F97-6 POLICY AND ASSURANCE FOR HUMANE CARE AND USE

OF ANIMALS AT SAN JOSE STATE UNIVERSITY

Legislative History:

At its meeting of December 1, 1997, the Academic Senate approved the following policy recommendation presented by Don Keesey for the Curriculum and Research Committee.

Supersedes: S90-8

ACTION BY THE UNIVERSITY PRESIDENT:

"Approved as University Policy." Signed Robert Caret, 12-17-97

POLICY RECOMMENDATION POLICY AND ASSURANCE FOR HUMANE CARE AND USE OF ANIMALS AT SAN JOSE STATE UNIVERSITY

WHEREAS: San Jose State University recognizes the need to address ethical issues

concerning

the care and use of animals at University facilities; and

WHEREAS: San Jose State University must have a current and complete policy

assuring the

humane care and use of animals; and

WHEREAS: That policy must be in accord with current Federal guidelines; and

WHEREAS: That policy should indicate clearly what procedures are to be followed and

what

committees and individuals are responsible for overseeing the humane care

and use of animals; now therefore be it

RESOLVED: That the Academic Senate approve the attached Policy and Assurance for

Humane

Care and Use of Animals at San Jose State University.

F97-6 ATTACHMENT

POLICY AND ASSURANCE FOR HUMANE CARE AND USE OF ANIMALS AT SAN JOSE STATE UNIVERSITY

Preamble: Ethics and the Care and Use of Animals

San Jose State University (SJSU) recognizes this statement as a common point of reference in addressing ethical concerns within discussions, evaluations and the implementation of all policies and procedures concerning the care and use of animals at SJSU by all SJSU personnel and students.

SJSU recognizes the legitimacy, importance and sensitivity of the public debate concerning the ethics of animal care and use. We recognize that within this debate there are a number of legitimate and responsible perspectives, concerns, and unresolved issues that are expressed in various ways. We, therefore, commit ourselves to be a respectful and responsible party within this on-going public debate.

SJSU recognizes the relevance, value and significance to animal care and use of the principles of humane treatment of animals. Therefore, we commit ourselves continually to seek satisfactory means that do not entail the use of animals, and continually to seek ways to minimize the number of animals used, the degree of physical and psychological discomfort caused, and the number of deaths entailed in our work.

SJSU holds that a fundamental basis for our ethical responsibilities in the treatment of animals depends on the relationships we have with the rest of the animal kingdom. Therefore, we view our role in the care of animals to be one of stewardship -- which includes the responsibility to meet at all times the needs of animals in our charge.

We view our role in all instances of animal use to be one that must reflect a deep sense of humility. Our corresponding responsibilities must include efforts to seek and employ methods that embody most fully both respect for the life of individual animals and reverence for life itself.

Section I. Purpose

Animals are used for instruction and research at San Jose State University (SJSU). We will strive to be certain that our faculty, staff, and students understand their ethical and scientific obligations with respect to animals. This policy sets forth the guidelines and procedures by which the university will seek to assure compliance with those principles and with all appropriate governmental regulations applying to animal care and use. While this policy pertains specifically to vertebrate animals, San Jose State University affirms that our philosophy extends similar respect for invertebrates used in instruction and research.

Section II. References

The references used in developing this policy and assurance are the Animal Welfare Act (Public Law 89-544 as amended), the Guide for the Care and Use of Laboratory Animals (National Academy Press, 1996), and the Public Health Service Act (Public Law 99-158, 1985). Also included as references are applicable provisions and regulations of the Endangered Species Act (Public Law 93-205, 1972), the Marine Mammal Protection Act (Public Law 92-522, 1972), and the State of California Departments of Health Services, Fish & Game, and Agriculture, and Title 9 of the California Administrative Code.

