Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Science at the heart of medicine

Institutional Animal Care and Use Committee

Jack and Pearl Resnick Campus
Van Etten Building, Room 468
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# POST-APPROVAL MONITORING PROGRAM

## Performance Standard:

The goal of post-approval monitoring is to work with, and in support of, research staff members and to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner.

## Background:

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

After a protocol is approved, the IACUC has the responsibility to ensure that the procedures carried out in the laboratory or animal housing areas are as described in the protocol. In order to ensure continuing compliance, post approval monitoring (PAM) of IACUC-approved protocols will be conducted.

PAM is intended to be a focused attentiveness which helps meet the requirements for ongoing oversight of animal use activities. Post approval monitoring of IACUC approved protocols is performed to provide assurance to regulatory agencies and Einstein that animal experiments are monitored for compliance with approved IACUC protocols.

PAM activities are performed by the Animal Program Compliance Coordinator (CC) and/or designated members (DM) of the IACUC based on expertise with the activity being monitored.

## PAM Process:

The CC or DM will serve as the eyes and ears of the IACUC to confirm consistency with approved protocols and accuracy of practices. The CC or DM will confirm compliant performance by observation and document review; assuring the animal care and use activity is being performed in accordance with federal regulations, IACUC approved protocols and Einstein policies.

The PAM process is essentially educational in nature. Protocols to be monitored will be either randomly chosen, suggested by personnel, or as means of follow-up of past non-compliance issues. PAM can be carried out at any time by either visiting a laboratory with an IACUC approved protocol or by visiting the animal housing facilities.

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The CC or DM will compare what is described in the approved protocol with the techniques and procedures being conducted on animals.

The CC will also review items such as the training of individuals in each laboratory, the storage and expiration dates of pharmaceuticals, personnel and animal safety issues and general laboratory/facility maintenance.

All occurrences of PAM will be reviewed by the IACUC. Any cases of serious non-compliance will immediately be brought to the IACUC to determine the appropriate course of action.

**Roles and Responsibilities:**

- The CC will be familiar with IACUC policies and the USDA and Guide requirements and knowledgeable about changes in regulations and standards that may affect the way in which research is conducted. The CC will provide educational and training support as required to facility/lab personnel.
- The CC will work in conjunction with Principal Investigators (PIs) and research personnel during the visit to facilitate observation of procedures and document compliance with approved protocols.
- The CC will work with the investigator and research personnel to perform protocol reviews, prepare accurate reports, and if necessary, provide training and recommendations for maintaining compliance.
- The CC will coordinate visits, correspondence and documentation, maintain records, and communicate with the IACUC.
- Designated Members (DMs) will perform PAM function for procedures that require a particular level of expertise (surgical procedures for example) and will report any finding s to the CC for inclusion in the PAM reports and records.

**Required Protective Measures:**

All personnel performing PAM shall wear the PPE or appropriate attire prescribed for the specific activity/procedure of the laboratory.

**Policy Expectations:**

**A) Facilities/Procedures subject to review**

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a. Protocols utilizing USDA covered species

b. Laboratory run Satellite Housing areas

c. Laboratories performing surgical procedures

d. Laboratories performing behavioral experiments

e. Any activity determined by the CC, IACUC or IAS Director to require monitoring

## B) Methodology of Assessment:

a. Routine Review: The CC schedules a monitoring session with the PI or delegated laboratory personnel based upon factors listed in section A.

b. Select or "For Cause" Review: "For cause" monitoring may be conducted at any time, with or without advance notice to the PI or research personnel. "For cause" reviews may be performed when requested by the IACUC or based on previous non-compliance.

c. Follow-up Review: These assessments will be performed for the purpose of confirming resolution on any concern found during the Semiannual Inspection Process and will be unannounced.

## C) The Monitoring Process:

a. Advisement of a Routine Review:

- The CC shall make an appointment for visits by e-mail. Initial correspondence with the PI should contain the information noted in the PAM visit memo (Appendix B)
- The CC will arrange a visit according to the PI/research personnel calendar and scheduled animal use procedures.

b. Performing a Review:

- The CC shall use the approved PAM Checklist for the review to compare procedures conducted in the laboratory with those listed in the approved protocol.
- When reviewing satellite housing areas the CC will consider and compare actual housing conditions to the approved description provided by the investigator.

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- Documented discrepancies between procedures performed in the lab and those listed in the protocol will be brought to the attention of the PI. Issues that pose an immediate threat to animal welfare shall be referred to the attending veterinarian and the IACUC for immediate resolution.

c. Exit Briefing of a Routine Review:

- At the conclusion of the review, the CC shall discuss the observations with the personnel who performed the work as well as the PI or designee.
- The goal of this interaction is to confirm observations are accurate and the CC and laboratory staff agree on the observations. The laboratory may offer additional information, but the CC may not negotiate but can request a specific laboratory corrective action plan.

d. Post Review:

- If potential deviations/concerns exist: An e-mail will be sent to the PI or designee describing the observed concern(s). Corrective actions performed by the PI/laboratory staff shall also be reflected in the e-mail. A copy will be retained by the IACUC office, in a separate file. (See Appendix C for a template of the message)
- If no deviations/concerns exist: An e-mail shall be sent to the PI noting the fully compliant nature of the review. (See Appendix D for a template of this message).
- In cases where the PI desires to initiate corrective actions the CC may assist the laboratory if requested. Assistance may include coordinating/providing training and or assistance with protocol addendum process.

