately owned animals. The subcommittee members can provide comments to the assigned designated reviewer for consideration.
3. ORRP staff will send information via email to all committee members on at least a weekly basis indicating which documents are to be reviewed, who is assigned to do the review and the deadline for submitting comments or requesting it to be reviewed at a convened meeting.
4. The Designated Member Reviewer has 3 options for voting:
 - a. Approve
 - b. Require Further Information
 - c. Refer to Full Committee Review
5. Any committee member may provide a comment within the eProtocol system, but it is up to the designated reviewer as to whether to include the comment when requesting further information. The reviewer should indicate whether additional comments should not be included.
6. ORRP staff will send requests for further information back to the investigator along with any administrative requirements that will need to be completed before approval is granted.
7. Responses from PIs will be forwarded to the original designated reviewer, if possible. The IACUC Chair can reassign reviewers if the original designated reviewer is not available.
8. Administrative requirements will be determined as being complete by the ORRP staff based on information received from the IBC, Environmental Health and Safety office or other entities. If administrative requirements are not completed within 90 days of IACUC review, ORRP staff will forward the amendment or protocol to the IACUC Chair or designated reviewer, once administrative requirements are completed, for re-review to ensure no additional changes to the protocol are needed.
9. Once approved by the IACUC and all administrative requirements are completed, ORRP will finalize approval in the eProtocol system, generating an automatic email notifying all study team members that the protocol or amendment has been approved.

10. For protocols and amendments, the approval date will be set as the date of FCR or DMR approval and completion of all administrative requirements, whichever is later.

Review of Amendments

1. Amendments are reviewed by either FCR or DMR as described above if considered to be a significant change to the protocol.
2. The following significant changes will be reviewed by full committee:
 - a. addition of a major survival surgical activity in a USDA covered species and other non-rodent species
 - b. addition of unrelieved pain or distress activities (not including rodent stress models)
 - c. addition of death as an endpoint activities
3. The following significant changes will be reviewed by the DMR process unless a member calls the amendment for review by the full committee:
 - a. change of species
 - b. addition of animal numbers greater than 10% of those already approved
 - c. housing outside of a designated area for longer than 12 hours for USDA species or longer than 24 hours for non-USDA species
 - d. any change in use location not previously approved by the IACUC
 - e. change of non-survival surgery to survival surgery
 - f. change in duration, frequency, type or number of procedures performed on an animal
 - g. increased invasiveness of a procedure
 - h. increase in the duration of pain, discomfort or distress to an animal
 - i. hazardous agents administered to animals
 - j. Principal Investigator (PI) change
 - k. addition of neuromuscular blocking agents
 - l. change in euthanasia procedures
 - m. any change in anesthetic or analgesic drug regimens
 - n. change in study objectives
 - o. change in humane endpoints

Review of administrative changes to the protocol

1. Amendments may be considered minor when there is:
 - a. An increase in numbers of animals less than or equal to 10% of the approved numbers
 - b. An addition of another strain/stock of the same animal species
 - c. A change in funding source
 - d. A change in animal use location to an area already approved by the IACUC.
2. If it is not clear that a change should be considered significant, the determination will be made by the IACUC Chair.
3. Administrative changes to the protocol are initiated by the PI by creating an amendment which is processed through the eProtocol system. Initial routing is to the OAV staff, then to the IACUC. Once received by the IACUC office, the ORRP staff will forward to the IACUC Chair or designee to indicate approval of the change in the system.

4. Information on the administrative changes approved by this process will be provided when information for Designated Member Review is sent to members. Any member can request further review of any amendment that is submitted.
5. Proposed change requests that involve only adding or removing personnel other than the Principal Investigator on a protocol are submitted to the IACUC utilizing the *IACUC Personnel Addition/Removal Process* in eProtocol. The electronic system will allow changes to be made only if everyone listed on the protocol is up to date on study team requirements.

Annual Reviews

1. Annual reviews of protocols involving USDA-covered species or other required entities are reviewed by the standard DMR process. Committee members should review the protocol in addition to the annual review form to determine if approved activities are still appropriate.

Annual reviews involving non-USDA species are reviewed by ORRP staff to ensure that all institutional training requirements are up to date.

Applicable Regulations

1. Animal Welfare Act (AWA, Public Law 89-544, 7 U.S.C.)
2. Animal Welfare Act Regulations (AWAR, 9 CFR, Chapter 1, Subchapter A)
3. Health Research Extension Act of 1985 and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals
4. National Research Council *Guide for the Care and Use of Laboratory Animals*, Eighth Edition. National Academy of Sciences, 2011
5. AVMA Guidelines for the Euthanasia of Animals
6. The Federation of Animal Science Societies *Guide for the Care and Use of Agricultural Animals in Research and Teaching*

Additional Information/Guidance

1. IACUC policy "IACUC Review of Protocols with Privately Owned Animals"
2. IACUC policy "Vertebrate Animal Field Studies"
3. IACUC policy "Training Requirements"
4. OLAW FAQ A3, A4 and A5
5. NOT-OD-14-126 NIH Guidance on Significant Changes to Animal Activities

History of Revisions

101-00 New SOP to combine procedures from 4 different policies into one SOP document, approved 05/15/2015

101-01 Minor changes to reflect options for decisions at convened meetings as described in the regulations and updated IACUC policy on administrative requirements prior to final approval given. Approved 12/18/2015

101-02 Decrease the types of protocols and amendments that must be reviewed by convened committee. Approved 05/19/2017

101-03 Update to remove exemption from IACUC review of privately owned animals in clinical studies. The separate CVM review process is now incorporated into the IACUC review process. Approved 05/18/2018