



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

**PURPOSE:** To establish policy regarding care and management of animals used in research and instruction.

**POLICY:**

- 0.0 CONTENTS
  - 1.0 Applicability
  - 2.0 Policy
  - 3.0 Composition and Governance of the Institutional Animal Care and Use Committee (IACUC)
  - 4.0 Responsibilities of the Institutional Animal Care and Use Committee (IACUC)
  - 5.0 Responsibilities of the Investigator/Instructor
  - 6.0 Responsibilities of the Department Chair or Cognizant Administrator
  - 7.0 The University's Institutional Animal Care and Use Program (IACUP)
- Appendix: Forms and Protocols

1.0 APPLICABILITY

SUU recognizes that the proper care and management of animals used in research and instruction is essential to the well being of the animals, to the validity of research data, to the quality of instruction, and to the health and safety of those caring for and using animals. Therefore, this policy is applicable to all research and instruction activities conducted at or under the auspices of SUU that involve vertebrate animals, including non-laboratory species.

2.0 POLICY

2.1 It is the policy of the university that use of live vertebrate animals in research and instruction will conform to all applicable laws, rules, and regulations of the United States Government and the State of Utah. Furthermore, all such research and instruction must be performed in compliance with the highest standards of ethics, practice, and conduct of each of the fields or disciplines involved in each of the specific research projects or instructional activities.

2.2 To ensure compliance with regulations regarding the humane care and use of animals in research and instruction, SUU's President will appoint an Institutional Animal Care and Use Committee (IACUC) which meets regulatory requirements and is charged with the responsibility of ensuring the humane care and use of animals at the University.

2.3 SUU and the Institutional Animal Care and Use Committee recognize the following regulatory authorities for the care and use of animals:



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

2.3.1 The U.S. Department of Agriculture (USDA). The Animal Care (AC) section of the Animal and Plant Health Inspection Service (APHIS) of the USDA is responsible for implementing the regulations and standards promulgated by the Secretary of Agriculture under the mandate of the Animal Welfare Act. The regulations define institutional responsibility for assuring compliance with the Animal Welfare Act. The standards set minimal requirements for humane handling, housing, space, feeding, watering, sanitation, ventilation, exercise, and psychological well being of various species. Compliance requirements include annual reporting, application of standards for animal care and use during experimentation, documentation of the number of animals used, and summaries of exceptions granted for scientific necessity. USDA personnel perform unannounced inspections of institutional animal facilities.

2.3.2 The Office for Laboratory Animal Welfare (OLAW) is found at:  
<http://grants.nih.gov/grants/olaw/olaw.htm>

OLAW is responsible for the general administration and coordination of National Institutes of Health (NIH) policy regarding animal care and use. Public Health Service (PHS) awarding units may not make an award for a project involving vertebrate animals unless the institution submitting the application or proposal is on the list of institutions that have an acceptable animal welfare assurance letter on file with OLAW, and the responsible institutional official has provided verification of approval by the Institutional Animal Care and Use Committee. All records that directly relate to applications, proposals, and proposed changes in ongoing research reviewed and approved by the Animal Care Committee must be maintained for at least three years after completion of the research and must be accessible to OLAW with reasonable notice.

2.4 SUU and the Institutional Animal Care and Use Committee (IACUC) further recognize the following guidelines, and any others, which are subsequently officially adopted by the IACUC, for the care and use of non-laboratory animals in research and instruction.

2.4.1 Guidelines for Use of Fishes in Field Research. American Society of Ichthyologists and Herpetologists (ASIH), American Fisheries Society (AFS), and American Institute of Fisheries Research Biologists (AIFRB); Fisheries. Available at <http://www.asih.org/pubs/fishguide.html>.

2.4.2 Guidelines for Use of Live Amphibians and Reptiles in Field Research. American Society of Ichthyologists and Herpetologists (ASIH), The Herpetologists' League (HL), and Society for the Study of Amphibians and Reptiles (SSAR). Available at <http://www.asih.org/pubs/herpcoll.html>.



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

2.4.3 Guidelines for the Use of Wild Birds in Research. Edited by Abbot S. Gaunt & Lewis W. Oring, Special Publication of The Ornithological Council, 1997. Available at <http://www.nmnh.si.edu/BIRDNET/GuideToUse>.

2.4.4 Guidelines for the Capture, Handling, and Care of Mammals. The American Society of Mammalogists (ASM); 1998. Available at <http://www.mammalsociety.org/committees/commanimalcareuse/98acucguidelines.PDF>.

2.4.5 Guidelines for Ethical Conduct in the Care and Use of Animals. Developed by the American Psychological Association's Committee on Animal Research and Ethics (CARE), 2003. Available at <http://www.apa.org/science/anguide.html>.

3.0 COMPOSITION AND GOVERNANCE OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

3.1 The Institutional Animal Care and Use Committee (IACUC) will be appointed by the Provost and will advise the Provost (Institutional Official) about matters pertaining to animal care and utilization in research and instruction.

3.2 The membership of the IACUC will meet the requirements of Federal regulations and will include members who are qualified through experience and expertise. The IACUC will include at least three voting members. One will be a Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine who will have responsibility for providing veterinary care to the animals. At least one member of the committee will not have any affiliation with the University except service on the IACUC.

3.3 Other than the attending veterinarian, who will be an ex-officio member, IACUC members are appointed for a term of three years with reappointment possible.

3.4 The terms of voting IACUC members will be staggered with at least one member completing his/her term each academic year. (The academic year is August 16 to August 15.)

3.5 An IACUC Chair and an IACUC Vice-Chair will each be elected for a three-year term at the first IACUC meeting of the academic year.

3.6 In the event of resignation of the Chair from the position but not the committee, the Vice-Chair will assume the Chair position and will complete the departing Chair's term of office. A new Vice-Chair will then be elected from among the voting members.



