

University at Buffalo Animal Care and Use Program

Post-Approval Monitoring of Approved Protocols

Introduction

According to the *Guide for the Care and Use of Laboratory Animals*, the Institutional Animal Care and Use Committee (IACUC) is responsible to oversee and evaluate the University's animal program, procedures, and facilities to ensure they are consistent with the recommendations in the *Guide*, the regulations of the Animal Welfare Act, and the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Policy

The IACUC has the responsibility to ensure that the procedures carried out in the laboratory or classroom are conducted as described in the approved protocol. It is the policy of the IACUC to conduct post approval monitoring (PAM) of approved protocols to ensure continuing compliance; PAM is accomplished through several IACUC programs. The PAM program described here will involve site visits to specific investigator laboratories to discuss and observe the day-to-day application of approved IACUC protocols with, and by, the faculty, students, and staff listed on the protocol.

This PAM program will serve as a more focused monitoring tool in the post-approval oversight of individual protocols approved by the IACUC.

While the IACUC will select one member of the IACUC to serve as the primary liaison for PAM, other IACUC members will be available for consultations and assistance with the site visits.

Protocol Selection

Protocols will be selected for PAM review bi-annually or as recommended by the IACUC committee. Protocols will be selected randomly from the pool of all approved IACUC protocols by priority, i.e., high priority, medium priority or average priority.

High priority: protocols with a pain category E, protocols involving USDA covered animals in pain category D, protocols involving multiple survival surgeries, major survival surgeries in investigator labs, or protocols with a history of suspension.

Medium priority: USDA covered animals in pain category C, minor survival or major non-survival surgeries in investigator labs, or major survival surgeries in all other facilities.

Average priority: Pain categories B and C, or those not included in the other two groups.

All protocols for which there is a report of an animal welfare issue (health of the animal is endangered), a prior uncorrected deficiency, or a continuing protocol deviation, will be subject to PAM.

PAM Monitoring Procedures

The PI will receive an informational e-mail indicating that his/her protocol has been selected to be site visited. The email will include the key procedure in the protocol that will be discussed and/or observed and the reason why the protocol was selected, i.e., random selection from a specific priority or as a consequence of a report of an animal welfare issue, prior uncorrected deficiency, or a deviation from the protocol.

A follow-up email will be sent to schedule the PAM site visit and to discuss the protocol and the research being conducted.

At a time mutually agreed upon with the PI, the PAM liaison will observe and discuss the procedures with the faculty, students, and/or staff. Time will be provided for questions or comments after the procedures have been completed to ensure observations are accurately documented.

If for whatever reason, the animal procedures are not performed at the scheduled observation time, the meeting will be cancelled and rescheduled.

PAM Reporting Requirements

The PAM liaison will report their findings directly to the IACUC. The IACUC will notify the Institutional Official of all PAM site visits.

The IACUC will send a follow-up report to the PI, notifying him/her of the results of the PAM site visit, noting whether or not deviations were noted, and if so, provide a time table for corrections. If any issue of serious non-compliance is found during the PAM site visit, procedures as stated in the IACUC Policy of Non-Compliance will be followed.

Post-Approval Monitoring Checklist/Inspection Sheet

Date: Inspector: Participant(s): PI: Protocol #: Approval period: Title: Species:	Room	Room
Personnel		
Do the PI and/or laboratory personnel have access and/or knowledge of most recent version of complete IACUC-approved protocol, including amendments?		
Are people performing the study listed on the protocol?		
Study Procedures		
Does protocol # on cage card match approved protocol #?		
Are lab personnel appropriately trained to perform protocol procedures?		
Are investigators wearing required PPE and/or other attire (masks, gloves) for the species and procedures performed?		
Investigator Laboratory		
If animals housed in lab >12 hrs, has lab been approved by IACUC?		
Survival procedures: Are drugs, suture material, and other items within the noted package expiration dates?		
Are controlled substances stored appropriately and records maintained?		
Are there any safety issues or other concerns that pose a treat to human or animal safety, or animal welfare (bio-, radiation, or environmental safety concerns)? If so, list:		

Anesthesia		
Are methods of anesthesia in compliance with protocol?		
Are anesthetized animals monitored in manner consistent with IACUC policy and the approved method described in protocol?		
Are the animals maintained at an appropriate depth of anesthesia for the procedure performed?		
Inhalant machine: calibrated regularly? Scavenging appropriate?		
Are animals weighed and drug dosages calculated properly before administration?		
If using a Bell Jar, are animals separated from cotton via a perforated floor and is the procedure conducted under a Fume hood?		
Is supplemental heat provided?		
Are fluids provided?		
Is eye ointment administered?		
Are pharmaceutical grade drugs used?		
Are drugs expired?		
If using MS222, is it made fresh or kept dark, and pH neutralized?		
If using Avertin, is it made fresh and kept dark? Is it yellow; have precipitates?		
Are they using a Bain circuit for animals under 10 lbs?		
Are animals appropriately restrained for injections?		
If drugs need to be diluted (mice), are dilutions calculated correctly in a separate labeled tube?		
Surgery		
	<i>(if no surgical procedures check here)</i>	
Performed in location approved by IACUC? If conducted in lab, is space dedicated to surgery? Is it cluttered, disinfected?		
Is individual performing surgery properly trained in anesthetic, surgical, and post-operative monitoring techniques?		
Is individual performing surgery wearing PPE during surgery as described in protocol?		

Is surgical field prepared as described in IACUC-approved protocol?		
Is surgical field maintained?		
Is incision site shaved and 3-Prep solutions used?		

Are implanted devices sterilized before use? Is alcohol used? Are instruments sterilized by autoclaving, cold sterilant or beads?		
Are incisions closed appropriately and in accordance with the approved protocol? Are abdominal incisions closed in separate layers?		
Is the suture type, size and patterns in accordance with the protocol?		
Is an appropriate heat source used to keep the animal warm throughout the procedure?		
Is there an appropriate recovery area for this species?		
Post-Surgical Care	<i>(if no surgical procedures check here)</i>	
Are the methods of analgesia (dose, frequency, duration) consistent with the approved protocol?		
Are fluids administered?		
Is post surgical (post procedural) care adequately documented? Are forms completed?		
Were animals observed and monitored during recovery?		
If any, were post-operative problems reported to the Attending Veterinarian?		
Euthanasia		
Does method of euthanasia correspond with what is written in protocol?		
If using CO2 is a secondary method used to ensure death?		
Are animal verified dead before disposal?		
General Record Keeping		
Is there an up to date and complete surgical log		
Are medical and post-procedure care progress notes complete and accurate?		
Is medication administration accurately documented?		
Are injections, blood collection, and fluid collection amounts dated and documented?		
Non-Compliance (IACUC To Provide)		

Have any non-compliance issues occurred on this protocol or in the lab relating to this protocol? If so, please list and include the results from the non-compliance.		
Comments/clarifications:		

