

## **Algoma University Animal Care Committee Animal Use Protocol Form Information and Directions**

Algoma University Animal Care Committee (AUACC) has an ethical, scientific, and social responsibility to apply protocol review and approval criteria in a fair, equitable and consistent manner. This requires the provision of complete and appropriate information by the investigator. Not all protocols, however, require the same level of review: the intensity of the review should vary directly with the level of invasiveness of the procedures ([Categories of Invasiveness in Animal Experiments](#): CCAC, *Guide to the Care and Use of Experimental Animals, Vol. 1, 2nd Ed., 1993*, pp. 201-202). Protocols involving physical and/or psychological distress (pain, fear) must be fully reviewed and require strong scientific justification that is clearly supported by current knowledge.

All aspects of the review process, including protocol approval status, amendments, clarifications, modifications, and renewals must be documented, regardless of the category of invasiveness.

A summary of the primary aims and proposed use of animals must be provided in a language understandable to a layperson. This should include a description of procedures designed to assure that animal suffering will be prevented or at least minimized. The submission of sections of grant proposals containing excessive detail of procedures not related to the use of animals is inappropriate, but may be helpful if related to scientific merit or statistical analysis. The ACC members should request investigators to provide all descriptions with a minimum of technical jargon: the ACC is primarily interested in the responsible, humane use of animals.

Each protocol must be reviewed annually (via the Renewal Form) and must take into consideration changes in standards and guidelines, and developments in the replacement, reduction, and refinement of experimental animal use. Renewal applications (up to a maximum of 3 per protocol) should permit the ACC to review the progress of the research.

Minor modifications proposed prior to annual renewals must be documented in a Modification Form, and is subjected to the same level of review and information requirements as a new application. Major modifications require the completion of a new Animal Use Protocol, and must be approved and documented by the ACC before being initiated by the investigator. A protocol cannot be renewed more than three times; after three renewals, a complete, new protocol should be submitted. Examples of Major and Minor modifications are provided at the end of this document.

A faculty and/or staff member must accept responsibility for the project. In addition, a knowledgeable member of the research project must be available for contact at all times. Requirements for permits for wildlife studies, use of radioactive compounds, biohazards, and other special circumstances must be reported in the protocol. Generally, copies of permits/licences should be filed with the ACC before the project begins. When the acquisition of a Provincial Wildlife Permit is directly relevant to issues of animal use, a copy of the Permit should accompany the protocol.

All animal users must complete an Animal Use Protocol form for each proposed project to be reviewed by the AUACC. Please use the information below as a general guideline to the type and level of detail of information required in this Form. Please respond to each of the points in a manner that is clear and that all members of the ACC can readily understand. You may attach separate sheets should more space be required.

## **Detailed Information**

### **1 – 4. PERSONAL INFORMATION**

Provide detailed contact information for the Principle Investigator and all others that might play a role in the care and use of the animals.

### **5. FUNDING**

ACCs must ensure that all Animal Use Protocols under review have been peer reviewed for scientific merit. Proposals associated with competitive funding applications to agencies (e.g., NSERC, CIHR) with adequate peer review processes generally do not require further review for scientific merit. The requirement for scientific merit should normally be satisfied if the application is funded. Where ACC approval is required by the funding agency before it will review the application, ACC approval should be provisional, pending assurance from the funding agency that the application has high scientific merit.

Projects approved and funded by some agencies or organizations, or from internal funds may have been subjected to little or no peer review. Some funding agencies award "Program Grants" which, unlike their "Project Grants", may include animal use that is not subjected to a focused peer review for scientific merit. When evidence of good peer review is absent, it is the responsibility of the Research Office to ensure that scientific peer review of the objectives, hypotheses, methods and contributions of the project is conducted by knowledgeable scientists who do not collaborate with the investigator. The reviews must be documented and must contain sufficient information to support the reviewers' conclusion(s).

### **7. TYPE OF EXPERIMENT**

The use of animals for educational purposes is markedly different in its objectives than the use of animals in research or testing. Animals used for educational purposes are not being used to discover, prove or develop new ideas or techniques, but rather to demonstrate principles which are already well-known or to learn manual skills and techniques. The repetitive use of animals in this manner should be based on sound ethical justification and proven educational objectives.

There should be justification provided for the use of animals over the use of alternatives such as models, videos, computer simulations and emulations, etc. The level and type of training of the students (graduate/postgraduate, specialized/non-specialized) are important considerations in ascertaining the need to use animals.

