

University of Vermont

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Post-Approval Monitoring of Protocols Policy and Procedures

Protocol Monitoring Policy

An integral part of UVM's program for the care and use of animals is meaningful monitoring of protocols which have been approved by the IACUC. Each protocol submitted to the IACUC requires the Principal Investigator (PI) to sign an assurance that the protocol accurately reflects the procedures and care which affect research animals in any way. Protocol-monitoring is an ongoing process which ascertains that investigators are adhering to their protocol and documenting that adherence.

According to the Guide for the Care and Use of Laboratory Animals (NRC, 2011), the IACUC may utilize a variety of opportunities to monitor a protocol, including but not restricted to: "continuing protocol review; laboratory inspections (conducted during regular facility inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members, and external regulatory inspections and assessments." Post-approval monitoring should "support a culture of care focusing on the animals' well-being."

At UVM, the University Veterinarian is primarily responsible for the thoroughness and accuracy of post-approval monitoring. Compliance will be monitored during both scheduled and unscheduled visits to the animal and laboratory facilities. If assistance is required with this monitoring, the University Veterinarian may draw on technical staff or members of the IACUC for help in reviewing animal and laboratory records.

The protocol follow-up and monitoring process will address the following areas:

1. Protocol: up-to-date, agrees with procedures used by researchers
2. Personnel: listed in the protocol, verify adequacy of training by actual observation of procedures
3. Records: animals identified, activities documented, proper surgery & anesthesia records, animal observation documented, unscheduled deaths or other health problems documented and veterinarians notified
4. Laboratory: locations stated correctly in protocol, lab maintained in proper condition, correct storage of pharmaceuticals and other chemicals

Laboratory personnel will be notified to correct any noncompliant areas identified in the process. The PI and the IACUC will receive a written report of the visit. It is the responsibility of the PI to correct deficiencies in a timely manner. It is the responsibility of the IACUC to confirm with the PI that corrections have been made and adequately documented.