1. Purpose

For both humanitarian and scientific reasons, the University is committed to ensuring that animals involved in research and teaching receive humane care and treatment. This policy sets forth the guidelines to follow regarding institutional animal care and use.

2. Policy

a. Personnel are required to submit the SDSU Animal Usage Information Form when conducting research using vertebrate animals, in accordance with this policy, and must be properly trained in animal care and use.

b. The United States Public Health Service (PHS) and the U.S. Department of Agriculture (USDA) require that when working with vertebrate animals, individuals are trained in their care and use in research and in educational or training programs. Specifically, when conducting vertebrate animal research, important principles to follow include:

   i. Weigh the use of animals against the potential benefits gained;

   ii. Use the minimum number of animals possible to obtain valid results;

   iii. Reduce the amount of pain and distress experienced by animals used in experimentation; and

   iv. Seek alternatives to using vertebrate animals, such as using computer modeling, in vitro procedures, or invertebrates when appropriate.

c. To ensure protection of all vertebrate animals and to apply this policy uniformly, this policy applies to all research and teaching using vertebrate animals conducted at the University, including those sponsored and paid for by non-University organizations, or by University faculty, staff, or students when acting as representatives of the University.
at off-campus locations. It also applies to the Agricultural Experiment Station and individuals acting as representatives of the Agricultural Experiment Station at off-site locations. This policy does not apply to the SDSU Cooperative Extension Service.

d. The University recognizes the classification of animal use in research and teaching into three categories for the purpose of specifying the standards for animal care and use within each category. These three categories and their corresponding standards are as follows:

i. Biomedical Research and Teaching: research and teaching whose goal is to generate or communicate knowledge that will contribute to improving the health and well-being of humans and/or animals not involved in agricultural production. For biomedical research and teaching, the University endorses the standards for animal care and use contained within three separate documents. These are 1) the Animal Welfare Act, 2) the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and 3) the Guide for the Care and Use of Laboratory Animals (the Guide). It is the policy of the University that each of these documents will apply to those species specified in each document. Anyone conducting biomedical research and teaching with a vertebrate species not covered by these documents should work closely with the SDSU Institutional Animal Care and Use Committee and the University Veterinarian to develop appropriate guidelines for the particular species being studied.

ii. Agricultural Research and Teaching: research and teaching whose goal is to generate or communicate knowledge that will contribute to the improvement of commercial food or fiber production from animals. For agricultural research and teaching, the University endorses the standards for animal care and use contained within the Guide for the Care and Use of Laboratory Animals and the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Ag Guide), prepared by the Federation of Animal Science Societies.

iii. Field Research and Teaching: research and teaching whose goal is to generate or communicate knowledge that will contribute to our understanding of animals living in the wild. This category is limited to the study of animals that are living in the wild. If wild animals are captured and brought into the laboratory for study, all use conducted in the laboratory will be subject to the standards for biomedical research and teaching outlined in the previous section.

e. The University endorses the standards for animal care and use contained within the following documents and any subsequent revisions:

i. For mammals: Guidelines for the Capture, Handling and Care of Mammals;

ii. For birds: Guidelines to the Use of Wild Birds in Research;

iii. For amphibians and reptiles: Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research; and

iv. For fishes: Guidelines for the Use of Fishes in Research.

f. For standards of euthanasia in all categories of research and teaching, the University endorses the 2013 Report of the AVMA Panel on Euthanasia, or any subsequent revision.

g. For the purpose of classification, research and teaching not clearly identifiable as agricultural or field research and teaching will be classified as biomedical research and
h. University oversight for animal care and use is vested in the Institutional Animal Care and Use Committee (IACUC) and supporting personnel. In keeping with federal regulations, the IACUC shall consist of no fewer than five (5) individuals, including the Chair, University Veterinarian, one individual whose interests are primarily non-scientific, and one individual not affiliated with the University and who is not a laboratory animal user.

i. The Chair shall serve as champion and spokesperson for animal care and use and the IACUC. The Chair shall convene and preside over meetings, make initial determinations to declare proposals as exempt from the policy, arrange for designated/directed review of protocols as outlined in the Guide and oversee all written communication between the IACUC and the Principal Investigator. A vice-chair shall be assigned by committee consensus on an as-needed basis.

ii. The University Veterinarian shall have the authority to direct staff to carry out activities related to maintaining optimal animal care. The University Veterinarian shall report to the Institutional Official. The duties of the University Veterinarian, in addition to sitting on the IACUC, include the following:

1. Work with the IACUC to develop institutional guidelines and programs concerning veterinary care for animals used in research or teaching and to assure compliance of animal facilities with the requirements of the Animal Welfare Act, applicable state and local laws, PHS Policy, the Guide, and those of any accreditation organization.