Teaching protocols are subject to the relevant aforementioned review considerations, as well as to the factors of student inexperience and "group" projects. Thus, the description should include the number of students per animal, and the student/teacher ratio. The level of experience and competence of the instructors and/or teaching assistants must be adequate to assure successful preparations and procedures. The disposition of the animals at the end of the teaching session must be clearly described.

Painful experiments or multiple invasive procedures on an individual animal, conducted solely for the instruction of students in the classroom, or for the demonstration of established scientific knowledge, cannot be justified.

### **9. SUMMARY OF OBJECTIVES AND BENEFITS**

Clear statements on the purpose (specific scientific objectives) and potential value of the study (originality and importance of the new information) are required. Information provided within the protocol review form should provide the ACC with a clear sense of the need for the experimental project, and of the relationship between the proposed experiment and the overall objective.

### **10. CATEGORY OF INVASIVENESS**

The following are examples for each of the Categories of Invasiveness, as derived from the CCAC's policy statement.

#### **A. Experiments on most invertebrates or on live isolates**

**Possible examples:** studies in which the animals are observed without any disturbance to them; the use of tissue culture and tissues obtained at necropsy or from the slaughterhouse; the use of eggs, protozoa or other single-celled organisms; experiments involving containment, incision or other invasive procedures on metazoan.

#### **B. Experiments which cause little or no discomfort or stress**

**Possible examples:** observational studies in which there is some disturbance to the animals but not to the point that the same individuals are repeatedly observed so as to habituate or otherwise modify their behaviour; census or other surveys which disturb animals but which do not involve capture or marking individuals; non-invasive studies on animals that have been habituated to captivity; short periods of food and/or water deprivation equivalent to periods of abstinence in nature.

Also, domestic flocks or herds being maintained in simulated or actual commercial production management systems; the short-term and skillful restraint of animals for purposes of observation or physical examination; blood sampling; injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral, but not intrathoracic or intracardiac (Category C); acute non-survival studies in which the animals are completely anesthetized and do not regain consciousness; approved methods of euthanasia following rapid unconsciousness, such as anesthetic overdose, or decapitation preceded by sedation or light anesthesia; short periods of food and/or water deprivation equivalent to periods of abstinence in nature.

#### **C. Experiments which cause minor stress or pain of short duration**

**Possible examples:** capture, using methods with little or no potential to cause injury and marking of animals for immediate release; long-term observational studies on free-ranging animals where the behaviour of individuals may be altered by repeated contact; brief restraint for blood or tissue sampling; short periods of restraint beyond that for simple observation or examination, but consistent with minimal distress; short periods of food and/or water deprivation which exceed periods of abstinence in nature; exposure to non-lethal levels of drugs or chemicals; low velocity darting and slow-injection darts with immobilization chemicals. Such procedures should not cause significant changes in the animal's appearance, in physiological parameters (such as respiratory or cardiac rate, or fecal or urinary output), in social responses or inability to survive.

Also, cannulation or catheterization of blood vessels or body cavities under anesthesia; minor surgical procedures under anesthesia, such as biopsies, laparoscopy; short periods of restraint beyond that for simple observation or examination, but consistent with minimal distress; short periods of food and/or water deprivation which exceed periods of abstinence in nature; behavioral experiments on conscious animals that involve short-term, stressful restraint; exposure to non-lethal levels of drugs or chemicals. Such procedures should not cause significant changes in the animal's appearance, in physiological parameters such as respiratory or cardiac rate, or fecal or urinary output, or in social responses.

*Note: During or after Category C studies, animals must not show self-mutilation, anorexia, dehydration, hyperactivity, increased recumbency or dormancy, increased vocalization, aggressive-defensive behavior or demonstrate social withdrawal and self-isolation.*

## D. Experiments which cause moderate to severe distress or discomfort

**Possible examples:** capture, using methods that have the potential to cause injury (e.g., high velocity darting and rapid-injection darts with immobilization chemicals, net gunning, etc.); maintenance of wild caught animals in captivity; translocation of wildlife to new habitats; major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioural stresses such as maternal deprivation, aggression, predator-prey interactions; procedures which cause severe, persistent or irreversible disruption of sensorimotor organization.

Other examples include induction of anatomical and physiological abnormalities that will result in pain or distress; the exposure of an animal to noxious stimuli from which escape is impossible; the production of radiation sickness; exposure to drugs or chemicals at levels that impair physiological systems.