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

3.7 In the event of resignation of the Chair from the committee, the Vice-Chair will assume the Chair position and will complete the departing Chair's term of office. He/she will then identify and recommend a replacement member for appointment by the President. A new Vice-Chair will then be elected from among the voting members to complete the departing Vice-Chair's term of office.

3.8 In the event of resignation of the Vice-Chair from the position but not the committee, the Chair will hold a special election to select a new Vice-Chair from among the voting members. The new Vice-Chair will complete the original Vice-Chair's term of office.

3.9 In the event of resignation of the Vice-Chair from the committee, the Chair will identify and recommend a replacement member for appointment by the President. The Chair will then hold a special election to select a new Vice-Chair from among the voting members. The new Vice-Chair will complete the departing Vice-Chair's term of office.

3.10 In the event of resignation from the committee of a voting member who is not an officer, the Chair of the IACUC will identify and recommend a replacement for appointment by the President. The member appointed to fill the vacancy will assume the remaining term of the departing member.

3.11 The Director of the Institutional Animal Care and Use Program (IACUP) will serve as a non-voting consultant to the IACUC.

3.12 The Office of Sponsored Projects (OSP) will provide staff support to the IACUC by providing announcements and agendas for its meetings, recording the minutes of its meetings, serving as a repository of all IACUC correspondence and records, and the like.

3.13 The Office of Sponsored Projects will serve as the first and primary contact point for inquiries and submissions to the IACUC. SPO staff will forward applications to IACUC members for review.

3.14 If deemed necessary by the IACUC, during the Spring semester of each year, the Director of Sponsored Projects will issue a request to the faculty for nominations to replace outgoing IACUC members. Current IACUC members may also submit nominations. Nominations will be submitted to the Office of Research and Sponsored Projects.

3.15 The Director of Sponsored Projects, after consultation with the IACUC Chair, and the Director of the Institutional Animal Care and Use Program, will submit to the Provost a slate of individuals recommended to replace outgoing IACUC members. The Provost will appoint the new members.



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

3.16 The IACUC will meet at least once per month during September, January, and May to review protocols and to tend to other business as needed. Meeting dates and protocol review application deadlines will be made public to the university at the beginning of each semester. Other meetings will be held as needed.

3.17 In addition to its regular meetings, the IACUC will meet at least once every six months to review the institution's animal care and use program and to inspect the animal facilities. These meetings and inspections may be conducted immediately preceding or immediately following a regularly scheduled IACUC meeting.

3.18 A simple majority of the voting members will constitute a quorum.

3.19 Alternate members may be appointed by the Provost to serve and participate on the IACUC in the absence of voting members. When a quorum of voting members is not present, the IACUC Chair may delegate full responsibilities of membership (including voting privileges) to an alternate member.

3.20 The IACUC may solicit ad hoc reviewers with specific expertise to assist in protocol reviews on a case-by-case basis. Ad hoc reviewers may participate, but not vote, in the designated reviews.

**4.0 RESPONSIBILITIES OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**

4.1 The Institutional Animal Care and Use Committee will conduct semi-annual reviews of the University's Institutional Animal Care and Use Program (IACUP) and will report findings to the Provost.

4.2 The IACUC will conduct semi-annual inspections of all of the university's animal facilities, including satellite facilities, and will report findings to the Provost.

4.3 The IACUC will receive and review concerns or complaints reported by faculty, staff, students, or members of the general public concerning the care and use of animals at the SUU.

4.4 The IACUC may make written recommendations to the Provost regarding any aspect of the University's animal care and use program, facilities, or personnel training.

4.5 The IACUC will review all research and instruction protocols involving vertebrate animals conducted at, or under the auspices of, any unit of the SUU, whether or not



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

supported by an external agency. The following types of projects are subject to IACUC review and approval:

- 4.5.1 Externally or Internally Funded Research Proposals. Prior to submitting a grant proposal for extramural or intramural funding, or as soon thereafter as possible, the investigator must submit an Animal Care and Use Protocol Review Application (ACUPRA). No animals may be acquired for research or instruction before review and approval of the protocol by the IACUC.
- 4.5.2 Independent Faculty Research or Laboratory Exercises. All independent faculty research with vertebrate animals, including pilot experiments conducted to obtain data necessary to the preparation of extramural grant proposals, and other laboratory exercises require approval of the experimental protocols and husbandry methods by the IACUC before being initiated.
- 4.5.3 Field Research and Biological Surveys. All fieldwork involving vertebrate species, whether research or instruction, must be approved by the IACUC prior to initiation. Particular attention must be given to activities that may involve animals that are on the State or Federal threatened, endangered, or protected species lists, that require special permits for handling, or that involve use of equipment and procedures that may be construed by some as inhumane.
- 4.5.4 Independent Student Research (excluding senior paper). Faculty members who supervise independent research projects may submit a set of procedures for approval by the IACUC from which the student may select to address the independent research question identified. Procedures not included in those approved for the class instructor and specific for the laboratory will require submission of an independent request for protocol evaluation. Students should be made aware by the faculty member that this may delay their research and may adversely affect their ability to complete the course in the prescribed time interval.
- 4.5.5 Senior Paper Research. All Senior Paper research protocols involving animals, including pilot or exploratory research, must be approved by the IACUC prior to initiation of the work with animals. Student submissions must be cosigned by their major professor or advisor, who will have ultimate responsibility for proper training of the student in the care and handling of the animals and in any specialized techniques required for the research.
- 4.5.6 Classroom Instruction. All classroom instruction activities involving the use of live vertebrate animals must be approved by the IACUC prior to initiation.
- 4.5.7 General Animal Care and Use Protocols. The Investigator or instructor responsible for general animal care and use in any facility must submit an Animal Care and Use Protocol



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

Review Application (ACUPRA) for these tasks. Included under this project classification are procedures for animal display facilities and animal breeding programs. These submissions must include a list of the species to be maintained and an estimate of the numbers of each animal bred or used annually. If animals maintained or produced under such an approval are transferred to an Investigator for use in experiments or to an instructor for educational purposes, the investigator or instructor must have a valid IACUC approved project for use and maintenance of the transferred animals and must notify the IACUC of the species and number of animals transferred.