Section III. Definitions

- A. Animal. Any live vertebrate non-human creature which is being used or is intended for use in research, experimentation, testing, training, education, demonstration or related purpose which includes the in vivo acquisition of tissue.
- B. Animal Care Facility Manager [ACFM]. An individual with the appropriate education and certification who: is responsible for the Animal Facility and any animals resident therein; coordinates requests for use of animals; and maintains appropriate records of animal care and disposition.
- C. Animal Facility. Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities under the administrative control of SJSU, used for animal confinement, care, transport, maintenance, breeding or experiments, including surgical and non-surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.
- D. Animal User. Any faculty member, professional researcher, staff member, or any graduate or undergraduate student who uses animals, as defined in III-A, in a SJSU facility.
- E. Campus. Any facility under the administrative control of SJSU.
- F. Institutional Animal Care and Use Committee [IACUC]. A committee (hereinafter referred to as IACUC) appointed by the University President, composed of representative persons who will assure complete and adequate review of animal facilities and procedures under jurisdiction of San Jose State University. The IACUC shall include:
- (1) One Doctor of Veterinary Medicine, with training and experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the university as Campus Veterinarian;
- (2) One faculty member from each college or administrative unit where animal use in the classroom or in research projects is current or probable, at least one of whom is a practicing scientist experienced in research involving animals;
- (3) One faculty member whose primary concerns are in a non-scientific area;

- (4) One individual who is not currently affiliated with the university in any way other than as a member of IACUC, and is not a member of the immediate family of a person who is affiliated with the university; and
- (5) One academic dean (normally the Dean of the College of Science) who represents the administration of a college using animals in instruction and/or research;
- (6) The Associate Vice President for Undergraduate Studies, to represent curricular concerns; and
- (7) The Associate Vice President for Graduate Studies and Research, to represent research policy.

Faculty members shall receive three-year appointments. Community members shall serve one-year terms. University administrators and the Campus Veterinarian shall serve exofficio with vote.

Section IV. Policy

Humane care, use, and treatment of animals for instruction, research, or related purpose is a university-wide responsibility. It is the policy of San Jose State University to comply with federal, state, university, and other regulatory requirements as they relate to the acquisition, care, and use and treatment of animals in the performance of authorized instruction and research. The Campus Veterinarian, in association with the IACUC, must provide assurance to a number of agencies that animals in all projects and activities are receiving humane care, and are used and treated in accordance with professionally acceptable standards. Accordingly, the IACUC has been charged with oversight and review of all university animal care and use facilities and procedures.

In order to provide for the adequate discharge of this responsibility, all proposed projects or activities in which animals are involved must be reviewed and approved by the IACUC prior to commencement. This policy is applicable regardless of whether extramural funds or intramural funds are used, and includes those cases where no reimbursement for such study is involved.

Section V. Principles for Use of Animals

A. Personnel

(1) Experiments involving live, vertebrate animals and the procurement of tissues from living animals for research must be performed by or under the immediate supervision of a qualified scientist.

(2) The housing, care, and feeding of all experimental animals must be supervised by a properly qualified veterinarian or other biological or behavioral scientist.

B. Research Practices

- (1) Experiments should be based on knowledge of the disease, problem or issue under study and be designed by the investigator to yield useful results.
- (2) Experiments should be conducted so as to avoid all unnecessary suffering and injury to animals.
- (3) The scientist in charge of an experiment must be prepared to terminate the experiment whenever s/he believes that its continuation may result in unnecessary injury or suffering to the animals.
- (4) If an experiment or procedure is likely to cause greater discomfort than that attending anesthetization, the animals must first be rendered incapable of perceiving pain and be maintained in that condition until the experiment or procedure is ended. The only exception to this guideline should be in those cases where the anesthetization would defeat the purpose of the experiment and data cannot be obtained by any other humane procedure. Such procedures must be carefully supervised by the principal investigator or other qualified senior scientist.
- (5) Post-experiment care of animals must minimize discomfort, in accordance with acceptable practices in veterinary medicine.
- (6) If it is necessary to terminate an experimental animal, the animal must be promptly euthanatized in a humane manner in such a way as to insure immediate death in accordance with procedures approved by the AVMA or as excepted by the IACUC. No animal shall be discarded until after the animal is dead. Though not generally recommended, healthy surplus animals may be donated to schools and others with a legitimate and humane purpose as an alternative to euthanasia. The IACUC must approve donations and those who receive donations must first sign a statement assuming responsibility for the animals to be received.

