

Policies and Procedures

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CHAPTER: Institutional Animal Care and Use Committee	ISSUED: 11/2006	REV. A: 07/2007	REV. B: 07/2008	REV. C: 11/2009
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1.0 PURPOSE

The Creighton University Institutional Animal Care and Use committee (IACUC) is dedicated to the humane care and use of animals in activities related to research and teaching conducted at Creighton University or by individuals associated with the university. The IACUC is guided by federal regulations and ethical principles intended to ensure the humane care and use of animals in research and teaching. All research and teaching involving vertebrate animals that is conducted or authorized under the jurisdiction of Creighton University is subject to review by the IACUC.

1.1 DEFINITIONS & ACRONYMS

The IACUC uses the following definitions and acronyms in reference to its activities:

AAALACi—Association for Assessment and Accreditation of Laboratory Animal Care International.

Animal—An unqualified use of the term “animal” refers to live vertebrates beyond the fetal stage (mammals) or that have hatched (other vertebrates). The IACUC does not regulate activity associated with non-vertebrate animals or vertebrate animal carcasses from recognized vendors or institutions (see RC IACUC 3.0 section 3.1).

Animal Incident Report—A report filed with the IACUC documenting any unanticipated or atypical event associated with animal use that results in unexpected pain, distress, or death for the animal(s).

Animal Use—Any contact with live vertebrates, including care and handling, for research or teaching purposes is classified as “animal use” and is governed by the IACUC.

AOHS—Animal Occupational Health and Safety Program. When not specified, the term AOHS in these policies and procedures refers specifically to the Creighton University Animal Occupational Health and Safety Program.

Application—This refers to the IACUC Animal Use Protocol Application. The term indicates that the protocol has not yet been approved.

APHIS—The Animal and Plant Health Inspection Service, a division of the USDA.

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ARF—The Creighton University Animal Resource Facility. This term excludes any satellite animal holding areas unless otherwise specified.

ARF Standard Operating Procedures—These procedures govern the daily operation of the Animal Resource Facility.

Attending Veterinarian—The Creighton University Attending Veterinarian serves on the IACUC, has delegated authority for all protocols, animal facilities, and all animals at the university. The Attending Veterinarian is available to make recommendations and provides veterinary care.

AWA—Animal Welfare Act of 1966. This term is normally used to both the Act itself and the resulting regulations. The AWA governs use of USDA-covered species (all mammals and birds except mice, rats, and birds bred for research purposes).

Designated Member Review (DMR)—A mechanism of application review in which one or more committee members, rather than the committee as a whole, have the authority to approve the protocol, as set forth in Policy R&C-IACUC 3.0 Section 3.2.2.

Designated Reviewer(s) (DMR)—A mechanism of application review in which one or more committee members, rather than the committee as a whole, have the authority to approve the protocol, as set forth in Policy R&C-IACUC-3.0 Section 3.2.2.

Full Committee Review (FCR)—A mechanism of application review involving all IACUC members present at an IACUC meeting, as set forth in Policy R&C-IACUC 3.0 Section 3.2.1.

The Guide—*The Guide for the Care and Use of Laboratory Animals* is published by the National Academy of Sciences under the auspices of the National Research Council (NRC), and serves as a standard for laboratory animal welfare.

IACUC—Institutional Animal Care and Use Committee. When not specified, the term “IACUC” in these policies and procedures refers specifically to the Creighton University Institutional Animal Care and Use Committee.

Instructions—Instructions for Protocol Application for Animal Use.

Investigator—Any faculty member using animals (live vertebrates) in research or teaching is classified as an Investigator for IACUC purposes. In addition, any other person serving as

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Principal Investigator on a research grant is also considered an Investigator, regardless of whether they will have physical contact with animals.

NIH—The National Institutes of Health, is the primary federal agency for conduction and supporting medical research.

Noncompliance—Any action or inaction that does not follow the procedures or design specified in an approved protocol, and/or that violates animal welfare regulations or Creighton University IACUC Policies and Procedures.

NRC—The National Research Council, a non-government group that is part of the National Academies.

OLAW—Office of Laboratory Animal Welfare, which oversees the care and use of research animals in Public Health Service (PHS)-funded research.

