

A campus of The California State University

Office of the Academic Senate • One Washington Square • San Jose, California 95192-0024 •408-924-2440 Fax: 408-924-2451

F06-4

At its meeting of November 20, 2006, the Academic Senate passed the following Policy Recommendation presented by Senator Debra David for the Curriculum and Research Committee.

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

Rescinds F97-6

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

concerning the care and use of animals for University activities; and

WHEREAS: San José State University must have a current, comprehensive

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 how animal activities are to be organized

and conducted, what procedures are to be followed, what individual responsibilities are with regard to the care and use of animals, and what University committee oversees the humane care and use of animals; now

therefore be it

RESOLVED: That the attached policy be implemented.

Approved: October 9, 2006

Present: Buzanski, Campbell, Cooper, David, Flouris, Henderson, Kaufman, Nance,

Nelson, Stacks, van Hooff, and Von Till

Absent:

Vote: 11/1/0 Financial Impact: None

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Preamble

Ethics and the Care and Use of Animals at San José State University

San Jose State University (SJSU) recognizes this policy as its reference for the humane care and use of animals and for in addressing ethical concerns in discussions, evaluations and policy matters regarding the care and use of animals by all individuals at SJSU and its affiliates.

SJSU acknowledges the public debate about the legitimacy, importance and relevance of 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 of the ideals of the humane treatment of animals as part of conducting sound scientific research and quality teaching. Therefore, we commit ourselves actively to: seek satisfactory means that do not entail the use of animals, employ ways that minimize the number of animals used, minimize physical and psychological discomfort, and minimize the amount of euthanasia entailed in our work.

SJSU holds that among the sources of our ethical responsibilities in the care and use of animals are the relationships we have with the other members of the animal kingdom, and the life that we hold in common with them. Therefore, we view our role in the care of animals to be one of stewardship, which includes the responsibility actively to assess and meet the needs of animals in our charge and to provide for their comfort. 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

When animals are used for legitimate academic activities at SJSU, we will strive to ensure that our faculty, staff, contractors, and students understand the ethical and scientific obligations with respect to their care and use. This policy sets forth guidelines and procedures by which the University will ensure compliance with those obligations and with all respective government statutes applying to animal care and use.

Operationally, this policy pertains to the care and use of vertebrate animals. In addition, SJSU affirms that the purview of this policy may extend to the university-related use of invertebrate animals (for examples, refer to Section V, part D of this policy).

Section II. References

These references have been used collectively in developing this policy and assurance: the Animal Welfare Act (Public Law 89-544 as amended), the Guide for the Care and Use of Laboratory Animals (NRC, 2000), the Health Research Extension Act (Public Law 99-158, 1985), the 9 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985), Endangered Species Act (Public Law 93-205, 1972), the American Veterinary Medical Association Panel's Guide on Euthanasia (2000), and the California State University System Executive Order 890.

Section III. Definitions

- A. <u>Animal</u> means any live or dead non-human member of the kingdom Animalia that is acquired, utilized or held for intended use in a legitimate academic activity, which includes the acquisition or utilization of animal blood or tissues (including hair, bone, feathers, scales, excrement or secretions) from archived sources.
- B. <u>Activity</u> means any University supported project, whether it is publicly or privately funded, involving the use of animals for purposes of research, field studies, experimentation, teaching, demonstration, training, display, or related academic purpose.
- C. <u>Handling</u> means the physical care, feeding, holding, petting, capture, manipulation, exhibition, separation, breeding, transport, immobilization, dissection, treatment, training, or related interaction with an animal.
- D. <u>Facility</u> refers to any and all buildings, laboratories, rooms, spaces, enclosures, land, vessels or vehicles under the administrative control of SJSU or designated sites at off-campus locations used to support animal housing or an activity.
- E. <u>Personnel</u> refers to any SJSU faculty member, research affiliate, employee, volunteer, contractor, or student who is involved with the handling of an animal for purposes of a legitimate University activity.

Section IV. Animal Care and Use Policy Oversight

Humane care, use and treatment of animals for all activities, is a university-wide responsibility. It is the policy of San Jose State University to comply with Federal, state, and other regulatory requirements that pertain to the acquisition, care, handling and treatment of animals used for purposes of authorized instruction, research or artistic display.

A. As CEO, the University President must provide assurance that all animals associated with legitimate academic activities are receiving humane care, and are used and treated in accordance with professionally acceptable standards.

B. Institutional Official

Formally appointed by the CEO as the designated senior official with the authority to administer the institution's program of animal care and use, and to institute changes necessary to ensure compliance with all applicable regulations governing the care and use of animals. The Institutional Official will rely on the Campus Veterinarian, the Institutional Animal Care and Use Committee (IACUC), and the Dean of the College of Science (or other individual as designated by the University President) to oversee the institution's program and facilities, to develop plans to correct program deficiencies, to address concerns that may arise concerning the institution's use of animals, and to make recommendations for improvement with regard to the institution's program of animal care and use.

C. Campus Veterinarian

One Doctor of Veterinary Medicine who is appointed by the University President or by his or her designee, acting as the institution's attending veterinarian with training and experience in laboratory animal science and medicine (with Board certification in laboratory animal medicine or equivalent) to have authority and direct program responsibility for the health and welfare of all animals involved in or associated with a University supported activity, as well as the institutional training program for personnel working with animals.

D. Institutional Animal Care and Use Committee [IACUC].

The IACUC is an administrative committee composed of representative persons who will assure complete oversight and adequate review of all animal activities, facilities, programs for animal care and use, and investigate reported concerns of animal use within the jurisdiction of San Jose State University. Upon the recommendation by the Institutional Official, IACUC members are to be appointed by the University President on an annual basis with the expectation of serving for at least, but not limited to, three consecutive years. Removal of an IACUC member from the committee may be voluntary or at the discretion of the University President or the Institutional Official.

In order to provide for the adequate discharge of this responsibility, the IACUC must review and approve all animal activities, including modifications to an approved animal care and use protocol, prior to commencement of the project or modification thereof. Individuals who, in their use of animals, fail to adhere to this policy are subject to suspension of animal activities by IACUC and referral to the Institutional Official for appropriate action.