C. Facilities and Transportation

- (1) Standards for the construction and use of housing, service, and surgical facilities should meet those described by applicable federal and/or state guidelines.
- (2) Transportation of animals must be in accord with applicable standards and regulations intended to reduce discomfort or stress to the animals, or spread of disease. All animals being received for use as experimental subjects, having arrived at the terminal of a common carrier, must be promptly picked up, delivered, and placed in acceptable facilities.

Section VI. Implementation Responsibilities

In order to insure proper implementation of this policy, areas of responsibility are hereby designated for those persons engaged in activities involving animals as subjects and for those persons involved in the administration of this policy.

- A. The University President is charged with the overall administrative responsibility for implementing and maintaining a university animal care and use program to assure that all humane, ethical, and legal requirements are met. The IACUC will carry out this responsibility.
- B. The Associate Vice President for Graduate Studies and Research [AVP/GS&R] will serve as the Institutional Official who will maintain the institutional assurance approved by the Department of Health and Human Services and records of accrediting body determinations, and will make required reports to governmental agencies.
- C. The Campus Veterinarian will be appointed by the President and will have delegated responsibility for the health of all animals involved in teaching and research. The Campus Veterinarian will have unlimited access to all animal facilities with due respect for the demands of research in progress and will approve all training programs for animal users. The Campus Veterinarian has the authority to suspend any activity involving animals when the health of the animals or investigators is deemed to be inappropriately in jeopardy, including those activities with a protocol approved by the IACUC.
- D. The Dean of the College of Science (or the dean serving as representative for each college using animals in the classroom or in research) is charged with maintaining the record-keeping of the IACUC. Responsibilities shall include maintaining: (1) minutes of IACUC meetings, including records of attendance; (2) records of applications, protocols, and proposed significant changes in the care and use of animals in protocols, including whether IACUC approval was given or withheld; (3) records of any IACUC reports and recommendations forwarded to the institutional official.

All records shall be maintained for at least three years. Records that relate directly to applications, protocols, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be accessible for inspection and copying by authorized government officials at reasonable times and in a reasonable manner.

- E. The IACUC is charged with developing, recommending and monitoring university policies and standards relating to animal acquisition, care and use. The IACUC shall have the responsibility and authority to:
- (1) Review at least once every six months the university's program for humane care and use of animals;

- (2) Inspect at least once every six months all of the university's animal facilities and submit reports evaluating these facilities to the Institutional Official [AVP/GS&R];
- (3) Make recommendations to the Institutional Official [AVP/GS&R] regarding any aspect of the university's animal program, facilities, or personnel training;
- (4) Review and approve, require modifications in (to secure approval) or withhold approval of proposed sections of applications or protocols related to care and use of animals, as specified in the IACUC's Principles of Animal Use (Section V above);
- (5) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities; and (f) suspend activities involving animals in accord with specifications set forth in the Animal Welfare Act and Guide for the Care and Use of Laboratory Animals (see section II).
- F. The Animal Care Facility Manager [ACFM] is responsible for implementing professionally acceptable standards for the proper care and use of all animals within all animal facilities, and assuring that those standards are met. The ACFM shall be supervised by the Dean of the College of Science. All animal users will coordinate their activities through the ACFM. The ACFM serves as staff to the IACUC.
- G. Animal Users must follow the procedures and guidelines set forth by the IACUC and accept the responsibility that all animal use will be in accordance with the above-referenced policies and regulations and carried out with deliberate consideration of the statement on ethics and the care and use of animals in the preamble to this policy.