4.6 The use of vertebrate animals in research or instruction covered by this policy will not be permitted until the IACUC has reviewed and approved the protocol. The IACUC will not normally consider any requests for retroactive approvals.

4.7 The IACUC will exercise its responsibility and authority to approve, withhold approval of, or require changes in research or instructional protocols involving vertebrate animals in accordance with Federal regulations and accepted guidelines.

4.8 The IACUC will review, approve, withhold approval of, or require modifications to proposed significant changes regarding the use of vertebrate animals in previously approved research or instruction protocols.

4.9 The IACUC will notify the investigator or instructor, the Office of Research and Sponsored Projects, the Department Chair/Cognizant Administrator, and the Provost in writing of decisions to approve, withhold approval of, or require modifications to those proposed protocols reviewed.

4.10 The IACUC may suspend any activity involving vertebrate animals that is not being conducted in compliance with applicable provisions of Federal or State law or university policy or in accordance with a protocol approved by IACUC.

4.11 The IACUC will report suspended activities or continuing or serious non-compliance with the requirements of this policy to the investigator's/ instructor's Department Chair and Dean and the Provost and to Federal authorities as required by the Federal Animal Welfare Act available at <http://www.animal-law.org/welfact/> and the Public Health Service Policy on Humane Care and Use of Laboratory Animals which is available at: <http://grants.nih.gov/grants/olaw/references/phspol.htm> and to any applicable funding agency.

4.12 When research or instruction involving vertebrate animals is conducted through a cooperative project at, or in cooperation with, another entity, all provisions of this policy remain in effect. The SUU IACUC may accept, for the purpose of meeting the IACUC



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

review requirements, the review of an IACUC established in accordance with U.S. Department of Agriculture and U.S. Department of Health and Human Services, Public Health Service, rules and regulations. Such acceptance must be in writing and must be signed by the Chairs of the Institutional Animal Care and Use Committees at each of the cooperating institutions.

5.0 RESPONSIBILITIES OF THE INVESTIGATOR/INSTRUCTOR

5.1 The investigator/instructor who anticipates using vertebrate animals should become knowledgeable about, and conduct all research and instruction in accordance with, approved policies governing the care and use of animals.

5.2 The investigator/instructor should participate in continuing education and training programs designed to keep animal users abreast of the latest regulations and procedures. The investigator/instructor should also emphasize the role of animals in their studies when presenting research results or discussing human and animal diseases with lay audiences and should describe the contributions of humanely conducted animal studies to the development of new technologies and treatment capabilities.

5.3 The investigator/instructor should maintain a scholarly, sensitive, and respectful environment during all experimentation and instructional activities involving the use of animals.

5.4 The investigator seeking external funding should indicate the involvement of vertebrate animals on the University's Office of Research and Sponsored Projects Pre-Award Proposal Routing Sheet which may be found at:  
<http://www.suu.edu/academics/provost/grants/pdf/GAFrouting.doc> for sponsored projects.

5.5 The investigator/instructor should prepare an Animal Care and Use Protocol Review Application (ACUPRA), giving a complete description of the proposed animal care and use protocol. (Application forms are available from the Office of Research and Sponsored Projects). The investigator/instructor will make provisions for the humane care and use of the animals and will ensure that pertinent laws, regulations, and guidelines are observed.

5.6 The investigator/instructor will ensure that all protocols involving vertebrate animals are submitted to the Institutional Animal Care and Use Committee through the Office of Research and Sponsored Projects and approved by the IACUC prior to initiating the proposed work.



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

5.7 The investigator/instructor will submit a protocol modification request to the IACUC when the plans for use of vertebrate animals previously submitted will be different from that which was initially approved by the IACUC. The investigator/instructor will not initiate changes without prior IACUC review and approval, except when necessary to eliminate apparent immediate hazards to the animals or to humans.

5.8 The investigator/instructor using vertebrate animals will comply with all IACUC decisions, conditions, and requirements.

5.9 The investigator/instructor will maintain and use animals only in approved animal facilities whenever possible. IACUC approval is required when animal use protocols dictate unusual environmental, dietary, or colony requirements that cannot be met in approved animal care facilities.

5.10 The investigator/instructor will ensure that animal care and use records are retained for a minimum of three years after animal use is completed and that they are easily accessible by U.S. Department of Agriculture inspectors and IACUC monitors. These records may not be removed from the campus without the prior approval of the IACUC.

5.11 The investigator/instructor will submit continuing review applications to the IACUC as often as, and in the manner, prescribed by the IACUC, but not less than once per year, as long as the use of animals is ongoing.

5.12 The investigator/instructor will report promptly to the IACUC, the Director of the Institutional Animal Care and Use Program, and/or the Attending Veterinarian any injuries to or illnesses of the animals.

5.13 The investigator/instructor will report promptly to the IACUC any non-compliance with the requirements of this policy or the determinations of the IACUC.

5.14 To facilitate the review of research and instructional protocols involving the use of vertebrate animals, the investigator/instructor is expected to attend IACUC meetings when requested by the IACUC.

5.15 To facilitate the review of research and instructional protocols involving the use of vertebrate animals, the investigator/instructor may request a meeting with the IACUC. Requests should be submitted to the Chair of the IACUC.

**6.0 RESPONSIBILITIES OF THE DEPARTMENT CHAIR OR COGNIZANT ADMINISTRATOR**



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

6.1 Department Chairs (or cognizant administrators) will review and approve applications for use of vertebrate animals in research and instruction prior to their submission to the Office of Research and Sponsored Projects for consideration by the IACUC.

6.2 Department Chairs (or cognizant administrators), through appropriate procedures established within their respective departments/units, will review research protocols for ethical considerations and for scientific and/or educational merit.

6.3 In conjunction with the investigator/instructor, Department Chairs (or cognizant administrators) will report promptly to the IACUC any serious or continuing non-compliance with the requirements of this policy or the determinations of the IACUC.

