



POLICY MANUAL

RESEARCH

Number 4104

Subject: Animal Care and Use

Effective Date: May 26, 2010

4104.1 INTRODUCTION

The purpose of this policy is to govern the use of animals in the conduct of teaching, research, and outreach activities at USU. The University is committed to providing for the proper and humane care of animals owned by or under the direct care of the University, or involved in University-sponsored activities. All employees of the University involved in the care and use of live animals have a direct responsibility for promoting animal welfare within the programs of the University, and for adhering to all applicable ethical and legal standards for animal use.

In accordance with the Animal Welfare Act (AWA), USU supports the use of animals in teaching, research, and outreach programs to investigate and demonstrate scientific principles, and contribute to the body of knowledge. The use of animals shall be carried out in ways that avoid or minimize discomfort whenever possible, and that avoid duplication of experiments. The use of animals shall be reduced, refined, or replaced by other methods whenever such actions are consistent with sound scientific practice and the mission of the University.

4104.2 DEFINITIONS

2.1 Research

For the purposes of this policy, "Research" shall mean "a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge." USU's position as a land grant institution requires it to support a significant research program involving agricultural animals. USU also carries out biomedical, wildlife, behavioral, and other research using animals. Employees shall be responsible to become familiar with and adhere to all laws, regulations, and policies governing the care and use of animals in these settings.

2.2 Animal

"Animal" or "Animals" are defined as all live vertebrate animals including but not limited to mammals, amphibians, fishes, birds, turtles, crocodilians and reptiles.

2.3 Animal Activity

"Animal Activity" or "Animal Use " is defined as any activity that meets the standard set under 9 CFR 1.1, including research, testing, or teaching procedures that involve the care and use of animals. This definition does not extend to pest control procedures that are not otherwise connected to research, testing, or teaching.

2.4 Resources

USU's Laboratory Animal Resources (LAR) facilities and personnel and the USU Institutional Animal Care and Use Committee (IACUC) act as resources to University personnel to fulfill their ethical and legal obligations in caring for and using animals. The IACUC is authorized to approve, require modifications to, disapprove, suspend, and/or terminate specific animal activities at USU, and to monitor the use of animals under approved protocols.

4104.3 APPLICABILITY

This policy applies to USU personnel (faculty, staff, and students), who must adhere to ethical and regulatory standards as set forth in Section 7 of this policy for the use of animals in University-sponsored activities. Such standards include laws, regulations, guidance, and statements of policy originating in international, federal, state, and local authorities and in the University. These standards have been established to protect the welfare of animals in the research, instructional, and outreach programs of the University. Any activity that departs from institutionally approved standards violates University policy, and could result in sanctions as outlined in USU Policy #4006 Academic Due Process: Sanctions and Hearing Procedures, and elsewhere in USU policies.

All research, teaching, or outreach conducted under the auspices of USU, including cooperative research conducted with one or more public or private entities, in which animals are used, must be reviewed and approved by an IACUC (or equivalent body), except as set forth in Section 309.4. Members of USU's IACUC are appointed by the Vice President for Research, under the direction of USU's President.

This policy shall also apply to animals raised and used for agricultural purposes that are owned by the University, whether on University or private property, and that are under the direct care of the University, except as set forth in 309.4, or as determined by the Institutional Animal Care and Use Committee (IACUC) of the University in accordance with federal regulations.

4104.4 LIMITATIONS

This policy shall apply only to animals that are owned by, are under the direct care of, or are subjects of research, teaching or outreach programs as set forth in Section 3 of this

policy. It shall not apply to:

4.1 Animals of the following types: (1) privately-owned animals reasonably described as pets; or (2) feral animals for which there is no recognized owner, if those animals are not part of a university sponsored research, teaching or outreach activity.

4.2 Animals used for incidental or recreational activities sponsored or hosted by the University. Animals brought to the University for such activities shall be cared for under rules of the organization sanctioning the activity such as, for example, the 4-H or Future Farmers of America.

4.3 Animals that are, and at all times remain in, the legal possession of individuals who use such animals in incidental exhibitions or demonstrations in University facilities.

4.4 Activities involving animals or fetuses that are deceased.

4.5 Activities with privately owned animals at facilities that are not owned or controlled by USU when those activities are not research, teaching or outreach as set forth in Section 3. For example, activities carried out by third party owners of animals for agricultural or agro-business purposes shall not be regulated by this policy.