Section VII. Procedures

A. Protocols

- (1) All research projects and classroom exercises using animal subjects must be approved by the IACUC before the study or exercise begins. Prior approval is mandatory, whether the project is funded or not. Animal users shall submit research protocols for review using the university form not less than 30 days prior to the proposed start date. Animal users are encouraged to review the protocol with the ACFM and, if necessary, the Campus Veterinarian before submitting materials to the committee.
- (2) Animal users must provide a project description, including all scientific procedures, as attachments to the protocol to be reviewed. Animal users have the primary responsibility for submitting the appropriate materials to the ACFM, who shall submit the documents to the IACUC for review.
- (3) Any project involving animals and seeking external support must be submitted to the IACUC for approval before being submitted for external funding. Verification of IACUC

approval may be filed at a time not to exceed sixty (60) days after submission of applications or proposals to funding agencies.

- (4) Once approved, no changes in the project plan may be made without prior approval of the IACUC. For their own protection, animal users will bring to the IACUC's attention, for action, any emergent problems or proposed procedural changes which may affect the conditions of the project.
- (5) All projects and classroom exercises involving animals, regardless of prior approval, must be reviewed and reapproved by the IACUC every three years. Reviews at shorter intervals may be required by the IACUC for externally funded projects or for classroom projects where the curriculum has undergone significant modification.

B. Protocol Review Standards

The IACUC will meet each month for protocol review, as needed, and to conduct other appropriate business. Emergency meetings may be convened in the event that the IACUC must address issues surrounding violations of approved protocols or animal health and safety problems. The IACUC shall evaluate each protocol and project description for:

- (1) Adherence to the provisions and standards cited in the policy statement references (Section II above).
- (2) Procedures with animals that avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.
- (3) Procedures that may cause more than momentary or slight pain or distress to the animals performed with appropriate sedation, analgesia or anesthesia, unless the procedure is justified for scientific reasons in writing by the animal user.
- (4) Assurance that the animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanatized at the end of the procedure or, if appropriate, during the procedure.
- (5) Assurance that the number of animals to be used is at minimum and that alternatives to animal use have been considered seriously but cannot meet scientific or instructional need, and that continued effort will be made to find alternatives where appropriate.
- (6) Written assurance that animal projects proposed for off-campus implementation will be governed by standards for animal use and care comparable to those that guide the university for on-campus studies (appropriate living conditions, potential medical attention by a qualified veterinarian, proper training for personnel who will handle the animals).
- (7) Assurance that methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia (JAVMA, 202(2): 229-249, 1993 or succeeding revisions), unless a deviation is justified for scientific reasons in writing by the investigator.

C. Protocol Review Procedures

Each IACUC member will receive and review all animal protocols. Upon reviewing each protocol, the IACUC members will provide in writing to the ACFM by the date specified comments, concerns, and suggestions about the protocol, including, if deemed necessary, a

request for full IACUC review.

- (1) If a full IACUC review is requested, the IACUC will meet in a timely fashion to vote on approval, modification for approval, or disapproval of the protocol. Approval, specification of modifications for approval, or disapproval by full IACUC review will require a majority of the IACUC quorum (one more than half the membership).
- (2) If no member of the IACUC requests a full IACUC review, the ACFM will notify the IACUC Chairperson and the Chairperson will designate one or more qualified IACUC members to review the protocol, address any comments, concerns, and/or suggestions from the IACUC members, and approve, require modifications needed for approval, request a full IACUC review or disapprove the protocol. Absent a request for full IACUC review [see (a) above], when the designated reviewer(s) are satisfied the protocol meets review standards, the reviewer(s) will approve the protocol.
- (3) A complete listing of protocols approved by the designated reviewer(s) will be made an agenda item at the next regular meeting of the IACUC. Only a convened quorum of the IACUC membership may consider the suspension of a previously approved protocol, and the required vote is a majority of the quorum.
- (4) If a protocol is not approved, the animal user may appeal to the IACUC by appearing at the next scheduled IACUC meeting. The Committee will reconsider the protocol and revote, according to the rules in (1), above. The result of the post-appeal vote will be final.

