FAQs for Post-Approval Monitoring

What is Post-Approval Monitoring?

* Post-approval Monitoring (PAM) is an observation of the research and verification of study documents. Conducting post approval monitoring is common in animal care and use programs and will help to ensure the safety of the research animals, appropriate applications and supporting documents are executed as approved, and any changes or adverse events are reported.
* PAM is not meant to be a “gotcha” moment nor are you being punished. You may actually see a benefit.

Seriously, a benefit?

Sure! Benefits that may be gained from a review include:

* Increased awareness of the policies and regulations that guide research at Appalachian State University;
* Increased communication between the IACUC and researchers;
* Being potentially identified as having a “best practice”;
* Having an opportunity to ask the IACUC any questions you have.

How are Research Projects Selected?

* The majority of protocols are selected randomly. Studies may be randomly selected from all approved and active protocols, without cause, no more than once per year. A study may be selected more than once in a given year if a “for cause” review is deemed necessary (i.e. At the IACUC’s request from a review, part of an investigation for non-compliance, upon PI’s request).
* Protocols that are pain class E, have USDA covered species, are funded, or considered higher risk to the animals, are more likely to be selected. Should a PI have multiple protocols, it is possible that each protocol may be selected once per year individually or all protocols may be reviewed at once.

What Should I Expect?

* Our goal is to make this as unobtrusive as possible. You will be asked to pull records/lab notebooks that demonstrate the protocol was followed as approved. You will be asked questions about how the research project is going in relation to problems or adverse events. The scope of review varies greatly depending on the research, but it will include:

1. Reviewing all records with the PI associated with animal care logs, animal health logs and drugs given to the animals;
2. Reviewing all animal housing, protocol facilities and animals on the protocol;
3. Reviewing the names of all personnel working with the animals;
4. Completion of the PAM Review Checklist.
5. Viewing a procedure at a future date (by appointment)

What are the possible outcomes?

Results from a PAM review include:

* **A highlighted best practice**: The practice will be shared with the IACUC and may be incorporated into guidelines;
* **Compliant with the protocol**: No further information or follow up is needed;
* **Minor deficiencies are noted:** The investigator provides a written plan in the resolution column to address the issues found within **30 calendar days**, and e-mails the document back to the Post-Approval Monitor;
* **Significant deficiencies are noted**: The IACUC chair and the committee are notified of significant deficiencies. The investigator provides a written plan to address the issues found within **15 calendar days**, and e-mails the document back to the Post-Approval Monitor; the protocol may be subject to a more in-depth review and monitoring to ensure all issues regarding compliance are met.

When will I know of the outcome of the PAM review?

If there are no findings or once the investigator satisfactorily responds to requests for clarification or revisions, a written report will be provided to the investigator within approximately a week from the review date. The IACUC will review a summary of PAM visits at each convened meeting.