UCC Universidad Central del Caribe	**Universidad Central del Caribe** **POST-APPROVAL MONITORING (PAM) GUIDELINES**	PAM	
		Version#	**# 1**
		Implementation Date	2023.10.26
	Institutional Animal Care and Use Committee (IACUC)	Last Reviewed/Update	
		Approval by IACUC	2023.09.28

Purpose:

The Universidad Central del Caribe (UCC) Institutional Animal Care and Use Committee (IACUC) is under a federal mandate to oversee all research activities involving animal use. According to the eighth edition of 'The *Guide for the Care and Use of Laboratory Animals* (Guide),' this oversight includes monitoring approved animal activities to ensure ongoing protocol evaluation and regulatory compliance (p. 33-34). This continued oversight is referred as Post Approval Monitoring (PAM). According to the Guide, PAM activities may include the following: continued protocol review, laboratory and facility inspections, veterinary or IACUC observation of selected procedures, daily animal observation, and external regulatory inspections. However, there are no regulatory guidance outlining the specific activities that must be performed. This document outlines the PAM process at UCC, including the participants, the nature and frequency of monitoring activities, and the reporting mechanisms used to document these activities.

Objectives:

The primary goal of the PAM program is to ensure compliance by monitoring the consistency between laboratory practices and the approved IACUC protocol. In addition, the PAM program can serve as a method to monitor the overall animal program, provide input to the IACUC on processes and identifiable risks, and promote a positive research culture. The PAM program should also keep investigators informed about new policies, regulations and guidelines that may impact protocol compliance and laboratory best practices. Finally, the program should establish a collaborative partnership with investigators to enhance animal welfare, encourage a culture of compliance, and facilitate open communication between investigators, the IACUC, and research staff.

Participants:

According to the eighth edition of *The Guide for the Care and Use of Laboratory Animals,* PAM activity can be carried out by the IACUC members, veterinary staff, animal care technicians, and others. The participation and responsibilities of the following groups are defined here.

- **Investigators and research personnel**: They will grant the PAM Team access to the laboratory facilities, allow observation of procedures and provide documentation in accordance with approved protocols.

- **PAM Team:** PAM members will monitor the procedures, prepare accurate reports, and, if necessary, facilitate training and provide recommendations to ensure compliance. The PAM Team is also responsible for managing PAM records and communicating with the IACUC.

- **IACUC members:** IACUC members participate in several activities within the framework of the PAM program. These activities include conducting biannual inspections and program reviews at the Animal Resource Center (ARC), reviewing and approving protocols, ensuring appropriate training and continuing education of staff. Furthermore, IACUC members collaborate with PIs and research staff to perform certain PAM program activities. They will participate in activities such as conducting preparation rounds in laboratories before inspections, sharing educational materials and policy/guidance, and providing training and guidance on protocol preparation and submission. Finally, IACUC members will perform the formal PAM processes described in more detail below.

- **Animal Care Staff:** This group includes individuals with various levels of responsibility, such as consultant veterinarians and veterinary technical staff from the UCC. They are actively involved in the PAM program and perform a variety of tasks related to animal care. Specific activities include but are not limited to participation in surgical training and competency evaluations of research personnel, routine animal care, observation of animals in active studies, performing or supervising surgeries, including monitoring anesthesia and analgesia, monitoring endpoints, and providing training for routine laboratory animal practices.

PAM Processes:

Below are the detailed activities that the PAM typically involves. Some of these activities are performed on a continuous basis to fulfill the IACUC's overall oversight responsibility, while others are specifically part of the formal PAM program. These activities are designed to be performed periodically, or as needed, following an assessment of the risk of animal welfare issues or protocol non-compliance. The IACUC Chair or designee will assign at least two IACUC members to each laboratory with an active project using laboratory animals. The principal investigator will be notified in writing one week in advance of the monitoring visit. All active animal care and use protocols are subject to PAM. The frequency of PAM activities directed at a specific protocol will be ranked in the following descending order:

1) Protocols with a history of serious previous animal welfare issues.

2) Protocols carried out in high-risk laboratories (Chemical hazards, BSL2 or higher), identified as such by the IACUC based on a combination of concerns for species used, activity, performance location, past poor performance, and other factors.