6.4 To facilitate the review of research and instructional protocols involving the use of vertebrate animals, Department Chairs (or cognizant administrators) are expected to attend IACUC meetings when requested by the IACUC.

7.0 THE UNIVERSITY'S INSTITUTIONAL ANIMAL CARE AND USE PROGRAM (IACUP)

7.1 Responsibility for the University's Institutional Animal Care and Use Program (IACUP) rests with the Office of the Provost. Day-to-day management of the program is the responsibility of the Director of the IACUP, who reports to the Provost. The IACUP was established to assure compliance with applicable standards, laws and regulations for humane treatment of animals used in research and instruction, to provide professional expertise and services to the University in matters concerning the care and use of vertebrate animals, and to facilitate implementation of this policy.

7.2 The responsibilities and authority of the Director of the Institutional Animal Care and Use Program include:

7.2.1 Supervising the operation of all animal facilities, including direct supervision of animal care staff and provision of all animal care.

7.2.2 Interpreting Federal and State laws, regulations, policies and guidelines concerning the utilization of animals in research and teaching activities.

7.2.3 Developing and documenting all procedures and working policies pertaining to the animal care and use program and facility management.



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

7.2.4 Coordinating and monitoring all vertebrate animal procurement and ensuring that appropriate permits and transportation arrangements are completed properly.

7.2.5 Maintaining an information resource center pertaining to the utilization of animals.

7.2.6 Providing information and services to investigators regarding requirements and procedures necessary to achieve a level of animal care and use that meets or exceeds contemporary professional standards and Federal and State regulations.

7.2.7 Sponsoring and coordinating seminars and training programs for campus faculty, staff, and students on topics of appropriate animal utilization and care as required by Federal law.

7.2.8 Providing a consulting service to investigators on matters of animal research, including housing; appropriate methods of handling and restraint; selection of analgesics, anesthetics, and tranquilizers; and methods of euthanasia.

7.2.9 Monitoring and providing recommendations on all aspects of surgery programs, including preoperative procedures, surgical techniques, and postoperative care.

7.2.10 Ensuring that appropriate monitoring programs are implemented to detect and treat ill or injured animals.

7.2.11 Providing or otherwise ensuring the provision of veterinary care services to university owned and/or housed animals.

7.2.12 Ensuring that the Attending Veterinarian is contacted whenever it appears that veterinary services are necessary.

7.2.13 Making independent emergency decisions concerning the treatment regimen of individual animals found to be experiencing unalleviated pain or suffering, and ensuring that these animals are provided appropriate veterinary care or are humanely euthanized, unless this is in direct conflict with experimental goals that have been previously described in a protocol approved by the IACUC. (Whenever possible, the investigator will be consulted prior to initiating treatment or euthanasia. In all cases, however, the welfare of the animal will be the primary consideration.)

7.2.14 Suspending activities that do not comply with this policy until they can be reviewed by the IACUC.



---

**SUBJECT: CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH AND INSTRUCTION**

---

7.2.15 Immediately reporting suspended activities to the Provost, the Director of Research and Sponsored Projects, and the Chair of the IACUC for resolution.

7.2.16 Serving as a consultant to the IACUC.

7.2.17 Coordinating semiannual inspections of animal facilities by the IACUC.

7.2.18 Hosting and escorting persons inspecting the animal facilities (e.g., U.S. Department of Agriculture inspectors).

7.2.19 Developing and submitting annual plans and budget requests for the Animal Care and Use Program to the Director of Research and Sponsored Projects.

7.2.20 Preparing annual reports, Letters of Assurance, and Applications for Registration as required by the USDA and PHS.

7.2.21 Acting as a liaison between faculty, university administrators, the IACUC and regulatory and funding agencies concerning animal welfare and use activities.

## Appendix: Forms and Protocols

**Field Studies and Biological Surveys Supplement**  
**Southern Utah University**  
**Institutional Animal Care and Use Committee**  
(Use a separate form for each species or assemblage)

---

**This form is a supplement to the Animal Care and Use Protocol Review Application and is required for all protocols that use vertebrate animals in a field setting.**

Protocol Title: \_\_\_\_\_

---

PI or Faculty Sponsor (s): \_\_\_\_\_

---

Department(s): \_\_\_\_\_

Instructions: Answer the following questions. If the information is already provided in the Animal Care Protocol Review Application simply refer to the to appropriate section of that document.

**Species**

Indicate the species or species assemblage to be studied. (Include the Common Name as well as the Genus and Species).

**Effect on Target Species**

What effect will your study have on the natural populations of the species under study? If the population status of the species is unknown, explain the potential benefits of your research on the population.

### **Ecological Impact**

Describe any potential disturbance to other species that may result from your study.

### **Special Status**

Will the study involve species on CITES, state or federal lists of protected, threatened or endangered species? If yes, describe the listing.

### **Permits**

Are state or federal permits required for collections and/or survey work? If yes, list the required permits. A copy of the permit must be submitted to the IACUC before final approval of the protocol.

### **Sampling Methods**

Describe the sampling method(s) to be used. Include the kind of net or trap and whether kill or live type sampling apparatus will be used.

- a. If kill type sampling devices are used, describe time interval from capture to death and describe the pain or discomfort involved.
- b. If animals are to be euthanized, in the field following live capture, describe the method of euthanasia.
- c. Will voucher specimens be kept? If yes, will they be accessioned? If so, where?

**Restraint or handling**

If live-captured animals are to be released, describe the kind of restraint, handling, sampling and marking or tagging methods to be used. Also describe the conditions for their release.

**Husbandry and Housing**

If animals are to be held longer than 12 hours, describe husbandry/housing.

# **Guide for the Care and Use of Laboratory Animals**

## **Introduction**

This edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) strongly affirms the conviction that all who care for or use animals in research, teaching, or testing must assume responsibility for their well-being. The *Guide* is applicable only after the decision is made to use animals in research, teaching, or testing. Decisions associated with the need to use animals are not within the purview of the *Guide*, but responsibility for animal well-being begins for the investigator with that decision. Additional responsibilities of the investigator, and other personnel, are elaborated in Chapter 1.