4.6 Clinically necessary (e.g., diagnostic or therapeutic) procedures and euthanasia carried out under the direction of a duly licensed veterinarian, whether performed in conjunction with animal activities as defined in Section 2.3 or not.

4.7 Provision of outreach activities by USU personnel, including extension employees and USU veterinarians, that may, for example, constitute the demonstration of husbandry practices and are not otherwise related to research or the teaching of USU enrolled individuals.

4.8 Collection of data in connections with clinically necessary procedures and other services as provided under 4.6 and 4.7 that may be used in retrospective research and quality improvement programs. For further information concerning collection of samples and coordination of activities at privately owned facilities, see Sections 10.9 and 10.10, below.

4104.5 REGULATORY REVIEW

The IACUC review and approval process shall be conducted in accordance with all federal, state and local laws and regulations including the Animal Welfare Act and the Health Research Extension Act, and all University policies and regulations that govern the care and use of animals. Except as provided in this policy, the requirements for IACUC review and approval apply to all University animal activities in all locations, whether funded or not, and whether conducted by faculty, students, or other University employees. It also applies to persons unaffiliated with the University when they are conducting research using animals that are owned by or under the direct care of the University. As indicated in Section 4.5, IACUC review is not expected for activities carried out by private parties involving animals which are privately owned and controlled unless those activities qualify

as animal activities as defined herein, and are carried out at the specific request of USU.

Approval by the IACUC must be obtained before any live animal work may begin. No other entity at the University may approve animal activities that have been disapproved or terminated by the IACUC, although other University entities may, for reasons beyond this policy, restrict, suspend, or terminate animal activities.

4104.6 PRECEDENCE OF REGULATIONS

Where an international and a U.S. federal regulation are in conflict with one another, and the work is being performed outside the U.S., any animal use being conducted by USU personnel, or involving USU animals, or being funded through a USU grant shall be conducted using the standards applicable in the place where the work is being conducted. However, in the absence of regulatory requirements controlling animal care and use, U.S. regulations and this policy shall apply. Where work is being done in another state within the U.S., that state's regulation shall take precedent.

4104.7 REGULATORY CITATIONS

Employees are referred to the following documents and regulations, and any future revisions of such documents, hereby made a part of this policy by reference:

- Animal Welfare Act, 7 U.S.C. 2131-2159, also at 9 CFR Chapter 1, Part 2, Subpart 3 & Part 3, Subpart A-F.
- 7 CFR 2.22, 2.80
- The Guide for the Care and Use of Laboratory Animals. Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C. 1996.
- Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. Federation of Animal Science Societies, Savoy, IL, 1999.
- IRAC - U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, 1985.
- Health Research Extension Act of 1985, Public law 99-158 "Animals in Research."
- 2000 Report of the AVMA Panel on Euthanasia. Journal of American Veterinary Medicine Assoc, 218(5): 669-696. March 1, 2001
- Public Health Service Policy on Humane Care and Use of Laboratory Animals. Office of Laboratory Animal Welfare, National Institutes of Health, Department of Health and Human Services, Bethesda MD.

- Utah Division of Wildlife Resources Administrative Rule R-657-3-11, "Certificate of Registration Required," pertaining to wildlife research conducted in Utah (see Section 3.2, below, for wildlife permits outside Utah).
- Occupational Health and Safety in the Care and Use of Research Animals. Committee on Occupational Safety and Health in Research Animal Facilities, Institute of Laboratory Animal Resources, National Research Council. National Academy Press, Washington, D.C., 1997.

4104.8 ASSURANCE

The IACUC is authorized under OLAW Animal Welfare assurance # A3801-01, valid through 31 JAN 2014, to conduct PHS supported activities involving live animals.

4104.9 REPORTING DEVIATIONS

Significant deviations from approved protocols must be reported to the IACUC, and, based on the nature of the deviation, the IACUC will have responsibility for assessing whether the project protocol requires modification or the activity should be suspended or terminated. Significant deviations of protocols being performed under the OLAW assurance shall be reported to OLAW. Deviations involving animals covered under the AWA may be reportable to the institutional official and the USDA.