D. University Museums/Collections

The IACUC requires appropriate permits from state and/or federal authorities for all species collections. Proper documentation regarding date, time, and circumstances of collection is mandatory. Serendipitous contributions to collections (e.g., roadkills) are also subject to appropriate record-keeping regulations. Inventory of museums and other collection sites will be reviewed annually.

E. Facilities

The University Animal Care Facility presently occupies a combined total of 6,148 sq. feet in Duncan Hall, Phase II. The seventh floor area takes up 4,440 sq feet, and includes three animal rooms, a feed storage area, a cage washing area, a cage storage area, and three research support areas. Animal support space includes 3,376 sq. feet (DH 740, 740A, 741A, 742, 743, and feed storage area); research support space includes 1,064 sq. feet (DH 739A, 739B, 741). The university also supports a sea lion holding pen in Monterey Bay, occupying 484 sq. ft.

F. Complaints

- (1) Complaints regarding animal use and care at San Jose State University may be filed at any time by contacting either the Chairperson of the IACUC or the Associate Vice President for Graduate Studies and Research in person or in writing. Identity of the complainant will be held in confidence.
- (2) Complaints shall be investigated by at least two members of the IACUC. Review of complaints shall be made a matter of record and shall be reported to the IACUC in writing.

- (3) If the investigation reveals information that requires full IACUC review, the complainant and the investigator may be asked to meet with the IACUC. The IACUC may consider a wide variety of actions following such a meeting, including termination of an approved protocol.
- (4) If an approved protocol is terminated, or if there is a serious violation of university principles for use of animals (Appendix A), the institutional official will notify appropriate federal authorities (notice is required by federal guidelines) in writing regarding the issues involved and their resolution.

Att: Protocol

San Jose State University
Institutional Animal Care and Use Committee (IACUC)

Protocol For Animal Use

In accordance with SJSU policy (Academic Senate Policy #S87-3, and any subsequent revisions), a "Protocol For Animal Use" form (insert) is to be used when procedures call for the use of live vertebrate animal subjects in instruction and/or research within the jurisdiction of SJSU, including studies of animals in their native environment. The following outline is designed to be a self-explanatory guide to using this protocol form. Questions should be directed to the University Animal Care Office, Duncan Hall, Room 435 (408-924-4923). THIS FORM IS TO BE TYPEWRITTEN.

It is extremely important that you take the time to follow this outline carefully. Your protocol form will be returned to you for correction if not properly filled out, which may delay its approval. You are ineligible to begin work with animals until the project has obtained IACUC approval.

Please submit the original plus 12 copies of the completed protocol form to the IACUC at least 30 days prior to project start date. Original and copies are to be made and forwarded to the University Animal Care Office after securing department - level approval.

NOTE: This is not an Animal Order form. Orders are to be placed through the University Animal Care Office only. For information, contact the University Animal Care Office. Animal orders will not be placed if this protocol is not approved by the IACUC.

INSTRUCTIONS

Provide at the top of the form the following information: title of the investigation; the date that this form is being initiated; and whether this protocol is new, a renewal of an existing approved protocol, or a modification of an existing, approved protocol. This protocol form is to be used for instruction-related investigations (classroom experiments, or individual student projects for class credit), funded and non-funded research projects (faculty research), or grant proposals. Indicate the appropriate category(ies) for this protocol.