The goal of this *Guide* is to promote the humane care of animals used in biomedical and behavioral research, teaching, and testing; the basic objective is to provide information that will enhance animal well-being, the quality of biomedical research, and the advancement of biologic knowledge that is relevant to humans or animals. The use of animals as experimental subjects in the 20th century has contributed to many important advances in scientific and medical knowledge (Leader and Stark 1987). Although scientists have also developed nonanimal models for research, teaching, and testing (NRC 1977; see Appendix A, "Alternatives"), these models often cannot completely mimic the complex human or animal body, and continued progress in human and animal health and well-being requires the use of living animals. Nevertheless, efforts to develop and use scientifically valid alternatives, adjuncts, and refinements to animal research should continue.

In this *Guide*, laboratory animals include any vertebrate animal (e.g., traditional laboratory animals, farm animals, wildlife, and aquatic animals) used in research, teaching, or testing. When appropriate, exceptions or specific emphases for farm animals are provided. The *Guide* does not specifically address farm animals used in agricultural research or teaching, wildlife and aquatic animals studied in natural settings, or invertebrate animals used in research; however, many of the general principles in this *Guide* apply to these species and situations.

## **REGULATIONS, POLICIES, AND PRINCIPLES**

This *Guide* endorses the responsibilities of investigators as stated in the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (IRAC 1985; see Appendix D). Interpretation and application of those principles and this *Guide* require professional knowledge. In summary, the principles encourage

- Design and performance of procedures on the basis of relevance to human or animal health, advancement of knowledge, or the good of society.
- Use of appropriate species, quality, and number of animals.
- Avoidance or minimization of discomfort, distress, and pain in concert with sound science.
- Use of appropriate sedation, analgesia, or anesthesia.
- Establishment of experimental end points.
- Provision of appropriate animal husbandry directed and performed by qualified persons.
- Conduct of experimentation on living animals only by or under the close supervision of qualified and experienced persons.

In general, the principles stipulate responsibilities of investigators, whose activities regarding use of animals are subject to oversight by an institutional animal care and use committee (IACUC).

Animal facilities and programs should be operated in accord with this *Guide*, the Animal Welfare Regulations, or AWRs (CFR 1985); the Public Health Service Policy on Humane Care and Use of

Laboratory Animals, or PHS Policy (PHS 1996); and other applicable federal (Appendixes C and D) state, and local laws, regulations, and policies.<sup>1</sup> Supplemental information on breeding, care, management, and use of selected laboratory animal species is available in other publications prepared by the Institute of Laboratory Animal Resources (ILAR) and other organizations (Appendix A). References in this *Guide* provide the reader with additional information that supports statements made in the *Guide* or presents divergent opinions.

## EVALUATION CRITERIA

The *Guide* charges users of research animals with the responsibility of achieving specified outcomes but leaves it up to them how to accomplish these goals. This "performance" approach is desirable because many variables (such as the species and previous history of the animals, facilities, expertise of the people, and research goals) often make prescriptive ("engineering") approaches impractical and unwarranted. Engineering standards are sometimes useful to establish a baseline, but they do not specify the goal or outcome (such as well-being, sanitation, or personnel safety) in terms of measurable criteria as do performance standards.

The engineering approach does not provide for interpretation or modification in the event that acceptable alternative methods are available or unusual circumstances arise. Performance standards define an outcome in detail and provide criteria for assessing that outcome, but do not limit the methods by which to achieve that outcome. This performance approach requires professional input and judgment to achieve outcome goals. Optimally, engineering and performance standards are balanced, thereby providing standards while allowing flexibility and judgment based on individual situations. Scientists, veterinarians, technicians, and others have extensive experience and information covering many of the topics discussed in this *Guide*. Research on laboratory animal management continues to generate scientific information that should be used in evaluating performance and engineering standards. For some issues, insufficient information is available, and continued research into improved methods of animal care and use is needed.

The *Guide* is deliberately written in general terms so that its recommendations can be applied in the diverse institutions and settings that produce or use animals for research, teaching, and testing; generalizations and broad recommendations are imperative in such a document. This approach requires that users, IACUCs, veterinarians, and producers use professional judgment in making specific decisions regarding animal care and use. Because this *Guide* is written in general terms, IACUCs have a key role in interpretation, oversight, and evaluation of institutional animal care and use programs. The question frequently arises as to how the words *must* and *should* are used in the *Guide* and how IACUCs should interpret their relative priority. In general, the verb *must* is used for broad programmatic or basic aspects that the Committee to Revise the *Guide* considers are imperative. The verb *should* is used as a strong recommendation for achieving a goal. However, the committee recognizes that individual circumstances might justify an alternative strategy.

## FARM ANIMALS

Uses of farm animals in research, teaching, and testing are often separated into biomedical uses and agricultural uses because of government regulations (AWRs), institutional policies, administrative structure, funding sources, or user goals. That separation has led to a dual system with different criteria for evaluating protocols and standards of housing and care for animals of the same species on the basis of perceived biomedical or agricultural research objectives (Stricklin and Mench 1994). For some studies, this separation is clear. For example, animal models of human diseases, organ transplantation, and major surgery are considered biomedical uses; and studies on food and fiber production, such as feeding trials, are usually considered agricultural uses. However, the separation often is not clear, as in the case of some nutrition and disease studies. Administrators, regulators, and IACUCs often face a dilemma in deciding how to handle such studies (Stricklin and others 1990).

The use of farm animals in research should be subject to the same ethical considerations as the use of other animals in research, regardless of an investigator's research objectives or funding source (Stricklin and others 1990). However, differences in research goals lead to fundamental differences between biomedical and agricultural research. Agricultural research often necessitates that animals be managed according to contemporary farm-production practices for research goals to be reached (Stricklin and Mench 1994). For example, natural environmental conditions might be desirable for agricultural research, whereas control of environmental conditions to minimize variation might be desirable in biomedical research (Tillman 1994).