Personal Supervision—IACUC defines “personal supervision” as meaning the supervisor is present in the room with the person being supervised while animals are being used.

PHS—Public Health Service, a federal organization that includes the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and other federal agencies.

PHS Policy—Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Post-Approval Monitoring (PAM)—Audits of the animal procedures, recordkeeping, occupational health and safety risks, etc., that occur as part of an active protocol. PAM is conducted on a routine (“Not for Cause”) and as-needed (“For-Cause”) basis by the QA Monitor or IACUC members.

Principal Investigator (PI)—A single individual who has overall responsibilities on a protocol. The principal investigator on a protocol is normally a Creighton University faculty member. Postdoctoral researchers may act as principal investigator on a protocol if a grant’s funding contract is in their name. Any other investigator involved with the project must be listed on the protocol.

Protocol—Normally refers specifically to an Animal Use Protocol that has been approved by the IACUC, as opposed to an application submitted for review. Subcategories include:

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- **Open** – An approved protocol that has not yet expired or been closed.
- **Closed** – A protocol that was approved but has either expired or been terminated at the request of the principal investigator or by IACUC action.
- **Active** – An open protocol under which work is being conducted and/or animals are being held.
- **Inactive** – An open protocol under which the Principal Investigator is not currently conducting any work or holding any animals.
- **Administrative Hold** – A protocol on Administrative Hold is one in which no work is being conducted and any animals have been transferred to a holding protocol.
- **Suspended** – A protocol on which the IACUC has halted all activity, for example, for reasons of noncompliance.

QA Monitor—The QA (“Quality Assurance”) Monitor is a Research and Compliance Officer responsible for post-approval monitoring.

Research and Compliance Office—Creighton University’s Research and Compliance Office is responsible for ensuring observance of feral, state, and local regulation with regard to research.

USDA—United States Department of Agriculture.

1.2 Regulatory Authorities Governing Animal Use

The Creighton University IACUC Policies and Procedures were developed by the IACUC based upon requirement set forth by the following:

- USDA under statutory law (Animal Welfare Act [7USC, 2131-2159]) and regulations (Federal Animal Welfare Regulation [Title 9, Chapter 1, Subchapter A, Parts 1 to 4]).
- PHS under statutory law [42 USC 289d], the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), and *The Guide for the Care and Use of Laboratory Animals* (The Guide).

1.3 U.S. Department of Agriculture

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The USDA, through its division of the APHIS, administers the AWA and its amendments, codified at 7 USC 2131 et seq. and 9 CFR 2.31 et seq. 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 the use of all warm-blooded vertebrates (Mammalia and Aves), with the exception of mice of the genus *Mus*, rats of the genus *Rattus*, and bird species bred specifically for use in research.

The AWA requires the establishment of an IACUC at all institutions that use animals in research, teaching or testing. The IACUC is responsible for reviewing all activities that involve animals in research, teaching or testing to ensure humane use of animals. The IACUC is also responsible for conducting semiannual assessments of the Creighton University IACUC Policies and Procedures for animal care and use programs, including inspections of all animal study areas and facilities. As a research facility, Creighton University is subject to random inspections by USDA and must file an annual report concerning its IACUC Policies and Procedures. Failure to comply with USDA law and regulations pertaining to the use of live animals can result in civil or criminal prosecution and suspension of animal research activities.

Every Investigator at Creighton University is given access to a current copy of the AWA and related regulation's, which are accessible to everyone who works with animals through the [APHIS Animal Care Publications website](#).

1.4 Office of Laboratory Animal Welfare at the National Institutes of Health

The PHS Policy was created to implement the provisions of the Health Research Extension Act of 1985. OLAW at NIH administers the policy. The policy applies to institutions conducting PHS-supported project involving live vertebrate animals.

The PHS Policy requires that such institutions establish an IACUC. In accordance with the policy, the IACUC, using The Guide, is responsible for reviewing the use of animals and conducting semiannual assessments of the Creighton University IACUC Policies and Procedures, including inspections of all animals study areas and facilities.

