Wake Forest University
Animal Care & Use Program
Standard Operating Procedure

Post-Approval Protocol Monitoring (PAM)

PERFORMANCE STANDARD: The goal of compliance monitoring follow-up is to work with and in support of the research staff and to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner.

BACKGROUND: Post-approval monitoring of Institutional Animal Care and Use Committee (IACUC) protocols is performed to 1) ensure animal welfare, 2) ensure institutional regulatory compliance, 3) provide assurance to regulatory agencies and the WFU IACUC that animal experiments are performed in accordance with approved IACUC protocols, 4) provide proactive self-regulation by researchers, 5) increase transparency between IACUC, ARP, and the researchers and 6) create a culture of compliance. The Oversight & Outreach staff (O&O staff) confirms consistency and accuracy of approved protocols and practice.

ROLES:

- Investigators and laboratory staff: Will work with the O&O staff to schedule and perform the procedure(s) that will be observed and make available all necessary records and documentation.
- O&O staff: Will work with the investigator and laboratory staff to observe procedures, review records, provide recommendations for maintaining compliance, and provide training opportunities.

PROTECTION PROCEDURES REQUIRED: O&O staff (and other visitors) shall wear the PPE prescribed for the specific activity or laboratory.

SOP EXPECTATIONS: The goal of the post-approval monitoring program is to review active protocols on a regular basis.

Selection of protocols for review

Selection of protocols includes a cross section of species, campuses and departments with an emphasis on:

1) Pain category: All active protocols involving the use of Category E will be monitored at least once annually, and at the discretion of IACUC and veterinary personnel. A minimum of 10% of protocols involving Pain Category C and D procedures will be monitored at least once annually..
2) Survival Surgery
3) USDA regulated animals
4) Labs with past compliance issues
5) Protocols that require the use of satellite facilities

Monitoring Process

1) O&O staff will schedule routine monitoring sessions with the Principal Investigator or other laboratory personnel in advance. “For cause” monitoring may be conducted at any time, with or without advance notice to the Principal Investigator. Follow-up noncompliance visits may or may not be scheduled.
2) O&O staff will use one of the “*Post-Approval Protocol Review*” forms for all reviews.
3) During the monitoring session, O&O staff will compare procedures conducted in the laboratory with those listed in the approved protocol. Required records will be reviewed. These could include Individual Training Logs of the research team, controlled drug use logs, surgical records, post-op monitoring records and satellite facility cleaning records.
4) Documented discrepancies between the procedures performed in the lab and those listed in the protocol will be brought to the attention of the Principal Investigator. Such discrepancies may include:
    a. Personnel performing procedures who are not listed in the approved protocol.
    b. Procedures performed in the labs that are not listed in the approved protocol.
    c. Anesthetics, analgesics, tranquilizers, antibiotics or other medications used in the lab that are not noted in the protocol, or different from those listed in the protocol, or not used in accordance with the protocol.
    d. Procedures listed in the protocol to promote animal welfare (e.g. post-op monitoring procedures) that are not being performed as approved in the protocol.
    e. Survival surgery that is not performed aseptically.
    f. Euthanasia procedures that differ from those listed in the protocol and/or a method for ensuring euthanasia (e.g. after CO2 exposure) that are not employed.
    g. Lab personnel who appear to lack the necessary training to appropriately perform procedures listed in the protocol.

h. Supporting documentation for animal care, post-op care or other study procedures that is incomplete or unavailable.
i. Conditions that are not safe for humans and/or animals.
j. Outdated materials (drugs, suture, etc.) are used.
k. Equipment (e.g. anesthetic vaporizers) in use that is not calibrated/certified as required.

Deliberate animal misuse, mistreatment, or neglect, or those concerns which involve willful disregard for appropriate animal care will be immediately reported to the IACUC Chair. Issues that pose an immediate threat to animal welfare shall be referred to the Attending Veterinarian or another staff veterinarian and the PI for immediate resolution. Corrective action will be determined by the IACUC Committee in accordance with its policies.

Process of Sharing Information Concerning the Review

When possible, O&O staff will discuss monitoring results with the Principal Investigator and/or other lab personnel before leaving the laboratory as part of the exit interview.

O&O staff will send a written draft report of the review to the Principal Investigator and the Director of the IACUC. Both the PI and the Director of the IACUC will have 7 days to respond to the draft report before the final report is prepared. The report will include the procedures that were monitored, any noted deficiencies, recommendations for best practices/clarifications to protocol, etc.

O&O staff will send a final written report of the review to the Principal Investigator, IACUC Chair, Director of the IACUC, and the Assistant Dean for Research. If the protocol needs to be amended, the PI should submit an amendment within 30 days. If an amendment has not been submitted within 30 days, notification will be forwarded to the IACUC Chair for possible disciplinary action.

The IACUC Chair will review any minor deficiencies and approve their resolution. Serious concerns or noncompliance issues are brought before the full IACUC for discussion and resolution. All PAM reviews are listed in the minutes of the monthly IACUC meetings.

Process of Follow-up

O&O staff will follow up on any issues that require protocol modifications, orientation of new personnel, or training. O&O staff will support the laboratory corrective action by facilitating access to the required training and / or guiding the revision of the protocol to bring it into current compliance. O&O staff will inform the IACUC staff that all items noted in the PAM review have been addressed.

The IACUC will then review any amendment submitted to correct/clarify the protocol for any issues identified during the PAM review.

On occasion, additional monitoring sessions may be part of the follow-up to assist with proper corrective actions.

Process for Appeal by Principal Investigator
Investigators who disagree with PAM report and/or recommendations may appeal to the IACUC by a written memo.

Recordkeeping
A hard copy of the final PAM report shall be kept in a PAM folder in the O&O office.