

POST-APPROVAL MONITORING

What, why, and how?

Jennifer A. Klahn, MA, CPIA
Director, Research Safety & Animal Welfare
University of California, Los Angeles

UCLA Research Policy & Compliance

1

SESSION GOAL

Understand expectations for post-approval monitoring (PAM) and different approaches to conduct PAM within an animal care and use program.

2

LEARNING OBJECTIVES

- 1. Define post-approval monitoring
- 2. Identify regulatory and oversight body expectations for PAM
- 3. Outline different methods of PAM
- 4. Recognize value of PAM in your program

3

1. DEFINE PAM

4

THE GUIDE

Continuing IACUC oversight of animal activities

All types of protocol monitoring after initial approval

5

2. REG/OB EXPECTATIONS

6

PHS POLICY

IV.C.5: The IACUC shall conduct **continuing review** of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.

IV.B.2: **Inspect** at least once every six months all of the institution's animal facilities (including satellite facilities) using the *Guide* as a basis for evaluation. (see also OLAW FAQ E.1)

7

OLAW FAQ

G.6. Is post approval monitoring required?

- Monitoring animal care and use is required by the PHS Policy
 - NOTE: The Policy does not require protocol or SOP comparison
- Program oversight responsibilities include program eval, protocol review, noncompliance/AW concerns, personnel training
- Different individuals in the ACUP contribute in different ways
 - Examples: daily observation by animal care personnel, post-op care by trained personnel, facility monitoring, hands-on training.

The institution has flexibility in how it achieves compliance

8

USDA ANIMAL WELFARE REGULATIONS

§2.31(d)(5): The IACUC shall conduct **complete reviews** of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than every 3 years.

§2.31(c)(2): **Inspect**, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation.

9

ANIMAL WELFARE INSPECTION GUIDE

7.2.1. Inspection Protocol Review Guidance

Protocols and the **IACUC approval and monitoring of protocols** should be completely and thoroughly reviewed during an inspection.

7.2.2. Sampling Guidance

The inspector is responsible for conducting a thorough review of:

- The protocol approval process
- **The IACUC's monitoring of protocol activity**
- IACUC-approved protocols and changes to protocols

www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf

10

AAALAC FAQ C.5

The 2011 Guide notes the value of having a mechanism in place to help ensure that animal study procedures are conducted in accordance with the approved protocol. Post-approval monitoring (**PAM**) programs **vary** from reliance on existing activities performed by the IACUC (or comparable oversight body) to very extensive supplemental audits of protocols and the entire program conducted by compliance staff. Although AAALAC agrees that ensuring compliance with approved protocols is critical, AAALAC International interprets the Guide recommendation for a PAM program in the broadest sense for the international community, namely that **there will be a system for ensuring animal procedures conform with the approved protocol or study plan.**


11

3. DIFFERENT METHODS

12

HOW DO YOU DO PAM?

- Take a minute to think about how PAM is performed at your institution
- Share your strategies and ideas in the chat



13

PAM METHODS

- Continuing review (e.g., annual, TR, amendments)
- Lab/vet/IACUC meetings, training
- Semiannual and other facility inspections
- Vet observations
- Animal care staff rounds
- Document review (e.g., protocol audit, surgery records)
- External visits / inspections

14

CONTINUING REVIEW

- Triennial review
 - PHS Policy IV.C.5
 - 9 CFR § 2.31(d)(5)
- Annual review (no longer required)
- Amendments

15

MEETINGS

- May be for-cause, upon lab request, educational, new to program
- Include PI, all personnel who work with animals
- Invite relevant veterinarian(s)
- Include IACUC staff
- Potential topics:
 - Institutional policies (new, relevant to lab)
 - Training needs/requirements
 - Experimental progress, problems

16

FACILITY INSPECTIONS

- Requirement for semiannual (i.e., every 6 months) inspection of animal holding and procedure rooms, surgical areas, dedicated/satellite areas
 - PHS Policy IV.B.2
 - OLAW FAQ E.1
 - § 2.31(c)(2)

17

FACILITY INSPECTIONS

- All other animal use locations should be visited too!
 - OLAW FAQ E.1: Institutions have discretion with regard to how they oversee areas used for routine weighing, dosing, immunization, or imaging, but should monitor such areas on a random or fixed schedule to effectively oversee activities at the institution
 - Frequency of inspections may vary based on usage, risks to animals/personnel

18

VETERINARY OBSERVATIONS

- New research teams (to the institution, species)
- New surgeons
- Surgery with sensitive species
- Novel procedures, model development
- Procedures expected to cause unrelieved pain, distress
- Complicated procedures with high mortality

19

ANIMAL CARE STAFF ROUNDS

- Personnel working in the facilities see animals regularly
- Well-positioned to identify changes, problems
- Provide access to relevant protocols
- Meet and greet with PIs/labs to discuss upcoming studies, experience, support

20

DOCUMENT REVIEW

- Protocol audits (with or without lab)
- Surgical records
- Research records (e.g., behavioral, FFR)
- Occ health injury reports
- Reports of adverse events, unexpected experimental outcomes involving animals

21

EXTERNAL VISITS & INSPECTIONS

- USDA Inspections
 - Annual (but can be more frequent), unannounced
 - Routine = evaluate facilities, records, animals
 - Focused = specific to a complaint, allegation
 - Both may generate recommendations
- AAALAC Site Visits
 - Triennial, planned
 - Site visit team evaluates entire program
 - Preparation of program description = great form of PAM

22

4. VALUE

23

WHAT ARE SOME BENEFITS OF PAM?



24

PAM BENEFITS

- Ensure animal well-being
- Provide opportunities for refinement
- Identify (and correct) potential noncompliance before it occurs
- Establish positive relationship with the research community
- Internal QA prior to regulatory/accreditation inspections
- Fulfill expectation of oversight bodies

25

IN CONCLUSION...

26

TAKE AWAY POINTS?

- PAM is everything we do after IACUC approval
- PAM can be educational or punitive, formal or informal
- Inspections, additional training, observations, audits, educational meetings, continuing review



27

LEARNING OBJECTIVES - RECAP



1. Define post-approval monitoring



2. Identify regulatory and oversight body expectations for PAM



3. Outline different methods of PAM



4. Recognize value of PAM in your program

28

QUESTIONS?

29