

Appendix A

CALIFORNIA POLYTECHNIC STATE UNIVERSITY, SAN LUIS OBISPO

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

INSTRUCTIONS FOR: "PROTOCOL FOR ANIMAL USE" FORM

NOTE: THIS IS NOT AN ORDER FORM. ORDERS ARE TO BE PLACED THROUGH YOUR COLLEGE OR DEPARTMENTAL TECHNICIAN OR THROUGH THE ANIMAL TECHNICIAN, BIOLOGICAL SCIENCES DEPARTMENT. ORDERS WILL NOT BE MADE UNTIL PROTOCOL AND PROCEDURE HAVE BEEN APPROVED BY THE ANIMAL WELFARE COMMITTEE.

The protocol for animal use is to be used when investigative procedures call for the use of live, warm-blooded animals in instruction and/or research within the jurisdiction of the University. This outline is meant to be a self-explanatory guide to using the protocol form. Questions may be directed to the Chair of the Animal Welfare Committee.

Please take the time to follow this outline *carefully*. Your protocol form may be returned to you for correction if not filled out properly and this may delay its approval.

Indicate in the spaces provided at the top of the form the date that the form is being initiated. Also, indicate whether this protocol is new, a renewal of an existing protocol, or a modification of an existing protocol.

(1) "Investigator" refers to the responsible student (graduate or undergraduate), faculty or staff researcher. For special classroom (e.g., independent study) or graduate research projects, students must fill out a protocol form and have their instructor/advisor sign in the space provided, verifying that the information on the form is accurate. In the case of instructional use, the instructor responsible for the class must sign a *completed* protocol space (1) to verify that the information is accurate. In the case of repetition of experimentation for instructional or research purposes, it is unnecessary to fill out the same protocol each time; a signed photocopy with the correct dates and number of animals needed is sufficient (this method would be considered a renewal).

NOTE: RESEARCH PROTOCOLS MUST BE REVIEWED AND APPROVED EVERY THREE YEARS BY THE COMMITTEE.

(2) Indicate where the investigation shall take place (building and room number). List course number (if applicable) and the responsible department.

(3) Indicate the date the project is to begin and end. The project must have an ending date. There is no guarantee that space will be available for projects that extend beyond the date specified herein.

(4) Use common name of species. *A protocol form must be filled out for each species to be used, as well as for each experiment.* Use back of form if more than two strains are to be used.

(5) Self-explanatory.

(6) (a) This system categorizes the level of pain and/or discomfort to which the animal(s) involved will be subjected. Each experiment using animals shall be ranked *by the investigator* in one of the five categories listed at the end of this set of instructions. For any category III, IV, or V projects, the principal investigator should provide adequate justification for such procedures.

(b) Investigators are encouraged to use non-animal models (fertilized chicken eggs, videotapes, in-vitro biological systems, computer simulations, mathematical models, etc.) whenever possible, especially for instructional demonstrations where repetition of experiments is frequent.

(c) The Attending Veterinarian of the Animal Welfare Committee is available to answer any questions and/or to make suggestions pertaining to the humane care and use of animals at this university.

(7) The project description must answer a, b, c, and d. The description must also justify the need to use an animal model. Literature citations may be used to justify specific techniques, procedures, etc.

It might be prudent to request the following additional information:

1. *Verification of scientific validity of project - by P.I., Peers, Faculty Advisor, Dept. Chair, Dept. Grad. committee, etc.*

2. *Statement of qualifications from all personnel involved in the project. Specifically - education, experience, training, planned training programs, or independent specialists or consultants that will enable University personnel to comply with all USDA and PHS laws, regulations, and policies.*

3. *Certification by attending Veterinarian that preoperative / surgical / postoperative care / anesthesia / analgesia / therapy / restraint / euthanasia meet accepted AVMA standards.*

4. *Written rationale for involving animals, appropriateness of the species selected, and appropriateness of the number of animals used.*

5. *Written narrative of alternative procedures / protocols considered and rejected; including a description of the methods and sources used to determine that alternatives should be rejected.*

6. *Written description of procedures employed to assure that discomfort, distress, and pain to animals will be limited to that which is unavoidable in order to obtain scientifically valuable results.*

7. *Special scientific justification for any procedures that would produce unrelieved pain, distress, or discomfort.*

NOTE: ALL EXTRAMURALLY FUNDED RESEARCH *MUST* HAVE A DETAILED EXPERIMENTAL PROTOCOL ATTACHED TO THE "PROTOCOL FOR ANIMAL USE" FORM. THE PROJECT PROPOSAL AND THE "PROTOCOL FOR ANIMAL USE" FORM SHALL BOTH MEET THE APPROVAL OF THE IACUC BEFORE THE RESEARCH CAN BEGIN.

