

<b>Washington State University</b> <b><i>Institutional Animal Care and Use Committee</i></b>	
<b>Policy # 25</b>	<b>“Post Approval Review Policy”</b>
<b>Approval Date: 3/17/2021 (Replacing Version 7/31/2019)</b>	

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### **A. Purpose**

The Post-Approval Review (PAR) program at Washington State University 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 program so that they can achieve their research and teaching goals. The PAR program also enhances animal well-being and performs focused protocol reviews and observations. The reviews and observations performed are not intended to be negative or punitive but rather a collegial review of approved activities, and an opportunity for education and sharing expectations.

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### **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) Providing a resource to the research and academic community by disseminating information and answering questions.
- 2) Establishing a relationship of advocacy between the researchers, Office of the Campus Veterinarian (OCV), the IACUC and the Office of Research Assurances (ORA).
- 3) Acknowledging compliant laboratories on campus, resolving unintentional non-compliances and assisting laboratories with maintaining compliance with Federal regulatory requirements and WSU 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

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The PAR program at WSU includes both tabletop reviews and observational reviews. These reviews assist researchers that use animals in maintaining compliance with the WSU IACUC and Federal regulatory agencies. PARs are not intended to comprehensively cover all procedures in all protocols but rather to collect information about the agreement between animal use practices as proposed in protocols vs those actually applied to animals. Reviews also provide a framework for IACUC to follow-up on specific events of concern (e.g., unexpected animal death, disease or 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 as 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, OCV and ORA. PARs can also be performed by IACUC members, Director of the Office of Research Assurances, the Attending Veterinarian (AV) and Office of the Campus Veterinarian's Clinical Veterinarians and Veterinary Technicians.

**PAR Frequencies:** The IACUC has determined the frequency of PAR visits to be based upon a risk assessment regarding the species and the level of procedure invasiveness. The IACUC may also 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 USDA 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 WSU 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, OCV, or the IACUC concerning possible non-compliance with WSU 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 the research personnel is highly recommended. Research personnel to be included in tabletop review is 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://iacuc.wsu.edu/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://iacuc.wsu.edu/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 WSU 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, OCV, or the IACUC concerning possible non-compliance with WSU IACUC policies, federal regulatory agencies or deviations from approved procedures.
- 3) PI requests.
- 4) To prepare for a PAR Observational review, please go to <https://iacuc.wsu.edu/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://iacuc.wsu.edu/forms/>.

#### D. Resources

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**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
- USDA Animal Care Policy Manual
- AVMA Guidelines for the Euthanasia of Animals: 2013 Edition
- AAALAC Policies, Position Statements and FAQs
- Washington State University IACUC Policies