Creighton University is required to file an Animal Welfare Assurance of Compliance Statement (Assurance every four years with OLAW, providing written documentation of the institution's commitment to animal welfare and detailed information on the Creighton University IACUC Policies and Procedures. The Assurance commits Creighton University to compliance not only with the PHS Policy and The Guide, but also with the AWA.

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Failure to comply with the PHS Policy and/or The Guide may lead to various actions, including the termination of PHS funding for all projects at Creighton University involving the use of animals.

Every investigator at Creighton University must review the PHS Policy and The Guide. A current copy of the PHS Policy and The Guide are accessible to everyone who works with animals from the Creighton IACUC website.

1.5 Administrative Organization

The Institutional Official has the authority to legally commit, on behalf of Creighton University, that regulatory requirements will be met under the AWA and PHS Policy. The IO is responsible for appointing members to IACUC and sign the Assurance.

1.6 Attending Veterinarian

The Creighton University Attending Veterinarian serves on the IACUC as a voting member and has delegated authority and responsibility to implement the PHS Policy and recommendations of the Guide and the AWA. The Attending Veterinarian routinely inspects the animal facilities and all animals at Creighton University. The Attending Veterinarian is available to make recommendations concerning preventive health programs for animals, disease treatment, analgesia, anesthesia, post-operative recovery, euthanasia, general animal welfare, and technical training. The Attending Veterinarian provides routine veterinary care, preventive medical care, and on-call emergency care and consultation for Creighton University's animals. The Attending Veterinarian provides routine veterinary care, preventive medical care and on-call emergency care and consolation for Creighton University's animals. The Attending Veterinarian has the authority to immediately halt activity on any protocol if animal welfare is endangered.

1.7 Institutional Animal Care and Use Committee

The IACUC was established pursuant to the AWA and the PHS Policy and reports to the Institutional Official. The Institutional Official appoints the members of the IACUC, who serve until they resign or are removed. The IACUC staff includes one administrative personnel.

1.7.1 Membership

The IACUC consist of at least seven members, of varying professional and personal backgrounds, including at least one veterinarian, one non-scientist, one practicing scientist, one biostatistician, and one person who is not affiliated with Creighton University in any way other

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than as a member of the IACUC (for example, a community member). The community member may be either a scientist or non-scientist. Not more than three members shall be from the same department. The IACUC members, including the community member, may be reimbursed for expenses related to their duties on the IACUC (for example, travel or mileage, meals, parking, IACUC seminars).

A university faculty member who is not the ARF Director or the Attending Veterinarian is selected by the Institutional Official as the IACUC Chair. The IACUC appoints one person from among its members as Vice Chair of the IA CUC. The Vice Chair serves as the IACUC Chair in the temporary absence of the Chair or when the Chair has a conflict of interest with an IACUC review or other activity. The IACUC may, from time to time, consult with other professionals (for example, legal counsel) in fulfilling its responsibilities.

1.7.2 Meeting and Quorum Requirements

The IACUC meets at least once monthly on the last or second to the last Monday of the month, depending on the university's holiday schedule. The IACUC will meet more than once a month if necessary to fulfill its responsibilities. A Quorum is required at any meeting at which formal action is taken by the IACUC , and a majority vote of those present at the meeting is required for any formal action (for example, approval or suspension).

A quorum requires the present of a majority of the current voting members of the IACUC. Members must be physically present at a meeting to be counted toward a quorum. Any member who has a conflict of interest in a matter under consideration by the IACUC (for example, is personal involved in the matter) shall not be counted toward a quorum for that portion of the meeting. If a quorum is lost at any time during the meeting, the meeting shall be adjourned and no further formal action shall be taken until a quorum is attained.

In the event of a pandemic or other significant emergency situation, the IACUC may conduct official business through alternatives other than face-to-face meetings, such as video conferencing or teleconferencing. After the pandemic or significant emergency situation has subsided, the IACUC will return to conducting official business in a face-to-face manner.

1.7.3 Meeting Minutes

Recorded minutes from IACUC monthly meetings are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the committee

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such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or noncompliance would be recorded in the minutes if it were germane to the discussion. Minutes may include references to the historical discussion about the IACUC from members who have served on the committee and observed the procedures being proposed, served as reviewers for protocols involving similar procedures, or participated in past IACUC discussions about procedures. According to PHS policy, IACUC minutes must reflect:

- Records of Attendance
- Activities of the Committee
- Deliberations

Minutes will be reviewed by the IACUC at the following meeting and voted on for approval.