Housing systems for farm animals used in biomedical research might or might not differ from those in agricultural research. Animals used in either biomedical or agricultural research can be housed in cages or stalls or in paddocks or pastures (Tillman 1994). Some agricultural studies need uniform conditions to minimize environmental variability, and some biomedical studies are conducted in farm settings. Thus, the protocol, rather than the category of research, should determine the setting (farm or laboratory). Decisions on categorizing research uses of farm animals and defining standards for their care and use should be based on user goals, protocols, and concern for animal well-being and should be made by the IACUC. Regardless of the category of research, institutions are expected to provide oversight of all research animals and ensure that their pain and distress is minimized.

This *Guide* applies to farm animals used in biomedical research, including those maintained in typical farm settings. For such animals in a farm setting, the *Guide for the Care and Use of Agricultural Animals* in Agricultural Research and Teaching (1988), or revisions thereof, is a useful resource. Additional information regarding facilities and management of farm animals in an agricultural setting can be obtained from the Midwest Plan Service's *Structures and Environment Handbook* (1987) and from agricultural engineers or animal-science experts at state agricultural extension services and land-grant colleges and universities.

## **NONTRADITIONAL SPECIES**

A species not commonly used in biomedical research is sometimes the animal model of choice because of its unique characteristics. For example, hibernation can be studied only in species that hibernate. An appropriate environment should be provided for nontraditional species, and for some species it might be necessary to approximate the natural habitat. Expert advice on the natural history and behavior of nontraditional species should be sought when such animals are to be introduced into a research environment. Because of the large number of nontraditional species and their varied requirements, this *Guide* cannot provide husbandry details appropriate to all such species. However, several scientific organizations have developed guides for particular species of nontraditional animals (e.g., ILAR and the Scientists Center for Animal Welfare, SCAW). A partial list of sources is available in Appendix A.

## **FIELD INVESTIGATIONS**

Biomedical and behavioral investigations occasionally involve observation or use of vertebrate animals under field conditions. Although some of the recommendations listed in this volume are not applicable to field conditions, the basic principles of humane care and use apply to the use of animals living in natural conditions.

Investigators conducting field studies with animals should assure their IACUC that collection of specimens or invasive procedures will comply with state and federal regulations and this *Guide*. Zoonoses and occupational health and safety issues should be reviewed by the IACUC to ensure that field studies do not compromise the health and safety of other animals or persons working in the field. Guidelines for using animals in field studies prepared by professional societies are useful when they adhere to the humane principles of the *U.S. Government Principles for the Utilization and Care of*

*Vertebrate Animals Used in Testing, Research, and Training* (Appendix D) and this *Guide* (see Appendix A, "Exotic; Wild, and Zoo Animals" and "Other Animals").

## OVERVIEW

In an attempt to facilitate its usefulness and ease in locating specific topics, the organization of this edition of the *Guide* is slightly different from that of the preceding edition. Material from the preceding edition's Chapter 5, "Special Considerations," has been incorporated into Chapters 1-4. Genetics and nomenclature are now discussed in Chapter 2; facilities and procedures for animal research with hazardous agents and occupational health and safety are considered in Chapter 1. Recommendations for farm animals are incorporated throughout the text where appropriate.

This edition of the *Guide* is divided into four chapters and four appendixes. Chapter 1 focuses on institutional policies and responsibilities, including the monitoring of the care and use of animals, considerations for evaluation of some specific research procedures, veterinary care, personnel qualifications and training, and occupational health and safety; the latter section summarizes another National Research Council committee report (NRC In press) and includes information about facilities and procedures for animal research with hazardous agents. Chapter 2 focuses on the animals themselves and provides recommendations for housing and environment, behavioral management, husbandry, and population management, including discussions of identification, records, genetics, and nomenclature. Chapter 3 discusses veterinary medical care and responsibilities of the attending veterinarian; it includes recommendations relative to animal procurement and transportation, preventive medicine, surgery, pain and analgesia, and euthanasia. Chapter 4 discusses the physical plant, including functional areas and construction guidelines, with expanded discussions of heating, ventilation, and air-conditioning (HVAC) systems and facilities for aseptic surgery.

The appendixes in this edition remain largely the same as in the preceding edition. Appendix A contains an updated bibliography, categorized by topic; Appendix B lists selected organizations related to laboratory animal science; Appendix C presents federal laws relevant to animal care and use; and Appendix D provides the PHS endorsement of the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (IRAC 1985).

## REFERENCES

CFR (Code of Federal Regulations). 1985. Title 9 (Animals and Animal Products), Subchapter A (Animal Welfare). Washington. D.C.: Office of the Federal Register.

Consortium for Developing a *Guide for the Care and Use of Agricultural Animals* in Agricultural Research and Teaching. 1988. *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*. Champaign. Ill.: Consortium for Developing a Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching.

IRAC (Interagency Research Animal Committee). 1985. U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Federal Register, May 20, 1985. Washington. D.C.: Office of Science and Technology Policy.

Leader. R. W., and D. Stark. 1987. The importance of animals in biomedical research. *Perspect. Biol. Med.* 30(4):470-485.

Midwest Plan Service. 1987. *Structures and Environment Handbook*. 11th ed. rev. Ames: Midwest Plan Service. Iowa State University.

NRC (National Research Council). 1977. The Future of Animals, Cells, Models, and Systems in Research, Development, Education, and Testing. Proceedings of a Symposium of the Institute of Laboratory Animal Resources. Washington, D.C.: National Academy of Sciences. 341 pp.

NRC (National Research Council). In press. Occupational Health and Safety in the Care and Use of Research Animals. A report of the Institute of Laboratory Animal Resources Committee on Occupational Safety and Health in Research Animal Facilities. Washington, D.C.: National Academy Press.