*Note: Procedures used in Category D studies should not cause prolonged or severe clinical distress as may be exhibited by a wide range of clinical signs, such as marked abnormalities in behavioral patterns or attitudes, the absence of grooming, dehydration, abnormal vocalization, prolonged anorexia, circulatory collapse, extreme lethargy or disinclination to move, and clinical signs of severe or advanced local or systemic infection, etc.*

## E. Procedures which cause severe pain near, at, or above the pain tolerance threshold of unanesthetized conscious animals

This Category of Invasiveness is not necessarily confined to surgical procedures, but may include exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs or chemicals at levels that (may) markedly impair physiological systems and which cause death, severe pain, or extreme distress; completely new biomedical experiments which have a high degree of invasiveness; behavioral studies about which the effects of the degree of distress are not known; environmental deprivation that has the potential to seriously jeopardize an animal's well-being; use of muscle relaxants or paralytic drugs without anesthetics; burn or trauma infliction on unanesthetized animals; a euthanasia method not approved by the CCAC; any procedures (e.g., the injection of noxious agents or the induction of severe stress or shock) that will result in pain which approaches the pain tolerance threshold and cannot be relieved by analgesia (e.g., when toxicity testing and experimentally-induced infectious disease studies have death as the endpoint); capture methods with a high potential of causing severe injury that could result in severe chronic pain and/or death (e.g., leghold traps).

# 11. PURPOSE OF USE

The following are examples of each of the possible purposes of animal use, as derived from the CCAC's policy statement.

## A. Studies of a fundamental nature in sciences relating to essential structure or function (e.g., biology, psychology, biochemistry, pharmacology, physiology, etc.)

**Possible examples:** studies designed to understand the cellular and/or molecular basis of inflammatory reactions or other basic physiological or biochemical reactions; studies designed to understand one or some of the various facets of the role played by a hormone or other compound produced by mammals; studies designed to better understand the behavior of various species; studies designed to better understand the population dynamics of various species

**B. Studies for medical purposes, including veterinary medicine that relate to human or animal diseases or disorders** (e.g., studies carried out to better understand a specific disease or disorder and to help find therapies for it.)

**Possible examples:** development of a mouse model for a specific type of cancer or other disease; studies to determine which antibodies are the most likely to contribute positively to the therapy of a specific type of cancer; studies to determine which molecule within a particular class of compounds is the most likely to contribute to maintaining stable blood glucose levels in an animal model of diabetes

**C. Studies for regulatory testing of products for the protection of humans, animals, or the environment**

**Possible examples:** safety testing, regulatory toxicology, vaccine efficacy trials, and testing of new therapeutic compounds (if it is to generate data that is going to be used in a submission for an Investigational New Drug Application (IND) or for a New Drug Submission (NDS)); shellfish toxin

**D. Studies for the development of products or appliances for human or veterinary medicine** (e.g., studies carried out to investigate potential therapies (as determined following studies of PAU 2) for humans or animals, before regulatory testing (PAU 3) is carried out on the most promising therapies)

**Possible examples:** studies undertaken in animals to investigate the role and effects of a specific drug or immunotherapy candidate for cancer; studies undertaken to develop physical devices to assist heart function; studies undertaken to develop artificial organs.

**E. Education and training of individuals in post-secondary institutions or facilities** (e.g., teaching or training programs where animals are used to introduce students to scientific work and teach manual skills and techniques)

## **12. PROCEDURES PERFORMED (please refer to, and attach, all Standard Operating Procedure documents (SOPs))**

### **PHYSICAL RESTRAINT**

Physical restraint, e.g., short-term hand-held or mechanical (stocks or squeeze cages) restraint is often required for examination, collection of samples, and a variety of other clinical and experimental manipulations. Restraint induced stress can be minimized by conditioning of the animal, use of appropriate devices suitable in size and design, and proper operation by experienced personnel.

Physical restraint extending beyond a few minutes should only be used on conscious animals after alternative procedures have been considered and found to be inadequate. Steps must be taken to condition the animals to the restraining device to minimize stress and discomfort during the experimental procedures. If restraint is necessary, the device must provide the animal with the greatest opportunity to assume its normal postural adjustments, and the duration of restraint must be minimized. The prolonged chairing of non-human primates must be avoided.

