



THE UNIVERSITY OF UTAH

IACUC

Institutional Animal Care and Use

Committee



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Regulatory

- The University of Utah maintains an institutional animal care and use program using the U.S. Department of Agriculture (USDA) Animal Welfare Act (AWA) regulations and the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) regulations governing the use of vertebrate animals.
- The program operates under a Public Health Service (PHS) Animal Welfare Assurance.
- The program also follows the requirements of the USDA Animal Welfare Act for applicable species.
- The University of Utah is fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, int.).



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USDA-APHIS

- The U.S. Department of Agriculture (USDA), through its division of the Animal and Plant Health Inspection Service (APHIS), administers the Animal Welfare Act.
- The AWA regulates the **transportation, purchase, care and treatment of animals** used for exhibition, sold as pets, or **used in basic and biomedical research, education and product safety testing**.
- The AWA specifically applies to certain species being used, or intended for use for research, teaching, testing and experimentation.
- The AWA requires the establishment of an IACUC to review all activities using animals to ensure their humane use in research activities and to conduct semi-annual assessments of the institution's animal care and use program, including inspections of all animal study areas and facilities. The university is subject to random inspections by the USDA and files an annual report with USDA concerning its animal care and use program.



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PHS, NIH, & OLAW

- The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) was created to implement the provisions of the Health Research Extension Act of 1985. The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) administers the Policy.
- The Policy applies to institutions conducting U.S. Public Health Service-supported projects involving live vertebrate animals. The Policy requires that the institution establish an Institutional Animal Care and Use Committee.



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About IACUC

- The University of Utah Institutional Animal Care and Use Committee (IACUC) oversees the university's animal care and use program. The University of Utah IACUC is comprised of faculty members (i.e., experienced scientists), veterinarians, and representatives from the community appointed by the Institutional Official, the Vice President for Research.
- The IACUC is required by Federal law to oversee the humane care and use of laboratory animals.
- The IACUC reviews and approves proposed activities involving animals, reviews the animal care and use program, and monitors University animal facilities to ensure compliance with standards and regulatory requirements.
- Federal law requires the IACUC to conduct semi-annual inspections and evaluations of the animal care and use program and all animal facilities.
- The IACUC prepares reports of all evaluations conducted and submits them to the Vice President for Research. In addition, the IACUC makes recommendations to the Vice President for Research regarding the institution's animal program, facilities, or training.
- By performing these and other duties, the IACUC ensures that the highest ethical and animal welfare standards are met, consistent with applicable federal and state laws and regulations, and University policies.

U of U IACUC Vision Statement:

To cultivate a culture of compliance through ***research data integrity and interdepartmental regulatory cooperation and collaboration***, to ensure humane use of research subjects while building a national and international reputation of research excellence at the University of Utah.

University of Utah Statistics

474 Approved protocols
~15 New protocols a month
70+ Amendments a month
27 Buildings with animal housing
395+ Procedure rooms

University of Utah Species

Goat
Swine
Ovine
Canine
Feline
Rabbit
Guinea Pig
Hamster
Non-human Primate
Alligator

Rat
Mouse
Lizard
Frog
Bird
Fish

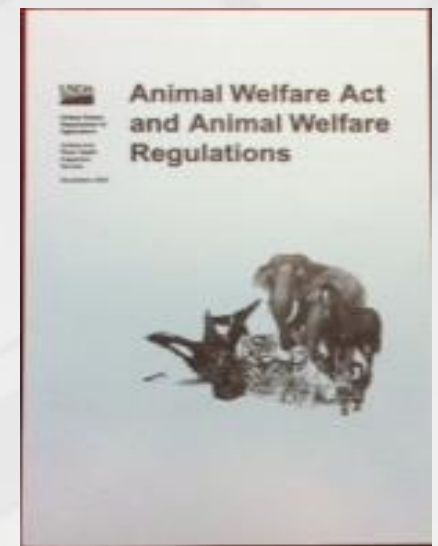
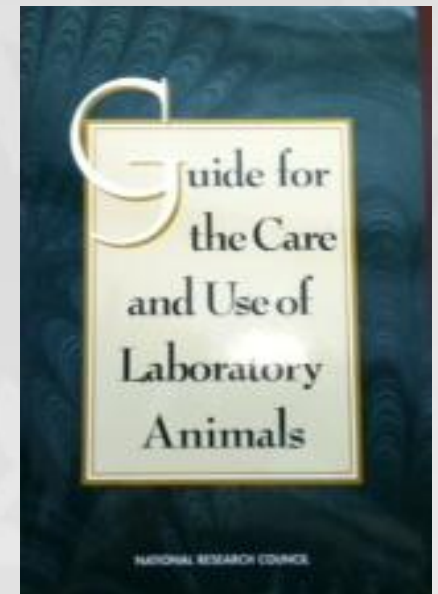