4104.10 PROCEDURES

10.1 Application to the IACUC

Except as excluded under Sections 2, 3 or 4 of this policy, an "Application for Live Animal Use in Research, Teaching and Training" (hereinafter Application) must be submitted, reviewed, and approved before any activity involving the on-campus or off-campus use of animals (research, teaching, training, public service; internally or extramurally funded regardless of source or amount; and including animals being bred, conditioned, or held for future use) may begin. The application is a form that allows investigators to communicate to the IACUC their reasons for and methods of animal use. The IACUC reviews the application and notifies the Principal Investigator (PI) of its decision to approve, require modification of, or withhold approval of the application. Animal use in the absence of IACUC approval is a serious violation of University policy and a may be a violation of federal law.

10.2 Completing the Application

Additional information regarding applications can be obtained from the website: <http://rgs.usu.edu/iacuc/policies>. Applications should be written in such a manner as to be understood by lay individuals. Each section must be answered in specific detail or noted "not applicable". Each application is to be a stand-alone document; therefore, it is not sufficient to answer a question by simply referring to a more detailed paper or reference or attached document. All applications require an original signed application form. Syllabi are needed for teaching activities. Submit all applications through the IACUC Office. After

review and approval, the IACUC Office will send the approval letter to the Principal Investigator for submission to the appropriate offices or federal agencies. If approval is withheld, the PI will be informed in writing regarding the reasons for withholding approval.

10.3 Wildlife Activities

In addition to submission of the application, and as a condition of application approval by the IACUC, PIs conducting research involving wild vertebrate animals shall secure and maintain any required certificate of registration or equivalent wildlife use permit issued by the appropriate state, federal, or foreign government agency prior to initiating animal activities. Investigators may consult with the IACUC and cognizant agencies concerning use of wildlife. Investigators must be aware of and follow the guidelines of relevant professional societies when conducting animal activities involving wildlife.

10.4 Timely Submission

The IACUC will not expedite the review of an application because the investigator failed to submit it in time to meet various deadlines. It is the responsibility of the Principal Investigator to submit a new application or protocol renewal with sufficient lead-time to meet all University and agency deadlines.

10.5 Multiple Activities

Under certain circumstances, it may be possible to include vertebrate animal use for more than one project or course under a single application. Investigators should consult with the IACUC Office or the director of the Laboratory Animal Research Center (LARC) for guidance concerning the need for applications. Co-submission of the same proposal to two or more granting agencies requires only one application, accompanied by a copy of each proposal. Resubmission of an unfunded proposal will not require re-review as long as it is not significantly revised over the previous submission and as long as the previous submission was within the last 12 months. A renewal of a previously funded project does not require animal use re-review if: (1) it has not been significantly revised and has been reviewed by the IACUC within the last three years, or (2) it has already been subject to a continuing review within the previous 12 months because it involves animals covered by the AWA that must be re-approved yearly.

10.6 Review by Another IACUC

If USU employees are participating in animal research conducted at non-USU sites either:

- 1) as a graduate student where the student is working toward a degree to be awarded by USU,
- 2) as a PI on a project when the employee maintains a paid position at USU during the project, or
- 3) when USU is receiving funding for the research, either as a grantee or subgrantee, and the research has been reviewed and approved by IACUCs (or equivalent bodies) at other institutions, then employees shall submit a copy of the IACUC approval letter and a copy of the approved protocol from the other reviewing institution to USU's IACUC. The USU IACUC shall assess such situations on a case-by-case basis and reserves the right to require submission of

a USU application regardless of whether or not an activity has received approval from a separate institution.

10.7 Protocol Approval

The application, when approved, becomes an approved animal use protocol (hereinafter "Protocol") that is valid for a period of one year if animals to be used are covered by the AWA, or three years from the date of approval for all other species. The PI is required to submit an annual report for three-year approved protocols detailing any changes that may have occurred during the year. The IACUC Office distributes the form for annual reports to the PI at the appropriate time. After the approved period, a new application must be submitted and reviewed by the IACUC.

10.8 Requirements to Act as PI

Principal Investigators submitting an application must be of faculty rank or otherwise approved by a department head, or must be an animal facility manager. PIs are responsible for animal use by their students and staff. The PI heading a research group or teaching a course must have an approved protocol (based on the application) on file for each project and/or course under his/her supervision. Collaborators, technicians, and students must care for and use animals according to the protocols described in the approved applications. Deviations should be reported to the IACUC as set forth in 309.6.