PHS (Public Health Service). 1996. Public Health Service Policy on Humane Care and Use of Laboratory Animals. Washington, D.C.: U.S. Department of Health and Human Services, 28 pp. [PL 99-158. Health Research Extension Act. 1985]

Stricklin, W. R., and J. A. Mench. 1994. Oversight of the use of agricultural animals in university teaching and research. ILAR News 36(1):9-14.

Stricklin, W. R., D. Purcell, and J. A. Mench. 1990. Farm animals in agricultural and biomedical research in the well-being of agricultural animals in biomedical and agricultural research. Pp. 1-4 in Agricultural Animals in Research, Proceedings from a SCAW-sponsored conference. September 6-7, 1990. Washington, D.C.: Scientist's Center for Animal Welfare.

Tillman, P. 1994. Integrating agricultural and biomedical research policies: Conflicts and opportunities. ILAR News 36(2):29-35.

### **Institutional Policies and Responsibilities**

Proper care, use, and humane treatment of animals used in research, testing, and education (referred to in this Guide as animal care and use) require scientific and professional judgment based on knowledge of the needs of the animals and the special requirements of the research, testing, and educational programs. The guidelines in this section are intended to aid in developing institutional policies governing the care and use of animals.

Each institution should establish and provide resources for an animal care and use program that is managed in accord with this Guide and in compliance with applicable federal, state, and local laws and regulations, such as the federal Animal Welfare Regulations, or AWRs (CFR 1985), and Public Health Service Policy on Humane Care and Use of Laboratory Animals, or PHS Policy (PHS 1996). To implement the recommendations in this Guide effectively, an institutional animal care and use committee (IACUC) must be established to oversee and evaluate the program.

Responsibility for directing the program is generally given either to a veterinarian with training or experience in laboratory animal science and medicine or to another qualified professional. At least one veterinarian qualified through experience or training in laboratory animal science and medicine or in the species being used must be associated with the program. The institution is responsible for maintaining records of the activities of the IACUC and for conducting an occupational health and safety program.

## **MONITORING THE CARE AND USE OF ANIMALS**

### **Institutional Animal Care and Use Committee**

The responsible administrative official at each institution must appoint an IACUC, also referred to as "the committee," to oversee and evaluate the institution's animal program, procedures, and facilities to ensure that they are consistent with the recommendations in this Guide, the AWRs, and the PHS Policy. It is the institution's responsibility to provide suitable orientation, background materials, access to appropriate resources, and, if necessary, specific training to assist IACUC members in understanding and evaluating issues brought before the committee.

Committee membership should include the following:

- A doctor of veterinary medicine, who is certified (see American College of Laboratory Animal Medicine, ACLAM, Appendix B) or has training or experience in laboratory animal science and medicine or in the use of the species in question.
- At least one practicing scientist experienced in research involving animals.
- At least one public member to represent general community interests in the proper care and use of animals. Public members should not be laboratory animal users, be affiliated with the institution, or be members of the immediate family of a person who is affiliated with the institution.

The size of the institution and the nature and extent of the research, testing, and educational programs will determine the number of members of the committee and their terms of appointment. Additional information about committee composition can be found in the PHS Policy and the AWRs.

The committee is responsible for oversight and evaluation of the animal care and use program and its components described in this Guide. Its functions include inspection of facilities; evaluation of programs and animal-activity areas; submission of reports to responsible institutional officials; review of proposed uses of animals in research, testing, or education (i.e., protocols); and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution.

The IACUC must meet as often as necessary to fulfill its responsibilities, but it should meet at least once every 6 months. Records of committee meetings and of results of deliberations should be maintained. The committee should review the animal-care program and inspect the animal facilities and activity areas at least once every 6 months. After review and inspection, a written report, signed by a majority of the IACUC, should be made to the responsible administrative officials of the institution on the status of the animal care and use program and other activities as stated herein and as required by federal, state, or local regulations and policies. Protocols should be reviewed in accord with the AWRs, the PHS Policy, U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (IRAC 1985; see Appendix D), and this Guide (see footnote, p.2).

### **Animal Care and Use Protocols**

The following topics should be considered in the preparation and review of animal care and use protocols:

- Rationale and purpose of the proposed use of animals.
- Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
- Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (see Appendix A, "Alternatives").

- Adequacy of training and experience of personnel in the procedures used.
- Unusual housing and husbandry requirements.
- Appropriate sedation, analgesia, and anesthesia. (Scales of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, "Anesthesia, Pain and Surgery.")
- Unnecessary duplication of experiments.
- Conduct of multiple major operative procedures.
- Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
- Postprocedure care.
- Method of euthanasia or disposition of animal.
- Safety of working environment for personnel.

Occasionally, protocols include procedures that have not been previously encountered or that have the potential to cause pain or distress that cannot be reliably controlled. Such procedures might include physical restraint, multiple major survival surgery, food or fluid restriction, use of adjuvants, use of death as an end point, use of noxious stimuli, skin or corneal irritancy testing, allowance of excessive tumor burden, intracardiac or orbital-sinus blood sampling, or the use of abnormal environmental conditions. Relevant objective information regarding the procedures and the purpose of the study should be sought from the literature, veterinarians, investigators, and others knowledgeable about the effects on animals. If little is known regarding a specific procedure, limited pilot studies designed to assess the effects of the procedure on the animals, conducted under IACUC oversight, might be appropriate. General guidelines for evaluation of some of those methods are provided in this section, but they might not apply in all instances.

### **Physical Restraint**

Physical restraint is the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy, or experimental manipulation. Animals are restrained for brief periods, usually minutes, in most research applications.

Animals can be physically restrained briefly either manually or with restraint devices. Restraint devices should be suitable in size, design, and operation to minimize discomfort or injury to the animal. Many dogs, nonhuman primates (e.g., Reinhardt 1991, 1995), and other animals can be trained, through use of positive reinforcement, to present limbs or remain immobile for brief procedures.