The IACUC is hereby granted the authority to take necessary measures or action to ensure that any SJSU activity involving animals is being conducted as approved by the IACUC.

- (1) Composition of the Committee: the IACUC shall be comprised of, but not be limited to, five (5) members:
 - a. One Doctor of Veterinary Medicine with training and experience in laboratory animal science and medicine;
 - b. One individual who is not affiliated with the University in any way other than as a member of the IACUC, in the past or present, and is not a member of the immediate family of a person who is affiliated with the University who provides "representation for general community interest" with regard to animal use;
 - c. A committee chairperson who is a faculty member from one of the colleges within SJSU;
 - d. One member whose primary concerns or expertise is in a non-scientific area (for example, ethicist, philosopher, member of the clergy, lawyer, peace officer); and
 - e. One faculty member who is a practicing scientist with adequate background, knowledge, and experience conducting activities involving animals whether in the laboratory, classroom or in the field.

Section V. Principles for the Use of Animals

A. Animal Activities

- (1) Activities involving the use of live vertebrate animals must be led and/or supervised by an established faculty member or the Campus Veterinarian, to be identified as the Principal Investigator. Principal Investigators and personnel must follow the procedures and guidelines set forth by the IACUC and accept the responsibility that all animal activities will be conducted in accordance with the policies, standards and regulations outlined herein and carried out with deliberate consideration of the statement on ethics and the care and use of animals in the preamble to this policy. All animal care and use protocols must be signed with a statement by the Principal Investigator signifying that she or he has read and will abide by this policy.
- (2) Organizing the procurement, delivery and receipt of live animals will be the duty and responsibility of University Animal Care (UAC) personnel. The housing, care and feeding of all animals must be in accordance with UAC standards and be supervised by an experienced veterinary professional or otherwise qualified individual as determined by the Campus Veterinarian.
- (3) The conduct of all animal-related activities must be done utilizing practices consistent with acceptable scientific standards by personnel properly trained and experienced, while providing animals adequate veterinary care and monitoring. As it relates to individual projects, all involved personnel are to be familiar with and follow all relevant procedural guidelines as set-forth by the IACUC for husbandry practices (UAC-SOP; H series), research practices (UAC-SOP; R series),

operational guidelines (UAC-SOP; O series) and clinical and surgical procedures (UAC-SOP; CS series), which are available in the UAC office.

(4) The IACUC must approve the final disposition or transfer of live animals upon initiation or completion of a project. The Principal Investigator or his/her designee is required to notify the Animal Care Facility Operations Manager (ACFOM) in writing no less than 14 days prior to acquiring and holding captive live vertebrate animals at an IACUC approved facility. Written notification to the ACFOM must include: a) the genus and species of the animal(s) to be held; b) number of animals to be held; c) location of where the animals are to be held; and d) verify the IACUC approved protocol reference number(s) for which the animals are to be held. With regard to the release or transfer of live vertebrate animals from one IACUC approved study to another, the ACFOM must be notified prior to release/transfer of animals to ensure all institutional requirements have been met.

B. Activities involving the use of non-living tissues or voucher specimens for University collections

Use of tissues and specimens that are collected and shared by consulting individuals for legitimate activities (whether within or outside the University) must first be approved by the IACUC as an independent submission or as an addendum to an existing protocol addressing the manner in which the animals or samples are handled. As well, the IACUC must approve projects that involve the receipt or analysis of tissues or specimens collected and shared from collaborators at outside institutions for the purpose of evaluating sample acquisition methods, including appropriate permits. Additional review requirements may be imposed by outside institutions for the handling or transfer of animals or their parts.

The IACUC requires that all appropriate government permits be in place in conjunction with peer review for the humane care and use of animals for all specimen collections prior to approval. Proper knowledge and documentation regarding date, time, and circumstances of collection is mandatory. Serendipitous contributions to collections (e.g., road kills) are also subject to appropriate record-keeping regulations. Inventory of University museums and other collections will be reviewed and reported annually in writing. Copies of these reviews will be provided to all IACUC members.

C. Activities Involving Fertile Eggs

The IACUC does require review and approval for the handling of vertebrate fertile eggs. A typical 5-page or abbreviated submission form may be used, depending on the species studied and the time manipulations will occur during the gestation period. Determination as to which submission form is most appropriate will occur upon consultation with the Animal Care Facilities Operations Manager or the Campus Veterinarian prior to IACUC consideration.

D. Activities Involving Invertebrate Species

For the use of invertebrates, the IACUC requires review and approval of projects that entail permission from a government agency to access, collect or deploy the species being studied, even if specimens are obtained commercially. For projects involving invertebrate species in which the pain and distress category is considered a category level V (as defined by the IACUC for vertebrate species and attached to this document as *Appendix One*), the IACUC will require

review and approval before the work is initiated. The provision for IACUC approval of invertebrate studies also extends to work involving animal species considered a threat to public health, poisonous/venomous, endangered, threatened or of special concern [Endangered Species Act, 1972].

All other invertebrate studies do not require IACUC review and approval. However, it is highly recommended (or as otherwise requested by SJSU Foundation or the Office of Graduate Studies and Research) that investigators pursue committee approval for graduate or research projects to be kept on file with the University Animal Care office.

E. Observational Studies Involving Animals

For purely observational studies that do not involve handling or disturbing of a live animal in its natural habitat, the IACUC requires review and approval of projects that entail permission from a government agency to approach the species being studied or to gain regional access to conduct the study.

All other observational studies do not require IACUC review and approval. However, it is highly recommended (or as otherwise requested by SJSU Foundation or the office of Graduate Studies and Research) that investigators pursue committee approval for graduate or research projects to be kept on file with the University Animal Care office.

F. Activities Conducted by Faculty on Sabbatical, and Visiting Scholars or Other Outside Individuals

The IACUC must review and approve any activities involving the use of animals by all individuals associated with the University or utilizing University facilities, including SJSU faculty on sabbatical, and visiting scholars and other outside individuals. Therefore, visitors to the University must be supported and represented by an SJSU faculty member or the Campus Veterinarian to pursue IACUC approval for animal activities. SJSU affiliates involved with animal activities at other institutions are subject to all applicable provisions set forth at those institutions.

