ANIMAL EYE CONSULTANTS OF IOWA

Animal Eye Consultants of Iowa	
Institutional Animal Care and Use Committee	
Policy #2	**"Protocol and Amendment Review"**
Approval Date: 11/12/2025 (Replacing version: 1/26/2022)	

A. Purpose

The Animal Eye Consultants of Iowa (AEC) Institutional Animal Care and Use Committee (IACUC) is responsible for reviewing the use of live vertebrate animals and cephalopods used in research and teaching at AEC. This policy describes the IACUC review process for new Animal Subjects Approval Forms (ASAFs), three-year resubmissions, and amendments to existing ASAFs.

B. Background

Research and teaching activities involving live, vertebrate animals and/or cephalopods require IACUC approval before these activities can occur. Changes to IACUC approved ASAFs (amendments) must also be approved prior to initiation. Public Health Service (PHS) Policy and the United States Department of Agriculture (USDA) Animal Welfare Act (AWA) charge the IACUC with the responsibility to review, approve, require changes to secure approval, or withhold approval of proposals that involve live vertebrate animals and/or cephalopods and subsequent amendments. The AEC IACUC will review each ASAF and amendment to ensure consistency with the USDA AWA, the Guide for the Care and Use of Laboratory Animals and PHS Policy and that exceptions/exemptions to these documents are scientifically justified. The AWA and PHS Policy require that IACUC approved activities go through a de novo review at least every 3 years.

C. Submission and Pre-Review of Protocols

New protocols, three-year renewals and amendments must be submitted using the Online ASAF form on the MyResearch portal (New Protocol Instructions; Amendment Instructions). All the work proposed in the protocol and/or amendment **must** be

approved by the IACUC before animals can be acquired and the work can begin. If an amendment fundamentally changes the aim of the study or has significant funding changes (e.g., new Department of Defense grant), Principal Investigators (PIs) are encouraged (and may be required by the IACUC or funding agency) to submit a new ASAF.

All protocols submitted to the IACUC will be subject to an administrative pre-review by the Animal Welfare Program (AWP) staff before beginning IACUC review. AWP staff will check for completion of mandated training of all personnel listed on the protocol, the approval of SOPs and Animal Care Plans, inclusion of appropriate attachments (client consent forms, etc.), housing areas, compliance with IACUC Approved Policies and inconsistencies in the submission. The mandatory training requirements are listed in IACUC Policy #20. Final protocol approval may be delayed should any of these points be incomplete.

Any pre-review questions raised by the AWP Staff will be sent to the PI and Co-I's via the MyResearch database and an opportunity to revise the ASAF will be given. Two months will be provided to make the requested revisions. If no revisions are made or if no correspondence is received from the PI after two months, the AWP Staff will withdraw the ASAF from IACUC review and a copy will be created for resubmission at a later date.

D. IACUC Review of Animal Care and Use Proposals

1. Protocol Review (New, 3-year Resubmissions, Amendments)

After completion of pre-review, protocols are then sent out for IACUC review. Protocols submitted for review are made available to all IACUC members, who are notified of the submission via email and provided a link to access the protocol. Every IACUC member receives an identical version of the protocol for review that can be accessed via the online MyResearch database at any time. Any IACUC voting member may request Full-Committee Review (FCR) of any protocol or amendment at any point during the review process. If requested, protocols requiring FCR will be discussed at the next convened IACUC meeting.

Newly submitted protocols and amendments to previously approved protocols that include animal research practices that constitute exceptions to standards outlined in the

Guide for the Care and Use of Laboratory Animals will typically be reviewed via FCR using the process described below. If an exception to the Guide is approved for a protocol, additional protocols submitted by the same PI or designee that request the same exception may be referred for Designated-Member Review (DMR), provided that no IACUC member calls for FCR. The IACUC Chair or designee can decide to send these requests via DMR when adequate justification is provided. The IACUC will be made aware of these requests and any member may call for FCR. Exceptions may be required to be re-reviewed via FCR during three-year renewals.

IACUC members evaluate the referred protocols for all criteria defined in the federal and institutional animal care and use regulations and policies. Particular attention is paid to the justification of the proposed animal use, the appropriateness of the treatments and animal numbers proposed, and to the possibility of modification by application of the 3 R's (Reduce, Refine, & Replace).

