

Office/Contact: Division of Research and Economic Development
Source: Animal Welfare Act (Public Law 89-544 and subsequent amendments); USDA implementing regulations at 9 CFR Subchapter A, Parts 1, 2, 3 and 4 (AWA); Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy); Publication: *Guide for the Care and Use of Laboratory Animals*, (the *Guide*)

Link: <https://www.nal.usda.gov/awic/animal-welfare-act>;
<http://grants.nih.gov/grants/olaw/references/phspol.htm>;
<https://insidestate.sdsu.edu/research/iacuc/default.aspx>

Associated Forms: [Animal Use Proposal](#)

SOUTH DAKOTA STATE UNIVERSITY Policy and Procedure Manual

SUBJECT: Institutional Animal Care and Use
NUMBER: 8:6

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. 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.
- b. 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.

- c. 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. For biomedical research and teaching, the University endorses the standards for animal care and use contained within three separate documents: 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 (IACUC) and the Attending Veterinarian (AV) 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 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 animals that will be collected from or manipulated in the field, or whose behavior in the field will be substantially modified. 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. For field research and teaching, the University endorses the standards for animal care and use contained within the following documents and any subsequent revisions:
 1. For mammals: *Guidelines for the Capture, Handling and Care of Mammals*;
 2. For birds: *Guidelines to the Use of Wild Birds in Research*;
 3. For amphibians and reptiles: *Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research*; and
 4. For fishes: *Guidelines for the Use of Fishes in Research*.
- d. For standards of euthanasia in all categories of research and teaching, the University endorses the 2020 Edition of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, or any subsequent revision.
- e. For the purpose of classification, research and teaching not clearly identifiable as agricultural or field research and teaching will be classified as biomedical.

- f. The Institutional Official (IO), a representative of senior administration with the authority to allocate the necessary resources, bears ultimate responsibility for the University's animal care and use program (Program). Oversight for the Program is vested in the AV, the IACUC, and supporting personnel. In keeping with federal regulations, the IACUC shall consist of no fewer than five (5) individuals, including the Chair, AV, 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 IO will designate a Chair from the University members. 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 member review (DMR) of protocols as outlined in the *Guide*, and oversee all written communication between the IACUC and the Principal Investigator (PI). A vice-chair shall be assigned by committee consensus on an as-needed basis.
 - ii. The AV shall have the authority to direct staff to carry out activities related to maintaining optimal animal care. The AV shall report to the IO. The duties of the AV, 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 any organization that has accredited the Program.
 2. Assure that education and research endeavors involving animals are conducted according to acceptable practices and as approved by the IACUC.
 3. Facilitate the development of proposed animal research projects and provide counsel to the PI 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 PI and appropriate institutional officials of problems that arise pertaining to physical plant problems or deviations from accepted practices or procedures.
 8. Confer with the IO on matters of animal care and use in research and teaching.
 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.
 10. Assist in the preparation of reports and statements as requested or required by various regulatory or accreditation agencies.

11. Provide veterinary consulting on 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 PI and the committee. Files shall be destroyed three (3) years after the close or completion of the project.
 - iv. The Research Integrity and Compliance Officer (RICO) shall serve as a liaison between the IACUC and the IO and will coordinate IACUC activities with other compliance requirements and committees. In consultation with the Chair and AV, the RICO will ensure that all members of the IACUC are appropriately trained, file annual updates and other reports to the USDA and PHS, maintain registration with these agencies, monitor federal and state regulations, and suggest revised policies and procedures to remain in compliance with those regulations.
 - v. IACUC member candidates may be nominated by the Dean from each of the colleges that use vertebrate animals for research or teaching, and/or by current members. Members will be appointed by the IO after consultation with the AV, the Chair, 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 AV, 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.
- g. 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. 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 Program, using the *Guide* as a basis for evaluation;

- iii. Inspect at least once every six (6) months all of the University's animal facilities and surgical sites, using the *Guide* as a basis for evaluation of all biomedical animal research facilities;
 - iv. Prepare or review reports of the IACUC evaluations as set forth in the PHS Policy and submit the reports to the IO;
 - v. Review concerns involving the care and use of animals at the University;
 - vi. Make written recommendations to the IO regarding any aspect of the Program, facilities, or personnel training;
 - vii. Review and approve, require modifications in (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 PI in the *Animal Use Proposal*.
 - viii. Notify PIs 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 to suspend institutional approval for an activity involving animals as set forth in the PHS Policy, and suspend an activity.
- h. All activity that involves the use of vertebrate animals requires the submission of the *Animal Use Proposal*. 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.
 - i. Research involving animal care that falls under certain categories of research will be deemed exempt from full committee review (FCR) but not from this policy. PIs may not make a unilateral determination of a project's exempt status and must submit the *Animal Use Proposal* for review. A single qualified individual (the Chair, the AV, or a person designated by the Chair) will make the determination as to exempt status. Activity that may be deemed exempt includes 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.
 - j. If a proposal does not involve animals in pain category E, major survival surgery, or particularly risky procedures, it is eligible for DMR. All members will be provided information regarding the protocol, with the opportunity to request FCR. If FCR is not called for, the Chair will appoint one or more members to review the proposed research with the authority to approve, seek modifications to secure approval, or request FCR. A protocol may not be disapproved using DMR.