G. Project Risk Assessment, Personnel Safety, and Occupational Health Services

All activities will be examined by the IACUC for a safe and healthy work environment to ensure that risks associated with experimental use of animals are reduced to acceptable levels. Participation in the institution's Laboratory Animal Occupational Health Program (LAOHP) will be mandatory for personnel involved in high-risk projects. An effective LAOHP will be in-place to ensure personnel services for: animal bites and scratches, pre-employment screening and medical surveillance for animal care professionals, and monitoring personnel exposure to chemicals, allergens or zoonotic diseases. The extent and level of personnel participation in the LAOHP will be determined by the IACUC at the time of protocol review. The IACUC's decision to require LAOHP participation will be based on the potential hazards posed by the animals and materials used; on the exposure intensity, duration, and frequency; on the susceptibility of personnel and on the history of occupational illness and injury in the particular workplace (IACUC guidelines for protocol health risk assignment is attached as *Appendix Two*).

H. Research and Teaching Practices

- (1) Experimental designs shall be outlined and justified by the Principal Investigator to yield useful results, not practically obtainable without the use of animals.
- (2) Procedures involving animals must minimize pain, discomfort or distress to the animals, while being consistent with sound research design.
- (3) The Principal Investigator or personnel in charge of an experiment or demonstration must be prepared to terminate the study whenever she or he believes that its continuation may result in undue or unnecessary injury or suffering to the animal.
- (4) If a procedure or manipulation 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 Principal Investigator or other qualified individual must directly supervise such procedures, as well as the post-treatment care of animals must minimize discomfort, consistent with current veterinary practices.
- (5) All drugs, medical materials, specialized feed and housing products used for animals must be appropriately stored and be kept in-date. Expired materials must be properly segregated and promptly disposed of at each facility. Drugs used for experimental procedures, anesthesia, analgesia, euthanasia, and emergency care must never be used beyond their expiration date and shall be of pharmaceutical grade wherever possible. The use of non-pharmaceutical grade compounds or expired materials (for terminal procedures) must first be revealed to and approved by the IACUC to determine that the use of such a product will not adversely affect the animal's well-being or compromise the validity of the scientific study.
- (6) Methods of euthanasia will be performed in a humane manner by a qualified individual in a way that induces a rapid state of unconsciousness as to assure an immediate and painless death for the animal. Euthanasia procedures shall be in accordance with the recommendations made by the American Veterinary Medical Association (AVMA Panel's Guide on Euthanasia, 2000; and subsequent revisions thereof) or as accepted by the IACUC with sufficient scientific justification for alternative approaches. No animal shall be discarded until after it has been assessed by a qualified individual to be confirmed dead.
- (7) The living conditions of animals shall be appropriate for their species and contribute to their health and comfort. The housing, feeding and care of all animals will be directed by the Campus Veterinarian or designee qualified and experienced in the species of interest. Every effort will be made to provide physical and psychological enrichment unless to do so would negatively impact the scientific results. Standards for the construction and use of housing, service, and surgical facilities must meet those described by applicable Federal guidelines (i.e., the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals).
- (8) All personnel shall be appropriately qualified and experienced in conducting procedures on live animals. Arrangements shall be made for all persons to have in-service training including the proper and humane care and use of animals as indicated by the Principal Investigator or the IACUC before being allowed to handle animals.
- (9) The transportation, care and use of animals shall be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.), the Public Health Service Policy on the Humane Care and Use of

Laboratory Animals, the Guide for Care and Use of Laboratory Animals and all other applicable laws, regulations and policies intended to reduce discomfort or stress to the animals and the spread of disease. All animals being transported by an approved carrier must be promptly received, delivered, uncrated and placed in acceptable facilities. Any internal transport of animals must be in accord with applicable institutional standards, which stipulate that animals must be transported in an inconspicuous manner within clean containers that safely contain them.

(10) Any deviations from any of the above provisions (Section V of this policy) must be presented in writing by the Principal Investigator and granted IACUC approval before the activity is performed.

Section VI. Policy Implementation and Individual Responsibilities

In order to ensure proper implementation of this policy, areas of responsibility are hereby designated to both personnel engaged in activities involving animal subjects and those identified herein to administer this policy.

- A. The University President is charged with the overall administrative responsibility for implementing and maintaining the institution's animal care and use program to assure that all humane, ethical and legal requirements are met. The University President will: (1) have the authority to amend or otherwise make required changes to this policy for University activities to conform to applicable laws; (2) have the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with applicable laws and policies.
- B. The Associate Vice President for Graduate Studies and Research [AVP/GS&R] is designated by the University President to serve as the Institutional Official and will: (1) receive, review and be responsible to act upon all official correspondence, including the IACUC semiannual reports; (2) route all required reports and responses to the appropriate individuals or agencies; (3) maintain the institutional assurance approved by the Office of Laboratory Animal Welfare (OLAW) and the Academic Senate; (4) correspond with external agencies with regards to animal care and use; and (5) submit to the respective agencies the following reports, and others as required:
 - 1. USDA Report Policy #17 Annual Report for Research Facilities (APHIS forms 7023 and 7023-A) to the Animal Care Western Regional Office on or before December 1 of each year, or as required.
 - 2. Annual Report to OLAW (per the Public Health Service Policy on Humane Care and Use of Laboratory Animals) to be counter-signed by the Chair of IACUC and submitted in January for the preceding year, or as required.
- C. The Campus Veterinarian will have delegated responsibility for the health of all animals involved with University activities and will have unlimited access to all facilities with due respect for the demands of research in progress. The Campus Veterinarian will have the authority to suspend any activity involving animals when the health or welfare of the animals or personnel involved is deemed to be inappropriately in jeopardy, including those activities approved by the IACUC.

- D. The Dean of the College of Science (or other individual as designated by the University President) is charged with providing direct oversight over the Animal Care Facilities and of the day-to-day activities of the Animal Care Facility Operations Manager, including availability of the ACF and internal records for inspection by governmental agencies. Record keeping responsibilities shall include maintaining: (1) minutes of IACUC meetings, including records of attendance; (2) records of application submissions, active animal use protocols, and proposed significant changes to animal use protocols, including whether IACUC approval was granted or withheld; (3) governmental inspection reports or oral/written communications with governmental representatives, and (4) forwarding immediately any government reports and recommendations to the IACUC and Institutional Official.
- E. The Animal Care Facility Operations Manager [ACFOM] will have the appropriate experience, education and veterinary certification (i.e., Registered Veterinary Technician and/or AALAS certified Laboratory Animal Technologist) and is responsible for maintaining the Animal Care Facilities and any animals resident therein. The ACFOM will: (1) provide adequate veterinary care as directed by the Campus Veterinarian; (2) coordinate requests for procurement or transfer of live animals; (3) be responsible for implementing professionally acceptable standards for the proper care and use of all animals within all SJSU animal facilities, and assuring that those standards are met; (4) distribute and maintain documents related to animal use and welfare including: animal protocols, IACUC semi-annual inspection reports, correspondence with government agencies, including annual reports and site inspections; (5) serve as the IACUC coordinator, whereas all animal users will coordinate their required protocol activities through the ACFOM who will keep the IACUC informed; (6) be available for any inspections of the SJSU animal facilities as required.
- F. The IACUC is charged with approving proposed animal activities, monitoring all University facilities, the institution's animal care program, and investigating reports related to concerns regarding animal care and use. The IACUC shall meet no less frequently than every three (3) months to ensure this provision, and shall have the authority to recommend changes to this policy for consideration by the Institutional Official.
- G. Convened meetings of the IACUC are to be considered closed-sessions. Outside attendance may be permitted by consent of the committee, following receipt of a request submitted to the IACUC by the party requesting permission to attend. If permission is denied, the minutes of the IACUC will reflect the reason for the denial.

The IACUC shall have the responsibility and authority to:

- (1) Assemble a subcommittee of at least 2 persons within its membership to conduct a semi-annual inspection (at least once every six months) of the University's animal care and use program using the Animal Welfare Act and Guide for the Care and Use of Laboratory Animals as a basis for its evaluation and prepare a written report for full committee review.
- (2) Assemble a subcommittee of at least 2 persons within its membership to conduct a semi-annual inspection (at least once every six months) of all University facilities using the Animal Welfare Act and Guide for the Care and Use of Laboratory Animals as a basis for its evaluation and prepare a written report for full committee review.

- (3) Prepare and approve by a quorum of its members and submit a written semi-annual report to the Institutional Official in a timely manner concerning both the animal care and use program review and facilities inspection reports, including recommendations regarding any aspect of the University's animal program, facilities, or personnel training.
- (4) Notify the US Department of Agriculture (USDA) and/or the Office of Laboratory Animal Welfare (OLAW), through the Institutional Official, within fifteen (15) days of the institution's failure to adhere to time tables presented for corrective action on significant deficiencies noted in the institution's Animal Care Program or its facilities.
- (5) Review and approve, or require protocol modifications to secure approval, impose provisional approval or withhold approval of all proposed animal care and use protocols.
- (6) Review and approve, or require protocol modifications to secure approval, impose provisional approval or withhold approval of proposed changes regarding the care and use of animals in ongoing activities; and suspend activities involving animals (if warranted) in accord with specifications set forth in the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals and this policy.
- (7) Complaints or concerns regarding animal use and care at SJSU facilities are to be reported by contacting the Campus Veterinarian, the ACFOM or IACUC chairperson by telephone, in person or in writing. Contact numbers for the Campus Veterinarian, ACFOM and IACUC chairperson are to be displayed outside the UAC office and all animal-holding rooms. Identity of the complainant will be held in confidence up to the fullest extent of the law. If any IACUC member notes a violation of this policy or has a complaint about animal use and care under the auspices of San Jose State University, this violation or complaint must be immediately communicated in its entirety to the IACUC chairperson and the Institutional Official.

Any complaints of animal care and use will be promptly investigated and reviewed by the Institutional Official, the Campus Veterinarian, and the IACUC chairperson (or IACUC subcommittee, as deemed appropriate by the Institutional Official). Review of complaints shall be immediately reported to the IACUC in writing and the complainant and/or the Principal Investigator may be required to meet independently with the Institutional Official, Campus Veterinarian or the IACUC. The IACUC may consider a wide variety of actions following such a meeting, including termination of an approved protocol and recommended disciplinary action by the Institutional Official.

If an approved protocol is terminated or if there is a serious violation of University principles, the institution's Assurance with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals or the Animal Welfare Act, the Institutional Official will promptly notify the appropriate agencies, as required, in writing regarding the issues involved and their resolution.

G. Records that relate directly to animal care and use applications, approved protocols and proposed significant changes to ongoing activities that have been 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 IACUC records shall be accessible for inspection and copying by authorized government officials at reasonable times and in a reasonable manner.

Section VII. Procedures

A. Animal Use Protocols

- (1) All animal activities must be approved by the IACUC before the study or exercise begins. Protocol application submissions must be reviewed, approved and submitted by a University faculty member or by the Campus Veterinarian (Principal Investigator). The appropriate submission form must be submitted and cannot be modified or otherwise altered (Protocol application for animal care and use is attached as *Appendix Three*). The Principal Investigator shall submit all animal care and use protocols for IACUC review using the appropriate application form no less than 60 days prior to the proposed project initiation date. In an effort to expedite the protocol review process, Principal Investigators are encouraged to allow pre-review of the protocol application by the ACFOM or Campus Veterinarian before formally submitting materials for IACUC consideration.
- (2) The Principal Investigator must provide a detailed lay description of the animal use activity and must include the following information in the animal care and use application: (a) identify all species and approximate numbers to be used; (b) a complete description of the proposed use of animals, (c) a description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, (d) a description of any euthanasia method to be used, (e) all facilities and research localities, (f) all scientific and husbandry procedures to be conducted on live vertebrate animals with due consideration of the provisions set forth by this policy, (g) all relevant Federal and state collection or handling permits with attachments as required; (h) other information as deemed necessary by the IACUC during the initial review of the protocol application. To maintain IACUC approval of field study projects, the Principal Investigator is responsible for ensuring that all study permits are kept current and that copies thereof are provided to the ACFOM to be included in the protocol file.
- (3) Any project involving animals and seeking external support must be approved by the IACUC before the work commences.
- (4) Once approved, no changes in the approved animal use protocol may be made without prior written approval by the IACUC, except particular incidents where the immediate well-being of the animal is at stake. Personnel must bring to the IACUC's immediate attention, for action, any emergent problems or proposed procedural changes, which may affect the conditions of the project or the health and well-being of the animal.
- (5) An individual animal care and use protocol shall not be granted IACUC approval for a period that extends beyond three (3) years. Animal protocol activities to extend beyond the three-year approval period must be fully rewritten and resubmitted for IACUC review and approval before the approved protocol expires. All animal care and use protocols approved for greater than one year must fully reviewed and re-approved by the IACUC annually based on the protocol anniversary date. Failure to comply with IACUC requests for conducting an annual review of an ongoing project will result in immediate revocation of institutional approval to continue the use of animals for that project. At the discretion of the IACUC, a shorter project approval period from that which did the Principal Investigator request or additional project monitoring requirements may be imposed.

(6) Falsification of information on an animal use application or deviation from approved protocol by the Principal Investigator or personnel may be considered by the IACUC as immediate grounds for suspension of an activity, revocation of IACUC approval for the use of animals for the project and notification of the Institutional Official.

B. Protocol Review Standards

The IACUC will meet regularly as needed for protocol review 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, what is viewed by the Campus Veterinarian to be an urgent, significant change to an approved study, issues related to animal use or welfare, the animal facility and/or safety concerns.

The IACUC shall evaluate each animal use protocol and project description for (but not limited to):

- (1) Adherence to the provisions and standards cited in Section V of this policy.
- (2) Assurance that the listed pain and distress category for each proposal is appropriately assigned and that routine supplementation, enrichment and adequate veterinary care are provided (and documented where appropriate) for all animal subjects unless written justification is provided.
- (3) Assurance that all procedures that may cause more than momentary or slight pain or distress to animals are performed with appropriate sedation, analgesia or anesthesia, with accompanying documentation and scientific justification that less painful or distressful procedures are not available.
- (4) Assurance that all procedures conducted on animals are appropriately detailed and are current, acceptable practices, including, as required by law, written justification in support of any proposed procedure that will cause more than momentary or slight pain or distress to any animal.
- (5) Assurance that the number of animals to be used is the minimum necessary to achieve valid results and that alternatives to live animals have been adequately considered.
- (6) Assurance that animal activity locations and facilities are properly described in the animal care and use proposal. For proposed facilities located off-campus, the IACUC must consider incorporating them into the institution's animal use program whereas the care and use of animals will be governed by standards, policies and recommendations outlined herein before the project begins.
- (7) Assurance in writing from the Principal Investigator that the proposed animal activity has been examined and is not unnecessarily duplicating work that is ongoing or has already completed, whether in publication or curriculum.
- (8) Assurance that the level of personnel involvement, animal handling experience and training (or required training and supervision) is described and that all individuals are properly trained and deemed proficient by the Principal Investigator in the humane care and use of animals before engaging in an animal-related activity.

(9) Assurance that all necessary and applicable Federal, state or local collection or handling permits are obtained and kept current.

C. Protocol Review Procedures

- (1) The IACUC will not consider, accept or conduct retroactive review of animal protocol applications for sponsored, experimental or other academic activities involving the use of animals if the animal use aspect of the project has been completed or is considered ongoing. Ongoing activities involving animals that are not approved by the IACUC must immediately be halted and reported to the IACUC for proper investigation and action. Activities that involve the use of animals that have not been previously approved by the IACUC and become evident to the committee must be investigated and reported to the Institutional Official for recommended action.
- (2) Each IACUC member will receive and review all animal use submissions. Upon reviewing each protocol, the IACUC members will provide in writing to the ACFOM by the date specified any comments, concerns, and suggestions about the protocol, including, if deemed necessary, a request for full IACUC review. If full IACUC review is requested, the IACUC will meet in a timely fashion to discuss the protocol.
- (3) If no member of the IACUC requests full committee review, the ACFOM will notify the IACUC chairperson who may designate review of a proposal with committee approval by one or more qualified IACUC members to address any comments, concerns and/or make suggestions to the Principal Investigator.
- (4) The ACFOM will maintain a tracking record of protocols with categories for submission status, any revision required by the IACUC, and final status to be entered in the minutes of IACUC and approved. Once the full committee or designated reviewer(s) are satisfied the protocol meets review standards, the reviewer(s) will forward their approval to the ACFOM who will notify the chair of the IACUC, whose signature on the application for animal use is required for formal approval assuming all stipulated conditions of IACUC approval are met. The IACUC reserves the right to suspend review of proposals and require full resubmission of an animal use application at any time.
- (5) Final IACUC review of a protocol will result in: (1) approved as presented; (2) required modifications (to secure approval), (3) provisional approval imposed with conditions; (4) or approval withheld. Approval, specification of provisions or modifications for approval, or disapproval by full IACUC review will require a majority vote by a quorum of the IACUC and details will be provided to the Principal Investigator in writing as to all reasons for the action taken.
- (6) If IACUC approval of a protocol is withheld, the Principal Investigator may appeal to the IACUC and request to appear at a convened session of the IACUC. The committee may reconsider the animal protocol approval status and re-review the protocol in accordance with Section VII, part C of this policy. If a re-review of protocol is conducted, the end result of any post-appeal vote will be final. Additionally, the Institutional Official shall have the authority to deny approval for an animal-related activity to be conducted regardless if IACUC approval is previously obtained.

D. IACUC Approval Exemptions

In cases where there is question as to whether or not IACUC approval is required for a proposed animal activity, investigators are to contact the University Animal Care office for advice. Upon consultation with the ACFOM, the Principal Investigator of a proposed study involving animals may request IACUC approval exemption. Upon consultation with the IACUC Chairperson (and another consulting member of the IACUC, as appropriate), the ACFOM will send a request of project exemption to the Principal Investigator of a study. If the request for IACUC approval exemption based on the responses from the Principal Investigator in relation to the provisions set forth in this policy. If applicable, a notice of project exemption will be provided to the Principal Investigator, SJSU Foundation, Office of Graduate Studies and Research or outside agencies to satisfy any legal or institutional requirement for use of animal subjects.

ACTION BY UNIVERSITY PRESIDENT: Approved by President Don Kassing on

December 11, 2006

Appendix A

Project Categorization of Pain and Distress in Laboratory Animals

Category I: Use of non-living tissues, invertebrates, fertile eggs or observational studies

Most category I level projects require IACUC approval, as specified below, and are to be submitted using one of the three abbreviated forms described here. All applicable collection or access permits must accompany the submission along with a cover letter to include the project title and any other pertinent information that could not be included on the application short form. Proposals identified by a higher pain category level (II, III, IV or V) are to be submitted using the standard protocol application for animal care and use. Contact the University Animal Care office for assistance in categorizing/inquiring about an animal care and use proposal.

The *abbreviated component for the use of non-living tissues* covers investigations that involve acquiring, handling or manipulating preserved non-human tissues or specimens (i.e., excrement, hair, feathers, bone, or secretions) that are to be obtained from archived sources or opportunistically in the field. The Principal Investigator must be able to provide details as to the humane methods in which a sample was obtained or collected as requested by the IACUC.

The abbreviated component for the use of invertebrate species or fertile eggs covers investigations that entail the use of invertebrate species or manipulation of fertile eggs that does not extend beyond a defined stage of gestational development. For the use of invertebrates, the IACUC requires review and approval of projects that entail permission being sought from a government agency or granting of special permission (whether written or verbal) by private individuals to access, collect, or deploy the species being studied, even if specimens are obtained commercially. The provision for IACUC approval of invertebrate studies also extends to work involving animal species considered venomous or a threat to public health, endangered, threatened or of special concern. Although IACUC approval is not mandatory for all invertebrate work, it is highly recommended that investigators pursue committee approval for graduate or research projects to be kept on file with the University Animal Care office should questions arise.

The *abbreviated component for observational animal studies* covers purely observational studies that do not involve the handling or disturbing of a live animal in its natural habitat. The IACUC requires review and approval of observational studies that entail investigator permission from a government agency or granting of special permission (whether written or verbal) by private individuals to approach the species or to gain regional access to conduct the study. Although IACUC approval is not mandatory for observational studies not requiring permits, it is highly recommended that investigators pursue committee approval for graduate or research projects to be kept on file with the University Animal Care office should questions arise.

Category II: Activities that may produce little to no pain or distress in animals

<u>In General:</u> Category level II investigations involve the handling or manipulation of live vertebrate species that produce little or no physical pain or distress and would not warrant relief of discomfort.

Animal Care is to comply fully with University Animal Care specifications and standards pertaining to routine husbandry practices, physical space requirements and food/water restrictions for the proposed species. *Procedures* include momentary and skillful restraint, administration of intra-venous, intra-muscular, intra-peritoneal, sub-cuticular or intra-dermal injections and oral dosing of IACUC approved compounds; field studies that involve IACUC approved trapping and release methods; non-invasive identification methods (i.e., superficial tag placement, ear notching), non-invasive tissue sampling methods, or to obtain intra-vascular blood samples (with pre-sedation as deemed appropriate). *Chemical usage* includes the administration of harmless substances such as antibiotics, sedatives or tranquilizers. The use of anesthetics or analgesics is not appropriate for this category. *Euthanasia* methods are limited to intra-venous administration of IACUC approved compounds (e.g., barbiturates); inhalation methods that induce rapid unconsciousness (e.g., isoflurane, carbon dioxide), or an IACUC approved physical method preceded by chemical immobilization or sedation.

Category III: Activities that may produce mild to moderate pain or distress in animals

<u>In General</u>: Category level III investigations may produce minor distress, discomfort or short-duration pain in live vertebrate species in which every effort is made to relieve discomfort and to ensure the animal's well being by providing supportive care.

Animal Care that retracts from University Animal Care specifications and standards pertaining to routine husbandry practices, physical space requirements or food/water rations or restrictions for the proposed species. *Procedures* include the use of local anesthetics, IACUC approved adjuvant systems and techniques, tumor harvesting, ascites production, repetitive chemical restraint and minimally invasive surgical procedures such as chronic catheter implantation, tissue biopsy, superficial internal transponder placement or routine headstage implantation. Procedures conducted on anesthetized subjects include retro-orbital sinus bleeding, tattoo identification or invasive tissue sampling methods. Investigators are expected to outline an appropriate supportive care regimen for manipulations known to impair an animal's ability to eat, drink or ambulate normally. Chemical usage includes the administration of dissociative and general anesthetics, substances that produce a mild to moderate, but tolerable localized tissue reaction, including low-level infectious or chemical agents. The use of analgesics will be required if deemed necessary by the IACUC. Psychological distress is limited to behavioral testing on conscious animals whereas mild to moderate noxious stimulation is produced for short periods and escape is impossible or such stimulation is introduced for longer periods and escape is possible. Euthanasia methods that support the scientific objective and are performed within the recommendations of the American Veterinary Medical Association panel's guide on euthanasia, such as exsanguinations and total body perfusion/organ fixation under general anesthesia, IACUC approved physical means without prior chemical sedation and intravenous administration of potassium chloride on anesthetized subjects.

Category IV: Activities that involve analgesic relief of significant pain or distress in animals

<u>In General:</u> Category level IV investigations may produce significant pain or distress in live vertebrate species in which every effort is made to alleviate pain or discomfort with analgesics and to ensure the animal's well being by providing adequate supportive and veterinary care. 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.

Procedural considerations include invasive surgical procedures that involve significant post-operative discomfort, multiple major survival surgeries, organ transplantation/grafting, intrusive craniotomies or the use of paralytic drugs as part of the approved anesthetic protocol. Survival studies of this nature require that the Principal Investigator maintain post procedural animal health records documenting monitoring assessments, pain management, and supportive veterinary care schedules. 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.

Category V: Activities that produce substantial or unavoidable pain and distress in animals

<u>In General:</u> Category V level investigations involve producing substantial or unavoidable pain and distress in live vertebrate species whereas the means to alleviate or manage adverse suffering is contraindicated. Such activities are considered highly questionable and must be deemed irrefutably necessary by design to receive IACUC approval.

Chemical usage includes the use of paralytic agents on conscious animals without general anesthesia, administration of substances whose effects are unknown or exposure to compounds that may prolong suffering or result in death. Procedural considerations include conducting novel biomedical experiments with a high degree of invasiveness or maintaining study animals with marked cognitive or physical impairment without providing the appropriate means of supplementation or veterinary care. Euthanasia methods which deviate from the recommendations of the American Veterinary Medical Association Panel's guide on euthanasia in support of the scientific objective, including death as an endpoint.

Appendix B

IACUC Guide for Health Risk Assignment of Protocols

Applicability:

In addition to their normal responsibilities surrounding animal welfare, IACUC members will now review incoming animal protocols along occupational health and safety dimensions in order to identify potential animals-related risks to protocol personnel. Each protocol will be assigned a "Risk Category" as described below at the time of its review. This process is meant to facilitate a safer work environment through education (e.g., zoonosis information), assessment and surveillance (e.g., Health Center Physician), and training (e.g., UAC safety tutorial).

Risk Category Descriptions:

Appropriately, the IACUC's criteria for protocol risk category assignment will be based on the potential hazards posed by the animals and materials used; on the exposure intensity, duration, and frequency; on the susceptibility of personnel and on the history of occupational illness and injury in the particular workplace. The extent of personnel participation in the LAOHP is dependent upon individual risk of exposure and IACUC assignment to Health Risk Category 1 (RC-1), Category 2 (RC-2) or Category 3 (RC-3).

- RC-3 is considered the highest acceptable risk, which includes duties performed by UAC veterinary professionals, dedicated animal care staff, and individuals who are at **serious risk of exposure** (e.g., working with non-human primates, hoofed animals or highly toxic compounds). Specific risk factors are variable and are dependent on individual contact with live animals or materials as identified in the approved protocol. Personnel involved with projects identified by the IACUC as RC-3 will be informed they must participate in the LAOHP for medical consultation and to receive health clearance by the LAOHP physician prior to working with live animals or hazardous materials. The LAOHP physician will evaluate personnel using the LAOHP questionnaire as a basis to determine individual participation and what preventative health measures are necessary and dictate what procedures shall be followed in the event of an chemical or animal-related exposure.
- RC-2 indicates average to potential high risk of exposure (such as bites, scratches, allergies or zoonotic diseases) for personnel having **routine contact** with purpose-bred animals or participating in certain field studies. At the time an RC-2 level protocol is approved, the IACUC will provide the Principal Investigator with relevant information, educational materials and/or periodic updates on health and safety issues associated with the particular animal species to share with all personnel listed in the protocol. Upon reviewing this information with the Principal Investigator, personnel associated with the study may then determine whether or not they should proceed by participating in the LAOHP for prior medical consultation and evaluation (including pregnant or immuno-compromised individuals).
- **RC-1** covers all approved animal activities posing minimal risk of exposure to personnel having **minimal contact** with purpose-bred animals or participating in field trips. Through general training in laboratory animal use, personnel will be informed of the risks associated with Animal Bio-Safety Level One projects and inherent risks associated with field work. Investigators and their staff will be informed of the LAOHP services available to them and are encouraged to complete and submit an LAOHP questionnaire at any time during the study as required.

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

(FOR IACUC USE)	

Protocol for Animal Care and Use

This Form Must Be Typed. Refer to application instructions when completing this form.						
	ate Submitted ection 1: Project In	farmatian		Renewal of #		
Α.	Title of Study:					
В.	Principal Investigator			Department:		
	Mailing Address/ Pho	ne Number:				
	Fax Number:	Ema	il:			
C.	Co-Investigator:			Affiliation:		
	Phone Number:	Fax Numl	oer:	Email:		
D.	Project Start Date:		1	Project End Date:		
Ε.	Type of Study (Check	all that apply):				
	[] Classroom or Inst	ructional; include cou	rse numbe	ers		
	[] Research project	[] Field Study (Instructior	or Research related)	[] Grant pi	oposal
	[] Privately funded	[] Publicly funded	Fundir	ng source		
S	ection 2: Animal Sp	pecifications				
	Common Name 1 2			3		Number/Project
	3					
	4. Attached is requested i				d on this page	
	Are permits required		or handle	the animals used for	this project? [] Yes [] No t)
Н.	I. Are any of the above-mentioned animals a species of concern, threatened, or endangered? [] Yes [] No (If yes, provide details in Section 8 addendum)					
S	ection 3: Ethical Inf	formation				
I.	Project Categorization	of Pain and Distress in	Laborato	ry Animals: (check t	he highest applicabl	le category)
	Category One: [Do Not Us	e This Form] Category Tv	vo: []	Category Three: [] C	ategory Four: []	Category Five: []
J.	I. Is the quantity listed in Section 2-F the minimum number of animals necessary for this study? [] Yes [] No (If no, provide rationale in Section 8 addendum)					'[]Yes []No
K.	Can preserved specin (If no, provide rationale in S	nens or the use of non- Section 8 addendum as to v				y? []Yes []No

Section 4: Personnel Working with Animals

L.	Name	Affiliation	Animal Experience and Necessary Training in Animal Care and Use			
[]	Attached is requested	information on additional p	personnel that could not be included on this page.			
	(If yes, provide details		the University Animal Care staff for this project? [] Yes [] No here UAC services are requested) is Involving Animals			
N.	_	lural Outline: [] No				
			Route: [] IV [] IP [] Other			
			Frequency			
			rrequency			
		·	Route: [] IV [] IP [] SQ [] IM [] Other			
			Noute: [] IV [] III [] Star [] IIII [] Other			
			Method of Restraint			
			Route: [] IV [] IP [] SQ [] IM [] Other			
			Drug Concentration			
			Method of Restraint			
[]			procedures that could not be included on this page.			
-	5. Will animals be m	5. Will animals be maintained in the research or teaching lab for more than 12 hours? [] Yes [] No				
	If yes, what location	on? SJSU:	Other:			
Ο.	Surgical Procedure Outline: [] Not Applicable					
	1. Surgical Procedu	e				
	2. Survival Surgery?	[] Yes [] No	Multiple Surgeries? [] Yes [] No			
	3. Surgery to be per	formed at [] SJSU:	[] Other:			
	4. Anesthetic Used _		Route: [] IV [] IP [] IM [] Other			
	Dose Administere	d	Anesthetic Concentration			
	Method of Restrai	nt	Administered by			
	5. Anesthetic Used _		Route: [] IV [] IM [] Inhalation [] Other			
	Dose Administere	d	Anesthetic Concentration			
	Method of Restrai	nt	Administered by			

•	6. Will the animals be endotracheally intubated?	[] Yes, tube size: [] No					
7	7. Name and affiliation of individuals performing surgery	Experience and any necessary training for performing surger					
[]/	Attached is requested information on additional personnel	that could not be included on this page.					
P . /	Post-Operative Care for Anesthetic Procedures:	Not Applicable					
		ed by: [] UAC [] Other					
	2. Observation frequency						
	3. Will observation records be maintained and made						
_	Dose Administered	Route: [] IV [] IM [] SQ [] Other					
		Administered by: [] UAC [] Other					
į		Route: [] PO [] IM [] SQ [] Other					
		Drug concentration					
		Administered by: [] UAC [] Other					
	2. Classification: [] Carcinogen [] Toxic [] Radioisotope [] Other 3. Physiological effects include: 4. Personnel to have contact with this agent:						
ţ	5. Personal protective equipment used:						
	Provide details on precautions to be taken with handling, o	decontamination & disposal in Section 8 Procedural addendum					
	•						
1	Will Biologically Infectious Agents be used in this stu 1. Organism/Agent						
2	2. Classification: [] Viral [] Bacterial [] Fungal [] Other						
	3. What Bio-Safety Level is this work considered?						
4	4. Personnel to have contact with this agent:						
	5. Personal protective equipment to be used:						
(1	Provide details on precautions to be taken with handling de	econtamination & disposal in Section 8 Procedural addendum)					

Section 7: Euthanasia of Animals S. Will animals be subject to "death as an endpoint?" []Yes [] No If yes, justify in Section 8 addendum. T. Will animals be euthanized as part of this study? [] Yes If yes, complete Section 7-U. [] No If not, will moribund or injured animals be euthanized by the methods described in the facility's Program of Veterinary Care as directed by the attending veterinarian? [] Yes [] No, description provided in addendum Can the animals be transferred to another SJSU approved protocol at the end of the study? [] Yes [] No U. Method of Euthanasia: 1. Physical Means: [] Not applicable a. Method used b. Will pre-sedation be used prior to physical means? [] Yes [] No If not, justify in Section 8 addendum. c. Will students be expected or allowed to perform this procedure? [] Yes 2. Chemical Injection: [] Not applicable a. Administration of ______ Route: [] IV [] IP [] Other _____ b. Dose Administered _____ Drug Concentration _____ Performed by _____ c. Method of Restraint 3. Inhalational Method: Not applicable a. Substance used b. Means of Administration V. Disposition of Live Animals, Carcasses or Tissue: 1. How will carcasses or tissues be disposed of? [] In biohazard bags and placed in cooler located in DH-437 2. Describe procedures for releasing or handling live animals upon completion of the study: [] Not applicable **Section 8: Project Description and Justification**

- W. Non-technical Description and Justification of Project. (To be typewritten and attached to the completed application)
 - 1. Name of Primary Investigator(s) and Title of Study;
 - 2. Project Purpose and Research Objective;
 - 3. Hypothesis being tested and Anticipated results of the study;
 - 4. Methods and Procedures* (detailed lay description of all aspects of animal care and use from acquisition to completion of the study)
 - 5. Rationale for using live animals and procedural justification, including literature search for sections b, c & d**
 - a. provide written justification/calculations as to the number of animals required for the study;
 - b. examine alternative use species of a lower phylogenetic order, inanimate models or non-living tissues;
 - c. investigators <u>must</u> explore alternatives to <u>all</u> procedures that cause more than momentary or slight pain, discomfort or distress in live animals and support that all proposed methods and procedures are current practice;
 - d. explore and conclude with a statement of assurance that there exists no unnecessary duplication of experiments.

^{*}The information requested in this section should amount to a concise and non-scientific lay depiction of all aspects in animal care and use for this project from animal acquisition to their disposition upon completion of the experiment.

^{**}The literature search should be presented in narrative format to include: 1) date the search was conducted, 2) search engines used or sources referenced, 3) key words used in the search, 4) date range of citations found (e.g., 1985 to present), 5) citing any articles in support of the search objective, 6) concluded in summary as to the results of the literature search and includes required justification as requested in Section W- 5 and elsewhere on this form.

Section 9: Investigator Signature and University Endorsement

X. Investigator/Instructor Statement and Signature:

	The care and use of the animals for this study will comply with all IACUC policies, including the SJSU Academic Senate Policy on the Humane Care and Use of Animals (F97-6 and any subsequent revisions thereof), which I have read and understand. By signing and submitting this proposal, I hereby assure the SJSU IACUC that all animal work described herein is complete, accurate and will not be unnecessarily performed or duplicated in research or curriculum. Furthermore, I understand that all animal manipulations (or modifications thereof) must be granted written IACUC approval before the work commences.					
	Faculty Sponsor/Advisor Name	Faculty Sponsor/Advisor Signature	Date			
Υ.	Department Chair or College Dean Sign	nature:				
		al, I hereby endorse the project on behalf of the d is part of the academic experience or to achieve t				
	Department Chair or College Dean Name	Department Chair or College Dean Signature	Date			
Se	ection 10: Institutional Animal Ca	re and Use Committee Approval				
Z.	IACUC Approval of Protocol #	Health Category: RC-1 R	PC-2 RC-3			
Re	SJSU IACUC Chairperson Name	SJSU IACUC Chairperson Signature	Date			
_						
	S51	n Jasé Staice				
	UN	IWERSITS				