3) Protocols that include high-risk procedures, such as pain or distress, or potential pain or distress that is **not** relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods. This category also includes protocols involving multiple survival surgeries, the use of death as an endpoint, and protocols involving prolonged restraint.

4) Protocols with moderate risk non-terminal procedures performed in the laboratory.

5) Facilities and areas not authorized for animal experimentation.

- **Semiannual site inspections:**

  Twice a year, site inspections are performed by IACUC members with the support of animal care staff. These inspections serve multiple purposes, including facility monitoring and protocol compliance review. The inspections cover various aspects, such as:

  a) Monitoring compliance with facility-related issues.

  b) Examining drug storage and usage.

  c) Examining surgical and procedure logs.

  d) Informal assessments of the laboratory personnel's knowledge of the protocols they work

  e) Determining if animal health or welfare is at risk.

  f) Disseminating information about new policies and reinforcing "best practices."

  To aid in this process, the IACUC members provides information to site inspectors regarding approved protocols within investigator-maintained procedural spaces. They also provide materials for dissemination to lab staff regarding relevant new or revised policies or standard operating procedures.

- **Ongoing protocol review:**

  Approved protocols are subject to review during the semi-annual inspection process and three-year renewal. Protocols may be reviewed in the following situations: noncompliance or whistleblower investigations, when specific questions are raised by IACUC members or the animal care team, or as part of a formal PAM investigation.

- **Training and continuing education:**

  The IACUC offers training opportunities through the CITI program and webinars. Formal classroom and hands-on training are primarily managed by the UCC

animal care program. Initial training and competency evaluations, as well as protocol-specific hands-on training and continuing education, are required as detailed in Handbook for the Use of Laboratory Animal, Page 10 (Training Programs).

- **Continuing monitoring by the Animal Resource Center:**

ARC staff routinely monitor and evaluate animal-related activities conducted at the facility. These activities include but are not limited to:

a) observing the health and welfare of animals

b) observing the execution of the procedures with the animal

c) ensuring compliance with rules regarding signage, use of personal protective equipment, and compliance with standard laboratory practices.

Furthermore, veterinary staff members play a significant role in performing specific procedures, particularly surgery and postoperative follow-up. Detailed records documenting activities required by IACUC policies are kept within the animal care programs and will be provided to the IACUC upon their request

- **Standard Periodic Monitoring:**

Standard periodic monitoring is performed by IACUC members and provides a mechanism for continuous and periodic review of animal-related activities conducted by a research team. The assessment is performed either on an individual protocol basis or for a group of related protocols under the same PI or group. The scope of the assessment varies depending on the case, ranging from a comprehensive review of the entire protocol(s) to a focused evaluation of specific activities of the protocol. The assessment may include, direct observation of procedures, examination of records, SOPs, and/or training documents, or a specific review of protocol content.

- **"For cause" protocol follow-up:**

There are numerous reasons for frequent or "after-hours" activities, as indicated in the descriptions below. These activities are generally performed by IACUC members, but may also be performed by others as defined below.

  - **Specific instances of non-compliance:** PAM visits are often part of the IACUC's responses to instances of non-compliance. These visits are conducted to ensure the completion of all corrective actions and to maintain future compliance. PAM monitoring may be a one-time request or may involve periodic visits. The particulars of the PAM activity will vary depending on the nature of the causing event. IACUC members and UCC-ARC veterinary staff may be involved retraining or competency assessment if needed. Supervision

sessions may be also included as part of the follow-up to facilitate the implementation of corrective actions.

- **Specific request (other than noncompliance):** In certain instances, concerns regarding specific protocols other than a non-compliance issue may be raised by the IACUC, veterinary staff, or others. It is critical that issues of this type be addressed promptly to prevent the emergence of more severe issues. Each concern will be handled on an individual basis considering its unique circumstances.

- **Required Protective Measures:**

  The PAM Team, as well as other visitors, shall wear personal protective equipment (PPE) deemed appropriate for the specific activity/procedure of the laboratory.

PAM Program Expectations:

- **Process of Monitoring:**

- The PAM Team is responsible for scheduling an appointment with the Principal Investigator to monitoring the procedures or check one or more protocols. In either case, follow-up appointments may also be scheduled.
- The PAM Team shall use the appropriate “PAM Checklist” while observing procedures or conducting protocol audits.
- The team may request training documents such as laboratory personnel training records as well as documents that track animal health and monitoring. During each monitoring session, the PAM Team will compare procedures conducted in the laboratory with those listed in the approved protocol. Documented discrepancies between procedures performed in the lab and those listed in the protocol will be brought to the attention of the PI.

