University Committee on Animal Care

Post-Approval Monitoring of Animal Study Protocols

Purpose:
After the UCAC has approved a protocol, it has the responsibility to ensure that procedures are carried out in the laboratory or classroom as described in the protocol.

Post-approval monitoring (PAM) is a comparison of the actual activities occurring under an approved protocol against the written protocol document, and includes the protocol-associated documents such as surgery records, animal orders, number of animals used, drugs used etc.

PAM is essential in order to ensure the well-being of animals involved in research and teaching activities, to ensure that activities are conducted in compliance with the regulations and standards of state and federal agencies and to ensure that activities are consistent and conducted in compliance with UCAC approved protocols as well as ETSU policies.

At ETSU PAM is accomplished in several ways and by various groups.

Monitoring of animal study protocols:
After the initial approval of a protocol it is re-reviewed by the UCAC every 6 months. The DLAR office initiates the review by sending a memo to the PIs with a synopsis of approved procedures and a list of participating personnel. The PI returns this memo with comments on any changes. If changes are noticed the PI must submit the necessary forms for addenda to the protocol. At least 2 members of the UCAC review the returned documents, and a summary report is submitted to the UCAC. Amendments are sent to the UCAC for review and approval.

Purchase of animals:
All warm-blooded vertebrate animals to be used for teaching, research, or testing at ETSU must be purchased or otherwise obtained through the DLAR. Animals will not be ordered, imported or otherwise acquired without an UCAC approved animal study protocol. According to the ETSU Animal Procurement policy the Director of the DLAR is responsible for approving the source of all animals to be housed in the animal facilities.

Monitoring and documentation of numbers of animals used.
All animal orders are entered into the DLAR data management system before they are placed with the vendor. This program tracks the species and number of animals approved in each pain/distress category for each protocol as well as the quantity ordered and received. When the preset limit of 80% of animals approved for a protocol is reached, the program will alert the DLAR and the PI is notified. If 100% is reached, the program will not allow the operator to enter the order and the order will not placed with the vendor. For in-house breeding colonies animals are entered into the data management system on the day they are weaned and the above limits are applied.

All animals/cages must be identified with cage cards listing the PI, his/her location, the animal=s species and strain and the animal study protocol number. From this cage card each animal can be traced to an approved animal study protocol.

Monitoring of experimental procedures.

1. By the UCAC: A subcommittee of the UCAC visits animal use laboratories at least once a year; laboratories where survival surgeries are performed are visited every 6 months. During these visits records on experimental procedures, anesthesia, analgesia, euthanasia and personnel training are reviewed for consistency with the approved protocol. The Subcommittee also monitors use of sterile procedures for survival surgeries and the expiration date on drugs used.
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2. **By the DLAR**: The trained DLAR staff provides routine day-to-day observation and monitoring of animal conditions and of animal research activities in the animal facilities. The Attending Veterinarian maintains a DEA license and dispenses controlled drugs to be used in animals only according to approved protocols. Dispensation records in the animal use laboratories are reviewed during the semiannual inspections, and every 2 years as mandated by the DEA.

3. **Policy for Reporting and Investigating Noncompliance with Animal Care and Use Policies**: Everyone at ETSU has the responsibility to report potential noncompliance with ETSU policies on animal care and use. No employee, member of the University Committee on Animal Care (UCAC), or laboratory personnel shall be discriminated against, or be subject to any reprisal, for reporting noncompliance with ETSU animal care and use guidelines. The UCAC will review and investigate any concern involving the care and use of animals arising from reports received and determines what actions are needed to correct a deficiency.

**ETSU Policies and Documents to Aid in Protocol Maintenance:**
- UCAC Guidelines: [http://www.etsu.edu/animals/dlar/UCACguidelines.pdf](http://www.etsu.edu/animals/dlar/UCACguidelines.pdf)
- Policies and Procedures for Reporting and Investigating Noncompliance with Animal Care and Use Policies: [http://www.etsu.edu/animals/dlar/noncomply.htm](http://www.etsu.edu/animals/dlar/noncomply.htm)
- Protocol review policy: [http://www.etsu.edu/animals/dlar/protocol.htm](http://www.etsu.edu/animals/dlar/protocol.htm)
- Animal Study Protocol incl. Special Forms: [http://www.etsu.edu/animals/dlar/protocol.htm](http://www.etsu.edu/animals/dlar/protocol.htm)
- Protocol amendments: [http://www.etsu.edu/animals/dlar/protocol.htm](http://www.etsu.edu/animals/dlar/protocol.htm)
- Use of Expired Medical Supplies and Drugs in Animals: [http://www.etsu.edu/animals/dlar/expired.htm](http://www.etsu.edu/animals/dlar/expired.htm)
- Guidelines for Aseptic Survival Surgery in Mammalian Animal Species Other than Rodents: [http://www.etsu.edu/animals/dlar/nonrodent.htm](http://www.etsu.edu/animals/dlar/nonrodent.htm)
- Guidelines for Rodent Survival Surgery: [http://www.etsu.edu/animals/dlar/rodent.htm](http://www.etsu.edu/animals/dlar/rodent.htm)
- Sterilization of Instruments & Supplies for Aseptic Surgery Procedures on Animals: [http://www.etsu.edu/animals/dlar/sterile.htm](http://www.etsu.edu/animals/dlar/sterile.htm)
- Studies for Field Studies Involving the Use of Vertebrate Animals: [http://www.etsu.edu/animals/dlar/FieldStudies.pdf](http://www.etsu.edu/animals/dlar/FieldStudies.pdf)
- The Use of Animals in Research and Education: [http://www.etsu.edu/animals/dlar/use.htm](http://www.etsu.edu/animals/dlar/use.htm)
- Animal Procurement: [http://www.etsu.edu/animals/dlar/procure.htm](http://www.etsu.edu/animals/dlar/procure.htm)
- Laboratory Animal Order Form: [http://www.etsu.edu/animals/dlar/order.doc](http://www.etsu.edu/animals/dlar/order.doc)
- Policy on Importation of Animals into ETSU Animal Housing Facilities: [http://www.etsu.edu/animals/dlar/import.htm](http://www.etsu.edu/animals/dlar/import.htm)