2. Assure that education and research endeavors involving animals are conducted according to acceptable practices and as approved by the IACUC.

3. Facilitate in the development of proposed animal research projects and provide counsel to the Principal Investigator during conception, performance, and completion of IACUC approved protocols.

4. Prepare and make available materials pertaining to policies and acceptable procedures.

5. Train and advise personnel as needed, and provide continuing education opportunities to all interested personnel.

6. Assist in developing comprehensive sanitation and general housekeeping programs for each animal housing unit and related facilities. Establish programs for aseptic techniques, surgical equipment care, and pharmacological usage and storage.

7. Apprise the Principal Investigator and appropriate institutional officials of problems that arise pertaining to physical plant problems or deviations from accepted practices or procedures.

9. Provide information as needed for the safety and protection of personnel as it relates to occupational health hazards. Coordinate occupational health efforts with the University Environmental Health and Safety Officer (e.g. biohazards, radioactive materials).

10. Assist in the preparation of reports and statements as requested or required by various regulatory or accreditation agencies.

11. Provide veterinary consulting to animals being used in a research or teaching project.

iii. An Administrative Assistant to the IACUC shall schedule meetings, take minutes in conformity with Robert’s Rules of Order, and assist in preparing reports and maintaining records. These records shall include a current roster of all committee members, files of all projects, and records of all correspondence between the Principal Investigator and the committee. Files shall be destroyed three (3) years after the close or completion of the project.

iv. The Compliance Coordinator shall serve as a liaison to and non-voting member on the IACUC and will coordinate IACUC activities with other compliance requirements and committees. In addition, the Compliance Coordinator will assist the Chair, University Veterinarian, and Institutional Official in filing annual updates and other reports to the USDA and NIH and will monitor federal and state regulations and suggest revised policies and procedures to remain in compliance with those regulations.

v. Representatives may be nominated by the Dean from each of the colleges that use vertebrate animals for research or teaching. The Institutional Official will designate a Chairperson from the University members. The non-affiliated representative will be appointed by the Institutional Official after consultation with the University President, IACUC chairperson and others.

vi. No more than three (3) members shall be from the same administrative unit at the departmental level of the University. Committee composition shall be structured to reflect the types of research generally conducted at the University.

vii. Committee members shall be appointed to three (3) year terms. Committee member terms will be staggered in order that continuity can be maintained. Committee members may be reappointed to additional terms, as needed, and if willing to continue service.

viii. The committee, through the Chair or the University Veterinarian, may seek the advice of experts in other disciplines to assist in the review of protocols on an ad hoc basis as necessary. These individuals shall not have voting privileges.

i. The IACUC shall meet as necessary to conduct business, generally once per month. Minutes of the previous meeting and materials for review will be made available to each member prior to the meeting. A quorum, which shall consist of a simple majority (over
half of the voting members on the committee) will be required to conduct business. Members may participate via video or teleconferencing. Meetings will be announced in advance and announced to the public so that members of the general public may attend if they desire. The minutes of the meeting shall be made available to the public. The level of discussion included in the minutes shall include sufficient detail for members of the general public to ascertain the nature of the discussion and the conclusions reached. Other IACUC responsibilities are to:

i. Recommend policies and procedures concerning the use, care, housing, and disposal of vertebrate animals held or used for research, teaching, or other activities;

ii. Review at least once every six (6) months the University's program for humane care and use of animals, using the Guide as a basis for evaluation;

iii. Inspect at least once every six (6) months all of the University's animal facilities (including satellite facilities) using the Guide as a basis for evaluation;

iv. Prepare or review reports of the IACUC evaluations as set forth in the PHS Policy and submit the reports to the University IACUC Institutional Official;

v. Review concerns involving the care and use of animals at the University;

vi. Make written recommendations to the University IACUC Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training;

vii. Review and approve, require modifications to (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy. This approval will be evaluated based upon information provided by the investigator in the SDSU Animal Usage Information Form.

viii. Notify investigators and the University in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy.

ix. When necessary, initiate steps toward suspension of institutional approval for an activity involving animals (as set forth in the PHS Policy), and suspend an activity.

j. All activity that involves the use of animals should be brought to the Chair or University Veterinarian for initial determination. Activity that may be determined to be excluded from this policy may include wild animal studies done on free-living wild animals in their natural habitat, activity with no intervention (observation only), activity that does not involve an invasive procedure, and activity that does not harm or materially alter the behavior of the animals under study. Activity conducted by or under the control of another organization where the University only provides labor is also excluded.

