



Institutional Animal Care and Use Application Instructions

Information and Instructions for Using CSUSM Form "Application to Use Vertebrate Animals in Research, Testing, and Instruction"

ATTENTION! As you complete the Application to Use Vertebrate Animals in Research, Testing, or Instruction, or the Application to Use Vertebrate Animals in Observational Research, please be aware that copies of completed applications may be released to the public. As you prepare the application, be frank in your responses but keep in mind that the completed application may become public knowledge after the project is approved and funded. If there is a request for your application, you will be notified prior to release. Please read all instructions and answer each question carefully. **If you do not follow appropriate procedures for obtaining approval, all Federal Funding for CSUSM may be jeopardized.**

GENERAL INFORMATION AND INSTRUCTIONS

University policy and federal law require a review of projects for humane treatment and safe use of vertebrate animals. At CSUSM, the review is conducted by the Institutional Animal Care and Use Committee (IACUC). Approved applications are valid for the specified project period or three years, whichever is less. Normally, IACUC will review the application within 30 days of receipt; the US Public Health Service requires verification of IACUC approval of animal care and use within 60 days after submission of an application or proposal.

With the exception of some observational research (see below), principal investigators and course directors must obtain approval from IACUC before initiating any research, testing or instructional project involving the use of vertebrate animals. Approval must be obtained for projects for which animals are purchased as well as for projects for which animals are not directly purchased (e.g. wild trapping, donated, "in-house breeding", obtained from other laboratories or other noncommercial sources). Only those species that are listed in the approved application may be procured. In conjunction with the start of a project, an approval number will be assigned. No project involving the use of vertebrate animals will be initiated without an approval number. IACUC approval must also be obtained prior to significant changes in approved protocols. IACUC does not review projects for scientific merit except as the question of merit bear on humane treatment or safe use of the animals. Scientific merit review is the responsibility of external agencies or the relevant university unit or department. IACUC's principle areas of concern are housing and husbandry, health status of animals, veterinary medical care, measures to minimize pain or discomfort, and the adequacy of training or experience of the personnel using the animals.

Observational research that is not federally funded does not need IACUC approval but it does require IACUC review to determine if the proposed study meets the definition of observational research. Observational research is defined here as investigations of either 1) free-living wild animals in their natural habitat that involve no capture or handling and do not harm or materially alter the behavior of the wild vertebrates under study; or 2) observations of captive animals that involve no capture or handling beyond what takes place in the context of normal husbandry activities. Investigators planning observational research should use the form, "Application to Use Vertebrate Animals in Observational Research."

Pain Categories: In item 1 of the Application to Use Vertebrate Animals in Research, Testing, or Instruction, investigators/course directors must categorize their use of vertebrate animals on the basis of the discomfort or pain involved. The IACUC has designated four categories. Examples of procedures in each category are given below.

Category B	Category C	Category D	Category E
<p>Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research or surgery but not yet used for such purposes.</p>	<p>Category C investigations involve handling, procedures in, or manipulation of live vertebrate species that produce momentary, little or no pain or distress and would not warrant relief of discomfort or pain.</p>	<p>Animals subjected to potentially painful or stressful procedures for which they receive appropriate nursing care, anesthetics, analgesics and/or tranquilizer drugs.</p> <p>Such projects present an explicit responsibility on the part of the Principal Investigator to justify the experimental design and to employ alternative methods wherever possible to ensure that pain and distress is minimized or avoided.</p>	<p>Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics, and/or tranquilizer drugs. Withholding anesthesia/analgesic must be scientifically justified in writing and approved by the IACUC.</p> <p>Such activities are considered highly questionable and must be deemed irrefutably necessary by design to receive IACUC approval.</p>
Examples	Examples	Examples	Examples
<ol style="list-style-type: none"> 1. Animals being housed, without any research manipulation, prior to transfer to another protocol. 2. Observation of animal behavior in the wild without manipulating the animal or its environment. 	<ol style="list-style-type: none"> 1. Handling or weighing animals in teaching, outreach, or research activities. 2. Procedures involving momentary and skillful restraint. 3. Observation of animal behavior in the lab. 4. Ear punching o rodents 5. Tail snips in mice ≤21 days old. 6. Peripheral injections (intra-venous, intra-muscular, intra-peritoneal, sub-cuticular, or intra-dermal), or percutaneous (non-surgical) catheter implantation. 7. Oral dosing of IACUC approved compounds. 8. Non-invasive tissue sampling or intra-vascular blood samples 9. Dietary or feed studies, which do not result in clinical health problems. <p><i>Continued on next page</i></p>	<ol style="list-style-type: none"> 1. Any Survival surgery. Including invasive surgical procedures that could involve significant post-operative discomfort, multiple major survival surgeries, organ transplantation/grafting, intrusive craniotomies, or the use of paralytic drugs, but for which appropriate post-operative analgesics, anesthetics and nursing care provide relief from the potential pain or distress. 2. Non-survival surgical procedures 3. Laparoscopy or needle biopsies 4. Retro-orbital blood collection (which is done under anesthesia) <p><i>Continued on next page</i></p>	<ol style="list-style-type: none"> 1. Toxicological or microbiological testing, cancer research, or infectious disease research that requires continuation after clinical symptoms are evident without medical relief or require death as an endpoint. 2. Ocular or skin irritancy testing. 3. Food or water deprivation beyond that necessary for ordinary pre-surgical preparation. 4. Application of noxious stimuli, trauma, or shock (such as electrical shock) that the animal cannot avoid/escape. <p><i>Continued on next page</i></p>

