Reinventing a Post Approval Monitoring Program into a Collaborative Process that Ensures the Highest standards of Animal Welfare
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What is PAM?
- A program through which the IACUC can review and document program activities and adherence to the approved protocols
- Can serve as a way to facilitate collaborative exchange between researchers, the IACUC, and the PAM
- Can ensure the well-being of the animals and may also provide opportunities to refine research practices
- Can provide assurance to USDA and IACUC that animal activities are monitored for adherence to approved IACUC protocols

Requirement or Best Practice?
- The Goals
  - More of a variety of mechanisms to facilitate ongoing protocol assessment
  - PAM is considered in the broader sense
  - Formalized PAM program is suggested

  USDA
  - Continuing IACUC oversight of animal activities is required
  - No mention of PAM in the AAALAC regulations
  - GLAM
  - Formalized PAM process is not required

Previous PAM program challenges
- IACUC had become a "police state" over the researchers
- Researchers were nervous and fearful during observations
- IACUC members did not communicate appropriately prior to observations
- Corrective actions often harsh and did not promote collaboration
- Follow up was often prolonged based on meeting schedules

Goals of the new program
- Ensure animal welfare standards are met and foster a collaborative environment to ensure continuous improvement
- Increase communication and transparency between the IACUC, Animal Welfare Assurance (AWA), Veterinary Sciences (VS), and Researchers
- Foster an environment of collaboration between persons conducting PAM and researchers
- Identify refinements
- Identify and communicate best practices
- Commitment to improving animal welfare, scientific quality and care of the staff (Culture of Caring)

Who Will Be Involved?
- Members of the Animal Welfare Assurance team
- Veterinary Sciences staff
- Veterinarians, SMEs (subject matter experts)
- IACUC
- Principal Investigator (PI) and Research Personnel (always)

Selection of Protocols
- Will include a cross section of species and departments with an emphasis on:
  - Pain category: Category D and E protocols against which animals are ordered should be monitored at the discretion of the IACUC
  - Survival surgery
  - Studies performed in laboratories located outside of the vivarium
  - Studies that include novel or novel procedures, or retroactively conducted procedures
  - Previously monitored procedures for which the original PAM required corrective actions

Simplified Form
- Use of standardized, simple form to be completed by PAM team during or after the observations

Examples of Areas of Focus
- Is the protocol available? Are the researchers performing the procedures, knowledgeable of the procedures outlined in the protocol? (if SOPs if applicable)
- Training of Personnel – verify documentation
- Animal Numbers
- Ethniasim – conforms to protocol and IACUC policies
- Documentation – concise, reflects what protocol outlines
- Animal Environment / Enrichment – Micro and Macro Environments are as described in animal maintenance and enrichment SOPs
- Social Housing – If animal is single housed, is there a clinical reason or scientific justification for an animal to be single housed? Check documentation

Corrective Actions Requiring Follow Up
- Depending on the nature of the observations, the PAM Team will identify the appropriate time period within which a response from the PI or appropriate personnel is required
- It is the responsibility of the PI to ensure written responses to the concerns are provided, by the appropriate personnel and in the time period requested by the PAM Team

Corrective Actions Requiring Follow Up (cont.)
- A PAM team will follow up on any concerns that require revision of protocols, SOPs, training of personnel, etc. to ensure completion of the task
- On occasion, additional monitoring sessions may be part of the follow-up process to assure proper corrective actions have been implemented
- The IACUC will be updated on any required corrective actions at each meeting until closure

Bristol-Myers Squibb

New PAM Process
- Templated email sent to PI to schedule
- 5-10 minute meeting prior to observations to set expectations for the monitoring session
- Ask questions about protocol and procedures about to be observed
- Ensure researchers are comfortable with the team asking questions during procedures
- Create a collegial environment
- The PAM Team may discuss monitoring results with the research personnel involved in the activities during or after the PAM is conducted, as deemed necessary based on the observations. Use of standardized, simple form to be completed during or after the observations

Post Observations
- Brief meeting with researchers post observations to go over best practices and areas for improvement (avoid blindside)
- PAM team meets to discuss observations and implement plan for corrective action if warranted
- Memo sent to PI, researchers observed and members of PAM team
- Highlight best practices
- Provide guidance on areas for improvement noted

Benefits
- Maintains good communication between VS, IACUC and researchers
- Identifies areas for refinement
- PAM teams are seen as a benefit to research instead of a roadblock
- Allows IACUC members to focus on protocol review and the science
- Recognition to their management for positive outcomes
- Highlights the importance of animal welfare