

 <p>Institutional Animal Care and Use Committee Guiding Principles and Procedures</p>	<p>Effective: March 21, 2019</p> <p>Revised:</p>
<p>Title: Post Approval Monitoring</p>	<p>Page 1 of 3</p>

Guiding Principle

The use of animals in research and teaching is a privilege granted to institutions, investigators, staff and students that commit to meeting high ethical and regulatory standards. To comply with federal regulations, guidelines, and institutional policy, NDSU requires that the IACUC review all research, teaching, or testing involving live vertebrate animals. This includes animal field studies defined as activities involving a live vertebrate animal not performed in a laboratory.

The IACUC must ensure that ongoing research accurately reflects activities outlined in the approved protocols. Post approval monitoring (PAM) is an examination of an approved protocol activities and documentation to assure the PI is in compliance with the protocol and applicable University and Federal regulations. Conducting PAM visits will help to ensure that appropriate applications and supporting documents are implemented as approved, and any changes or adverse events/outcomes are properly documented.

Requirements

The Public Health Service (PHS) Policy in accordance with Section IV.C.5. The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.

Animal Welfare Act in accordance with, (9 CFR Ch. 1), Part 2-Subpart C, 2.31 (5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC but not less than annually.

Goals: The primary goals of the PAM visit are to ensure animal well-being and to maintain regulatory compliance. The PAM visit conveys IACUC policies on matters of animal care and identifies education and training needs of laboratory staff. Ultimately, the PAM visit will confirm that the manner in which the IACUC understood and approved an animal protocol is consistent with the way its procedures are being performed.

Benefits: **1.** Increased understanding of the regulations that guide research projects. **2.** Increased communication concerning updates to Federal and University regulations. **3.** Access to resources and individuals to clarify the Federal and University regulations

Procedure

1. Protocol Selection- Protocols are randomly selected from a list of approved IACUC protocols. Protocols may also be selected based on pain category, as a result of a filed concern/complaint and/or reported adverse event.
2. Post-Approval Monitor Visit
 - 2.1. The IACUC Administrator will contact the PI to schedule the PAM visit. The PAM visit includes a review of records and lab notebook's as well as a discussion of the active project.
 - 2.1.1. The attached rubric will be used as the PAM framework. Questions will address progress of the research project as well as problems or adverse events.
 - 2.1.2. If appropriate, the review may include a tour of the animal room and surgery space.
3. Outcomes
 - 3.1. Following the PAM visit a report will be sent to PI summarizing the visit with the following actions:
 - 3.1.1. All procedures are compliant, no follow up needed.
 - 3.1.2. Minor comments/recommendations which may or may not require follow-up.
 - 3.1.3. Significant deficiencies noted
 - 3.1.3.1. A timeline to address deficiencies will be determined by the AV, IACUC Administrator, and PI.
 - 3.2. All PAM visits will be reported to the IACUC at the convened monthly meetings.
 - 3.2.1. Serious and/or significant findings will be discussed by the AV, IACUC Chair, and IACUC Administrator immediately.

PAM Visit Questionnaire

IACUC animal use form on site

Training log for personnel in which their training is clearly defined with date, trainer and procedures.

All personnel involved in animal work are listed on the animal use form

Whistleblower poster visible

Gas Anesthetics scavenged

Drug storage and expiration dates checked

Drugs listed are consistent with usage

Species consistent with IACUC protocol

Use of animal consistent with IACUC protocol

Animal husbandry consistent with IACUC protocol

Surgical and post-operative records available

Animal health records available

Euthanasia performed consistent with IACUC protocol

Adverse Events documented