- (1) "Investigator" refers to the animal user (faculty, student and/or staff) who is responsible for the investigation. In the case of instructional use, the instructor responsible for the class must have their name on Line 1. All approved protocol forms are valid for 3 years and must be renewed every 3 years. Records of these protocols are kept and the investigator will be notified in advance of the renewal date. If, at any time, modifications are necessary in the study, a new protocol form must be initiated. Please provide a campus telephone number and a campus mailing address where the investigator can be reached.
- (2) Indicate where the investigation shall take place (room number). List course number (if applicable) and the responsible department. For statistical purposes, please indicate the number of students in the class using this protocol.
- (3) Indicate the proposed dates the study is to begin and end. The proposed start date shall be the date the investigation is to be initiated. The study must have an ending date (up to 3 years from beginning date).
- (4) List names of personnel working under this protocol. Also state what experience they have with the procedures involved in this project (i.e., surgery, injections/withdrawals, euthanasia, etc). If personnel have pertinent certification in any of these techniques, please indicate in the space provided.
- (4)(A). If additional training is needed, specify what training will be given, by whom, and how the training is to be provided.
- (4)(B). Indicate affiliation with SJSU of personnel identified in #4 above.
- (5) List scientific (genus and species) and common name of animal. A protocol form must be filled out for each species to be used. Provide the total number of animals to be used during the duration of the study. Estimate the total number of animals needed, if necessary. NOTE: "Species" can be described as types of animals; "strains" can be described as

distinctions within a given species.

- (6) Permit information, as well as copies of pertinent rules and regulations, can be obtained from the University Animal Care Office.
- (7)(A) The categorization system used by the IACUC is for the purpose of determining whether the animal(s) involved will be used by the investigator in accordance with federal animal welfare regulations and institutional policies. Each investigation using animals shall be categorized by the investigator in one of the five categories outlined in this document. Studies classified in Categories III, IV, or V shall require strong justification upon submission of the protocol for review.
- (7)(B) Investigators are encouraged to use preserved specimens or 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. (See # 9C below).
- (8)(A) The University Animal Care Manager and/or Campus Veterinarian is available to answer any questions and/or to make suggestions pertaining to the humane care and use of animals. Investigators are encouraged to consult with the University Animal Care Manager and/or Campus Veterinarian prior to submission of the protocol for review by the IACUC.
- (8)(B) Facilities holding animals for more than 12 hrs. must be approved by the IACUC.
- (9) The description and the justification of the investigation are extremely important. Although the IACUC does not judge the investigation on the basis of scientific merit, this description will give the IACUC members a better overall picture of what the investigation entails. The investigator must answer items A, B, C, D, E and F. The description must also justify the need to use an animal model based on the category the investigation is classified under in #7A above. Citations from scientific references may be used to justify specific techniques, procedures, etc. Failure to provide a non-technical (lay) description of your study may result in the return of your protocol form for resubmission.
- (9)(C) The IACUC is required by federal law to ask the investigator to provide documentation and assurance that non-animal alternatives were considered, and that the proposed study is not unnecessarily duplicating previous studies. The criteria for such determinations are: 1) that the IACUC must be satisfied that the investigator made a good faith effort before making such assurances, and 2) the IACUC (and therefore SJSU) is in a defensible position if it becomes a matter of public concern or media scrutiny.
- (10) Answer all that are applicable. To aid in completing 10B and 10C, the following are defined: IM=intra-muscular; IP=intra-peritoneal; IV=intra-venous; PO=per oral (through the mouth); SC=sub-cutaneous; and ID=intradermal. These are the routes most frequently used to administer an agent. Do not write "standard methods" clearly state what the method(s) you use entail.

- (10)(F)(1) Unless otherwise stated in protocol, indicate whether animals in this study can be used again by another investigator or at the discretion of the University Animal Care Manager. Animals involved in invasive procedures will not be used again. Animals may not be given to other investigators without approval by the IACUC.
- (11) The Investigator shall read the statement and sign where indicated. Copies of the University Policy S87-3, and any subsequent revisions, are available to all investigators from the University Animal Care Office.
- (12, 13) If the departmental animal committee chair, the department chair or the IACUC chair is directly involved with the proposed experimental procedures, an alternate authorized signator must sign to indicate approval.