Origin of IACUC

- NIH (public funding source)
 - 1896 National Institute of Health was established
 - 1986 NIH Requires IACUC
 - Institutions that receive NIH funds must obtain an “Assurance” describing compliance with the PHS Policy
- USDA (US Federal Animal Welfare Act)
 - 1966 Animal Welfare Act was passed into law
 - Defines minimum standards of care and use
 - Covers animals bred for sale, used in research, exhibited
 - Prevents trade of lost or stolen animals
 - Prohibits animal fighting ventures
 - 1989 Law Requires IACUC (*Animal Welfare Act*)
 - **All Mammals except for rats and mice*

1960's

- Public concern in U.S. gained momentum
- Pressure builds on lawmakers to regulate commercial use of animals, including use of experimental animals
 - 1966 Life magazine article exposed animal abuse and pet theft by animal dealers



IACUC Authority

- Animal Welfare Act
- Public Health Service Policy
- U of U Institutional Policies

The **IACUC** is responsible for oversight of the animal care and use program and its components as described in the PHS Policy and the *Guide*. It's oversight functions include an ongoing assessment of animal care and use.

Reporting Structure



*The IACUC reports directly to the IO who must provide appropriate resources to allow the IACUC to meet its responsibilities.

Institutional Official

- The Vice President for Research serves as the Institutional Official (IO) with authority to legally commit the University of Utah to meet federal regulatory guidelines.
 - This authority is delegated from the President of the University.
- The IO is responsible for appointment of members to the IACUC.
- The IO is the signatory authority for the institution's PHS Assurance.

IACUC Chair

- In addition to the responsibilities of IACUC membership, the Chair has primary responsibility for conducting IACUC meetings.
- The IACUC Chair works with members and researchers to ensure that the welfare of animals used in teaching and research is adequately protected.

IACUC Office

- The IACUC Director reports directly to the Vice President for Research.
- The IACUC office is responsible for administration of the IACUC records and maintaining federal records and reports.
- The IACUC office also provides monitoring of approved animal use protocols.
- The IACUC office supports the functions of the committee.

IACUC Membership Requirements

Animal Welfare Act
Must have 3 members

Veterinarian
Non-affiliated
Chair

Public Health Service
Must have 5 members

Veterinarian
Non-affiliated
Scientist
Non-scientist
Chair

U of U IACUC

- The Institutional Official appoints the members of the IACUC, typically for renewable, three-year terms.
- The IACUC consists of not less than five members of varying professional and personal backgrounds, including at least one veterinarian, one non-scientist, one practicing scientist, and at least one person who is not affiliated with the institution in any way other than as a member of the IACUC (community member).
- No more than three members shall be from the same department.
- 15 committee members (currently)
- 5.5 IACUC office support employees

Conflict of Interest

- No IACUC member shall participate in the IACUC review or approval of an application or proposal in which the member has a real or apparent conflict of interest except to provide information requested by the IACUC.
- The IACUC member with the real or apparent COI must recuse themselves from voting and may not contribute to the quorum requirements for the specific application.
- To assure integrity of the program, IACUC members are responsible for disclosing any potential or perceived conflicts of interest that may exist for any business discussed by the IACUC.
- Common conflicts of interest include being an investigator on a study under review, having a financial interest in a study under review, being a family member of an investigator with a study under review, etc.

Regulated Responsibilities

- Every six months inspect all of the university's animal facilities
- Every six months review the university's program for the humane care and use of animals (SOP's, veterinary care, etc.)
- Prepare reports of IACUC evaluations and submit to the Institutional Official (IO), including minor or significant deficiencies and a plan for correction
- Make recommendations to the IO regarding any aspect of the animal program, facilities or personnel training
- Ensure adequate training
- Review and approve or not approve protocols
- Conduct post-approval monitoring
- Review concerns involving the care and use of animals at the institution
- Suspend an activity involving animals if necessary

IACUC Semi-annual Inspection

IACUC audit every six months (April & October)

- Under PHS Policy and USDA Regulations, the IACUC must inspect all Institutional animal **facilities** and review animal care and use **programs** every six months.
- The PHS Policy and the AWA requires the IACUC to evaluate the animal welfare program, to identify deficiencies and classify them as minor or significant, and to make recommendations for correction of deficiencies within a reasonable time.

