

Animal Care and Use Program Policies & Procedures



Post-Approval Monitoring For Non-Human Primate Species on West Campus

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BACKGROUND

Post-approval monitoring (PAM) is described in the Guide for the Care and Use of Laboratory Animals (2011) as continuing IACUC oversight of animal activities. The purpose of this policy is to define the OHSU West Campus IACUC program for PAM of Non-Human Primate (NHP) use on the OHSU West Campus.

SCOPE

This policy applies to all approved protocols using NHP in research and teaching protocols at OHSU facilities on the West Campus.

POLICY

Post approval monitoring for NHP species used on the OHSU West Campus will include the following:

- I. IACUC protocol review by a clinical veterinarian;
- II. Monitoring of the NHPs on research projects by DCM technical staff;
- III. Review of IACUC approved surgical procedures by the Surgical Services Unit Staff veterinarians;
- IV. Study overview conducted by the Research Integrity Officer (RIO) with the PI and research staff; and
- V. IACUC Semi-Annual Inspections and Program Review.

PROCEDURES

I. Veterinary Review:

As part of the pre-assignment physical of NHPs, the veterinary staff will review the animals' histories to alert PIs to potential health issues that may impact an animal while on study. Veterinarians also review an animal's surgical status (e.g. pool code) to ensure that animals selected are placed on study appropriately with regard to the necessity for major surgery.

II. Daily Observation:

All NHPs at ONPRC are observed daily by the DCM technical staff as part of their routine duties and in consultation with research staff, and any concerns associated with research protocols will be brought to the attention of a clinical veterinarian. Any issues related to the approved IACUC protocol by the clinical veterinarian will be forwarded to the Attending Veterinarian (AV) and if warranted, referred to the Principal Investigator (PI) and RIO for review. Unresolved concerns about the study

will be brought to the attention of the IACUC by the RIO or AV and reviewed as described in the [OHSU IACUC Animal Welfare Concerns Policy](#) .

III. Review by Surgical Services Veterinary Staff:

The Surgery Services Veterinary staff review IACUC protocols during the IACUC review process and are familiar with approved procedures. If there is any concern about the procedure that an NHP will undergo, they will review the IACUC protocol or contact the RIO for additional information.

IV. Study Overview:

- A. An interview will be performed by the RIO with the PI and the research staff at an appointed time. When possible, the interview will occur annually and may incorporate more than one protocol if the PI has multiple protocols.
- B. For consistency, the RIO will use the PAM questionnaire and report form as a guide and will use the headings as a starting point for discussion. These include training, IACUC protocol knowledge, procedures performed by staff, Occupational Health and biosafety, as well as questions regarding support from veterinary, IACUC and integrity staff.
- C. The RIO will summarize the information provided by the PI and research staff on the PAM questionnaire and report form, and submit it to the PI for review and signature. The RIO will then sign the completed PAM report form and submit it to the IACUC for review.
- D. The IACUC may request additional information or may require additional action prior to recommending that program oversight is complete.

V. IACUC Semi-Annual inspection and Program Review:

- A. Every six months (or twice each year) the IACUC will inspect all animal facilities and review the program of animal care as described in the OHSU Animal Welfare Assurance.
- B. If a potential deficiency is identified related to the conduct of a specific protocol, the RIO will gather further information and report the findings to the IACUC.

AUTHORITY

PHS Policy: "III. Institutional Program for Animal Care and Use." The IACUC will...Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. <http://grants2.nih.gov/grants/olaw/sampledoc/assursmp.htm#sectionIV>

AWA

REFERENCES

A. PHS FAQs: **Is post approval monitoring required?**

Monitoring of animal care and use is required, though neither the PHS Policy nor the *Guide* explicitly address or require specific or separate post approval monitoring (PAM) procedures to compare the practices described in approved protocols and SOPs against the manner in which they are actually conducted. IACUCs are charged, however, with

program oversight and as such are responsible for program evaluations, reviews of protocols, reporting noncompliance, ensuring that individuals who work with animals are appropriately trained and qualified, and addressing concerns involving the care and use of animals at the institution. Whatever methods an institution incorporates, it is important that the authority and responsibility of the IACUC not be contravened by a PAM program, institutional compliance officials, or other mechanism established to monitor animal care and use.

<http://grants.nih.gov/grants/olaw/faqs.htm#e>

B. Guide for the Care and Use Of Laboratory Animals 8th Ed, 2011 pp

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. Post-approval monitoring (PAM) is considered here in the broadest sense, consisting of all types of protocol monitoring after the IACUC's initial protocol approval. PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures. Methods include continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments. The IACUC, veterinary, animal care, and compliance staff may all conduct PAM, which may also serve as an educational tool.

<http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>