ANIMAL EYE CONSULTANTS OF IOWA

Animal Eye Consultants of Iowa	
Institutional Animal Care and Use Committee	
Policy# 25	**"Post Approval Review Policy"**
Approval Date: 7/9/24 (Replacing Version 3/17/21)	

A. Purpose

The Post-Approval Review (PAR) program at Animal Eye Consultants of Iowa is a key resource for helping researchers stay abreast of regulatory requirements and assist them in maintaining approval for all aspects of their animal care and use. The PAR program also enhances animal well-being through focused protocol reviews and observations.

B. Background

Federal laws and regulations require IACUC oversight of approved animal activities.

The PAR program aims to facilitate research and ensure animal welfare by:

1) Disseminating information to and answering questions from the research and academic community.

2) Establishing a relationship of advocacy between the researchers, Office of the AEC Veterinary Staff (AEC), the IACUC and the AEC Office (ORA).

3) Acknowledging compliant laboratories on campus, resolving unintentional non-compliances and assisting laboratories with maintaining compliance with Federal regulatory requirements and AEC IACUC policies.

4) Working to identify additional resources that may be needed to support investigator research needs.

5) Assisting researchers with the preparation for the Institutional Animal Care and Use Committee (IACUC) semi-annual site visits and regulatory and accrediting reviews.

C. Policy

The PAR program at AEC includes both tabletop reviews and observational reviews. These reviews assist researchers that use animals in maintaining compliance with the AEC IACUC and Federal regulatory agencies. PARs are intended to establish how well the animal use practices used (or planned) align with those proposed in the protocol as well as to identify unforeseen issues. Reviews also provide a framework for IACUC to follow-up on specific events of concern (e.g., unexpected animal death, disease, responses to treatments, etc.). PAR personnel report results to the IACUC, summarizing the tabletop and observational reviews with specific attention to emerging patterns of non-compliance that might require programmatic responses.

- Veterinary Rounds, IACUC semi-annual visits, and animal use deduction from protocols are also considered part of the PAR.

Post-Approval Reviewer: The PAR program's personnel conduct most of the PAR visits. They are also available to assist with development of animal use protocols and amendments prior to submission and help resolve any questions that arise during protocol review. PAR personnel may also contribute to investigating specific concerns, discrepancies, or questions at the direction of the IACUC, AEC and ORA. PARs can also be performed by IACUC members, Director of the AEC Office, the Attending Veterinarian (AV) and AEC Veterinary Staff?s Clinical Veterinarians and Veterinary Technicians.

PAR Frequencies: The frequency of PAR visits is based upon a risk assessment for the species and the invasiveness of the procedures. The IACUC may request PAR visits as part of the approval of new procedures, to assess the appropriateness of post-procedural monitoring and care or based upon the details of previous non-compliances.

1. PAR must occur within one year of a New or 3-Year Renewal protocol approval that includes animals in distress categories "D' or "E", contains prolonged restraint, or uses USDA-covered species.

    - After the ASAF is approved, PAR personnel will send the Principal Investigator a courtesy email with instructions on how to schedule the PAR. If animal

work is not yet occurring, it will be noted, and PAR personnel will check back at a later date.

2. A subset of Distress categories “B” and “C" protocols will be selected at random to undergo PAR to audit for general compliance with AEC policies, targeting specific protocols that include complex procedures or procedures that have an increased risk of non-compliance based on prior experience.

3. Specific protocols will undergo PAR when information is received by the ORA, AEC, or the IACUC concerning possible non-compliance with AEC IACUC policies, federal regulatory agencies or deviations from approved procedures.

Tabletop Reviews: Tabletop reviews are conducted in meetings between the PAR program’s personnel and the researchers. The reviews consist of systematic verbal reviews of all animal-related aspects of each protocol.

1) Tabletop review participation by both the Principal Investigator (PI) and research personnel is highly recommended, although research personnel are included at the discretion of the PI.

2) Tabletop reviews are less formal and less structured than observational reviews and are designed for information gathering and exchange between PAR personnel and researchers. Tabletop reviews include thorough verbal reviews of the animal procedures approved in the protocol as well as inspection of facilities, equipment, supplies and records (e.g., surgery, hands -on training, medical and procedural records).

3) To prepare for a PAR Tabletop review please go to https://animal-eye-iowa.com/forms/forms/ for the PAR Pre-Review checklist.

4) Issues noted during the review will documented on a Post Approval Review Check Sheet and emailed to the PI for a response/plan of action. The check sheet is also available at https://animal-eye-iowa.com/forms/forms/ .

Observational Review: Observational reviews consist of the direct observation of animal procedures as applied to animals by the research staff in the conduct of the research or teaching.

1) Random selection of a subset of protocols will undergo observational review to audit general compliance with AEC policies, targeting specific protocols that include complex procedures or procedures that have an increased risk of non-compliance based on prior experience.

2) Specific protocols will undergo observational review when information is received by the ORA, AEC, or the IACUC concerning possible non- compliance with AEC IACUC policies, federal regulatory agencies or deviations from approved procedures.

3) A PI may also request a PAR observational review.

4) To prepare for a PAR observational review, please go to https://animal-eye-iowa.com/forms/forms/ for the PAR Pre-Review checklist.

5) Issues noted during the review will be documented on a Post Approval Review Check Sheet and emailed to the PI for a response/plan of action. The check sheet can also be found at https://animal-eye-iowa.com/forms/forms/ .

D. Resources

The PAR program uses the following documents as standards, references, and guidance:

- Guide for the Care and Use laboratory Animals
- Animal Welfare Act & Regulations
- OLAW FAQ: PHS Policy on Humane Care and Use of Laboratory Animals
- AAALAC Policies, Position Statements and FAQs
- Animal Eye Consultants of Iowa IACUC Policies, SOPs, and Guidelines