1.7.4. Responsibilities

The IACUC has general oversight responsibility for Creighton University IACUC Policies and Procedures, AOHS Program, Veterinary Care Program and the ARF. Specific responsibilities of the IACUC include the review of animal use, inspection and review of ARF Standard Operating Procedures, AOHS Program, Veterinary Care Program, compliance activities, record keeping and community relations.

Review of Animal Use:

- Review and approve, require modifications to, or withhold approval of all new application or modification to existing protocols involving animals.
- Conduct continuing reviews of approved protocols, no less than annually.
- Conduct *de novo* review (similar to an initial review) of all open protocols at least once every three years if the PI does not which to close the protocol.
- Review all animal incident reports and determine whether any additional action is necessary (see Policy R&C IACUC 6.0 Section 6.2)

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Inspection and Review of ARF Standard Operating Procedures:

- Recommend procedures to be followed for the proper care and humane treatment of animals and review them every six months using Title 9 CFR (USDA) and *the Guide* (OLAW) as a basis of review, providing a written report to the Institutional Official
- Inspect every six months all Creighton University's animal facilities using Title 9CFR and *the Guide* as basis of inspect, providing a written report to the Institutional Official.
- Provide recommendations to the Institutional Official and Facility Director regarding any aspect of the animal program, facilities or personnel training.

Inspection and Review of Animal Occupational Health and Safety Program:

- Recommend procedures to be followed for the proper care and humane treatment of animals and review them every six months using Title 9 CFR (USDA) and *the Guide* (OLAW) as a basis of review, providing a written report to the Institutional Official.
- Provide recommendations to the Institutional Official and Facility Director regarding any aspect of the animal program, facilities or personnel training.

Inspection and Review of Veterinary Care Program:

- Recommend procedures to be followed for the proper care and humane treatment of animals and review them every six months using Title 9 CFR (USDA) and *the Guide* (OLAW) as a basis of review, providing a written report to the Institutional Official.
- Provide recommendations to the Institutional Official and Facility Director regarding any aspect of the animal program, facilities or personnel training.

Compliance Activities:

- Review and investigate noncompliance with the Creighton University IACUC Policies and Procedures, applicable regulations, *PHS Policy* or *the Guide*.
- Suspend any activity that is not in compliance with the *PHS Policy* and *the Guide*, the USDA regulations, or IACUC guidelines.

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Record Keeping:

- Maintain records of IACUC activities as required by regulation or the *PHS Policy*

Community Relations:

- Help serve as a liaison between the university and the community for matters involving animal research and welfare.

1.8 Animal Resource Facility Personnel

ARF Director – The ARF Director is responsible for managing the resources of the ARF. The IACUC consults with the ARF Director for input on the Creighton University IACUC Policies and Procedures affecting the daily operations of the ARF. The ARF Director or his/her designee normally attends IACUC meetings.

ARF Manager – The ARF Manager is responsible for the day-to-day activities in the animal facility, including supervising technicians, implementing policies and procedures, and communicating any problems or concerns to the Attending Veterinarian or the IACUC Chair. The ARF Manager, in conjunction with the IACUC Chair and Attending Veterinarian, also serves as a resource to the Principal Investigator and staff on appropriate procedural techniques involving animals. The ARF Manager may attend IACUC meetings in a non-voting capacity to advise the IACUC on issues related to ARF use and activities.

Facility Technicians and Support Staff – The Facility Technicians and Support Staff work closely with the animals. These personnel should be well qualified, by training or experience, to handle and care for the animals in the facility. They should be knowledgeable about the requirements for the species involved and about any special requirements imposed by specific research, testing or teaching programs.

1.9 Personnel Using Animals

All personnel using animals are responsible for complying with applicable government regulations and university policies. The following sections provide an overview of these responsibilities. More complete information is provided by federal and Creighton University publications, which are accessible through the IACUC web site.