<ol style="list-style-type: none"> 10. Food restriction that reduces the animals weight by no more than 20% of normal age matched controls 11. Routine non-invasive agricultural procedures associated with livestock husbandry. 12. Live trapping and non-invasive identification methods (i.e., superficial tag placement, ear notching). 13. Positive reward training or research. 14. Chemical usage such as antibiotics, sedatives, tranquilizers, dissociative and general anesthetics, substances that produce a mild to moderate, but tolerable localized tissue reaction including low level infectious or chemical agents. 15. Repetitive chemical restraint (NOT anesthesia). 16. Exposure to alterations in environmental conditioning and microenvironment with appropriate acclimatization. 17. AVMA approved euthanasia procedures limited to administration of IACUC approved overdose compounds, inhalation methods that induce rapid unconsciousness, or and IACUC approved physical method preceded by anesthesia. 18. Breeding of a new genetically engineered phenotype with unknown clinical health complications (but which is not expected to cause congenital pain/distress). 19. Mild symptoms after inoculation, tumor induction, or infection that do not require clinical treatment for pain relief or alleviation of symptoms. 20. Induced infections, tumors, or ascites production., depending on the expected endpoints and progression of the disease. 	<ol style="list-style-type: none"> 5. Exposure of blood vessels for catheter implantation 6. Induced infections or antibody production that will produce more than temporary or minor pain or distress and for which analgesics are given. 7. Tattooing (which is done under anesthesia) 8. Exposure of skin to UV light to induce sunburn 9. Tail snip in mice > 21 days old with appropriate analgesia or anesthesia 10. Genetically engineered phenotype that causes pain or distress that will be alleviated. 11. Chemical usage includes the administration of caustic substances with moderate to high-level tissue reactivity, inducing radiation sickness, or compounds that will significantly impair cognitive function or critical physiological processes, but for which appropriate nursing care, tranquilizers or analgesics are used to relieve any distress or pain. 12. AVMA approved methods of euthanasia involving anesthesia followed by perfusion, exsanguinations or other procedures that would cause pain or distress in an awake animal. 	<ol style="list-style-type: none"> 5. Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes. 6. Exposure to extreme environmental conditions that are expected to cause pain or distress that will not be relieved 7. Paralysis or immobilization of a conscious animal. 8. Administration of substances whose effects are unknown but are expected to cause pain or distress that will not be relieved or exposure to compounds that may prolong suffering or result in death. 9. Genetically engineered phenotype that causes pain or distress that will not be alleviated. 10. Novel biomedical experiments with a high degree of invasiveness and are expected to cause pain or distress that will not be relieved 11. Maintaining study animal with marked cognitive or physical impairment without providing the appropriate means of supplementation or veterinary care.
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Consideration *must* be given to methods that result in a lesser degree of unavoidable pain or discomfort, and methods that use the smallest number of animals consistent with accomplishing the scientific or education objectives. The following websites may prove useful in complying with this regulation: <http://www.aphis.usda.gov/audience/academic.shtml>
<http://books.nap.edu/books/0309072913/html/R11.html>;
http://dels.nas.edu/animal_pain/index.shtml