## D) Reporting of Findings:

All findings will be reported to the IACUC. Animal misuse, mistreatment or neglect (welfare issues), and discrepancies which result in animal welfare concerns (deliberate animal misuse or willful disregard for appropriate animal care) will be reported immediately to the IACUC Chair and attending veterinarian.

## E) Process of Sharing Information Concerning the Review:

- The CC shall discuss monitoring results with the Principal Investigator and/or other research personnel before leaving the laboratory. Issues that pose an immediate threat to animal welfare shall be referred to the AV and IACUC Chair for immediate resolution.
- The CC shall send a written draft report of the monitoring results to the PI and other research personnel. Investigators will have the opportunity to respond to the draft report before the final report is prepared.

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- The CC shall send a final written report and a follow up letter of significant findings to the PI and the IACUC.

**F) Process Follow Up:**

- The CC will follow up on any issues that require protocol modifications, orientation of new personnel, or training.
- On occasion, additional monitoring sessions may be a part of the follow-up to assist with proper corrective actions.

**G) Recordkeeping:**

- A copy of the final compliance monitoring report will be retained at the IACUC Office.

**H) Frequency of PAM:**

- PAM visits will be on an ongoing basis throughout the year. The visits will be coordinated with the CC.
- It is anticipated that a majority of these visits will occur during the periods between semi-annual inspections.
- PAM visits during semi-annual inspections will be kept to a minimum in order to avoid any confusion.

**I) Benefits of PAM:**

The following benefits are expected as a result of implementing the PAM program:

- Provides an ongoing mechanism for ensuring compliance with applicable animal care and use policies, guidelines and laws.
- Serves as an opportunity for constructive interaction and education for the research staff and animal care personnel.
- Helps Einstein prepare for visits by outside evaluators, such as USDA inspectors, OLAW staff, and AAALAC site visitors.

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**Appendix A**

## A. Protocol Selection Process for PAM Monitoring

a. Active protocols involving the use of USDA covered species or survival surgery will be monitored on a random basis.

b. First time submissions (new investigators) will be monitored on a random basis.

c. Protocols involving noxious behavioral studies, less invasive procedures, will be monitored at the discretion of veterinary and IACUC personnel.

d. A random sample of other protocols will also be reviewed.

## B. Facility Selection Process for PAM Monitoring

a. All labs with USDA covered animals that are found to have significant deficiencies or expired drugs during the semi-annual inspections will be visited by the CC two weeks after the inspection report is sent. The visit will be unannounced.

b. The CC will also visit a random sample of other laboratories identified with significant deficiencies or expired drugs two weeks after the inspection report is sent. These visits will be unannounced.

c. Unannounced monitoring will also be performed on those labs that have a record of repeat compliance issues found during past semi-annual inspections. Focus will be on compliance issues that directly affect animal welfare and on expired materials.

d. Unannounced visits will be performed on labs using protocols selected for review per d above. These will be scheduled in advance.

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**Appendix B**

PAM Visit

PI:

Protocol Number(s):

Dear Dr. <insert name>:

The Einstein IACUC Animal Program Compliance Coordinator will perform post-approval monitoring (PAM) visits to approved animal care or use activities. The purpose of this visit is simply to collect evidence of good performance and conclude with a commendation for your laboratory for adherence to the approved animal use protocol or SOPs.

The process is intended to be collegial and supportive of animal based research on our campus. The Compliance Coordinator will serve as the representative of the IACUC and will work diligently to facilitate your research and help your laboratory understand and stay fully compliant with the Institutional Animal Care and Use Program at Einstein.

After completing the protocol review, the Compliance Coordinator will provide an “exit briefing” to the Principal Investigator, lab manager, or designated individual in your laboratory. The purpose is to assure the accuracy of the observations. Protocol deviations or non compliant conditions will be shared with the laboratory staff members during the briefing.

Within a few days of the visit, an e-mail will be sent to the PI describing the outcome of the visit and identifying items (if any) that may require corrective action. We request that corrective actions, if required, in response to the e-mail be implemented within two weeks or a plan of action submitted. The IACUC appreciates your partnership to assure the integrity of the biomedical research enterprises at Einstein.

Thank you.

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**Appendix C**

PI:

Protocol Number(s):

Dear Dr. <insert name>:

On <insert date>, the Compliance Coordinator performed a Post Approval Monitoring review of your laboratory.