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1.9.1 General Responsibilities

- All individuals using live animals in the context of research or teaching, except those personnel classified as exempt (see Policy RC-IACUC-2.0 section 2.2.1), are governed by the following regulations and policies. Personnel classified as Investigators have additional responsibilities. Questions regarding these responsibilities may be addressed to the IACUC Chair or the Research Compliance Office.
- The IACUC requires that all personnel using animals:
- Receive and maintain IACUC Certification (see Policy RC-IACUC-2.0 section 2.4.1).
- Follow the procedures for animal care and use described in approved protocols.
- Adhere to the ARF Standard Operating Procedures when using the facility. These procedures are available on the IACUC website.
- Report noncompliant activity to the ARF Manager, IACUC Chair or Research Compliance Officer. Reports can be made anonymously (see Policy RC-IACUC-6.0 Section 6.1).

1.9.2 Responsibilities of Investigators

The IACUC relies on Investigators to uphold high standards in animal care and use. The following policies are designed to ensure that these standards are maintained and that applicable regulations are followed. Investigators also have the same responsibilities as all other personnel working with animals.

Requirements for Investigators:

- Receive and maintain IACUC Certification (see Policy RC-IACUC-2.0 section 2.4.1).
- Submit the Application (see *Protocol Application for Animal Use*), as described in this document and per Instructions (see *Protocol Application for Animal Use Instructions*), for any work involving animals and wait for approval before beginning such work.

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- Provide a copy of each approved protocol to every person participating in the research project, and ensure that each person understands his/her duties as well as the project as a whole.
- Ensure that all personnel on the protocol have adequate training and/or experience to carry out their designated roles.
- Be certain that all project personnel follow the procedures for animal care and use described in approved protocols.
- Request and receive approval for any modifications of animal procedures or other animal use before implementing such modifications (see Policy RC-IACUC-3.0 section 3.5.2).
- Request and receive IACUC approval for additions to project personnel prior to activity by these individuals (SOP for requesting protocol modifications).
- Consult the Attending Veterinarian or other appropriate IACUC or ARF personnel for assistance with unexpected health care problems with animals.
- Submit an Animal Incident Report within 72 hours of unanticipated incident (see Policy RC-IACUC-4.0 section 4.1).
- Maintain complete records of procedures undertaken during all animal experiments. Maintain a scholarly, sensitive and respectful environment during all animal experimentation. (See SOP for Lab Notebooks).
- When using animals for instructional purposes in classrooms or laboratories, ensure that animals receive the same humane care and treatment as those used for research purposes.

IACUC Recommendations to Investigators:

While the IACUC is available to assist Investigators in fulfilling their responsibilities under government regulations and university policies, each Investigator is responsible for his/her conduct in the care and use of animals. In addition, the Principal Investigator bears ultimate responsibility for all aspects of each project, including the activities of all project personnel.

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Research:

The continued use of vertebrate animals in research depends in part on an understanding by the public that such work is scientifically important and is carried out in a humane manner. The following recommendations are therefore directed to Investigators conducting research:

- Participate in continuing education and training programs designed to keep investigators abreast of the latest techniques and procedures in animal research.
- Discuss with students, post-docs, technicians, animal care workers and others participating in research the ethics of animal use in scientific studies, including the issues of humane treatment as well as replacement, reduction and refinement alternatives. Be sensitive to the needs of newcomers to adjust to participating in research performed on animals.
- Devote time and effort to institution-wide activities to promote a general understanding within the academic community and the lay public of the need for animals in research and instruction.
- Emphasize the role of laboratory animals when presenting research results or discussing human diseases with lay audiences and describe the contributions of humanely conducted animal studies for the discovery of new knowledge and development of new technologies and treatment capabilities.

Teaching:

Although there has been a dramatic reduction in the use of animals for instructional purposes over the past two decades, live animals remain an important and necessary adjunct teaching model in certain courses. The following recommendations are therefore directed to faculty members or others involved in this type of instruction:

- Promote sensitivity and concern among students for the need for humane care and treatment of animals.
- Promote understanding among students of the importance of humanely conducted animal studies for the discovery of new knowledge and for the development of new technologies and treatment capabilities.