10.9 Coordination of Animal Activities Involving Outside Entities

While the IACUC may choose not to conduct inspections of field and overseas research sites, the use of live animals under an appropriately approved protocol by USU personnel or individuals acting under the direction of USU personnel is expected to be in accordance with University policy. That portion of animal use (as defined in Section 2.3) conducted by USU personnel who are collaborating with outside researchers may be reviewed by the USU IACUC, even if it has already been reviewed and approved by an IACUC or similar committee at the collaborating institution.

10.10 Sample Collection

With regard to collection of samples (e.g., tissue or bodily fluids), if samples are being collected from any live vertebrate animal exclusively for the purposes of a USU employee's research or teaching projects, that individual must file an application with the USU IACUC. However, samples that are clinically necessary or approved by another IACUC may be used for research purposes without IACUC review. This policy also applies to field studies in which samples are being collected expressly for the purposes of an investigator's research or teaching projects and to studies covered by government permits. The IACUC reviews all such projects.

10.11 Amendments

If significant changes are anticipated in an on-going project, a protocol amendment must be submitted to the IACUC office prior to initiation of these changes. Changes that require

protocol amendment include, but are not limited to: changes in animal numbers requested, addition of new personnel, addition of new species to an existing protocol, or addition of new animal use procedures to an existing protocol. Consult the IACUC Office for information.

10.12 Appropriate Supervision and Training

The housing, care, feeding, and observations of all animals must be supervised by individuals trained in such matters. Managers of animal care facilities are expected to meet the guidelines set forth in the Guide for the Care and Use of Laboratory Animals (for biomedical research projects), the AWA or the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (for agricultural or research projects), or other guides as adopted by the IACUC. These guides are available from the IACUC Office.

10.13 Access to Animals

To ensure that activities involving animals are conducted in accordance with protocols approved by the IACUC, upon a request by the IACUC (or an IACUC designee) PIs and research staff shall allow members of the IACUC (or individuals designated by the IACUC) to observe animal activities. Additionally, upon request by the IACUC (or an IACUC designee) PIs and research staff shall allow members of the IACUC to observe animal activities regardless of the location of the activity, and participate in interviews with members of the IACUC (or an IACUC designee) to discuss animal activities.

10.14 Animal Acquisition

Acquisition of all animals whose use or care is controlled under the Animal Welfare Act and/or the Public Health Service Assurance shall be coordinated in advance with the LARC director or his/her designee. All animal purchases shall be processed through the LARC except livestock intended for food or fiber research (as defined in the AWA), or other livestock intended for recreation or for teaching. Wildlife collected in the field also need not be processed through the LARC. However, the LARC director or director's designee is to be notified in advance of intent to house wildlife species that are collected in the field in USU owned facilities. Except in the case of privately owned animals or wildlife collected in the field for which special arrangements have been made with the IACUC, all animals to be used in animal activities shall be housed in facilities specifically designated for this purpose, and approved by the IACUC. Access to all facilities where animal activities are conducted shall be provided to the IACUC. Upon request by the IACUC, facility managers and/or PIs will provide the IACUC with the numbers and species of animals currently in use and/or previously used in animal activities during a period of up to one year prior to the time of the request.

10.15 Minimizing Animal Discomfort

Whenever possible, animal use shall be planned and conducted so as to avoid or minimize pain and distress to the animals. Procedures involving animals must be performed by, or be closely supervised by, a faculty or staff member who is skilled in the procedure. All

personnel and students performing procedures under an approved USU protocol must be appropriately trained and supervised. If any experimental or demonstrative procedure or its consequences have the potential to induce significant and/or lasting pain, distress, or suffering, appropriate methods of tranquilization, anesthesia, and analgesia must be used whenever possible. The protocol attending veterinarian can provide guidance on appropriate methods. Painful or distress-inducing procedures (as covered under Principle IV of the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training as contained in the PHS Policy on Humane Care and Use of Laboratory Animals), regardless of whether they can or cannot be obviated, must be reviewed and approved in advance by the IACUC.

10.16 Euthanasia

Procedures for euthanasia must be performed in a manner consistent with the latest recommendations of the American Veterinary Association Panel on Euthanasia and all proposed methods must be approved in advance by the IACUC.