

Statement on Protocols and Protocol Violations

Federal and University policies require that all research and teaching activities conducted at the University of Wisconsin-Madison that include the use of animals be reviewed and approved by one of the campus Animal Care and Use Committees (ACUCs) before any procedures are initiated. An essential element in the required ACUC review and approval process is the submission of an animal use protocol containing a clear and comprehensive description of the proposed studies, a detailed accounting of experimental procedures and a justification for the inclusion of animals. Unlike a grant application that serves as a guidance document the specifics of which can be modified at the discretion of the investigator, ***an animal use protocol is considered a contractual agreement between the investigator and the ACUC.*** Modification of ***any*** element of an ACUC approved protocol without ACUC pre-approval of the specific change constitutes a protocol violation. Depending on the nature and/or frequency of such violations, the ability to conduct research involving animals may be temporarily suspended or revoked entirely.

The following list provides examples of common protocol violations cited by USDA inspectors and the Office of Laboratory Animal Welfare (OLAW):

- Using more animals than approved by the ACUC
- Changing species or strains used without ACUC approval
- Performing surgery or other procedures not described in the protocol
- Performing more surgeries than approved by the ACUC
- Repairing or replacing implants or performing surgical repairs if not approved by the ACUC
- Providing medical care for sick or injured animals without consulting an attending veterinarian
- Altering diet for experimental purposes without ACUC approval
- Collecting blood or tissue samples unless specified in an approved protocol
- Collecting more blood or tissue than described in the protocol or using an altered collection schedule
- Changing the type or dose of drug administered (unless approved by a campus veterinarian for clinical reasons)
- Failure to conduct pre-procedure blood panels if described in the protocol
- Failure to adhere to endpoints defined in an approved protocol
- Failure to document post-surgical or post-anesthesia monitoring
- Conduct pilot studies without ACUC approval
- Failure to monitor animals or make observations as specified in an approved protocol
- Restraining an animal for periods exceeding those approved by the ACUC
- Involving personnel not listed on the protocol