(8) Answer all that are applicable, especially "c."

(9) Answer all that are applicable.

(10) Answer "a" or "b."

(11) Indicate all procedures that must be followed when the animals used are a potential biohazard.

(12) The standard procedure at this University is to freeze all carcasses of laboratory animals in plastic bags (labeled as to species, date of sacrifice, investigator's name) until disposal is authorized by the IACUC Veterinarian and/or campus Safety Officer. These carcasses are held in a main freezer of the Biological Sciences Department Vivarium until a contracted rendering service collects and disposes of them. All animals that have been exposed to toxic materials are kept in a separate freezer and discarded through special procedures as toxic wastes. *No animals are to be put into the general trash collection system of the University.*

(13) No animals may be housed in an IACUC approved Vivarium and no experimental or instructional use of vertebrate animals may begin without protocol approval by the IACUC and other appropriate University officials (an experimental procedure may be defined as one which enhances the advancement of knowledge). Any change(s) in the original protocol (numbers of animals, procedural changes, dates, etc.) will require a re-submission of the protocol with the appropriate modifications and justifications. No procedures shall begin until the resubmitted protocol is approved.

CATEGORIES OF BIOMEDICAL EXPERIMENTS BASED ON INCREASING ETHICAL CONCERNS FOR NON-HUMAN SPECIES*

To be specified at Item 6 on the Protocol for Animal Use

CATEGORY	EXAMPLES AND COMMENTS
Category I Experiments involving plants bacteria, protozoa, invertebrate animals, coldblooded animals, dead vertebrate animals, live or dead animal tissues or cells.	Biochemical, botanical, bacteriological, or invertebrate animal studies; studies on tissues obtained from autopsy or from slaughterhouse, studies on embryonated eggs. Invertebrate animals and cold-blooded vertebrate animals have nervous systems and respond to noxious stimuli, and so must also be treated humanely.
Category II Experiments on vertebrate animal species that are expected to produce little or no discomfort.	Mere holding of animals captive for observational or experimental purposes; simple procedures such as injections of relatively harmless substances and blood sampling; physical examinations; induction of anesthesia, experiments on completely anesthetized animals which do not regain consciousness; standard methods of euthanasia that induce rapid unconsciousness, such as anesthetic overdose or decapitation preceded by sedation or light anesthesia.
Category III Experiments that involve minor distress or discomfort (short-duration pain) to vertebrate animal species.	With anesthesia, exposure of blood vessels or implantation of chronic catheters; behavioral experiments on awake animals that involve stressful restraint; food/water deprivation for short periods (a few hours); noxious stimuli from which escape is possible; surgical procedures under anesthesia that may result in some minor post-surgical discomfort. Category III procedures incur additional concern in proportion to the degree and duration of unavoidable distress or discomfort.

<p>Category IV</p> <p>Experiments that involve significant but unavoidable distress or discomfort to vertebrate animal species.</p>	<p>Deliberate induction of behavioral stress in order to test its effect; major surgical procedures under anesthesia that result in significant post-operative discomfort; induction of an anatomical or physiological deficit that will result in pain or distress; application of noxious stimuli from which escape is impossible; prolonged periods (up to several hours or more) of physical restraint; maternal deprivation with substitution of punitive surrogates; induction of aggressive behavior leading to self-mutilation or intra-species aggression; procedures that produce pain in which anesthetics are not used, such as toxicity testing with death as an end point, production of radiation sickness, certain infections, and stress and shock research that would result in pain approaching the pain tolerance threshold. Category IV experiments present an explicit responsibility on the investigator to explore alternative designs to ensure that animal distress is minimized or eliminated.</p>
<p>Category V</p> <p>Experiments that involve inflicting severe pain near, at, or above the pain tolerance threshold of unanesthetized, conscious animals.</p>	<p>Use of muscle relaxants or paralytic drugs such as succinyl choline or other curarieform drugs used alone for surgical restraint without the use of anesthetics; severe burn or trauma infliction on unanesthetized animals; attempts to induce psychotic-like behavior; killing by use of microwave ovens designed for domestic kitchens or by strychnine; inescapably severe stress or terminal stress. Category V experiments present an explicit responsibility on the investigator to explore alternative designs to ensure that animal distress is minimized or eliminated.</p>

*Modified from Barbara Orlans, "Effective Institutional Animal Care and Use," in press 1986.