The duration of restraint should take into consideration factors such as species, health and age of the animal, and level of restraint. A level of restraint which prevents movement of groups of muscles must be brief enough to avoid painful muscle cramping and requires constant supervision. Restraint which allows only restricted movement of muscle groups must also be brief enough to avoid painful physical discomfort or distress and requires constant supervision. Restraint which allows unrestricted movement of all muscle groups, but restricts locomotion and other activities requiring whole body movement should be interrupted regularly by periods of exercise. If not previously established, the acceptable duration and level of restraint should be established by a pilot study under veterinary supervision. Supervision of restrained animals must be done by qualified personnel.

### **INVASIVE/STRESSFUL PROCEDURES**

A description of the preparative regimen should be provided which includes, as applicable, a description of the

animal preparation and procedures, specification of any antibiotic or tranquilizers to be administered, ventilation procedures, instrumentation (i.v. lines, catheters, etc.). The dose (e.g., mg/kg) and route (e.g., i.m., i.v.) of any compound to be administered must be stated. When repetitive use of a particular methodology is anticipated, the ACC should require the investigator to develop a detailed Standard Operating Procedure for submission to the ACC.

The type of monitoring and the criteria used to assess the level of anesthesia/analgesia, e.g., respiration/heart rate, EKG, toe pinch, corneal reflex, color of mucus membrane, muscular relaxation, should be provided, as well as a brief technical description of the procedure. Other information should include the source, method, volume and frequency of sampling when blood or tissue recovery is employed. There should be a clear relationship between each procedure and the objective(s) of the research.

Estimation in advance of any potential adverse effects on the animal will assist in developing plans to prevent, monitor and relieve as much suffering as possible during the post-procedure period. All animals must be monitored at appropriate intervals which are dictated by the nature of the procedure(s), the degree and duration of potential post-procedure physical and/or psychological distress, and possibility of complications. For example, monitoring may be required at more frequent intervals during the immediate post-surgical period (e.g., first 24 hours post-operatively) and during the latter stages of tumor induction or toxicology experiments that have associated morbidity and mortality.

Criteria should be established to assess the presence and severity of post-procedure distress, and to provide a basis for analgesic administration or other procedures to minimize or eliminate the distress. In evaluating distress in animals, species-specific behavioral changes, e.g., in vocalization, appearance/posture, locomotion, temperament- and physiological signs, e.g., weight, heart rate, respiration, appearance of urine and feces, weakness/paralysis, must be looked for.

It is important to note that many sources of distress may be unrelated to the procedures performed. These include: variable or inappropriate temperature, humidity, illumination or ventilation; inappropriate cage or enclosure space; inappropriate intensity or type of noise; unsatisfactory species-specific sanitation practices; and negative social conditions (e.g., overcrowding, isolation, incompatibility, maternal deprivation). A description of the housing and transportation of animals is required, and the precautions used to mitigate the associated distress.

The administration of analgesics or use of other distress-reducing measures should be based on the premise that where physical and/or psychological distress is a concern, the animal should be given the benefit of the doubt. Conversely, the active withholding of these measures, where their use is indicated, must be based on scientific fact or experimental data, as documented by pertinent literature, or data from pilot studies.

Multiple surgical or other repetitive highly stressful procedures on a single animal are generally unacceptable and are not adequately justified by cost savings. These protocols must undergo stringent ethical and welfare review for justification.

## **CAPTURE, TRANSPORTATION, AND HOUSING**

Experimental procedures involving the capture, handling and release of wild animals are of special concern: lack of conditioning results in high degrees of stress in captured wild animals; therefore the necessity for capture, handling and/or administration of drugs or other compounds must be clearly established. Detailed descriptions of all pursuit, capture, handling and chemical restraint procedures, and explanations of their appropriateness, are essential. Criteria used to assess suitability for release must be clearly stated. Provision for recovery, treatment, or euthanasia of injured animals and disposal of carcasses must be specified.

If traps are to be used, the type of trap, its injury potential, and the monitoring frequency of the traps are important considerations. The collection of samples and affixing of devices to the animal subject(s) must be described (weight, method of attachment, duration) and be clearly related to the objective(s) of the study. Protocols for field studies involving population sampling by killing of animals, using methods such as shooting, must include justification for the method used. The use of such methods must be by individuals with sufficient experience and expertise to ensure that animals are humanely killed.

Wildlife research may involve the use of specialized holding areas and transportation of animals. The potential for injury to personnel and the animal subjects during these procedures should be minimized. The holding of wild animals in highly confined enclosures for extended periods should be avoided.