- Animal misuse, mistreatment, or neglect (welfare issues) and discrepancies that result in animal welfare concerns (i.e., deliberate animal misuse, mistreatment, or neglect, or those that involve willful disregard for appropriate animal care) will be immediately reported to the IACUC in accordance with the Public Health Service Policy. The IACUC Chair, will gather information for presentation to the IACUC for review and, if necessary, further investigation.

- At the discretion of the PAM Team, the research procedure(s) being observed may be placed on hold if animal welfare issues are observed.

Other PAM Activities:

- **Exemptions to standard policies:**

  In certain instances, the IACUC may grant exemptions to standard policies. Depending on the nature of these exemptions, periodic monitoring of activities or documentation of the receipt and distribution of standard reports can be required. Monitoring will be done on a case-by-case basis and is primarily the responsibility of the IACUC. Also, these issues are monitored during semi-annual facility inspections.

- **Policy changes:**

  Periodically, IACUC, UCC, or external agency policies or regulations change, requiring laboratory personnel to act to comply with the new standards. The IACUC will disseminate this information through email communications, by posting the new guidelines on the web, and through personal communications with laboratory personnel. If modifications to approved protocols are necessary, the IACUC will assist in this process. Compliance with these new standards will be primarily monitored through semi-annual facility inspections.

- **Data collection and distribution:**

  In some cases, the IACUC requests periodic or final reports from laboratories as a requirement for protocol approval or maintenance. The most common cases include pilot experiments and ongoing animal welfare reports. The IACUC will primarily be responsible for obtaining this data and making it available to investigators.

- **Random walk-through (Readiness Rounds):**

  One mechanism for developing a “culture of compliance” is to be available to investigators and to become familiar with their laboratories and facilities. To this end, IACUC staff will periodically visit laboratories and facilities to check in with investigators and their staff, answer questions, and disseminate information.

Data Collection and Reporting Mechanisms:

- **Initial report generation:**

  PAM activities performed by IACUC will be documented. Reports of findings will be generated and reviewed by the IACUC Director. Protocol violations affecting animal health and welfare will be immediately reported to the

veterinarian in charge. The results of inspections that represent an immediate danger to animal welfare will lead to on-site action. In such cases, both the veterinarian in charge or his/her designee and members of the IACUC will be notified to address the activity appropriately.

- **Reports to Investigators:**

  After completing the PAM activity, a letter i summarizing the findings will be sent to the PI. In case there are no significant deviations from the protocol, the PI will receive a commendation letter. However, if there are findings of protocol deviation, or other concerns identified during the inspection, the PI will be promptly notified. Additionally, guidance on taking appropriate actions to address the concerns will be provided.

UNIVERSIDAD CENTRAL DEL CARIBE
Institutional Animal Care and Use Committee (IACUC)

Post Approval Monitoring (PAM) Checklist

Principal Investigator (PI): _____

Protocol Number: _____

Protocol Title: _____

_____

Species: _____

Date of Monitoring: _____

PAM Team Member(s): _____

Y=Yes, N=No, N/A- not applicable

The Protocol and Research Staff			
Y	N	N/A	1. Are laboratory staff only performing procedures approved in the protocol?
Y	N	N/A	2. Do all personnel approved to work with animals in the protocol have an up-to-date enrollment in the Occupational Health Program?
Y	N	N/A	3. The room where the animals are worked, is it one included in the animal study protocol?
Y	N	N/A	4. Does the laboratory maintain the required in-lab training documentation for personnel working with live animals?

