

SESSION GOAL

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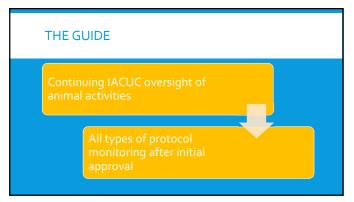
Understand expectations for post-approval monitoring (PAM) and different approaches to conduct PAM within an animal care and use program.

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1. DEFINE PAM

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2. REG/OB EXPECTATIONS

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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)

OLAW FAQ

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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

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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.

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

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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.

3. DIFFERENT METHODS

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HOW DO YOU DO PAM?

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



PAM METHODS

- · Lab/vet/IACUC meetings, training

- Animal care staff rounds

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CONTINUING REVIEW

- Annual review (no longer required)

MEETINGS

- May be for-cause, upon lab request, educational, new to program
- Include PI, all personnel who work with animals
- Invite relevant veterinarian(s)

- Potential topics:
 Institutional policies (new, relevant to lab)

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FACILITY INSPECTIONS

- Requirement for semiannual (i.e., every 6 months) inspection of animal holding and procedure rooms, surgical areas, dedicated/satellite areas

FACILITY INSPECTIONS

- - 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

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VETERINARY OBSERVATIONS

- Surgery with sensitive species

ANIMAL CARE STAFF ROUNDS

- Well-positioned to identify changes, problems
- Meet and greet with PIs/labs to discuss upcoming studies, experience, support

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DOCUMENT REVIEW

- Reports of adverse events, unexpected experimental outcomes involving animals

EXTERNAL VISITS & INSPECTIONS

- AAALAC Site VisitsTriennial, plannedSite visit team evaluates entire program

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4. VALUE

WHAT ARE SOME **BENEFITS OF** PAM?



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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

IN CONCLUSION...

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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



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

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QUESTIONS?