IOWA STATE UNIVERSITY
Office of Research Ethics
Post-Approval Monitoring Program for the
Use of Animals in Research, Teaching, and Testing

PI Self-Assessment

The goal of post-approval monitoring is to confirm, by observation, accurate and consistent protocol performance in a collegial and unobtrusive manner. The program is also designed to help investigators, their teams, and the University prepare for external audits by funding, regulatory, and accreditation agencies.

Perhaps the most effective way to prepare for a post-approval monitoring visit is to *carefully and objectively* read your approved protocol and make sure that you and your staff are performing the research, teaching, or testing activities as described and approved by the Institutional Animal Care and Use Committee (IACUC). Many variables can play into the need for adjustment in the design, procedures, etc., of your protocol. The main thing to remember is that any changes to the IACUC approved protocol *must be approved by the IACUC prior to implementation.* It is easy to get caught up in the progress of research, teaching, or testing and forget to submit an amendment. Likewise, an issue may seem trivial to an investigator, but it may be of great concern to the IACUC, federal regulators, or auditors.

The staff of the Office of Research Ethics is always willing to assist in answering questions, or to help facilitate amendments to your protocol. They can be reached at 515-294-9581 or iacuc@iastate.edu.

KEY QUESTIONS

Protocol

- Are the research procedures being carried out consistent with those that have been approved by the IACUC?
    - Do amendments need to be made to reflect current procedures?
    - Are all animal procedures being performed listed on the approved protocol, i.e., blood collection, surgeries, treatments, euthanasia?
    - Is the number of animals used within the amount approved?
    - Has the species, sex, age, and strain of animals used been approved?
    - Have you reported unanticipated events/unexpected problems to the IACUC?
- Are all personnel performing the procedures listed on the protocol?
- Has the protocol been read by, and is it easily accessible to, all personnel performing the procedures outlined in the protocol?

Training

- Have the personnel performing experimental procedures been properly trained? Do you have any documentation or a training program?

- If your personnel are providing basic husbandry for your animals, are they appropriately trained?

- Do your personnel openly communicate with you about any animal health or welfare concerns (related or unrelated to the study)?

Record Keeping

- Are accurate records/documentation of your procedures, i.e., blood collection, injections, biopsies, etc., maintained?

- Are accurate records/documentation of animal monitoring maintained as outlined in your IACUC-approved protocol?

- Is documentation of procedural training maintained where appropriate?

- Is a log of the number of animals used for your protocol maintained?

- Are records for documenting non-protocol-related animal health concerns and treatments kept?

- Are all drugs within the expiration date? Has your anesthesia machine been properly calibrated?

If you have identified discrepancies between your current practices and those outlined in the approved protocol and these key questions, please make the appropriate corrections. This may require submitting an amendment to your protocol, or simply implementing better documentation practices.

Remember, the goal of post-approval monitoring is not to "catch" you doing something you aren't supposed to be doing. Rather, it is designed to facilitate research, teaching, and testing by making sure it is conducted in a manner where the conditions of Federal Regulations and University Policy are met, and by assisting investigators to identify and correct any deficiencies.