Ecological disruption may result from the performance of some types of field studies. The type and degree of disruption expected (or its potential) must be indicated, e.g., the adverse consequences to survival and reproduction experienced by the herd, colony, or individual animal subject due to the study procedures.

## **14. HAZARDOUS AGENTS**

Appropriate approval for the use of hazardous agents (radioactive materials, recombinant DNA/RNA, human/plant/animal pathogens, acute toxins, chemical carcinogens, ethers) must be filed with the ACC before the project begins. Brief descriptions of the potential health risks to humans or animals, special animal care required, precautions for personnel, special containment requirements, specific storage, waste, and animal disposal requirements, and emergency procedures must be provided as part of the protocol form or in an appended copy of the approval application. In most cases, approval in the form of a permit from the institutional Occupational Health and Safety Committee will be required.

## **16. REPLACEMENT, REDUCTION, AND REFINEMENT**

### **(a) REPLACEMENT ALTERNATIVES TO ANIMAL USE**

If the scientific objectives of the study can be achieved by using available non-animal models or animals of low sentience, the ACC must require consideration by the investigator of the alternative to live and/or more sentient animals and justification for its rejection. The absence of replacement alternatives should be supported by a brief description of the methods and sources used to determine that alternatives were not available, and/or an explanation of the aspects of the protocol that preclude using non-animal models or animals of lower sentience. A simple statement that there is no replacement alternative is insufficient.

### **(b) REDUCTION OF ANIMAL USE/NUMBERS**

The information provided must include a clear description of the experimental design along with the statistical rationale which supports the size of the control and test group(s). A pilot study may be recommended by the ACC, particularly when large numbers of animals are requested for a new study, to provide data for a more accurate assessment of the invasiveness of the procedure and number of animals required. Overall, the number of animals to be used must be optimized to the greatest extent possible consistent with sound scientific and statistical standards, i.e., not below or in excess of the number required to produce statistically valid experimental data.

### **(c) REFINEMENT OF EXPERIMENTAL TECHNIQUE**

Once it has been determined that the use of animals is necessary and there is appropriate justification for the number requested, the ACC and the investigator have a shared responsibility to ensure that the husbandry practices and experimental procedures employed minimize or eliminate physical and/or psychological distress within the limitations imposed by the objectives of the research.

All members of ACCs and all investigators have the responsibility to continuously refine procedures. Some examples of potential areas of refinement include: increased training and expertise of personnel; environmental enrichment for captive animals; well planned, pre-, intra-, and post-procedure care management; proper anesthesia/analgesia; selection of more humane endpoints; proper methods of euthanasia; less invasive surgery; less toxic adjuvants; and appropriate transportation/transfer methods.

## **17. ENDPOINTS and EUTHANASIA**

The term “endpoint” is defined as the point at which an experimental animal’s pain and/or distress is terminated, minimized, or reduced by taking actions such as humanely killing the animal, terminating a painful procedure, or giving treatment to relieve pain and/or distress. An endpoint might also involve restoring a basic requirement (e.g., withdrawing an unpalatable experimental diet and restoring a palatable diet at a certain level of weight loss, or restoring group housing for a social species where isolation is determined to cause distress).

The [\*CCAC guidelines on: choosing an appropriate endpoint in experiments using animals for research, teaching, and testing \(1998\)\*](#) states: “In experiments involving animals, any actual or potential pain, distress, or discomfort should be minimized or alleviated by choosing the earliest endpoint that is compatible with the scientific objectives of the research.”

Researchers are expected to have in place a manner for identifying and objectively measuring the various stages of discomfort, pain, and distress. The AUACC has developed the Animal Illness Report and Checklist to assist in monitoring the behavioural and physiological effects of the study on the animals. Principal Investigators, in consultation with the laboratory animal veterinarian and the animal care committee, must determine at what point an animal’s pain and distress should be terminated.

The lack of a well-defined, humane endpoint is often a key issue in protocol review. When morbidity is anticipated, its time course and severity, monitoring frequency, training and expertise of the monitors, care and treatment, and provision for unexpected complications are all important considerations for the ACC. If the expected frequency, severity, and signs of morbidity are unknown, a pilot study under close veterinary observation should attempt to answer these questions. Death or morbidity as endpoints must be avoided. Animals must be euthanized at the earliest possible endpoint consistent with the scientific objective(s) of the proposal, and in accordance with acceptable criteria for determining the endpoint.