k. Research involving animal care that falls under the certain categories of research will be deemed to be exempt from full committee review but not from this policy. Principal Investigators may not make a unilateral determination of a project’s exempt status and
must contact the Chair or University Veterinarian and submit a protocol for review. A single qualified individual—the Chair, the University Veterinarian, or a person designated by the chair will make the determination as to exempt status. Annual review will be required, and the investigator must report any proposed changes to the protocol (that may change the status of the proposal so it is no longer exempt) and any unanticipated or anticipated but serious problems. Activity that may be determined to be exempt may include livestock or poultry undergoing standard agricultural husbandry practices or intended for use in improving animal nutrition; breeding, management or production efficiency; and activity for improving the quality of food or fiber, when methods causing no greater than slight or momentary pain or distress are employed.

l. Research involving animal care that is not exempt from this policy and does not request or warrant designated member review will be reviewed at a convened committee meeting. At a minimum, committee review will ensure that:

i. The procedures with animals avoid or minimize discomfort, distress, and pain to animals and are consistent with sound research design;

ii. If procedures cause more than momentary or slight pain or distress to the animals, the procedures will be performed with appropriate sedation, analgesia, or anesthesia; or a written scientific justification for not including these items will be included in the procedures;

iii. If procedures involving unrelied sever or chronic pain must be used, the animal be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

iv. Living conditions of the animals are appropriate for their species and contribute to their health and comfort. Feeding and nonmedical care are directed by an animal husbandry professor and/or veterinarian experienced in the proper care, handling, and use of the species being maintained or studied.

v. Medical care for the animals is available and provided as necessary by a qualified veterinary technician or veterinarian.

vi. Personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in procedures.

vii. The method(s) of euthanasia to be used is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel, unless a deviation is justified for scientific reason in writing by the investigator.

m. A protocol under review shall be deemed approved by the IACUC if accepted by a majority of voting members in attendance. The committee may require modifications to the protocol prior to approval. These modifications may be provided electronically or in writing; the Chair or his/her designee(s) shall determine if the modifications follow committee requirements or should be taken back to the full committee for final approval. The committee may require the resubmission of a protocol before any action is taken or may withhold approval of any research, with detailed comments/reasons provided to the investigator. The investigator may appeal the decision for disapproval to the committee. The Institutional Official may review committee decisions, impose additional
modifications or disapprove research activity approved by the committee. The IO or any other official may not approve research that the committee has disapproved.

n. Any changes in protocols must be reported to and approved by the IACUC prior to initiation. The Chair, or designee, will make a determination as to accept a minor change administratively or to accept a significant change using designated procedures or through committee review. Significant changes will include changes:
   
   i. In the objectives of a study;
   
   ii. From non-survival to survival surgery;
   
   iii. Resulting in greater discomfort or in a greater degree of invasiveness;
   
   iv. In the specifics or in approximate number of animals used;
   
   v. In Principal Investigator;
   
   vi. In anesthetic agent(s) or the use or withholding of analgesics;
   
   vii. In the method of euthanasia; and
   
   viii. In the duration, frequency, or number of procedures performed on an animal.

o. Projects will be approved for up to three (3) years. Annually, Principal Investigators shall be required to submit a continuing review and update that provides information on the status of the project (including information such as percent complete, not yet started, ongoing, temporarily stopped) and certifying that no changes have been made. Project extensions beyond three (3) years are allowed; protocols will undergo a complete review using full committee review or designated member review procedures as appropriate. The committee may review activities more frequently as they determine or conduct or direct others to conduct random audits of any approved project or laboratory facilities.

p. For some activities using animals, a designated review process may be followed. At the University, designated review will consist of review by one member of the IACUC, appointed by the Chair. All members will be provided information regarding the protocol, with the opportunity to request full committee review. The scope of review will be equivalent to the level of review carried out during full committee review. Under designated review, the reviewer may approve, require modifications in order to secure approval, request a resubmission of the protocol in order to approve, or refer the protocol to the full committee. A protocol may not be disapproved using designated procedures.

q. During the process of initial or continuing review of an activity, material provided to the Institutional Animal Care and Use Committee shall be considered privileged information and the committee shall assure the confidentiality of the data contained therein.