Facilities Review

Conducted at least once every six months

- Terrestrial/aquatic animal housing and support areas
- Cage wash
- Special facilities- aseptic surgery
- Special facilities- procedure areas, non-survival surgeries, laboratories, imaging, irradiation, hazardous agent containment, behavioral studies, etc.
- Veterinary care

Documents used to conduct the facilities audit:

- Guide for the Care and Use of Laboratory Animals
- OLAW Assurance
- PHS Policy
- Animal Welfare Act
- AAALAC Program Description
- U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research and Training

Program Review

Conducted at least once every six months

Institutional Policies and Responsibilities

- Animal Care and Use Program
- Disaster planning and emergency preparedness
- IACUC
- IACUC protocol review- special considerations
- IACUC membership and functions
- IACUC training
- IACUC records and reporting requirements
- Veterinary care
- Personnel qualifications and training
- Occupational health and safety of personnel
- Personnel security
- Investigating and reporting animal welfare concerns

Program Review

Veterinary Care

- Clinical care and management
- Animal procurement and transportation/preventive medicine
- Surgery
- Pain, distress, anesthesia, and analgesia
- Euthanasia
- Drug storage and control

Documents used to conduct the program review:

- AAALAC Program Description
- OLAW Assurance
- Animal Welfare Act
- PHS Policy
- Guide for Care and Use of Animals
- U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research and Training

Training

- Training at the University of Utah is mandated for all personnel using animals in research and training.
- The IACUC has in its employment a full-time Training Coordinator for this purpose.
- The IACUC must ensure that everyone working with animals is trained.
 - Researchers
 - Support/Maintenance Staff
 - Animal Care Staff
 - IACUC Members

Training and instruction available to personnel and IACUC members includes guidance in at least the following areas:

Humane methods of animal maintenance and experimentation –

- The basic needs of each species of animal;
- Proper handling and care for the various species of animals used by the facility;
- Proper pre-procedural and post-procedural care of animals; and Aseptic surgical methods and procedures;
- The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
- Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

- Instruction on the hazards associated with working with animals (Occupational Health Program).
- Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility.
- Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - On appropriate methods of animal care and use;
 - On alternatives to the use of live animals in research that could prevent unintended and unnecessary duplication of research involving animals; and
 - Regarding the intent and requirements of the Animal Welfare Act.

IACUC Protocol Review

IACUC approval is required prior to beginning research, teaching, or testing activities that involve animals.

- Scientific merit
- Justification for the use of animals
- Justification for the species chosen
- Justification for the number of animals
- Alternatives = The 3 R's
 - Reduction:** The right number of animals
 - Refinement:** Methods which alleviate pain and enhance well-being
 - Replacement:** Use of a non-animal model
- Procedures to minimize discomfort and pain
- List of individuals and qualifications

Protocol Review

The IACUC reviews those components of activities related to the care and use of animals to determine that the proposed activities are in compliance with the AWA, the AWRs, the PHS Policy, the NIH *Guide*, and applicable U of U policies and procedures.

Protocols must include a complete description of the proposed use of the animals; and, unless a protocol includes an acceptable justification for a departure from any of the following, it must demonstrate to the IACUC that the proposed activities will meet all of these requirements:

- Procedures involving animals are designed and performed with due consideration of their scientific relevance to human or animal health, the advancement of knowledge, or the good of society.
- The investigator certifies in writing that the proposed activities do not unnecessarily duplicate work that has been accomplished previously by the investigator or any other individual(s).
- There is an adequate rationale for using animals to conduct the proposed activities.
- The animals selected for use are of an appropriate species and quality, and the minimum number of animals will be used, to obtain valid results.
- Procedures using animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.
- The investigator has searched for alternatives to procedures that will or may cause more than momentary or slight pain or distress to the animals; and if no alternatives are available or appropriate, those procedures will be performed with appropriate sedation, analgesia, or anesthesia unless there is a justifiable scientific reason for withholding relief.

Protocol Review

- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- Methods of euthanasia will be consistent with current recommendations of the AVMA Panel on Euthanasia unless a deviation is justified for scientific reasons.
- The animals' living conditions will be appropriate for their species and will contribute to their health and comfort.
- The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species.
- Veterinary medical care for the animals will be available and provided as necessary by a qualified veterinarian.
- Investigators and other personnel conducting procedures on the animals will be appropriately qualified and experienced for conducting those procedures.
- Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques.
- Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose and which will be operated and maintained under aseptic conditions. Surgery on rodents, non-major operative procedures, and operative procedures conducted at field sites will be performed using aseptic procedures.
- No animal will be used in more than one major operative procedure from which it is allowed to recover unless it is justified for scientific reasons; it is required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or there are other special circumstances that have been determined to be necessary by the Regional Administrator of USDA APHIS for the specific protocol.