- k. Research involving animal care that is not exempt from this policy and is not eligible for DMR will be reviewed at a convened IACUC meeting. At a minimum, both DMR and FCR 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 provided in the proposal;
 - iii. If procedures involving unrelieved severe or chronic pain must be used, the animal will 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.
 - v. 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.
 - vi. Medical care for the animals is available and provided as necessary by a qualified veterinary technician or veterinarian.
 - vii. Personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in the procedures.
 - viii. The method(s) of euthanasia to be used is consistent with AVMA guidelines, unless a deviation is justified for scientific reason in writing by the PI.
- l. A protocol under review shall be deemed approved by FCR if accepted by a majority of voting members in attendance. The committee may require modifications to the protocol prior to approval. The Chair, or 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 PI.
- m. A PI may appeal a decision of the IACUC within two (2) weeks of notification by the Chair. The appeal process is as follows:
 - i. The investigator must submit an appeal in writing to the Chair, identifying specific points of disagreement with the Committee's decision, reasons for disagreement, and the desired outcome of the appeal.
 - ii. A quorum of the committee will hear (or read) the appeal from the investigator, discuss any concerns with the appellant, and determine an outcome.
 - iii. The investigator can appeal to the IACUC for a second hearing if

1. There was pertinent information that was available at the time of the initial hearing, but was not presented to the IACUC, or
 2. Policies and/or procedures were not adhered to during the first hearing.
- iv. If the investigator is dissatisfied with the result, further reconsideration of the matter may be requested by appealing to the IO in writing. Such written requests must be filed with the IACUC Secretary within ten (10) days of the IACUC reconsideration decision.
 - v. The IO will meet with the IACUC for further discussion, if warranted. The IO may review committee decisions, impose additional modifications, or disapprove research activity approved by the committee. The IO or any other official may not approve animal research activity that the committee has disapproved.
- n. 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 s/he 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.
 - o. Any changes in protocols must be reported to and approved by the IACUC prior to initiation. The only changes that can be made without prior consent are those necessary to eliminate apparent immediate hazards to animals. Initial review of proposed changes is conducted by the Chair. An increase of less than 10% in previously approved animal numbers for non-USDA species may be handled administratively without additional consultation or notification. The following changes may be approved administratively in consultation with the AV:
 - i. anesthesia, analgesia, sedation, or experimental substances;
 - ii. euthanasia following any method approved in the AVMA Guidelines; and
 - iii. duration, frequency, type, or number of procedures performed on an animal.
 - p. Significant changes, listed below, will be approved by either FCR or DMR:
 - i. from non-survival to survival surgery;
 - ii. resulting in greater pain, distress, or degree of invasiveness;
 - iii. in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC;
 - iv. in species;
 - v. in study objectives;
 - vi. in Principal Investigator; and
 - vii. that impact personnel safety.

- q. Projects will be approved for up to three (3) years. Annually, PIs 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 after protocols undergo a *de novo* review using FCR or DMR procedures, as appropriate. The committee may review activities more frequently, as they determine necessary, and conduct, or direct others to conduct, random audits of any approved project or laboratory facilities.
- r. During the process of initial or continuing review of an activity, material provided to the IACUC shall be considered privileged information and the committee shall assure the confidentiality of the data contained therein.
- s. The 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. Submitting completed *Animal Use Proposals* for approval;
 - ii. Ensuring that all participating personnel have completed the appropriate training in the care and use of animals;
 - iii. Overseeing all care to ensure that animals are being treated humanely;
 - iv. Following approved research protocols and receiving IACUC approval for any changes prior to implementing the changes;
 - v. Immediately filing a report of any unanticipated problems or anticipated, but serious, adverse events;
 - vi. Reporting on the progress of the research; and
 - vii. Filing all necessary project extensions.
- t. University faculty and staff may serve as PIs. Graduate students must name a faculty advisor as PI who will provide oversight. 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 University 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 Program review; and
 - ii. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IACUC.
- v. 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.

- w. When alleged incidents of noncompliance are reported, the IACUC will follow written procedures to resolve the concern. 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 AV. If there is found to be animal suffering, the AV 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 of the IACUC Chair, the IO, at the request of the Chair, may appoint a deputy chairperson who will assume 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.
 - iii. 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.
 - iv. 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 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. Revised; Approved by President on 1/03/2020.
Revised; Approved by President on 10/16/2020.