r. The Institutional Official (IO) is responsible for seeing that an organization is in institutional compliance. According to federal regulations, the IO must be granted this status by the University President. The IO shall maintain registration with USDA and PHS, help identify and upon consultation with others, appoint individuals to the IACUC, and review, recommend and report any actions taken as a result of non-compliance. Upon
consultation with the Chair and other individuals, the IO shall see that all members of the committee are appropriately trained and knowledgeable in administrative and substantive issues that would come before the committee. The IO will also ensure that sufficient resources, space, and staff are available to support the IACUC’s review and record keeping duties. The position of IO is currently delegated to the Vice President for Research.

s. The Principal Investigator (PI) is responsible for full compliance with the federal regulations, the Guide, and this policy. With regard to animal care and use, these responsibilities include:

i. Consulting with the Chair or University Veterinarian to determine if an activity falls under this policy;

ii. Submitting completed SDSU Animal Usage Information Forms for approval;

iii. Ensuring that all other participating personnel have completed training in the care and use of animals;

iv. Complete oversight for all care to ensure that animals are being treated humanely;

v. Following approved research protocols and notifying the IACUC of any changes prior to making changes;

1. The only changes that can be done without prior consent are those necessary to eliminate apparent immediate hazards to animals;

vi. Immediately filing a report of any unanticipated problems or anticipated, but serious adverse events; and

vii. Reporting on the progress of the research, and filing all necessary project extensions.

t. University faculty and staff may serve as Principal Investigators (PIs). Graduate students must name a faculty advisor as PI who will provide oversight. The IACUC may consider the experience and training of the individual as part of its review, and if deemed necessary, may recommend training above and beyond the current education in animal care and use. Individuals who are not University employees may serve as PIs if they are sponsored by a University administrator, faculty or staff member, or are under contract to use our facilities.

u. In accordance with federal regulations, the University will promptly report to USDA or the National Institutes of Health Office of Laboratory Animal Welfare and other appropriate federal agency officials the following:

i. Failure to correct significant deficiencies found during semi-annual inspections; and
ii. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IACUC.

v. In accordance with PHS Policy, no member of the IACUC may be involved (except to provide information requested by the committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct interest. The individual may not be counted toward a quorum for the project under consideration.

w. Individuals are encouraged to report concerns regarding noncompliance, including questionable use of animals or conditions affecting animal care or use. The University and federal policy prohibit reprisal against anyone who reports a potential concern involving animal care and use.

x. When alleged incidents of noncompliance are reported, the IACUC will meet to recommend the course of action, which may or may not result in an immediate suspension of the activity. The PI will receive a notification of the allegation, and any IACUC action and an investigation of the alleged violation will be initiated by the IACUC Chair and/or the University Veterinarian. If there is found to be animal suffering, the University Veterinarian may immediately suspend the activity and euthanize the animal(s) in question. The PI will be given the opportunity to address the committee.

i. The IACUC may use one of several options to resolve the issue, including:

   1. An immediate corrective response as appropriate and sufficient;
   2. A timeline for corrective action; and
   3. Suspension of the activity.

ii. If the PI is a member of the Department or the IACUC Chair, the IO, at the request of the Chair, may appoint a deputy chairperson who will assume the responsibility for the proceedings. The PI and all administrators will communicate with the Chair and vice versa, i.e., there will be only one line of communication. If the IACUC votes by simple majority of the members present to suspend the PI's animal use activity, the IO will be notified within one working day of the meeting. Once the IACUC has determined the response and informed the IO, further communications will be subject to the policies of that office. The IO will notify the PI and other individuals and regulatory authorities as appropriate.

iii. If an activity is suspended, subsequent meetings of the IACUC will determine if the PI has met the stipulations assessed by the committee and will vote on lifting the suspension. The IO will be notified of the results of this meeting immediately in writing by the IACUC Committee Chair, and the PI will be notified.

3. Responsible Administrator

   The Vice President for Research and Economic Development, successor, or designee is responsible for the annual and ad hoc review of this policy. The University President is responsible for approval of modifications to this policy.

SOURCE: Approved by President on 09/16/2014.
NOTE: The signatures below are required for policy and procedure approval; however, signatures will not be included in the published version of the Policy and Procedure Manual.

Recommended by: 
Norman O. Braaten, PhD.  Date
Research Compliance Coordinator
South Dakota State University

Legal Review by: 
Tracy A. Greene, JD  Date
University Counsel
South Dakota State University

Attested by: 
James J. Doolittle, PhD.  Date
Associate Vice President for Assurance and Sponsored Programs
South Dakota State University

Approved by: 
Kevin D. Kephart, PhD.  Date
Vice President for Research and Economic Development
South Dakota State University

David L. Chicoine, PhD.  Date
President
South Dakota State University