POST APPROVAL MONITORING IACUC F.A.Q.'s

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(1) What is Post Approval Monitoring?
Post Approval Monitoring is an examination of the research facility and study documents to assure that animal subjects are protected, and the investigator is in compliance with applicable University and Federal regulations. Conducting post approval monitoring will help to ensure that appropriate applications and supporting documents are executed as approved, and any changes or adverse events are reported.

(2) What are Some of the Benefits that an Investigator May Gain?
Some possible benefits that may be gained from a review include but are not limited to:

* increased understanding of the regulations that guide all our research projects
* increased communication concerning updates to federal and university regulations
* access to resources and individuals to clarify the federal and university regulations

(3) How are Research Projects Selected?
The majority of protocols are selected randomly. Projects whose subjects are at a greater risk have a higher chance of being selected. If a protocol has been selected, it does not necessarily mean the investigator is doing something wrong.

Protocols can be selected for-cause from a complainant (study personnel, anonymous, etc.).

(4) How Long Will the Assessment Take?
If your documents are complete and organized, the review will take about one hour. If an investigator is not prepared, the review may take several hours.

(5) **What Should I Expect?**
You will be asked to pull records / lab notebook’s 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 may include:

* a tour of the animal facility
* viewing a procedure at a future date (by appointment)

(6) **What are the Possible Outcomes?**
There are several actions that could result from a PAM review. They include:

* Compliant, no follow up needed.
* Minor deficiencies, the investigator completes the assessment's resolution comment column with their plans to address the issues within one month and emails the document back to the Post Approval Monitor.
* Significant deficiencies, the investigator completes the assessment's resolution comment column with their plans to address the issues within the specified time and emails the document back to the Post Approval Monitor. Furthermore, the investigator will be reviewed again within six months to assure compliance. The IACUC will be notified of significant violations.

(7) **When will I Know of the Outcome?**
About a week from the review date.

(8) **What if the Primary Investigator is Unable to Attend the Meeting?**
It is preferred; however, you may designate a representative if you cannot attend.