University Policy for the Disposal of Carcasses

The standard procedure at this university is to place all carcasses (including animals used for specimen preparation purposes) in plastic bags and freeze them until collected by the University Animal Care personnel. Syringes, needles, petri dishes, scalpels, cardboard, etc., are not to be put into bags with animal carcasses. Plastic bags containing animal carcasses must be labelled with name of the investigator (do not use cage cards) and protocol number assigned to the investigation. All carcasses are held in a main freezer 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.

REMINDER: No experimental or instructional procedures may begin without protocol approval by the IACUC. San Jose State University Classification of Animal Use*

The following categories are based on the increasing ethical concerns for the use of animals in education and research and the commitment of San Jose State University to ensure the humane care and ethical use of animals by all SJSU personnel. NOTE: The IACUC reserves the right to inquire about the investigator's ranking of the investigation.

CATEGORY I: Investigations involving either no living materials or the use of plants, bacteria, protozoa, or invertebrate animal species.

EXAMPLES: Biochemical, botanical, bacteriological, microbiological, or invertebrate animal studies, studies on tissues obtained from sources outside the university, and chicken egg embryos under 20 days old. Invertebrate animals have nervous systems and respond to noxious stimuli, and so must also be treated humanely.

CATEGORY II: Investigations on live vertebrate animal species that are expected to produce little or no discomfort.

EXAMPLES: Holding of animals for observational or experimental purposes; simple procedures such as injections of relatively harmless substances and blood sampling (intravenous only); physical examinations; induction of anesthesia; experiments on completely anesthetized animals which do not regain consciousness (ie. anesthetic overdoses, or decapitation preceded by light sedation or light anesthesia).

CATEGORY III: Investigations that produce minor distress or discomfort (short-duration pain) to live vertebrate animal species.

EXAMPLES: While under anesthesia, exposure of blood vessels or implantation of chronic catheters; behavioral research on awake animals that involves restraint; food/water deprivation for short periods (a few hours); noxious stimuli from which escape is possible; surgical procedures under appropriate anesthesia that may result in some minor post-surgical discomfort.

Category III procedures incur additional concerns in proportion to the degree and duration of unavoidable distress and discomfort.

CATEGORY IV: Investigations that involve significant but unavoidable distress or discomfort to live vertebrate animal species.

EXAMPLES: 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 anatomic 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 cannot be used (ie. toxicity testing with death as an end point, production of radiation sickness, certain infections), and stresses and shock research which result in pain approaching the pain-tolerance threshold.

Category IV procedures present an explicit responsibility on the part of the investigator to explore alternative designs to ensure that animal distress is minimized or eliminated.

CATEGORY V: Investigations that involve inflicting severe pain near, at or above the pain tolerance threshold on unanesthetized conscious animals.

EXAMPLES: 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; attempts to induce psychotic-like behavior; killing by the use of a microwave oven designed for domestic kitchens; killing by the use of strychnine; severe burn and trauma infliction on unanesthetized animals; inescapably severe stress or terminal stress.

Category V investigations are considered highly questionable or unacceptable irrespective of the significance of the anticipated results. Many of these procedures are specifically prohibited in federal policies and trherefore may result in withdrawal of federal funds and/or USDA registration. Procedures in Category V will require very strong justification from the investigator. * Modified from F. Barbara Orlans, "Effective Institutional Animal Care and Use", Laboratory Animal Science, Special Issue, Volume 37, 1987, p.12 San Jose State University Institutional Animal Care and Use Committee PROTOCOL REVIEW I, the undersigned member of the Institutional Animal Care and Use Committee (IACUC), have reviewed the following proposal submitted on _____: PROTOCOL #: _____ INVESTIGATOR NAME: _____ TITLE OF PROTOCOL: **COMMENTS AND SUGGESTIONS:** () () REQUEST FOR FURTHER INFORMATION:

(_)	REQUEST FOR CLARIFICATION:	
(_)	REQUEST FOR FULL COMMITTEE REVIEW	
SIGNATURE NAME (please print)		DATE
SJSU/UAC/rev. 12-96 jdm		