Procedures that involve sustained and/or inescapable severe pain or deprivation in conscious animals, i.e., [\*Category E\*](#) experiments, are considered highly questionable or unacceptable, irrespective of the significance of anticipated results. The CCAC’s [\*Ethics of Animal Investigation\*](#) document ([\*Appendix XV: CCAC, Guide to the Care and Use of Experimental Animals, Vol. 1, 2nd Edn., 1993\*](#)) states: "An animal observed to be experiencing severe, unrelievable pain or discomfort should immediately be humanely killed, using a method providing initial rapid unconsciousness" and "Studies such as toxicological and biological testing, cancer research and infectious disease investigation may, in the past, have required continuation until the death of the animal. However, in the face of distinct signs that such processes are causing irreversible pain or distress, alternative endpoints should be sought to satisfy both the requirements of the study and the needs of the animal".

In addition to the selection of an appropriate method of euthanasia, the training and competence of the individual(s) performing euthanasia should be specific for the species and method used ([\*CCAC guidelines on: euthanasia of animals used in science \(2010\)\*](#) and [\*Appendix XIV: CCAC, Guide to the Care and Use of Experimental Animals, Vol. 1, 2<sup>nd</sup> Edn., 1993\*](#)). The criteria for euthanasia, in terms of species-specific behavioral changes and physiological signs, or in relation to the experimental design, must be clearly described.

If surviving animals are not to be euthanized during, or upon completion of the study, a description of their future disposition must be included.

## **MAJOR VS. MINOR MODIFICATIONS**

Examples of change in animal use procedures that could affect animal welfare and are generally considered to be **major** (significant), therefore warranting a *new Animal Use Protocol* and full AUACC review:

- Change in purpose, specific aim or objectives of a study.
- Switching from nonsurvival to survival surgery.
- Change in protocol that would require an animal to undergo more than one survival surgery.
- Change in protocol that would require animals to be fed, housed or cared for in a way that is not standard for that species, or does not meet that species' minimum requirements.



- Increase in the degree of invasiveness of a procedure or discomfort to an animal.
- Change in protocol that would eliminate or restrict an animal's access to veterinary care.
- Change of species.
- Addition of another strain of the same animal species
- Addition of USDA-regulated species.
- Significant increase in number of animals used over that projected: for example, an increase of 10% for projects approved for greater than 20 animals, or, an increase of 3 animals for projects approved for 6 to 20 animals, or, an increase of 1 animal for projects approved for 5 or fewer animals.
- Withholding of analgesics.
- Change in methods of euthanasia.
- The duration, frequency, or number of procedures performed on an animal (e.g., repeating an experiment using the same animals).
- Addition of survival surgery.
- Addition of a painful procedure.
- Change in protocol where death becomes the experimental end point. For purposes of this criterion, death is defined as natural death resulting from experimental conditions (rather than euthanasia at a time when a set of criteria recognized as the end point is met).
- Unanticipated marked increase in clinical signs or proportion of animal deaths
- Increased number of animals to be captured
- Addition of blood collection to the protocol, if not previously proposed/approved

Examples of changes considered to be **minor** and therefore require the submission of a *Modification Form* for ACC approval:

- Substitution, addition or deletion of personnel or collaborator, excluding principal investigator.
- Change in sex of animal to be used
- Small increase in animal numbers
- Need to repeat an experiment using additional animals (i.e., small increase in the number of animals, see guidelines above under major modifications re: number of animals)
- Addition of minor surgery
- Change in the amount of previously approved sample(s) collections (e.g., blood), if within guidelines.
- A change in procedure that is more specific than the language required in the original protocol does not require an amendment or AUACC approval, provided the change is not expected to increase pain or distress. (e.g., changes in needle gauge, surgical instruments, vehicle for injections, and use of post-mortem tissue.)
- Replacing a procedure with another less painful, stressful or hazardous that achieves the same specific objectives
- Changing experimental design to reduce the use of animals
- Adding a comparable strain or treatment (e.g., Wistar to Sprague-Dawley; change in vector) if no change in pain, distress, or biosafety is expected.
- Removing a proposed experiment from a protocol.
- Updating the alternatives section of a protocol (including Policy 12).
- Changing or adding analgesia or anesthetic on veterinary recommendation.
- Adding a procedure or treatment that is considered pain category "B" if the change does not significantly increase the numbers of animals approved or the duration of the study (e.g., add a nonstressful behavioral test).