Post-approval Monitoring (PAM)

- The IACUC conducts continuing reviews of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 and the Animal Welfare Act at least once every three years.
- The *Guide* recommends a continuing program to audit approved animal use protocols. Post-approval monitoring is an essential component of a comprehensive animal care and use program.
- The University of Utah has a dedicated Post-approval Monitoring (PAM) program.

The purpose of a PAM program:

- Work with investigators to facilitate their animal research.
- Be proactive in identifying potential compliance problems with an emphasis on education and training.

Benefits of a PAM program:

- A mechanism for documenting compliance with applicable animal care and use policies, guidelines, and laws.
- An opportunity for dialogue, education, and exchange of information between individuals conducting research and teaching involving animals and the IACUC.

Investigate Concerns

Commonly called “whistle blower”

- IACUC investigates reports
- Reports deficiencies
- Recommends corrections/actions in consultation with the U of U Institutional Official
- Notice posted in all animal facilities

****Retaliation of any kind against an individual, who, in good faith, alleges misconduct or cooperated with the investigation, is prohibited and the retaliator may be subject to discipline under university policies. (University of Utah Policy 7-001: Policy for Research Misconduct. Sec. G)***

****No facility employee, committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Animal Welfare Act.***

NOTICE:

In compliance with the University of Utah and AWA et seq. the Chair of the IACUC will accept material from anyone regarding the performance of this Institution regarding the care and use of animals. The sections of the University of Utah Policy covering this information are:

- To the extent permitted by law and university policies, the university will protect the identity and privacy of those individuals who, in good faith, report apparent misconduct or furnish information regarding such alleged misconduct. Retaliation of any kind against an individual, who, in good faith, alleges misconduct or cooperated with the investigation, is prohibited and the retaliator may be subject to discipline under university policies. (*University of Utah Policy 7-001: Policy for Research Misconduct. Sec. G*)
- The university shall undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when such allegations are not confirmed, and to protect the positions and reputations of those persons who, in good faith, report apparent misconduct. (*University of Utah Policy 7-001: Policy for Research Misconduct. Sec. G*)

The sections of the AWA covering this information are:

- The IACUC will review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees. (*Sec 2:31; C:4*)
- No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act.

(*Sec 2:31; C:4*)

Please contact the IACUC Office at 581-5950 or iacuc@ocm.utah.edu.

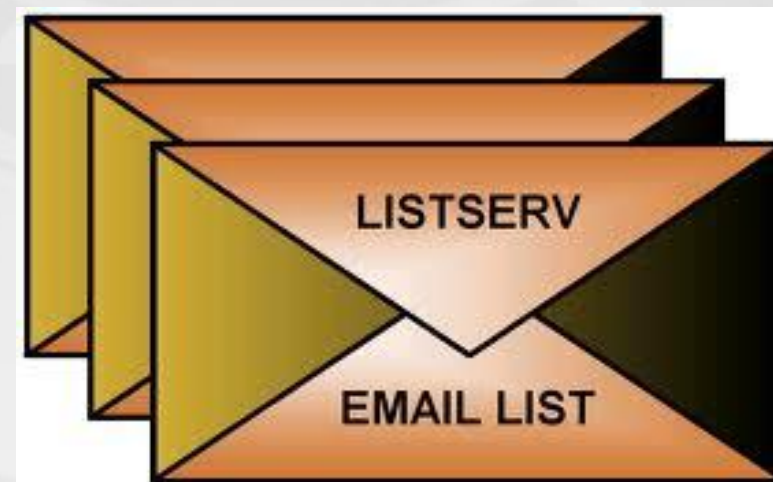
Suspend an Activity

- A protocol may be suspended if its conduct is not in compliance with regulations or consistent with conditions of approval.
- The IACUC may suspend a protocol only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
- The IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action to any federal agency based on requirements.



IACUC ListServ

- Provides a forum for sharing information
 - Difficult procedures
 - Excess or unused animals
 - Available tissues
 - Adoption of animals
 - Automatic enrollment for researchers
 - Provide updates to researchers



Supportive Resources

- IACUC WEBSITE <http://iacuc.utah.edu>
- Guide for the Care and Use of Laboratory Animals
<https://olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>
- Animal Welfare Act
- https://www.aphis.usda.gov/animal_welfare/downloads/AC_Blue_Book_AWA_508_comp_version.pdf
- PHS Policy
<https://olaw.nih.gov/sites/default/files/PHSPolicyLabAnimals.pdf>
- U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research and Training
- <https://olaw.nih.gov/policies-laws/gov-principles.htm>