**Post-Approval Monitoring Program**

# **P****ROGRAM EXPECTATIONS**

# The goal of post approval monitoring (PAM) is to work with, and in support of, academic and research personnel, and to confirm accurate and consistent Animal Care and Use Protocol performance in a collegial and unobtrusive manner. The PAM program at Oklahoma State University is designed to uphold the highest standards of animal care and use. Its specific obligations are to:

* **Safeguard Animal Welfare**-Ensure that no activities or conditions arise that may compromise the welfare of animals used in research or teaching.
* **Verify Protocol Adherence**-Confirm that research and teaching procedures are performed in accordance with the descriptions and stipulations outlined in the approved Animal Care and Use Protocol (ACUP).
* **Maintain Transparent Communication**-Keep the Institutional Animal Care and Use Committee (IACUC) informed about the status, findings, and ongoing processes research at Oklahoma State University.
* **Ensure Record-keeping Compliance**-Verify that records are accurately maintained in accordance with IACUC Policy #IACUC-013.
* **Protect Institutional Integrity**-Promote responsible animal use and protect the reputation of Oklahoma State University’s animal care and use program in teaching and research.
* **Support the Research and Academic Community**-Serve as a knowledgeable and approachable resource for researchers, educators, and staff engaged in animal-based activities.
* **Advance Scientific and Educational Goals**-Promote high-quality science and education by supporting ethical and compliant animal use practices.
* **Facilitate Regulatory Compliance**-Assist in meeting and exceeding all applicable federal, state, and institutional regulations and guidelines governing animal care and use.

# **SCOPE**

Post approval monitoring of active Institutional Animal Case and Use Committee (IACUC) Animal Care and Use Protocols (ACUPs) is performed to provide assurance to regulatory agencies and Oklahoma State University that research and academic programs using live animals is monitored for compliance with approved IACUC protocols. The Compliance Analyst will confirm compliant performance by observation and document review assuring the animal care of use activity is being performed in accordance with federal regulations, IACUC ACUPs and Standard Operating Procedures (SOPs) at OSU sites and facilities.

# **ROLES AND RESPONSIBILITIES**

# **Primary Investigators and Personnel:** Principal Investigators (PIs) and associated research personnel are expected to collaborate with the Research Compliance Analyst during monitoring visits. This includes facilitating the observation of procedures and providing access to records and documentation relevant to the Animal Care and Use Protocol (ACUP). Their cooperation ensures that monitoring activities accurately reflect the practices described in the approved protocol and support the institution’s commitment to compliance and animal welfare.

# **Research Compliance Analyst:** The Research Compliance Analyst will collaborate with Principal Investigators (PIs) and research personnel to observe animal care and use activities and review associated records and documentation as described in the approved Animal Care and Use Protocol (ACUP). Additionally, the Analyst will offer recommendations to support continued compliance with institutional policies, federal regulations, and best practices in animal research.

# **IACUC Manager:** The IACUC Manager provides operational oversight and management of the Research Compliance Analyst and the post-approval monitoring program. They are responsible for ensuring that the IACUC receives timely reports of any concerns or findings requiring attention. The Manager also offers regulatory guidance and support to promote ongoing compliance and facilitates the implementation of corrective actions when necessary.

**PROCEDURE**

**Selection of ACUPs for Review**

All active ACUPS at OSU are included in the selection process and may be subject to a PAM visit. The IACUC office will determine which ACUP sites will be visited.

**Protective Procedures Required**

The Compliance Analyst and all other visitors will wear the PPE prescribed for the specific activity at the site.

**Process of Monitoring**

1. **Notification of Selected Protocols**

After Animal Care and Use Protocols (ACUPs) are selected for monitoring, the Research Compliance Analyst will prepare and send formal notification emails to the Principal Investigators (PIs).

1. **Scheduling and Preparation**

The Compliance Analyst will coordinate with the PI to schedule a monitoring visit at the PI’s earliest convenience—ideally when specific procedures described in the ACUP are being conducted. The notification email will request that all relevant records and documentation be available for review at the time of the scheduled visit.

1. **On-Site Monitoring Visit**

During the visit, the Compliance Analyst will observe active procedures and compare them with those approved in the ACUP. Using a standardized checklist, the Analyst will evaluate areas including personnel participation, procedures, animal husbandry, and recordkeeping practices.

1. **Exit Briefing**

At the conclusion of the monitoring visit, an exit briefing will be conducted with the PI and/or study personnel. Any observed discrepancies or concerns will be discussed and documented at that time.

1. **Immediate Reporting of Animal Welfare Concerns**

Any observation of animal misuse, mistreatment, neglect, or other issues impacting animal welfare will be reported immediately to the Attending Veterinarian and IACUC Chair for prompt resolution. These reports will be made available to the full IACUC upon request.

1. **Follow-Up Visits**

If warranted, a follow-up monitoring visit may be requested by the IACUC Chair to ensure corrective actions have been implemented and compliance is maintained.

1. **Documentation and Recordkeeping**

All documents and records associated with PAM site visits will be stored electronically and attached to the corresponding ACUP within the OneAegis system.

1. **IACUC Reporting**

A summary report detailing visits and findings will be presented to the IACUC during its regularly scheduled monthly meetings.

1. **Recognition of Excellence**

Principal Investigators who demonstrate exceptional adherence to recordkeeping and exemplary animal care practices may be awarded a Certificate of Recognition by the IACUC.