Some amendments may qualify to be handled administratively by the AWP Staff or by Veterinary Verification and Consultation (VVC) by the AEC Veterinary Staff (AEC). Please refer to Policy #24 for details regarding processing of amendments or contact IACUC@animal-eye-iowa.com with any questions.

2. Designated-Member Review (DMR)

Assignments for DMR panels are approved by the IACUC Chair or Vice Chair and are sent to all IACUC members for review. If no member requests FCR during the 48-hour period following distribution to IACUC, the protocols are referred for DMR.

Each DMR member acts on behalf of the IACUC to evaluate the referred protocols. The DMR team may vote to approve, request modifications in order to secure approval or request FCR. Protocols are approved by unanimous vote of the DMR team and if one or more DMR members do not vote for approval, the protocol is referred to FCR.

All DMR sub-committees include the Attending Veterinarian (AV), their designated veterinary staff member(s) from AEC, or another designated DVM on the IACUC. They, along with the rest of the DMR sub-committee, are given the responsibility of performing a veterinary review of the protocol and communicating any questions or concerns to other DMR reviewers and the Animal Welfare Program (AWP). The AWP then compiles the questions received from each reviewer and sends the questions to the PI and Co-Is. Two months will be provided to make the requested revisions. If no

revisions are made or if no correspondence is received from the PI after two months, the AWP Staff will withdraw the ASAF from IACUC review and a copy will be created for resubmission at a later date.

After revisions are made, the entire DMR subcommittee is notified of the modifications via an email that contains a link to the revised ASAF and given an opportunity to re-review the ASAF to request additional modifications, approve, or request FCR. If a reviewer approves the protocol at any point during the DMR process, the approval is recorded and is carried forth through all revisions of that version under review. However, all reviewers are notified of all revisions returning to the DMR and may retract their approval to ask further questions or request FCR if deemed necessary.

3. Full-Committee Review (FCR)

If a request for FCR is received, then ongoing subcommittee/DMR review may continue but approval of the ASAF will be held until a discussion by a quorum of IACUC members occurs at a convened meeting. Meetings are typically held once a month and are conducted in person and/or remotely by using video/phone conferencing tools (such as Zoom) that allow for real time discussions with the members. Remote meetings are conducted in accordance with NIH NOT-0D-06-052.

Following careful review of the protocol under evaluation for all of the criteria defined in the federal and institutional animal care and use regulations and policies, the IACUC discusses/deliberates the protocol during FCR, and each committee member may vote to approve, abstain from voting, withhold approval or request modifications in order to secure approval of the proposed activities. Protocols are approved 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.

If additional information is required in order to secure approval, the IACUC may elect one of the following three options:

1) DMR subsequent to FCR: A quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modifications are required to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol again. This

option requires that all members have agreed in writing to the use of DMR subsequent to FCR. These agreements will be maintained by the AWP office.

2) DMR: Request that the revised protocol be sent out to DMR using the process described in D2 above (revised protocol sent out to full committee and if after 48 hours no member calls for FCR then the protocol is referred to DMR).

3) Deferred to a Future Convened Meeting: Request the protocol be deferred until the next convened IACUC meeting. This often occurs when significant additional information/revisions are needed regarding the proposal before a decision can be made. The PI will be notified of any needed revisions and provided an opportunity to respond and revise the protocol prior to the next meeting.

If the IACUC votes to withhold approval, the PI will be provided written notification of the IACUC's decision along with the reasons for denial. The PI has an opportunity to respond in person or writing and the IACUC can re-consider the decision based on any additional information provided.

4. Continuing Review

AWP Staff will perform annual renewals for all approved IACUC protocols. Per regulatory changes to the Animal Welfare Act (December 2021), USDA no longer requires that protocols be reviewed annually by the IACUC. Personnel training, animal numbers, and protocol status will be administratively checked by the AWP Staff at the time the renewal is processed.

In accordance with both the AWA and PHS Policy, a complete re-submission by the PI and de-novo review by the IACUC will be required every three years for all protocols. PI's will receive reminder notifications via email 120, 90, 60, and 30 days before the date their ASAF's approval will expire and is due for a three-year resubmission.