Thank you and your staff for assisting with this review. Post Approval Monitoring of protocols is one method that the Einstein IACUC uses to assure regulatory agencies that animal studies are conducted in accordance with policies dictated by the Animal Welfare Act, Public Health Service Policy, and the NIH's Guide for the Care and Use of Laboratory Animals.

With respect to PAM review there were the following issues that require attention:

ISSUE:

SUGGESTED CORRECTIVE ACTION

ISSUE:

SUGGESTED CORRECTIVE ACTION

Thank you for your consideration, clarification, and response to these items. Our review is intended to be a review of approved activities, and an opportunity for education and information sharing of the research process at Einstein.

Thank you

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**Appendix D**

PI:

Protocol Number(s):

Dear Dr. <insert name>:

On <insert date> a Post Approval Monitoring review of the facilities and the activities under the protocol(s) identified above was conducted by the Animal Program Compliance Coordinator on behalf of the Einstein IACUC.

With respect to the procedures observed under this protocol(s), all procedures observed were performed as approved in the protocol. Please commend your staff for the attention to detail, the professional manner in which the animal activities were conducted, and the humane manner in which the animals were being handled.

Successful reviews such as this provide clear evidence of institutional regulatory compliance, as dictated by the Animal Welfare Act and the Public Health Service policy.

Thank you and your staff for your support of our institution's commitment to quality care and progressive research. A copy of the monitoring report is attached for your records.

Congratulations for a job well done!

A copy of this memo will be maintained at the IACUC Office.

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**Post Approval Monitoring Checklist**

PI Name: Protocol #:

Protocol Title:

Species: Date of PAM:

**Participants:**

Lab Staff:

IACUC:

**The Protocol and Personnel**

1. Do the PI and/or personnel have the most recent version of the complete protocol, including amendments? Y_____ N_____
2. Do the PI and personnel have accurate knowledge of the protocol? Y_____ N_____
3. Have the investigators read the protocol? Y_____ N_____
4. Are the people performing the study listed on the protocol? Y_____ N_____
5. Is each room where animal procedures occur listed on the protocol? Y_____ N_____

**Study Procedures**

1. Are the procedures performed consistent with those in the approved protocol? Y_____ N_____
2. Are lab personnel appropriately trained to perform these procedures? Y_____ N_____
3. Are investigators wearing appropriate PPE for the specific procedure? Y_____ N_____

**Anesthesia**

1. Are the methods of anesthesia consistent with the protocol? Y_____ N_____

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2. Are anesthetized animals monitored in a manner consistent with the protocol? Y_____ N_____
3. Are animals maintained at an appropriate depth of anesthesia? Y_____ N_____
4. Is intra-anesthetic/operative monitoring adequately documented? Y_____ N_____
5. If inhalant anesthetics are used, are the scavenged properly? Y_____ N_____
6. Are anesthetic machines serviced and calibrated? Y_____ N_____

**Survival Surgery**

1. Is there a clean, uncluttered area for surgeries? Y_____ N_____
2. Is the operative field shaved/prepped? Y_____ N_____
3. Are sterile instruments being used? Y_____ N_____
4. For large animals, is surgical scrub/hand wash performed? Y_____ N_____
5. If allowed in the protocol, are instruments disinfected between animals? Y_____ N_____
6. Are implanted devices sterilized before use? Y_____ N_____
7. Are incisions closed in accordance with the approved protocol? Y_____ N_____
8. Is there an appropriate recovery area? Y_____ N_____
9. Is a heat source provided during recovery? Y_____ N_____
10. Are animals monitored appropriately during recovery? Y_____ N_____

**Post-Surgical Care**

1. Is post surgical care in compliance with the protocol? Y_____ N_____
2. Are methods of analgesia consistent with the protocol? Y_____ N_____
3. Is post surgical care adequately documented? Y_____ N_____
4. For rodents, is surgery “pink card” placed on cage? Y_____ N_____

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5. Are sutures/staples, if present, removed at interval specified? Y_____ N_____
6. Are post operative complications reported to IAS veterinary staff? Y_____ N_____

**Euthanasia**

1. Does method of euthanasia correspond with what is written in the protocol? Y_____ N_____
2. Is death assured as described in the protocol? Y_____ N_____

**General Record Keeping**

1. Is there an up to date and complete surgical log? Y_____ N_____
2. Are medical and post procedure care progress notes complete and accurate? Y_____N_____
3. Is administration of medication accurately documented? Y_____ N_____
4. Are injections, blood collection, and fluid collection amounts documented? Y_____ N_____

**Laboratory**

1. Are drugs, suture material and other items within the package expiration dates? Y_____ N_____
2. Are controlled drugs stored appropriately? Y_____ N_____
3. If controlled drugs are used, are records kept appropriately? Y_____ N_____
4. Are there any safety issues or other concerns that pose a threat to human or animal safety, or animal welfare? Y_____ N_____

**Comments:**

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