Study Procedures			
Y	N	N/A	5. Are the procedures performed consistent with those approved in the protocol?
Y	N	N/A	6. Are investigators/research personnel utilizing appropriate Personal Protective Equipment (PPE) and/or other equipment required for the species and procedures performed?
Y	N	N/A	7. Are the species, strains, and ages of animals consistent with those in the approved protocol?
Experimental Design			
Y	N	N/A	8. Are these any inconsistences between the laboratory practices and protocol approved?
Y	N	N/A	9. Are animals transported to/from the necessary animal housing and use areas via the appropriate route and acceptable means (e.g. blanket that cover the cage (s))?
Y	N	N/A	10. Are laboratory personnel able to identify signs of pain and/or distress in animals?
Y	N	N/A	11. Are restraint devices used appropriately and as approved in the animal study protocol?
Y	N	N/A	12. Are injection routes (e.g., ID, IM, SQ, IV, IP) in accordance with the animal study protocol approved?
Y	N	N/A	13. Are laboratory personnel knowledgeable regarding maximum blood collection volumes?
Y	N	N/A	14. Is acceptable heat support provided while animals are anesthetized?
Y	N	N/A	15. Are pre-, peri-, and post-operative drugs properly administered in accordance with the protocol?
Y	N	N/A	16. Does the laboratory ensure that aseptic technique is observed during survival surgery?

Y	N	N/A	17. Is post-operative monitoring and analgesia documented per IACUC policy?
Y	N	N/A	18. Can staff describe surgical preparation, procedures/surgeries in step-by-step fashion, including post-op procedures and monitoring?
Anesthesia			
Y	N	N/A	19. Are the agents or methods of anesthesia in compliance with the protocol?
Y	N	N/A	20. Are the animals being adequately monitored during anesthesia according to the approved methods in the protocol?
Y	N	N/A	21. Are the animals being maintained at an appropriate level of anesthesia?
Y	N	N/A	22. If inhalant anesthetics are used, are they being appropriately scavenged?
Surgery			
Y	N	N/A	23. Is the space prepared to perform surgical procedures?
Y	N	N/A	24. Is the method of animal preparation to surgery appropriate and in accordance with the approved protocol?
Y	N	N/A	25. Is survival surgery performed using sterile instruments, sterile gloves, a surgery mask and aseptic techniques?
Y	N	N/A	26. Are drugs, suture materials, and other items within their expiration date?
Y	N	N/A	27. Are controlled substances stored/logged appropriately?
Y	N	N/A	28. Is an appropriate heat source used to keep the animal warm throughout the procedure?

Y	N	N/A	29. Are incisions closed appropriately and in accordance with the approved protocol?
Y	N	N/A	30. Is there an appropriate designated recovery area for the animals?

Post-Surgical Care

Y	N	N/A	31. Do the methods of analgesia (dose, frequency, route) adhere to the approved protocol?
Y	N	N/A	32. Is an appropriate heat source used for the animal's recovery?
Y	N	N/A	33. Is there an up-to-date and complete surgical/procedure log (i.e., card, lab record)?

Record Keeping

Y	N	N/A	34. Is the weight of the animals recorded?
Y	N	N/A	35. Are the animals appropriately identified (e.g., cage cards, ear tags, tattoos)?
Y	N	N/A	36. Are the progress notes for medical and post-procedural care complete and accurate?
Y	N	N/A	37. Is the documentation of medication, anesthetic, and analgesic administration accurate?

Euthanasia			
Y	N	N/A	38. Are the agents/methods of euthanasia approved in the protocol?
Y	N	N/A	39. Is death ensured by performing an appropriate physical/secondary method of euthanasia when required?
Laboratory			
Y	N	N/A	40. Has the lab obtained approval from the IACUC if species are housed in the lab for more than 12 hours?
Y	N	N/A	41. Are drugs, suture materials, and other items within their expiration dates?
Y	N	N/A	42. Are controlled substances stored and logged appropriately?
Y	N	N/A	43. Is there a sharp container located within the laboratory or procedure room?
Y	N	N/A	44. Are there any safety issues or concerns that may pose a threat to human or animal safety or animal welfare?
Y	N	N/A	45. Were any unanticipated post-procedure health issues reported to veterinary staff?
Endpoints & Recordkeeping			
Y	N	N/A	46. Can staff describe their animal endpoints? Is there a primary and secondary method of euthanasia approved on the protocol, and are those the methods used by the laboratory?
Y	N	N/A	47. Is proper care taken when disposing of hazardous substances?

Y	N	N/A	48. Is the laboratory aware that documents relevant to the study must be maintained for the duration of the study and at least three years after its completion?
Y	N	N/A	49. Are personnel familiar with the procedures in place for reporting animal welfare concerns?

Comments/Clarifications: