Institutional Animal Care and Use Committee (IACUC)

Institutional Policies on the Monitoring of the Care and Use of Animals

Graduate and Research Affairs
Division of Research Affairs

PHS, OLAW Assurance #A3728–01
USDA REGISTRATION #93–R–0425

May 2004, Revised July 2008 and accepted December 2008
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1. GENERAL ADMINISTRATIVE AND ORGANIZATIONAL RESPONSIBILITIES

1.1 Institutional Commitment
This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by the Animal Welfare Assurance in accordance with the Public Health Service (PHS) Policy for Humane Care and Use of Laboratory Animals. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with the Assurance, as well as all other applicable laws and regulations pertaining to animal care and use. The Animal Welfare Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, involving live vertebrate animals.

This Institution has established and will maintain a program for activities involving animals in accordance with the “Guide for the Care and Use of Laboratory Animals” ("Guide").

1.2 Institutional Animal Care and Use Committee (IACUC)

1.2.1 General Responsibilities
The IACUC is a standing committee of the University Research Council. The IACUC is responsible for ensuring compliance and accountability with the U.S. Department of Agriculture (USDA) Animal Welfare Act and Public Health Service (PHS) policies. This responsibility minimally requires that the IACUC will:

Maintain appropriate membership.

Review all proposed uses of live vertebrate animals in research, teaching and testing, including regular reviews of all ongoing projects.

Inspect all animal facilities, at least once every six months. The Institute of Laboratory Animal Resources (ILAR) Guide for the Care and Use of Laboratory Animals (the Guide) is used as a basis for the evaluation. Deficiencies noted are classified as "significant" or "minor." Expected completion dates for deficiencies to be corrected are specified in a report and in correspondence to the responsible parties. Any corrections required by the USDA will be reported to the USDA.

Review the animal care and use program at least once every six months.

Submit semi-annual reports of facility inspections and program reviews to the Institutional Official (Vice President for Research).
Submit an annual report to NIH, PHS, and OLAW detailing changes in the animal care and use program, changes in IACUC membership, and the dates of the semi-annual facility inspections and program reviews.

- Submit an annual report to the USDA as long as registration is maintained. SDSU USDA Registration #93-R-0425.

- Submit Assurance renewal every 4 years to OLAW. SDSU Animal Welfare Assurance #A3728-01.

- Investigate all concerns involving the care and use of animals at SDSU.

- Make recommendations to the Institutional Official regarding the animal care and use program, animal facilities, and the care and use training programs available to personnel.

- Suspend a previously approved animal-related activity if the committee determines that the activity is not being conducted in compliance with the Animal Welfare Act, PHS policy, or IACUC policy.

- Ensure that investigators have appropriate training to use animals as proposed in the approved animal protocol forms (APFs).

- Cooperate with other SDSU administrative units (e.g., GRA, SDSURF, EH&S) to ensure compliance with related University policies and regulations involving animals (e.g., biosafety, material transfer, student research, sponsored research).

- Conduct meetings in accordance with Robert’s Rule of Order.

- Maintain all protocols for the duration of the activity and for an additional three years after the end of the activity.

- Maintain all other records (i.e., IACUC minutes, semiannual reports, OLAW assurance (4 year approval and annual reports) for at least three years after reported or expired.

- Copies of all protocol submissions are available in the Graduate and Research Affairs, Division of Research Affairs office for review by IACUC members.

1.2.2 Composition and Lines of Authority
The Vice President for Research appoints members to the IACUC for a one-year renewable term. The committee membership meets minimal federal requirements and includes a doctor of veterinary medicine; one practicing scientist experienced in research involving animals; and one non-affiliated member (not affiliated with the institution nor the immediate family of a person affiliated with the institution) who is a non-scientist to represent general community interests. The IACUC also includes a representative of the campus Environmental Health and Safety program and a
representative of the Institutional Official (IO) as ex-officio member. The vivarium manager may also serve as a member of the IACUC.

The IACUC Chair, in consult with the IO through the Director, Division of Research Affairs periodically evaluates the committee membership to ensure an appropriate number of scientists to provide expertise in the species most commonly used by animal users on campus. The need for additional members is proposed to the Institutional Official who then makes the appointment.

Graduate and Research Affairs, Division of Research Affairs oversees all research activity conducted through the University. The Vice President for Research has been designated as the IO with signatory authority for the SDSU Assurance of Compliance with the PHS Policy on Humane Use of Laboratory Animals. The Vice President for Research reports to the Provost and to the President. The Director, Division of Research Affairs is an ex-officio member of the Institutional Animal Care and Use Committee and reports to the Vice President for Research. A full time manager oversees the vivarium facilities and other duties associated with the Office of Laboratory Animal Care (OLAC) and reports to the Associate Dean of the College of Sciences. A faculty member appointed by the Vice President for Research serves as the IACUC Chair. The Veterinarian reports to the IO via the Director of the Division of Research Affairs and has open communication to both the OLAC Manager and the IACUC Chair. Both the Veterinarian and OLAC Manager are voting members of the IACUC.

Faculty who are active in the research community may be contacted to discuss service to the committee. Individuals may also volunteer to participate on the IACUC. The IACUC Chair, Director, Division of Research Affairs and the Vice President for Research discuss committee composition and membership prior to appointing new members. The Vice President for Research appoints members to the IACUC. Reappointment may occur on an annual basis provided the member demonstrates a continued interest in animal research, knowledge of regulations and ethical standards in ascertaining the acceptability of proposed research, and has the time to devote to associated responsibilities.

No member may participate in the review or approval of a research project in which the member has a conflicting interest (i.e., financial, personal or professional) except to provide information requested by the IACUC.

1.2.3 Frequency of Meetings
IACUC meetings are scheduled monthly, as needed.

1.2.4 Meeting Notification
Members are informed of the monthly meeting schedule at the beginning of the academic year. One week prior to an IACUC meeting an agenda is sent to the members listing protocol activity to be discussed at the meeting. The agenda also includes the status of all protocols reviewed by DMR. The minutes of the last meeting are also sent at this time.
1.3 Scope of SDSU IACUC Oversight

1.3.1 Activities requiring approval by the IACUC

All persons affiliated with SDSU conducting research or instructional activities involving vertebrate animals (living or dead) or specimens, who perform the work on or off campus, regardless of funding, are required to submit their research plan to the Division of Research Affairs for review determination. The IACUC Administrative Coordinator provides guidance to the PIs in determining the appropriate review for the performance of those activities.

Any questions as to whether an activity involving live animals needs IACUC approval should be discussed with the IACUC Chair. To facilitate the application process, the IACUC has developed three APF formats, one for work in a laboratory setting, one for field work, and one for tissue collection only. Some general examples of activities that require IACUC approval include, but are not limited to:

- SDSU faculty research with or without funding;
- SDSU graduate student research with or without funding;
- Classroom demonstrations using live animals;
- Field trips to collect or observe vertebrates;
- Observation of animals in captivity (e.g., San Diego Zoo);
- Analysis of animal tissues that others have collected;
- Field testing of an apparatus designed to be used in fish aquaculture;
- Generation of transgenic or other genetically altered animals;
- Projects being conducted using state or Research Foundation facilities regardless of the investigator’s affiliation with SDSU;
- Laboratory projects conducted at an off-campus location by SDSU affiliates.

1.3.1.1 Animal Tissue Use and Collection

The IACUC is charged with protecting animals and assuring compliance with all federal, state and institutional laws and regulations. All SDSU faculty, staff and students who have proposed to involve vertebrate animal tissues in their research or teaching under conditions in which they have no direct contact or other involvement with the live animals must submit an Application for Tissue Use and Collection Only form to the IACUC. The IACUC Chair, Campus Veterinarian and Environmental Health and Safety representative will review the application and determine if any further action or information is needed. The IACUC is informed of the submission, but does not require review of the application.

An APF number is assigned to the application for consistency of record keeping. The researcher completes one Application of Tissue Use and Collection Only form for all species of tissues to be used or collected (blood is considered a tissue). Yearly status confirmation from the investigator is required to maintain active status and to report any changes to the study that may impact review procedures.
Animal Health and Welfare Training is not required for personnel working only with animal tissues under this application; however, a copy of the application is sent to Environmental Health and Safety and additional training may be required.

1.3.1.2 Dead Animals
Use of tissue specimens from dead animals for research or teaching requires some IACUC oversight. This includes species used for another authorized purpose and intended for discard (“samples of opportunity”) and animals found dead along the road or in the wild. It is expected that any affiliated faculty, student, or employee proposing to harvest tissues from “already-dead” animals will notify the IACUC Chair and or the IACUC Administrative Coordinator and complete any necessary paperwork, including the Application for Tissue Use and Collection Only Form. This activity may also require the approval of Environmental Health and Safety, as animals found dead along the road or in the wild could have zoonotic diseases.

Prior IACUC protocol review and approval is required under the following circumstances: (1) killing animals for the purpose of obtaining or using their tissues or other materials, or (2) project-specific antemortem manipulation of animals prior to killing them.

The IACUC membership includes representation from the Division of Research Affairs and Environmental Health and Safety to further ensure compliance with institutional regulatory requirements involving animals. Any biological materials transferred on or off campus also may also require the completion of a Material Transfer Agreement (MTA) which can be filed through the Division of Research Affairs. In addition, the use of biological materials may require submission of a Biological Use Authorization (BUA) form to the Institutional Biosafety Committee.

1.3.2 IACUC Oversight of Pets on Campus
IACUC oversight does not extend to pets that may be on the SDSU campus. However, the IACUC recommends that principal investigators be familiar with the diseases that pets may carry, which could in turn be passed along to research animals.

1.3.3 Field Work and SDSU Field Stations
Field work involving live vertebrate animals conducted by SDSU faculty, staff or students must be approved by the IACUC as per federal requirements. Work conducted on SDSU field station property is unique in that SDSU is also the primary caretaker of resident animals at the field stations. Any researchers or instructors applying to work on SDSU field station property whose research or teaching activities could impact resident vertebrate animals must contact the IACUC for approval of this activity.

The field station director will make the determination of whether referral to the IACUC is appropriate and consult with the IACUC chair and campus veterinarian as needed. The principal investigator is then responsible for following through with the necessary APF approval and training requirements discussed below.
IACUC approval to conduct work or classroom activity proposed for field sites is limited to impact on animals and benefits to be gained. Permission to conduct work at the field station(s) for classroom activity must also be obtained from the IACUC before the activity may commence at the field station.

Work conducted at the field station that may impact animal health and welfare must have an approved SDSU APF. Students must have an SDSU faculty sponsor to supervise their work.

To obtain IACUC approval, individuals named on the APF must complete basic Animal Health and Welfare training for field work and occupational health and safety training. Training is provided through SDSU's Blackboard system. It may also be required to contact Environmental Health and Safety to obtain the necessary personnel protection equipment (e.g., respirator fitting). APF approval is contingent on obtaining required training of all personnel working on the project. The principal investigator is responsible for ensuring that all personnel have obtained the appropriate training.

1.3.3.1 Observational Studies of Wildlife

These studies must also be approved insofar as even the presence of the observer could potentially affect the psychological and physical health and well-being of wild animals and could also apply to animals being held in captivity. The Field Study APF is used for observational research. These projects also may require compliance with state and federal wildlife protection laws and the consent to observe.

1.4 Project Review and Approval

All persons affiliated with SDSU conducting research or instructional activities involving vertebrate animals (living or dead) or specimens, who perform the work on or off campus, regardless of funding, are required to submit their research plan to the Division of Research Affairs for review determination. The IACUC Administrative Coordinator provides guidance to the PIs in determining the appropriate review for the performance of those activities.

1.4.1 Investigator Responsibilities

Investigators and instructors using animals in research, testing, or teaching have a professional obligation to provide healthy conditions and humane care to animals in their care before, during, and after experimental or other procedures. The IACUC review process is designed to assist in fulfilling that responsibility. To ensure understanding of these responsibilities, investigators are asked to review the investigator assurance of compliance section of the Animal Protocol Form (APF) as part of their protocol submission.

Any use of live vertebrate animals for research or teaching requires review and approval of an Animal Protocol Form (APF). For sponsored research, an APF should be submitted at the time a principal investigator receives notification that the proposal will likely be funded. The SDSU Research Foundation will not authorize the release of funds until the investigator has obtained an approved APF.
Proposed involvement of animals in an SDSU course also requires prior IACUC approval.

1.4.2 Student Researcher Responsibility
A full-time faculty or professional staff member with an advanced degree must agree to accept responsibility for the project and serve as the Responsible Faculty (Principal Investigator). **Student researchers, and postdoctoral fellows may not serve as principal investigator.** Students who plan to conduct research involving the use of animals should discuss plans with their faculty advisor well before beginning the work. An APF or amendment to an existing protocol must then be submitted by the faculty advisor to the IACUC for approval. Students are required to complete the on-line Animal Health and Welfare Training and receive other necessary hands-on training for any procedures that may be performed and/or the necessary vivaria training.

1.4.3 Basis of APF Review
All persons affiliated with SDSU conducting research or instructional activities involving vertebrate animals (living or dead) or specimens, who perform the work on or off campus, regardless of funding, are required to submit their research plan to the Division of Research Affairs for review determination. The IACUC Administrative Coordinator provides guidance to the PIs in determining the appropriate review for the performance of those activities.

Generally, all new protocol submissions, renewals, or amendments to existing protocols are reviewed by Full Committee Review (FCR) however could be reviewed by Designated Review (DR).

1.4.4 Frequency of Committee Review
Protocols are approved for 3 years from the date of original approval. Protocols are reviewed annually during the approval period.

1.4.5 Categories of Animal Use

**CATEGORY 'A'**
Studies on non-living vertebrate animal material, observation of living wildlife, and/or where there is no contact with live animals. Examples include vertebrate animals tissues obtained at necropsy, slaughterhouse, and observational studies on wildlife and other animals that do not involve physical restraint, contact or handling.

Museum specimens or animal tissue purchased from a grocery store are excluded from IACUC review.

**As defined by the USDA:**

**CATEGORY 'B'**
“Animals that are being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.” This category is used solely for breeding that does **not** involve surgical implantation.
**CATEGORY 'C'**
“Animals upon which teaching, research, experiments, or tests are conducted involving no pain, distress, or use of pain-relieving drugs.”

**CATEGORY 'D'**
“Animals upon which experiments, teaching, research, surgery or tests are conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs are used.”

Examples include but are not limited to: surgery conducted with general anesthesia and postoperative analgesia; rodent retroorbital bleeding under anesthesia; prolonged periods (more than 15 minutes) of physical restraint; terminal exsanguination (euthanasia by removal of blood) under anesthesia.

**CATEGORY 'E'**
“Animals upon which teaching, experiments, research, surgery or tests are conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, research or interpretation of the teaching, research, experiments, surgery, or tests.”

Examples include application of noxious stimuli from which escape is impossible; induction of aggressive behavior leading to self-mutilation or fighting. Also included are studies in which death is the end-point, i.e. diseases are induced and infected animals are permitted to succumb rather than be treated or euthanized.

**Type E studies place an explicit responsibility on investigators to explore alternatives to ensure that these methods are essential to complete the work. Justification for using these procedures must be explained in a statement by the Principal Investigator.** This statement is required by federal law. For covered species, the IACUC submits this statement in the annual report to the USDA.

**1.4.6 Convened Full Committee Review**
Upon receipt of a new animal protocol form (APF) the IACUC Administrative Coordinator communicates with the PI as necessary to ensure the submission is complete and all necessary attachments have been included. A protocol number is assigned and a file created. The protocol is logged into various secure databases for tracking purposes (i.e., protocol submission title, date, number, etc., animal numbers and species to be used, training of personnel, etc.). The completion of necessary training for the PI and all other personnel listed on the protocol is verified, or the individuals are enrolled in training and scheduled for vivarium orientation as needed. Primary and secondary reviewers are assigned to evaluate the protocol, routing sheets and reviewer checklists are prepared, submission is routed to reviewers, Veterinarian, and to the OLAC Manager, as well as EH&S as needed. The PI is notified of the routing process, the APF number, the date of the convened IACUC meeting and whether any additional compliance reviews are required to secure approval.
Preliminary review comments are compiled by the IACUC Administrative Coordinator and forwarded to the PI for comment in advance of the meeting. The primary reviewer then presents and explains the proposed research activity to the IACUC at a convened meeting with a quorum present. After discussion, a vote is taken and the protocol is either approved, will require modifications to approve, or denied.

If approved, a letter is sent to the PI to notify of the approval, the first renewal due date (internal standard practice), and expiration date of the protocol.

If modification to the protocol is needed to secure approval, correspondence is sent to the PI summarizing the points in question. Upon receipt of the revised protocol addressing the points, Designated Member Review (DMR) process verifies acceptance on behalf of the IACUC consistent with guidance entitled “Guidance to IACUCs Regarding the Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR)).” An IACUC approval letter is then sent to the PI. When modifications to secure approval are substantive, the revised protocol will be brought before the committee at the next scheduled meeting. A written description of the DMR process to review IACUC-required modifications was presented to the SDSU IACUC and all members have signed indicating their understanding and approval of this process. As with other DMR, the Designated Reviewer (DR) can either approve the modified protocol, require additional modifications for DR approval, or require that it again be presented for full committee review if the DR feels the protocol still does not meet guidelines and policies that would support approval by the DR.

If denied, a letter is sent to the PI informing of the denial with an explanation for that action. The PI may resubmit a protocol for review provided the issues are correctable. Approval will be granted if revisions made are acceptable to the IACUC.

1.4.7 Designated Review
Generally FCR is used to evaluate proposals. However DMR can be used for new protocols, renewals, and modifications to an existing protocol. In addition, the DMR is used subsequent to FCR when additional modifications are required to secure approval and implemented in accordance with guidance entitled “Guidance to IACUCs Regarding the Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR)).”

All IACUC members receive a list of submissions to be reviewed by DMR and are given a brief overview of the submission with access to the necessary information and file. If any member feels that a submission should go before a full committee, then its review must be deferred to the next convened IACUC meeting. Any member can make the decision to send the submission to full-committee review at any time during the 2 to 5 day option to call for FCR. If FCR is not requested, at least one member of the IACUC, designated by the Chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modification to secure approval or request FCR of those research projects. The Veterinarian receives all submissions, the OLAC Manager and representative of Environmental Health and Safety may also receive a copy of the
protocol to review on an as-needed basis. The designated reviewer does not have the authority to withhold or deny approval, however, and must refer the protocol to the IACUC for full-committee review.

1.4.8 Administrative review
Additions and deletions of personnel, other than the PI, are administratively reviewed by the IACUC Administrative Coordinator. PI change in an existing protocol requires DMR. The IACUC Administrative Coordinator will ensure that all such personnel are appropriately identified, adequately trained, and enrolled in applicable occupational health and safety programs. All criteria regarding personnel training and qualifications are maintained and documented by the IACUC Administrative Coordinator.

1.4.9 Emergency Review
If necessary, meetings can be convened on an emergency basis provided a quorum of voting members is present.

1.4.10 Teleconference Review
Alternatively, emergency meetings could be conducted by teleconferencing consistent with guidance provided in NOT-OD-06-052 “Guidance on Use of Telecommunications for IACUC meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.” All members would be given sufficient notice to participate and a quorum of the voting members must convene on the same conferencing line.

An Amendment form must be reviewed and accepted any time a modification is desired in the work; for example, addition of animals or personnel, changes in procedures, addition of chemicals used, etc. When significant changes are requested on an Amendment form, the original APF must be consulted in order to evaluate the impact of the change on the entire project. In general, Amendment forms are handled in essentially the same way as original APF’s in terms of review process, possible outcomes, and actions taken with the exception of Administrative reviews. Multiple or more complex procedural changes (new agents to be administered, additional surgeries on the same animals, etc.) clearly warrant more careful scrutiny of the entire project to evaluate impact.

1.4.11 SDSU IACUC Forms
Main Animal Protocol Form (APF)
The Main APF form is used when performing research in a laboratory animal facility. For guidance in filling out the form see: Instructions for Main APF

Amendment of Approved APF Form
Principal investigator must complete this form when there are procedural or personnel additions or deletions during your study (i.e., addition of grant or another project, change in animal numbers, changes in procedures, etc.).

Renewal of Approved APF Form
Principal investigator must complete, submit and have this form approved annually.
**Personnel Amendment Form**
Principal investigator must complete this form when there are changes in personnel working on the project.

**Field Study APF**
Use the Field Study Form when you are performing research in a field setting. For guidance in filling out the form see: Instructions for the Field Study APF.

**Application for Tissue Use and Collection Form**
Use the Application for Tissue Use and Collection form when studies are being conducted on non-living vertebrate animal material and where there is no contact with living animals. Museum specimens and grocery store items are excluded. For guidance in filling out the form see: Tissue Use and Collection Guidelines.

**Breeding Colony Information Form**
This form must be filled out and attached to your Main APF if you intend to maintain a breeding colony for your research.

**Literature Search Form**
This form should be submitted in addition to the Amendment form when procedures are added to an existing study that would require a literature search.

**Environmental Health and Safety Supplemental Questionnaire**
This form must be completed if the study includes biological hazards, transgenic animals, controlled substances, chemical hazards and/or radioisotopes.

1.4.12 **Electronic Document Submission**
The PI can submit documents electronically to the Division of Research Affairs, provided one hard copy of the original, signed document(s) is forwarded for the permanent file. The electronic documents are housed on a secure server and backed up weekly.

1.4.13 **Non-Institutional Investigator Responsibility**
A request to conduct research on campus by an investigator who is not affiliated with the University will be evaluated on a case-by-case basis provided an appropriate contract is negotiated with the approval of the Institutional Official.

Any and all use of live vertebrate animals requires the submission of an Animal Protocol Form (APF). An APF should be submitted at the time a principal investigator receives notification that the proposal will be funded. The SDSU Research Foundation will not authorize the use of funds until the investigator has an approved APF. Proposed involvement of animals in an SDSU course also requires prior IACUC approval.

The Office of Laboratory Animal Care (OLAC) and the IACUC provide support for SDSU research and teaching activities. The facilities are not designed or equipped to operate like a "contract" facility. The University may elect to accommodate reasonable requests for assistance with short-term animal housing needs when it is appropriate and in the best interest of the University community.
Conditions of approval for use of campus facilities by "outside" individuals are as follows:

(1) Use is always on a space-available basis, with the needs of regular campus research and classroom activities receiving first priority.

(2) As with all activities involving animals in SDSU facilities, the research or other activity proposed must be approved by the IACUC before animals can be used or brought to the facility.

(3) All individuals must be affiliated with SDSU in some significant way while using the SDSU vivarium facilities (for example, as Adjunct faculty). However, a request to conduct research on campus by an investigator who is not affiliated with the University will be evaluated on a case-by-case basis provided an appropriate contract is negotiated with the approval of the institutional official.

(4) Funds to cover per diem charges must come through the SDSU Research Foundation as a grant or contract. As with any Research Foundation proposal, a proposal must be routed through the SDSU Research Foundation and the activity must be reviewed and approved by campus administration and by the IACUC and OLAC before animals can be brought to the facility. The objectives of the work must be consistent with the research and teaching mission of the University.

(5) Per diem charges can be expected to be higher than the normal charges (e.g., generally twice the current rate). The OLAC Billing and Per Diem Policy and rate sheet can be obtained from the OLAC Manager.

1.4.14 Researchers conducting Research at an off-campus location under an NIH/PHS assurance:
When conducting research at an off-campus research facility, the SDSU PI must have IACUC approval for the work prior to the initiation of the work. If the off campus location has its own IACUC and has a PHS assurance or is AAALAC accredited, a copy of the off campus IACUC approved protocol and current approval letter may be accepted for clearance by SDSU to initiate the work at the off campus location however, must be reviewed by the SDSU IACUC. All SDSU personnel working on the project must be listed on the protocol as personnel working on the project, the dates of approval and expiration must be current and reasonable.

The off-campus facility must provide verification of an Assurance on file with the National Institutes of Health (NIH), Public Health Service (PHS), Office of Laboratory Animal Welfare (OLAW) or of Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation.

If the PI/faculty sponsor is responsible for oversight of a student project being conducted at an off-site facility, the PI/faculty sponsor must agree to monitor and advise the student during the course of the research.
All personnel listed on the APF must complete the SDSU online Animal Health and Welfare Training or provide verification that they have received and successfully completed similar training elsewhere.

1.4.15 Researchers Conducting Research at an Off-campus Location WITHOUT an IACUC or NIH/PHS Assurance:
These projects will be evaluated on a case-by-case basis and may be approved and monitored by the SDSU IACUC. The PI must submit a written proposal to the SDSU IACUC and obtain IACUC acceptance of proposed work before the work can begin. The proposal must contain a description of the work to be conducted, justification of animal use and the expected outcome. Once the proposal has been accepted, a formal APF submission will be requested. There may be a fee assessed for SDSU IACUC oversight.

The committee will appoint an individual who holds a position of responsibility within the university who is knowledgeable about proper care and treatment of animals to serve as a deputy who ensures that campus guidelines for animal care are followed at the off-campus site. This deputy will report to the campus veterinarian. The committee must also approve the designated caretaker for the project; that is, the person responsible for maintaining the feeding and cleaning schedules and monitoring the health and welfare of the animals by daily inspection.

The off-campus site must be reasonably accessible to the committee and the campus veterinarian for announced and unannounced inspections of the site, to include, but not limited to, the laboratory where the work is conducted and the animal housing facility.

The expense associated with inspections, which should occur at least twice per year, and consultations with the campus veterinarian will be the responsibility of the principal investigator or of the department with which the principal investigator is affiliated.

Before an APF involving animals housed off campus can be approved, a copy of this policy must be acknowledged by the PI.

1.4.16 IACUC Responsibilities: Reviewing Potentially Painful Procedures
The Guide for the Care and Use of Laboratory Animals, the USDA and PHS regulations require that Institutional Animal Care and Use Committees review protocols involving the use of animals in research. One of the important items the committee is to review is the potential for pain during the course of the proposed study. If there is a potential for pain, the committee must assess the severity and duration of that pain. If it is not known whether pain may occur, the committee may require a pilot study to adequately assess the potential for pain during the proposed procedure. If pain will occur, the investigator must describe the ways he/she plans on alleviating the pain. Withholding postoperative analgesics (pain relieving drugs) requires scientific justification, beyond the concern that analgesics might interfere with the purpose of the experiment. Finally, if pain is likely to occur, then the protocol should describe criteria for early removal from the study when pain and/or distress becomes evident.
While recognizing the need to use animals in biomedical research, Congress made clear the intent to minimize animal pain, distress, and discomfort in the 1985 amendment to the Animal Welfare Act, and mandated the Secretary of Agriculture to promulgate regulations to ensure that animal pain and distress are minimized. To clarify the published regulations, USDA’s Animal Care division developed two policy statements, or interpretive rules, dealing specifically with the issue of pain and distress in laboratory animals.

Policy #11 Painful/Distressful Procedures (April 14, 1997)
Addresses the issue of painful procedures, defined as, "A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in a human being to which that procedure is applied. The Institutional Animal Care and Use Committee (IACUC) is responsible for ensuring that investigators have appropriately considered alternatives to any procedures that may cause more than slight or momentary pain or distress. A written narrative description of the methods and sources used to search for alternatives must be provided. Where specific testing procedures are required by Federal law, the CFR references or other legal guidelines requiring them should be noted."

The policy provides three specific examples of potentially painful procedures and states that animals exhibiting signs of pain, discomfort or distress are expected to receive appropriate relief unless scientific justification is provided in the proposal and approved by the IACUC. The important message here is the default position requires the use of pain-relieving medications unless there is scientific evidence to demonstrate that they would interfere with the validity of end results. See the USDA Animal and Plant Health Inspection Service (APHIS) for further information.

Policy #12 “Consideration of Alternatives to Painful/Distressful Procedures”
(July 21, 2000)
Alternatives or alternative methods are generally regarded as those that incorporate some aspect of replacement, reduction, or refinement of animal use in pursuit of the minimization of animal pain and distress consistent with the goals of the research. These include methods that use non-animal systems or less sentient animal species to partially or fully replace animals (for example, the use of an in vitro or insect model to replace a mammalian model), methods that reduce the number of animals to the minimum required to obtain scientifically valid data, and methods that refine animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being. Potential alternatives that do not allow the attainment of the goals of the research are not, by definition, alternatives.

There is a statutory requirement to minimize pain and distress to animals during experimentation as well as the requirement for principal investigators to consider alternatives to painful or distressful procedures. This policy includes the expectation that principal investigators will not stop searching simply because they
are unable to find a non-animal model. Rather, Animal Care would expect the concepts of refinement and reduction to be applied whenever and wherever possible in order to minimize animal pain and distress if it cannot be eliminated. See the USDA Animal and Plant Health Inspection Service (APHIS) for further information.

1.5 Response to USDA Inspections

It is the responsibility and the policy of the IACUC to be responsive to federally-mandated inspectors of vivarium facilities, and to notify appropriate campus personnel of their findings and complete necessary corrective actions, including reports, within a timely manner. Procedures for following this policy for USDA inspections are as follows:

1.5.1 Who Meets with USDA Inspectors

The OLAC Manager, or alternatively, a designee who is also an experienced member of the OLAC, will be available during normal work hours during the week when inspections are likely to occur. The OLAC Manager or the designee will be called to escort USDA inspectors arriving unannounced. If there are discrepancies noted by the inspector, then the OLAC Manager will either address those items in question, or if the information is only known by the Principal Investigator, then he/she will be notified for further clarification. Information collected in response to an USDA request will either be placed in the USDA file for review at the next inspection or sent to the inspector, if requested.

1.5.2 Reporting of Inspection Results within the SDSU campus

Results of all USDA inspections will be reported to the IACUC (and thus to the Institutional Official through membership of his designee on the IACUC) no later than at the meeting following the inspection, and within 24 hours in the case of any serious discrepancy discovered by a USDA inspector. Notification of the IACUC Chair will constitute notifying the IACUC. If deficiencies are noted, the written inspection report will transmit the information within an appropriate timeframe to the campus veterinarian and others on the IACUC, which includes a representative of the institutional official (ex-officio member).

If no deficiencies are noted, the report will be filed in the Division of Research Affairs office.

1.5.3 Follow up Reports to the USDA

The IACUC administrative coordinator will complete the necessary USDA inspection reporting requirements within the required timeframe, and will ensure that appropriate documentation exists that accurately reflects the outcome of each inspection.

1.6 IACUC Semi-annual Facility Inspections and Program Reviews

PHS Policy and USDA regulations require the IACUC to inspect all institutional animal facilities every six months.

The inspections provide an ongoing mechanism for ensuring that SDSU maintains compliance with standards of good animal care as directed by the applicable animal care and use regulations, policies, and guidelines. The interaction of the IACUC and
the animal care personnel should be constructive and not adversarial, as both ultimately share the same goals of good animal care.

The IACUC uses the PHS Sample Semiannual Facility Review Checklist to guide the facilities inspection. At least two IACUC members participate in this review, and all members are notified of the facility inspection schedule to allow for their participation if they so desire. A member of Environmental Health and Safety, the Veterinarian, the OLAC Manager, and the IACUC Administrative Coordinator also participate. The facilities review report is submitted to the full IACUC membership for review and comment.

The IACUC determines whether the supervisory personnel of animal facilities will be notified of the date and time of an inspection. Advance notification allows individuals to be available to answer questions, but an unexpected visit shows the facility during usual operation.

After an inspection, reviewer comments are forwarded to the IACUC Administrative Coordinator who prepares draft reports of the evaluations. The level of deficiency (A=Acceptable, M=Minor, S=Significant) and time schedule for corrections to be made is included. The report is reviewed by all IACUC members for approval and any minority opinions are then included in the report. The IACUC approved report is then forwarded to the Vice President for Research, who reviews and acknowledges receipt of the report by signature. If a significant deficiency (defined as one which is or may be a threat to the health and welfare of animals or personnel) is identified, the responsible party is immediately instructed to correct it and the significant deficiency is then reported to OLAW through the IO. If the plan for correction is unable to be met within a reasonable, specified timeframe, the Principal Investigator (PI) is notified that all work with animals must stop until the deficiency has been corrected. APHIS and the relevant funding agency(s) will also be informed if the significant deficiency is not corrected within the reasonable, specified timeframe. The IACUC communicates minor deficiencies to the responsible party through standard mail and/or electronic correspondence. The responsible party is given 30 days from the date of correspondence to correct or provide explanation of why more time is needed and provide a realistic timeline for correction. The IACUC Administrative Coordinator tracks and records deficiency correction dates and provides follow-up reports to the IACUC as needed.

1.6.1 Areas Subject to Facility Inspection
The USDA regulations specifically require inspection of the centrally designated or managed animal resource facility as well as any other animal containment facility in which animals are kept for more than 12 hours. PHS Policy requires inspection of all areas in which surgical manipulations (minor, major, survival, non-survival) are performed. All SDSU campus areas (including vivaria, prep areas, laboratories, classrooms, and Research Foundation space) where live vertebrate animals are housed more than 12 hours or where surgical manipulations are performed must be inspected semi-annually by the IACUC. All proposals submitted to the IACUC must contain the details of the locations at which animal research is to be performed. Laboratories where work involving live vertebrates is being conducted may be inspected at the discretion of the IACUC. These areas must be open for IACUC inspection at any time, not just for semi-annual inspections.
If the individual responsible for an area ensures there are no animals being housed or work with animals being conducted at the present time the IACUC may postpone the inspection visit until such housing or animal work is planned.

When an off-campus non-affiliated facility has an NIH assurance or are AAALAC accredited and IACUC, it is expected that they conduct their own semiannual inspections and will not require semi-annual inspection by SDSU's IACUC. However, in most cases, the SDSU principal investigator working at the off campus site will hold the responsibility to oversee the project and ensure compliance is maintained.

Field sites, including field stations managed by SDSU, must be made available should the IACUC and veterinarian wish visit and inspect these sites and observe procedures involving live vertebrates if requested. An example of a field activity that might be visited by the IACUC is one in which wild animals could conceivably be confined for prolonged periods in cages or traps.

1.6.2 Performing Facility Inspections

All proposals submitted to the IACUC must contain the details of the locations at which animal research is to be performed. A list of the facilities will be maintained, indicating room number and species housed. For satellite areas, the presence of a contact person will be arranged prior to inspection. A map of each facility will assist the inspectors.

Detailed notes should be taken throughout the visit to assist in preparation of the final report. Apparent deficiencies should be discussed with the person in charge of the facility to ensure that the inspection team’s perception of the situation is correct. In some cases, an apparent deviation will be due to the experimental procedure in process; i.e., withholding of food prior to surgery.

Field sites do not currently require inspection but the IACUC and veterinarian must be allowed to visit and inspect these sites and observe procedures involving live vertebrates. An example of a field activity that might be visited by the IACUC is one in which wild animals could conceivably be confined for prolonged periods in cages or traps.

1.6.3 Documentation of Facility Inspection

Following the scheduled facility inspection, a report is prepared by the IACUC Administrative Coordinator. Any deficiencies are categorized as minor or significant. A significant deficiency is defined as one of significant threat to animal health or safety. A plan and timetable for correction of all deficiencies must be included in the final report. A letter is sent by the SDSU IACUC Chair to the party(s) responsible for correcting any deficiencies noted. If the activity is federally funded, the relevant agency must be informed by the IACUC within 15 working days of any lapsed deadline for significant deficiencies only.

The final inspection report is reviewed and approved by a quorum of the IACUC. Minority views are included in the final document.
1.6.4 Program Review and Evaluation
The IACUC performs a semiannual evaluation of SDSU's animal care and use program. The Guide for the Care and Use of Laboratory Animals serves as an outline for the program review and evaluation. The reflective self-evaluation focuses on the efficacy of IACUC procedures and policies and on their conformity to federal rules and guidelines. Program evaluations will include evaluation of: IACUC operation, OLAC policies, veterinary care, record keeping, occupational health and safety program, and training programs.

The report is reviewed and approved by a quorum of the IACUC. Minority views are included in the final document.

1.6.5 Semi-annual Report to the Institutional Official
After review by the IACUC, the written reports detailing the results of the semiannual facility inspection and the program evaluation are submitted through the Chair to the Institutional Official (Vice President for Research), with a request for signature indicating receipt of the report. Copies of all reports must be kept on file a minimum of three years.

1.6.6 Other Notifications Concerning Repeat Deficiencies
If serious or repeated departures from the Guide or PHS policy are found after sufficient notice is given to the parties responsible for bringing the facilities or program back into compliance, then the IACUC may notify the appropriate external agencies charged with oversight of SDSU’s animal program (e.g., NIH/OLAW, USDA). Under normal circumstances, sufficient notice to responsible parties would include transmittal of written descriptions of deficiencies; development and dissemination of a reasonable schedule for remediation, established in consultation with those responsible; and acknowledgment by all parties involved of dates by which specific actions must be taken before the IACUC will be obliged to alert external agencies within 15 days of failure to adhere to the timetable for correction of significant deficiencies.

1.6.7 Guidelines on Classifying Deficiencies Identified During Semi-annual Reviews
The fundamental basis of the relationship between an institution and the regulatory and accrediting organizations is the trust agreement between the parties. The following sentences are abstracted from the Institutional Administrator's Manual for Laboratory Animal Care and Use, NIH Publication 88-2959:

"The Congress and PHS have mandated that institutions establish IACUCs to oversee programs of animal use with the objective that these committees form the foundation for effective self-regulation."

The PHS Policy requires the IACUC to evaluate the Animal Welfare Program, to identify the deficiencies, and to make recommendations for correction of deficiencies within a reasonable time. The IACUCs are charged by the Animal Welfare Act to inspect, at least semi-annually, all animal study areas and animal facilities and review, at a minimum, the condition of the animals and practices involving pain. Reports of the inspections and reviews are to be filed with the institution and are to include a description of all 'violations' and 'deficiencies' as well as minority views.
This guideline is intended to expand upon the specific language in paragraph IV. B. 3. of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), which states:

"The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency."

1.6.8 Significant Deficiencies
A significant deficiency is any deviation(s) in policy, procedure or facility condition from the standards enunciated in the Guide for the Care and Use of Laboratory Animals (Guide), PHS Policy, or the Animal Welfare Act Regulations, which is/are or may be a threat to the health and safety of the animals. Such a finding is one which the IACUC collectively judges to be a major problem and should be reported to the Institutional Official. In the event the correction of the underlying deficiency requires the execution of a planned modification or improvement over a period of time, then a reasonable and specific plan and schedule for correction must be established as quickly as possible. Those findings should again be addressed within the body of the next semiannual report to the Institutional Official. As a significant deficiency, by definition, is a threatening environment for the animals, it follows that the reasonable and specific plan and schedule for correction must indicate that management and/or policy changes will be put in place immediately to either:

1) remove the condition causing the significant deficiency until a permanent correction can be put in place; or
2) minimize the negative impact of the deficiency as much as possible and for as brief a period as possible.

OLAW requires prompt reporting, in accordance with PHS Policy, IV, F.3. and expects an institution to correct the deficiency and bring the situation into compliance with applicable standards and regulations.

1.6.9 Minor Deficiencies
Any other deviation(s) in policy, procedure or facility condition from the standards enunciated in the Guide, PHS Policy, the Animal Welfare Act regulations, or IACUC policies and procedures, which are/were not justified exceptions to those standards are considered minor deficiencies. In comparison to the significant deficiencies noted above, minor deficiencies are variances which require correction, but which are not serious breaches of policy or conditions endangering the health and safety of the animals.

The semiannual review process gives the IACUC an opportunity to formally and specifically deal with the entire scope of its IACUC policies, procedures, and facility conditions in support of its Animal Care and Use program. The degree of
identification and reporting of minor deficiencies is a direct reflection of the thoroughness of the IACUC's oversight of its Animal Care and Use program and facilities, and a very positive indication of their responsibility to the institution-at-large for performing effective self-regulation and concomitantly assuring continuing compliance with applicable regulations and standards.

In the event that the IACUC is dealing with a deficiency that remains uncorrected, that deficiency should be highlighted in the recommendations made to the Institutional Official in the IACUC's semiannual report.

1.7 Handling and Reporting of Concerns (v6-26-13)
The SDSU Program of Animal Care and Use includes program procedures for reporting and investigating apparent problems and issues related to animal welfare and animal care/research personnel safety, and for following through with appropriate actions to help prevent similar subsequent problems. Examples of such issues are cited in the February 2005 Guidance Notice (NOT-OD-05-034) issued by the Office for Laboratory Animal Welfare (OLAW) [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html).

**Reporting of Animal and Personnel Welfare Concerns by Any Concerned Individual**

Any individual working in or around animal care and research facilities at SDSU is obligated to report concerns they have about apparent problems involving animal welfare and animal procedure-related personnel safety. Those concerns can be made directly to the IACUC via the Division of Research Affairs or through the IACUC Chair, the SDSU Institutional Official, the Campus Veterinarian, the OLAC Manager or any IACUC member. Signs listing personnel to contact with questions or concerns regarding animal care and use are posted in all animal facility hallways and by the entries and exits of the animal facilities. There is no requirement that the concern be submitted in writing and anonymous complaints may also be investigated, as appropriate.

Upon knowledge of a concern, the IACUC Chair will initiate an evaluation of the incident in consult with the Attending Veterinarian and at least one other IACUC member, as well as any other appropriate individuals, who, taken together, will make up an IACUC subcommittee for investigation of the reported concerns.

If the issue involves noncompliance with federal regulations or the institutional program, an assessment is made as to whether the issue of noncompliance is deemed reportable and/or recurring (i.e., any serious or continuing noncompliance with the PHS Policy; any serious deviation from the provisions of the Guide; any serious deviation from the provisions of the USDA Animal Welfare Act Regulations; or any suspension of an activity by the IACUC). For examples of reportable situations see the NIH Guide Notice NOT-OD-05-034.

If the noncompliance is determined to be neither reportable nor recurring, the IACUC subcommittee will make recommendations for corrective action and the IACUC Chair will communicate the concerns and corrective action to the investigator. Actions taken by the IACUC subcommittee will be communicated in writing to the investigator with a copy of the report to the IACUC.
If the noncompliance appears to be reportable or recurring, and does not extend beyond the IACUC’s jurisdiction, the IACUC subcommittee will assess the information available immediately to determine if there is an elevated risk of harm to animals or personnel working with animals, and if so, determine corrective action. The IACUC Chair will communicate the concerns and action plan to the investigator. A written report summarizing the issues and corrective action required is given to the responsible faculty member and the IACUC. A copy is also given to the person initiating the review, if identified. A report is forwarded to the Institutional Official (IO) through the Director of Research Affairs, Institutional Official Representative for appropriate action upon the recommendation of the IACUC. If warranted, reports are provided to OLAW, APHIS and/or funding agency(s). Diligent efforts are made by SDSU, under the guidance of the IACUC, to assure that anyone reporting alleged animal care concerns in good faith is protected from retaliation, and that the reputation of anyone unfairly accused is not damaged or is restored.

If the incident associated with noncompliance extends beyond the IACUC’s jurisdiction, the IACUC chair will inform the College Dean, Director of Research Affairs and IO concurrent with consulting with the IACUC subcommittee.

Issues that involve making recommendations to the IO are discussed by the IACUC at a convened meeting, which is attended by the ex-officio Institutional Official Representative, Director of Research Affairs. Once the IACUC has determined a recommendation to the IO is appropriate, the IACUC Coordinator prepares the recommendation with input from the IACUC Chair, Veterinarian or OLAC Manager, and/or Director of Research Affairs as appropriate. The final document is then forwarded to the IO.

**Reporting of Animal Welfare Concerns by OLAC**

Daily activity by personnel in the SDSU Office for Laboratory Animal Care (OLAC) includes maintaining awareness of situations that may affect health and welfare of animals and personnel in the SDSU animal holding and research facilities (vivaria). OLAC standard operating procedures include communication to principal investigators and appropriate laboratory personnel regarding issues and situations that need correction to help assure animal welfare and human safety.

When an apparent compliance issue is recognized and communicated to a principal investigator and appropriate laboratory personnel, and there is apparent lack of effective and timely response by those research personnel to implement corrective action, an OLAC veterinarian and/or the OLAC manager (or designee) will submit a report in a timely manner via email to the IACUC Chair and IACUC Coordinator for further action as needed.

**1.8 Project Suspension**

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the committee. The IACUC may suspend an activity only after review of the matter, which may be conducted by a designated subcommittee of the IACUC. A report explaining actions and findings will be presented at a convened meeting of a quorum of the IACUC. If the recommendation is
to suspend an activity, then this may be enacted following a 'yes' vote of a majority of the quorum present.

The Institutional Official in consultation with the IACUC shall review the reasons for suspension. If the IACUC decides to suspend an activity involving animals that is regulated by the NIH/OLAW, APHIS, or any other federal agency, then the IACUC will take appropriate corrective action, including required notifications to these agencies and others as appropriate.

Some incidents involving animals may require an investigation by the IACUC but may not result in suspension. The seriousness of the incident (e.g., if many animals are harmed) will determine who should be notified in these cases.

1.9 Institutional Review
Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by the Vice President for Research (Institutional Official) or other University officials. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

1.10 Training of Personnel
SDSU assures that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. Training is made available and the qualifications of personnel are reviewed with sufficient frequency to fulfill SDSU's responsibilities under the Animal Welfare Act. San Diego State University’s Institutional Animal Care and Use Committee (IACUC) currently requires that personnel involved in research and teaching involving animals complete refresher training every three years. Training of personnel is documented and made available to the IACUC chair and/or any regulatory agencies upon request.

Training and instruction of personnel includes guidance in at least the following areas:

- Humane methods of animal maintenance and experimentation, including the basic needs of each species maintained at the facility, proper handling and care of each species, proper pre-and post-procedural care, and aseptic surgical methods and procedures.
- The concept, availability and use of alternative research or testing methods that limit the use of animals or minimize distress.
- Proper use of anesthetics, analgesics, and tranquillizers for any species used by the facility.
- Methods whereby deficiencies in animal care and treatment are reported.
- Utilization of resources available to provide information on appropriate methods of animal care and use, alternatives to the use of live animals in research, and the intent and requirements of the Animal Welfare Act.
- Occupational health and safety issues related to working with animals (also see policy in Part 4.0 of this policy).

It is the responsibility of every institution to ensure that the people caring for or using animals for research, teaching, or testing purposes are qualified to do so in a humane and scientifically acceptable manner. Continuing education activities
relevant to program responsibility are available at SDSU, with both formal and on-the-job training to ensure effective implementation. Special training programs are provided for technicians and staff who work with animals.

With this in mind, the SDSU OLAC has assembled a collection of educational printed and video materials that are available on request through the OLAC office. Additional titles are added as material is obtained. These may be checked out for overnight use. Other materials available through the OLAC office are posted on the OLAC/IACUC website.

The SDSU Animal Health and Welfare Training for research involving laboratory animals and for field studies is made available through an on-line course through Blackboard. Training covers the following information:

1.10.1 Animal Health and Welfare Training for Laboratory Personnel
- Working with your IACUC
- Federal Mandates
- Personnel Training and Experience
- Getting Started
- The Veterinary Consultation
- Alternatives to Animal Use for Research and Testing
- Avoiding Unnecessary Duplication
- USDA Pain/Distress Categories
- Endpoint Criteria
- Surgery (If applicable)

1.10.2 Field Study Training
- IACUC Basic Functions
- IACUC Responsibilities
- Euthanasia
- USDA Pain and Distress Categories

Occupational Health and Safety Training (This training to be completed by field and laboratory personnel working with animals):
The Occupational Health and Safety training is mandatory for all personnel working with animals. Contact the IACUC administrative office at iacuc@mail.sdsu.edu or (619) 594-0905 for access information. A “refresher” course is required every three years during an ongoing project. This training will include:

- Laboratory Animal Allergies
- Physical Hazards
- Biological Hazards
- Blood Borne Pathogens
- Zoonotic Diseases
- Chemical Hazards

Hands-On Training
In addition to the web based Animal Welfare Training, hands-on training is required for all personnel who will be in direct contact with animals. The specific
content and degree of detail will vary depending on the knowledge, previous experience and expertise of the target audience. This training can include but is not limited to:

- Handling/Restraint
- Anesthesia/Analgesia
- Blood Collections (retro-orbital, tail vein)
- Injection Techniques (IP, SC, IV)
- Euthanasia procedures
- Tail Snipping
- Ear Tagging

A vivarium orientation is included as part of the hands-on training to inform all users of vivarium policies. Keys are issued upon completion of training. The OLAC personnel and/or the campus Veterinarian coordinate and deliver training.

The intent of this program is to maintain compliance with federal regulations and to promote humane care and proper use of animals at SDSU. This collection of educational materials is intentionally broad to cover the spectrum of activities undertaken by SDSU personnel. The materials provide a valuable informational resource available to all SDSU personnel.

2. ANIMAL CARE POLICIES
The IACUC is charged with approving written policies and approving standard procedure (SOPs) for selected special procedures involving more than momentary pain and discomfort. Policy and procedures are developed on an as-needed basis, as it is not feasible to anticipate all needs and future activities of all investigators.

Written SOPs for special procedures may be generated for IACUC approval by OLAC personnel or by individual investigators. The campus veterinarian will advise the IACUC of current guidelines and standards to ensure compliance, and these policies and SOPs designated as special procedures will be reviewed at least annually to ensure currency with changing regulations and standards. Adoption of policies and SOPs for these special procedures requires review and approval by majority of the full IACUC membership. Dissemination of new information for use by investigators will be by appropriate means (website, newsletter, e-mail distribution list).

2.1 Euthanasia
Euthanasia means “good death,” better defined as a death that is rapid and painless. SDSU euthanasia guidelines follow those established by the American Veterinary Medical Association (AVMA) Panel on Euthanasia. Euthanasia is used to eliminate pain and suffering in animals that are seriously injured, sick, or dying. It is also a necessary final procedure in some experimental research. Euthanasia techniques must be reviewed and approved by the Institutional Animal Care and Use Committee during review and approval of the Animal Protocol Form.

Euthanasia may only be carried out by personnel properly trained in the procedures being used and must be performed in a way that minimizes reactions of other animals that may be present.
Proper euthanasia technique includes a follow-up exam to confirm the absence of a heartbeat, which is a reliable indicator of death. Monitoring respiration is not considered sufficient since with some euthanasia techniques heartbeat may be maintained after visible respiration has ceased. It is recommended that the primary method of euthanasia be followed by a secondary method to ensure nonrecovery of animals. Such methods include exsanguination, cervical dislocation and perfusion.

The need to minimize fear and apprehension must be considered in determining the method of euthanasia. Distress vocalizations, fearful behavior, and release of certain odors or pheromones by a frightened animal may cause anxiety and apprehension in other animals. Therefore, whenever possible, animals should not be present during euthanasia of others, especially of their own species. The resultant distress may lead to physiologic changes in other animals, such as a release of hormones, which may affect research results. The acceptable methods of euthanasia vary aesthetically. Perceptions of research staff, students, or others present must often be considered in addition to experimental requirements when a method of euthanasia is chosen.

2.2 Animal Adoption
SDSU does not adopt out research animals.

2.3 Vivarium Access
OLAC’s policy regarding admission to animal facilities exists to protect SDSU employees, students and the general public from unnecessary exposure to potential hazards and protect the animals from unknown contaminants that could interfere with the research in progress. The faculty and staff of the University are asked to assist in enforcing this policy and to report unusual or malicious incidents to the OLAC office (4-5421) and the University Police (4-1991).

All entrances to the animal facilities are locked 24 hours a day. Access is gained by authorized personnel assigned a key card. In addition to a key card, individual rooms within the facility may be locked with a standard key. To have access and/or individual keys assigned an individual must have completed the Animal Welfare training, OLAC orientation and be listed on an approved Animal Protocol Form (APF). Upon completion of required training, individuals must see the OLAC manager to obtain a signed request form that must be taken to the campus public safety office to receive them.

Unauthorized persons who desire entry for animal research reasons (i.e. to observe experimental procedures) require prior approval from the OLAC manager. An authorized member of the investigator’s staff or OLAC office must accompany all visitors. Because of the concern for human and animal health, children and pets are not allowed in the vivarium.

3. VETERINARY CARE
3.1 Assuring Adequate Veterinary Care
Despite the best efforts of all personnel working with laboratory animals on campus, abnormalities and illnesses may occasionally occur in one or more of the animals. The legal and moral obligations to administer veterinary care are shared by all animal users. The campus veterinarian is responsible for assuring adequate veterinary care. As veterinary medical care is not generally a planned part of animal use, any veterinary
intervention can affect the animal's use and outcome. Therefore it is imperative that the campus veterinarian work closely with investigators in administering care.

Often, the need for veterinary medical care occurs at inopportune times (Friday afternoons, weekends, holidays, etc.) when investigators are not readily available. Usually decisions about the affected animal’s health must be dealt with expeditiously. Veterinary care is available at virtually all times through the campus veterinarian. Similarly, animal users must make arrangements to provide guidance to the veterinarian on the animals’ use. To accomplish this in a systematic manner, the following procedures have been implemented:

- The home phone number of the responsible investigator must be readily available to the vivarium staff (on the cage card or posted in the animal room).
- Some knowledgeable person should be designated as backup to the investigator (such as another faculty member, a postdoc, a graduate student or a lab technician), and the home phone number of that person should be available to the Vivarium.
- Responsible persons must be prepared to meet on-site with the veterinarian so that a care plan can be discussed and agreed upon.

In those few instances when an investigator or his/her designated backup is not available, the condition of the animal and the provision of adequate veterinary care must be the primary obligations of the veterinarian. In every instance, the veterinarian will attempt to minimize how the medical care impacts the investigator’s study and will attempt to contact and discuss each case with the investigator staff. However, if the animal’s health and welfare would otherwise be negatively affected, the veterinarian may have to respond to the situation, using reasonable clinical judgment with the information available without contact with the investigator. It is hoped that investigators will understand and approve of such procedures.

3.2 Program of Veterinary Care (As revised October 2007):
San Diego State University (SDSU) employs two part-time campus veterinarians to develop, monitor and maintain the Program of Veterinary Care. Both veterinarians are experienced in laboratory animal medicine and qualified to respond to medical emergencies, to assist with model selection and protocol design, and to provide professional oversight of the general animal care program. The attending campus veterinarian serves as a member of the Institutional Animal Care and Use Committee (IACUC) and is in charge of the preventive medicine program. The associate campus veterinarian serves as an alternate member of the IACUC and is in charge of clinical veterinary medicine.

Both veterinarians report to the Vice President for Research and/or the Director, Division of Research Affairs, Graduate and Research Affairs and have authority over animal health and welfare aspects of the SDSU IACUC. The veterinarians establish, maintain, and supervise programs of disease control and prevention, pest and parasite control, pre-procedural and post-procedural care, nutrition, euthanasia, and other veterinary care for all animals held for research and teaching at SDSU. The veterinarians conduct routine rounds two times a week which involves facility visits, meetings with investigators and other personnel, and animal health inspections. Both
veterinarians are available via email and mobile telephone for efficient communication regarding animal program-related issues and for response to emergencies.

3.2.1 Medical Records
For USDA-covered species, a medical record is established for each animal upon arrival at SDSU. This record is maintained in the animal room. Investigators are advised that notes on all injections, blood sample collections, and other manipulations must be recorded in the animal's record. Records are maintained for three years after an animal's death.

3.2.2 Daily Observations
All animals in all campus facilities are checked daily, 365 days a year, for signs of disease or illness. During weekend and holiday checks, Laboratory Animal Technicians have been trained that, should they encounter an emergency situation involving any research animal in the facility, the following steps should be taken:

The OLAC manager and principal investigator and/or his/her representative are contacted. If warranted, the veterinarian will be contacted for advice about possible treatment or a determination may be made that the veterinarian should come and examine the animal.

If the situation cannot be remedied so that the animal is not suffering or in pain, the Laboratory Animal Technician may euthanize the animal. In the event that the OLAC manager, principal investigator, and veterinarian cannot be contacted, the technician may determine that an animal should be euthanized to prevent suffering. The welfare of the animal is the priority for our decision making process.

All Laboratory Animal Technicians are trained to give injections, provide euthanasia, and perform other procedures that would be necessary to provide an animal with a treatment for an emergency situation. Technicians that have not been trained in these methods are not allowed to conduct checks during times such as weekends and holidays when trained personnel would not be available to assist them.

3.2.3 Animal Procurement
OLAC has established a list of approved animal vendors. The list was developed in an effort to obtain the very best animals and to assure continued protection of the health and condition of animals already in use in campus facilities. Health reports from vendors are kept on file in the OLAC office and checked quarterly.

OLAC policy limits animal purchases to the list of approved vendors. No animals may be purchased without an approved animal protocol. All requests for animal purchases must be reviewed by the OLAC manager before animals are delivered. At that time, the OLAC manager will determine where the animals are to be housed, that an IACUC-approved protocol exists and then approve their purchase and arrival, assuring OLAC awareness as to when the animals will arrive.

Occasionally it is necessary to receive animals from sources other than approved vendors (such as other universities, etc.). In these instances, special arrangements must be made with OLAC by the investigator, to include prior testing for viruses and
other microorganisms. Upon arrival, animals must be quarantined until their health status is confirmed.

### 3.2.4 Animal Receiving
On arrival, animals are unpacked, inspected, caged, and provided fresh food and water within two hours. The shipment is verified for accuracy, the vendor’s health status report is reviewed, and the shipment is entered in the animal receiving log.

### 3.2.5 Quarantine/Stabilization
In spite of every effort to obtain healthy, robust animals, there may be instances when animals are received that do not meet institutional standards or are not of a quality to be acceptable for institutional purposes. Because of this, it is OLAC’s policy to maintain a quarantine/stabilization period to provide the time necessary for animals to recover from the stress of shipping and handling and to acclimate to new surroundings (stabilization) and to allow time for thorough observation of the animals. No routine vaccinations are available for any of the usual species of animals housed in SDSU facilities.

During the period of acclimation, rabbits are given a physical exam by the OLAC manager and/or the veterinarian. The exam includes checking the teeth for malocclusion, the ears for signs of ear mites, the toenails for abnormal length. Animals are weighed and individual medical records established. Animals from approved vendors are not routinely tested for pathogens on arrival. Animals from other sources will have at least a basic serology profile run as part of the quarantine process.

Stabilization and quarantine periods vary according to species, source, and intended use. The following list is a guideline provided to Investigators setting a schedule for research protocols.

#### Stabilization (for non-rodents and approved vendors):

<table>
<thead>
<tr>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbits:</td>
<td>7 days</td>
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<tr>
<td>Guinea pigs:</td>
<td>7 days</td>
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<tr>
<td>Rats:</td>
<td>3 days</td>
</tr>
<tr>
<td>Mice:</td>
<td>3 days</td>
</tr>
<tr>
<td>Reptiles:</td>
<td>7 days</td>
</tr>
<tr>
<td>Xenopus laevis</td>
<td>7 days</td>
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</tbody>
</table>

#### Quarantine:

<table>
<thead>
<tr>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbits:</td>
<td>Approved vendors only (no quarantine)</td>
</tr>
<tr>
<td>Guinea pigs:</td>
<td>Approved vendors only (no quarantine)</td>
</tr>
<tr>
<td>Rats:</td>
<td>7 weeks</td>
</tr>
<tr>
<td>Mice:</td>
<td>7 weeks</td>
</tr>
<tr>
<td>Reptiles:</td>
<td>7-21 days</td>
</tr>
<tr>
<td>Xenopus laevis</td>
<td>7-14 days</td>
</tr>
</tbody>
</table>

During the quarantine/stabilization period, all animals are checked daily for outward expression of disease or conditions that might render them unsuitable for their intended purpose. If warranted, all animals will receive treatment for any disease/injury identified during this time period, after consultation with the
veterinarian and principal investigator. Moribund or untreatable animals will be subjected to blood sampling and then euthanized. The bodies will be submitted for post mortem examination.

3.2.6 Separation by Species, Source, and Health Status
All species are physically separated whenever possible into separate rooms; otherwise at least on separate racks on different sides of the room. Since the number of vendors is limited, separate facilities are not maintained for animals from different sources/vendors. A rodent quarantine room is available.

3.2.7 Surveillance, Diagnosis, Treatment, and Control of Disease
Rabbits are given a physical exam semi-annually by the OLAC manager or veterinarians. This exam includes checking teeth for overgrowth, ears for evidence of ear mites and injury, injection sites for adverse reactions, weight for assessment of body condition, and overall appearance. Any negative findings are reported to the veterinarian. Documentation of each exam is placed in the medical record. If a rabbit is noted to be having gastrointestinal signs of illness, such as diarrhea or constipation, they are checked for intestinal parasites or other disease conditions.

Regular rodent colony surveillance measures and screening are conducted by serological sampling at quarterly intervals. Serological testing services are conducted an outside diagnostic reference laboratory. In the absence of symptoms, serology testing of rabbits is not routinely conducted.

All animals maintained at SDSU are observed for signs of illness, disease, or injury by Laboratory Animal Technicians trained to identify changes in behavior or condition. An animal whose appearance or behavior indicates substantial change from normal is identified by attachment of a health/observation notification card to the animal's cage. The observations are recorded on the Daily Health Report log and reported to the OLAC manager. The veterinarian reviews these logs and examines animals as needed. For more urgent clinical problems, the veterinarian is contacted in a timely manner and, if necessary, will examine the animal(s) and establish an appropriate plan as needed.

Investigators are notified immediately of animal health problems. If an animal is moribund or not treatable, the OLAC staff will request permission to euthanize the animal immediately. If the investigator cannot be located, the staff reserves the right to use their best judgment in determining whether euthanasia is indicated and perform such if necessary.

3.2.8 Anesthesia and Analgesia
The campus veterinarians and the IACUC have established general guidelines for the use of anesthetics, analgesics, and sedatives. These guidelines provide recommendations for the type and amount of drug and preferred route of administration. These recommendations follow generally accepted laboratory animal veterinary practices.

In unusual cases, investigators are encouraged to consult the veterinarians for assistance and recommendations. During initial training, investigators are informed that procedures, which are considered painful in humans should be considered
painful in animals and appropriate use of anesthesia and analgesia should be made.

Each Animal Protocol Form (APF) requires detailed information relative to use, type, and administration of anesthetics, analgesics, and sedatives in proposed research projects. The information provided in the APF is subject to review and approval by the IACUC.

3.2.9 Surgery and Post-Surgical Care
Presently, survival surgical procedures are conducted only in rodents (rats and mice). No dedicated surgical facilities are available at SDSU. Therefore no survival surgery is performed on species other than rodents.

The faculty member or principal investigator must assure appropriate conduct and supervision of surgical techniques and procedures by their personnel and students. When appropriate and/or requested, the campus veterinarian may review the surgical procedure and work with/train faculty, students, and laboratory personnel on surgical techniques.

If required by experimental design, the need for surgery and the procedures to be used will be outlined in detail on the APF submitted for IACUC approval. Rationale and justification for the project are important criteria for acceptance, as are the use of anesthetics and/or analgesics to relieve any pain associated with the procedures.

Although aseptic technique for rodents is not covered by USDA regulations, the IACUC endorses adherence to the NIH Guide for the Care and Use of Laboratory Animals when working with rodents. Therefore, all rodent recovery surgical procedures are to be performed in a clean, non-cluttered area with sterile instruments and surgical gloves, using aseptic techniques.

3.2.10 Sick or Injured Animals
Because of the limited number of vendors and their quality assurance methods, OLAC does not routinely treat incoming animals for parasites or other medical conditions but relies on observation of animals for signs of disease or illness. If internal or external parasites are suspected, animals and their body excrements are examined. If parasites are determined to be a problem, the use of properly prepared anti-parasitic drugs will be prescribed by the veterinarian for use against ectoparasites and internal nematode infections.

If an animal develops some other condition that requires treatment, the veterinarian will be consulted and an appropriate treatment instituted. Every effort will be made to contact the investigator for discussion of the treatment before it is initiated, but in the case of an emergency, the OLAC Staff reserves the right to treat animals if an investigator cannot be reached. In these cases, the veterinarian has sufficient laboratory animal experience to be able to prescribe treatment and/or euthanasia, if necessary, in such a manner that will impact the project as little as possible. However, the primary emphasis is for the welfare of the animal.
This Program of Veterinary Care will be reviewed at least every six months. Minor changes may be made over a two-year period. At the beginning of the third year, the Program will be updated to incorporate changes and to review all procedures.

4. OCCUPATIONAL HEALTH AND SAFETY
The SDSU campus occupational health and safety program is managed by SDSU's Environmental Health and Safety (EH&S). This document provides a description of how the programs EH&S administers address the requirement for an occupational health and safety policy and procedures that protect principal investigators, students and staff involved in animal-related work.

4.1 Injury and Illness Prevention Program (IIPP)
The campus occupational health and safety program is managed by SDSU's Environmental Health and Safety (EH&S). A comprehensive Injury and Illness Prevention Program (IIPP) was developed by EH&S and functions as an "umbrella" program to all occupational health and safety programs of the campus including Hazard Awareness and Communication, Hazardous Materials and Wastes Management, Biohazard Control, Chemical Hygiene, Personal Protective Equipment, Medical Surveillance. The IIPP facilitates the identification, evaluation and control of workplace hazards, to implement procedures for injury and illness investigation, and to train SDSU employees. The IIPP is designed to be generic and cover essentially all chemical, biological, and physical hazards that might be encountered, whether or not the activity involves animals.

IACUCs are expected to assume occupational health and safety oversight roles with respect to ensuring appropriate protection of certain employees and students from hazards that may be encountered in research, teaching and testing activities involving animals. To meet this responsibility and yet minimize duplication of ongoing efforts at SDSU, the IACUC works closely with EH&S to ensure that the IIPP satisfactorily addresses specific regulatory requirements and other needs that pertain to APF-authorized activities undertaken by students, staff or faculty that involve animals. EH&S is responsible for providing the IACUC with updates to the IIPP. Because the IIPP is a document produced by EH&S, questions about the IIPP should be directed to the EH&S Director.

4.1.1 Who is covered under the IIPP?
All campus employees and SDSU students are covered under SDSU's IIPP. Any personnel participating in the project who are neither SDSU or SDSU Research Foundation employees nor SDSU students must be covered under some appropriate health and safety program, if not SDSU's program, then another offered by their outside employer.

Students or investigators working under IACUC-approved APFs in off campus facilities where SDSU's EH&S has no direct oversight or enforcement ability can be asked to document, for the IACUC, that they are covered by occupational health and safety programs at those facilities if this is not readily apparent to the IACUC.

4.1.2 Coordination between the IACUC and EH&S
Simply stated, EH&S shall assume primary responsibility for knowing the regulations and developing health and safety policies and procedures for the
campus. This office shall consult with the IACUC for technical support and other assistance when an activity involves contact with research animals. The responsibility for enforcement of occupational health and safety regulations and policies when activities involve animals is shared by EH&S and the IACUC. Compliance is a shared responsibility involving many others on campus, as discussed in the next section.

A qualified member of the EH&S staff shall serve on the IACUC to foster coordination and ensure awareness of relevant new hazards and regulations that may be identified in the future. Other appropriate measures shall be taken by the IACUC whenever feasible to work through existing EH&S procedures and programs. This could include adapting existing IIPP-related training materials to suit specific IACUC training needs; working through existing EH&S-designated safety coordinators (see section below) to promote communication and occupational health and safety compliance at the departmental level; and coordinating semi-annual animal facilities inspections and program reviews with EH&S inspections that are already required.

### 4.1.3 Others with Responsibility for Implementing the IIPP

Insofar as maintaining the health and safety of the campus community necessarily involves a collective campus effort, other individuals and administrative units on campus are expected to play significant roles and assume some shared responsibility in this effort. Others with significant responsibilities include departmental campus safety coordinators designated by EH&S to address the pertinent workplace health and safety issues within their departments, including training and documentation; principal investigators submitting APFs who must acknowledge responsibility for ensuring that their project staffs and students are working in safe laboratory and field environments and receive proper training; SDSU Research Foundation development staff who assist with identifying projects that involve potential for hazardous situations through routing forms and other information that must be furnished by principal investigators; SDSU campus and Research Foundation facilities directors/managers and other staff expected to respond in a timely manner when potentially hazardous facilities deficiencies are identified; Student Health Services that provides certain emergency related services for students and OLAC staff; and campus Public Safety that may be called upon to respond in emergency situations. The Institutional Official, Academic Deans, Directors and Chairs may also be called upon to help with enforcement issues.

### 4.2 Occupational Health and Safety Training and Documentation

As noted above, at SDSU the Department of EH&S shall be primarily responsible for knowing the regulations and developing policies for occupational health and safety training programs, but shall work in consultation with the IACUC when hazards are associated with activities involving animal research or teaching. EH&S shall continue to provide existing programs for training investigators who work with radiation and other chemical and biological hazards, with information mostly provided on an as-needed, project-specific basis. The IACUC shall assist with identifying the need for and, if requested, the content of other supplemental training that may be warranted for those who need it. The EH&S representative on the IACUC shall continue to review requests to use animals from the perspective of specific occupational safety and health training needed if the APF is approved, and shall assist the IACUC by following up to help the PI
receive the necessary training. Extent and frequency of refresher training shall be consistent with both the level of risk involved and any pertinent regulations.

The IACUC shall work as much as possible with systems already in place that document training of individuals covered under the IIPP who also work with animals. For example, radiation safety training records required by the Nuclear Regulatory Commission are maintained by EH&S with cooperation from principal investigators responsible for staff and students working on their projects. Departmental safety coordinators designated by EH&S are already expected to document other personnel training in the area of handling and disposal of other chemical and biological hazards as required by Hazard Communication regulations. Ultimately it is the principal investigators who are responsible for making sure that their training and that of their staff is current and can be documented on request, and the IACUC shall stress this in orientations that it provides. The level of documentation shall be appropriate for the hazard involved. Minimal or no documentation may be appropriate for minimal risks. The EH&S representative on the IACUC shall continue to work with investigators to ensure appropriate documentation of individual projects when warranted by the risks involved or new regulations require this.

4.3 Employees Caring for Animals
All individuals employed by San Diego State University specifically to care for animals at SDSU (usually referred to as OLAC personnel) must be qualified to perform their duties in a work environment that does not jeopardize their health and safety.

These employees shall receive from EH&S:

1. Medical surveillance appropriate for detecting effects of hazards they are likely to encounter through their work with animals at SDSU.

2. Training in how to access appropriate information on the nature of potential chemical, biological, and physical hazards, personal protective equipment, and any situations that would prohibit or restrict work with animals (e.g., when immunocompromised). The OLAC staff shall provide input to areas that should be covered specifically for animal handlers. In addition, the following shall be provided by EH&S with consultation and other assistance provided by the campus veterinarian, the OLAC manager, and the IACUC:

3. Ongoing efforts to identify any methods currently available to detect and prevent zoonotic diseases (other than by training employees to avoid them).

4. Systems to document all of the above to the extent that is necessary to meet regulatory requirements.

4.4 Staff, Faculty, and Students Working with Animals
The previous section also applies to staff, faculty and students who work directly with animals, with the exception that SDSU is not expected to cover medical surveillance for these individuals who normally have significantly less exposure to hazards associated with research animal facilities. The health and safety hazard awareness training offered to these groups shall be tailored to adequately address the types of agents each
is likely to encounter. For example, this could include typical hazards associated with conducting field research or classes in specific terrestrial or aquatic environments.

As noted above, the ultimate authority and responsibility for ensuring the health and safety of these members of the SDSU campus community rests with EH&S; however, certain members of the IACUC and OLAC will participate in, reinforce, and help to enforce these efforts as appropriate.

4.5 Storage, Accessibility, and Retention of Occupational Health and Safety Records
Centralizing all occupational health and safety training and other records for a given APF-authorized activity is currently not feasible without additional resources. To avoid unnecessary duplication, copies of all relevant EH&S documents describing all of the activities in this section will not necessarily be maintained in the same location as other IACUC and OLAC records. On the other hand, all pertinent records that are not confidential (e.g., employee medical evaluation policies; training program content; radiation, controlled substance, and other chemical and biological hazard monitoring programs and records kept at SDSU, etc.) shall be accessible for review by the IACUC if such is deemed necessary for fulfilling their oversight function. The EH&S Director and/or representative to the IACUC shall assist the IACUC in locating pertinent records. Retention of these records shall be decided by mutual agreement of the directors of EH&S and the Division of Research Affairs.

4.6 Staying Healthy When Working with Animals in Vivarium, Lab or Field Environments
People working with animals in any setting should be aware of the associated risks and the measures in place to prevent injury or illness. Allergies and other zoonoses (diseases communicated to humans from other species of animals) are relatively common risks when working with animals. Bites and scratches are also to be expected by people who handle wild or laboratory-bred animals on a regular basis. The level of risk will depend upon the level of contact and the species of animal encountered. Management of risks should be appropriate to the situation. If you have any questions about safety risks of working with animals that your supervisor or principal investigator cannot answer to your satisfaction, then do not hesitate to contact SDSU's Department of Environmental Health and Safety for clarification or additional information.

4.6.1 Staying Safe and Healthy in the Vivarium and Lab

4.6.1.1 Washing Hands
The most common way to contract a zoonotic infection is to place the infectious material directly in your mouth. Smoking, drinking, or eating when working with or around animals is prohibited. Wash hands after handling an animal or anything that the animal has touched, including cages or traps. This applies even when protective gloves are worn. Certain infections are transmitted from animals to humans primarily by feces or urine contaminating your hands. Contamination can easily be transferred to face, eyes, or mouth. Examples of organisms utilizing this mode of transmission are species of Salmonella, Shigella, and Entamoeba. Every precaution should be taken to avoid this mode of transmission by staying alert and practicing careful personal hygiene. Allergies can arise in some people from contact with
proteins in urine, saliva, or animal skin/fur dander. Health problems in others living with the person who handles animals may occur when organisms are carried home and children or other family members are exposed.

4.6.1.2 Wear Protective Clothing
Wear protective clothing when working with animals. Protective clothing in a lab setting will consist of a lab coat or scrubs. When working in a vivarium, protective clothing must be laundered by a commercial laundry service. If a person does not work in the vivarium but does handle animals in a lab setting where commercial laundry service is not available, keep protective clothing separate from other personal items. Bag and launder separately. Never take protective clothing home with you. This will insure that you won't bring potentially contaminated material home with you and/or back to the laboratory or vivaria.

4.6.1.3 Use Personal Protective Devices
Some types of work require personal protective devices such as gloves, face shields, masks, respirators, boots, hoods, etc. Always use the protective devices where required and follow the principal investigator’s or supervisor's instructions.

4.6.1.4 Seek Medical Attention Promptly
If injured on the job, promptly report the accident to the principal investigator or other supervisor, even if it seems relatively minor.

4.6.1.5 Special Higher-Risk Situations: Get the Facts
Individuals who are pregnant or immunocompromised are considered at higher risk of infections and chemical toxicity than the general population. All at-risk persons working in a facility with animals should receive appropriate training on that facility's particular biohazards, precautions, and biohazard evaluation procedures. To arrange a training session to discuss zoonotic diseases or other occupational health issues, contact EH&S.

4.6.1.6 Clean up after Yourself
Decontaminate all work surfaces with the appropriate disinfectant on a daily basis and after any spill of animal-related material. Sanitize any equipment used before removal from the animal room or storage at the end of the day.

4.6.2 Staying Safe and Healthy in the Field
4.6.2.1 Safety in Field Research
The responsibility for health and safety in field research rests primarily with the people who directly supervise and carry out the research on location. Such individuals are expected to use good common sense. The University’s concern in this policy is to require that due diligence be exercised by all parties concerned in giving attention to the nature of and the means of dealing with the categories of risk that may be associated with each location and kind of field research. It is the intention of the University that participants enter into field research with an informed understanding of the associated risks and their consent to the means for dealing with such risks.
4.6.2.2 Hazards in the Field
Many wild vertebrates are capable of inflicting serious injury or transmitting disease to persons handling them. Appropriate handling and restraint techniques and training should be used to avoid injury to both animals and humans. Zoonoses (e.g., Hanta virus) and bites or stings from venomous animals are among the health hazards researchers could encounter while working in the field. Personnel should work in teams of at least two people at all times in the field.

4.6.2.3 Investigator Responsibilities in the Field
It is important that investigators understand the hazards to human safety when working with wild animals and take the necessary steps to protect personnel against possible injury or exposure to potentially dangerous wild animals or their fluids and waste.

The investigator should ensure that adequate protective measures are implemented during capture of wildlife. They also should make certain that all personnel fully understand the techniques to be used for restraint and handling.

Investigators should maintain a record of any injuries incurred while handling a wild vertebrate in the field or in holding facility.

When restraining wild vertebrates in the field, all personnel should wear protective clothing in order to prevent injuries due to biting, clawing and kicking. It may be necessary to use tranquilizers, sedatives, or other chemical restraint on the wild animal to prevent injury to an animal and/or personnel.

The investigator should ensure that safety equipment appropriate for the planned procedures for both the animals and the personnel is available and must know how it is to be used. When working in the field, protective clothing that is recommended should include at least full coverage of arms, legs, and hands. In field research settings where commercial laundry service is not available, keeping protective clothing separate from other personal items is recommended. Bag and launder separately.

Zoonoses Information for the Center for Disease Control. CDC’s Infectious Disease Information page includes information from zoonotic diseases below:
- Campylobacter
- Cryptosporidiosis
- Listeriosis
- Lyme Disease
- Pet Transmitted Diseases
- Plague
- Rabies
- Rocky Mountain Spotted Fever
- Salmonella enteritidis
The [CDC](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm) also publishes guidelines for Biosafety in Microbiological and Biomedical Laboratories for those who will be working with infectious disease agents in laboratories.