5. Conflict of Interest

For Full-Committee reviews, IACUC members who are the PI or have another potential conflict (spouse, affiliated with the grant, etc.) will be excused from the meeting room during consideration of those protocols and cannot contribute to the constitution of a quorum.

For Designated-Member reviews, IACUC members with a potential conflict will not be assigned to review panels for those protocols.

If a member is inadvertently assigned to a protocol for which they have a conflict of interest, it is their responsibility to notify the IACUC Chair and/or the AWP staff and excuse themselves from review of that protocol.

E. Protocol Review Flow Chart

Step 1—Protocol Submitted

1. Can be received by AWP Staff via two methods:
   a. From the PI or Co-I via the MyResearch Database (New Protocol, Three-Year Renewals, Amendment, Administrative/Minor Amendment): The PI and Co-Is will receive an automatic email response confirming submission to the IACUC/AWP.
   b. **From an AEC Veterinarian (VVC) via email: The PI will receive an email from the AEC Veterinarian verifying the VVC.

2. AWP Staff then:
   a. Pre-reviews the submission for completeness and follows up with the PI/Co-Is with any questions or recommended revisions. Should the protocol amendment be administrative/minor, it will be resolved by the AWP Staff and will not proceed to the next steps for IACUC review.
   b. Upon completion of pre-review for non-administrative protocols/amendments, the protocol will be submitted to the IACUC Chair for approval of DMR reviewers (New Protocols, Three-Year Renewals, and Regular Amendments only).
   c. After receipt of the IACUC Chair's approval of DMR assignments, the AWP staff sends the DMR List to the IACUC members to inform them of the protocol review request and assigned reviewers.
   d. Should the protocol require FCR, it will be listed on the agenda to be discussed at the next scheduled IACUC meeting. The PI and Co-I's will be informed via email if the protocol is requested for FCR.

**When an amendment is received from an AEC Veterinarian for a VVC, the changes will be administratively incorporated into the protocol. A written description of the VVC verification amendment must be provided to the AWP office within two business days,

and then the AWP office has 30 business days to add the change to the approved protocol.

Step 2—*IACUC Review*

1. Any IACUC member may request FCR on any protocol within 48 hours of submission to DMR. If FCR is requested, the protocol is added to the agenda of the next scheduled IACUC meeting.
2. If FCR is not requested within 48 hours, DMR sub-committee members can move forward with the IACUC review process.
3. Regular reminders are provided to reviewers to ensure timely review completions. DMR reviewers are typically given up to two weeks to submit their initial review.
4. DMR or FCR proceeds to IACUC committee voting. Committee members have the option to approve, approve with changes, or request revisions. A decision to withhold approval may only occur via FCR.
5. Any questions and/or revisions requested for the protocol/amendment are sent to the PI and Co-Is by the AWP Staff. The PI and Co-I's are then given the opportunity to make edits to the protocol.
6. Once revised and resubmitted, the protocol and any additional comments from the PI are returned to the DMR sub-committee (or the full committee for protocols requiring FCR) for re-review. Every IACUC member is able to access an identical version of the revised protocol via MyResearch.
7. If DMR does not result in consensus approval, the protocol is automatically referred for FCR at the next scheduled IACUC meeting.

Step 3—Approval

1. Protocols approved by DMR or FCR are reviewed for appropriate animal housing, SOPs, Biosafety Approval Forms (BAFs), addendums, training, permits or assurance of permit application (collection cannot begin unless permit is acquired), and other required supporting documents by the AWP staff before final approval.
2. Once finalized, the PI and Co-I are notified of the approval via an automatic notification from MyResearch.
3. If needed, the PI is notified regarding the Post-approval Review process via email after protocol approval.

Step 4—Post-approval Review

All approved protocols are subject to Post-approval Review to ensure that the procedures in use are in agreement with the procedures approved in the IACUC approved protocol. Post-approval reviews may include tabletop exercises, inspection of surgical or animal housing facilities, and/or direct observation of animal procedures, at the discretion of the IACUC. Details of Post-approval Review are found under IACUC Policy #25.