Prolonged restraint, including chairing of nonhuman primates, should be avoided unless it is essential for achieving research objectives and is approved by the IACUC. Less-restrictive systems that do not limit an animal's ability to make normal postural adjustments, such as the tether system for nonhuman primates and stanchions for farm animals, should be used when compatible with protocol objectives (Bryant 1980; Byrd 1979; Grandin 1991; McNamee and others 1984; Morton and others 1987; Wakeley and others 1974). When restraint devices are used, they should be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means or to prevent injury to animals or personnel.

The following are important guidelines for restraint:

- Restraint devices are not to be considered normal methods of housing.
- Restraint devices should not be used simply as a convenience in handling or managing animals.
- The period of restraint should be the minimum required to accomplish the research objectives.

- Animals to be placed in restraint devices should be given training to adapt to the equipment and personnel.
- Provision should be made for observation of the animal at appropriate intervals, as determined by the IACUC.
- Veterinary care should be provided if lesions or illnesses associated with restraint are observed. The presence of lesions, illness, or severe behavioral change often necessitates temporary or permanent removal of the animal from restraint.

### **Multiple Major Surgical Procedures**

Major surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function. Multiple major survival surgical procedures on a single animal are discouraged but may be permitted if scientifically justified by the user and approved by the IACUC. For example, multiple major survival surgical procedures can be justified if they are related components of a research project, if they will conserve scarce animal resources (NRC 1990; see also footnote, p.2), or if they are needed for clinical reasons. If multiple major survival surgery is approved, the IACUC should pay particular attention to animal well-being through continuing evaluation of outcomes. Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures (AWRs).

### **Food or Fluid Restriction**

When experimental situations require food or fluid restriction, at least minimal quantities of food and fluid should be available to provide for development of young animals and to maintain long-term well-being of all animals. Restriction for research purposes should be scientifically justified, and a program should be established to monitor physiologic or behavioral indexes, including criteria (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol (Van Sluyters and Oberdorfer 1991). Restriction is typically measured as a percentage of the ad libitum or normal daily intake or as percentage change in an animal's body weight.

Precautions that should be used in cases of fluid restriction to avoid acute or chronic dehydration include daily recording of fluid intake and recording of body weight at least once a week (NIH 1990)- or more often, as might be needed for small animals, such as rodents. Special attention should be given to ensuring that animals consume a suitably balanced diet (NYAS 1988) because food consumption might decrease with fluid restriction. The least restriction that will achieve the scientific objective should be used. In the case of conditioned-response research protocols, use of a highly preferred food or fluid as positive reinforcement, instead of restriction, is recommended. Dietary control for husbandry or clinical purposes is addressed in Chapter 2.

### **VETERINARY CARE**

Adequate veterinary care must be provided, including access to all animals for evaluation of their health and well-being. Institutional mission, programmatic goals, and size of the animal program will determine the need for full-time, part-time, or consultative veterinary services. Visits by a consulting or part-time veterinarian should be at intervals appropriate to programmatic needs. For specific responsibilities of the veterinarian, see Chapter 3.

Ethical, humane, and scientific considerations sometimes require the use of sedatives, analgesics, or anesthetics in animals (see Appendix A). An attending veterinarian (i.e., a veterinarian who has direct or delegated authority) should give research personnel advice that ensures that humane needs are met and are compatible with scientific requirements. The AWRs and PHS Policy require that the attending veterinarian have the authority to oversee the adequacy of other aspects of animal care and use.

These can include animal husbandry and nutrition, sanitation practices, zoonosis control, and hazard containment.

## **PERSONNEL QUALIFICATIONS AND TRAINING**

AWRs and PHS Policy require institutions to ensure that people caring for or using animals are qualified to do so. The number and qualifications of personnel required to conduct and support an animal care and use program depend on several factors, including the type and size of institution, the administrative structure for providing adequate animal care, the characteristics of the physical plant, the number and species of animals maintained, and the nature of the research, testing, and educational activities.

Personnel caring for animals should be appropriately trained (see Appendix A, "Technical and Professional Education"), and the institution should provide for formal or on-the-job training to facilitate effective implementation of the program and humane care and use of animals. According to the programmatic scope, personnel will be required with expertise in other disciplines, such as animal husbandry, administration, laboratory animal medicine and pathology, occupational health and safety, behavioral management, genetic management, and various other aspects of research support.

There are a number of options for the training of technicians. Many states have colleges with accredited programs in veterinary technology (AVMA 1995); most are 2-year programs that result in associate of science degrees, and some are 4-year programs that result in bachelor of science degrees. Nondegree training, with certification programs for laboratory animal technicians and technologists, can be obtained from the American Association for Laboratory Animal Science (AALAS). There are commercially available training materials that are appropriate for self-study (Appendix B). Personnel using or caring for animals should also participate regularly in continuing-education activities relevant to their responsibilities. They are encouraged to be involved in local and national meetings of AALAS and other relevant professional organizations. On-the-job training should be part of every technician's job and should be supplemented with institution-sponsored discussion and training programs and with reference materials applicable to their jobs and the species with which they work (Kreger 1995). Coordinators of institutional training programs can seek assistance from the Animal Welfare Information Center (AWIC) and ILAR (NRC 1991). The Guide to the Care and Use of Experimental Animals by the Canadian Council on Animal Care (CCAC 1993) and guidelines of some other countries are valuable additions to the libraries of laboratory animal scientists (Appendix B). Investigators, technical personnel, trainees, and visiting investigators who perform animal anesthesia, surgery, or other experimental manipulations must be qualified through training or experience to accomplish these tasks in a humane and scientifically acceptable manner.

## **OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL**

An occupational health and safety program must be part of the overall animal care and use program (CDC and NIH 1993; CFR 1984a,b,c; PHS Policy). The program must be consistent with federal, state, and local regulations and should focus on maintaining a safe and healthy workplace. The program will depend on the facility, research activities, hazards, and animal species involved. The National Research Council publication *Occupational Health and Safety in the Care and Use of Research Animals* (NRC In press) contains guidelines and references for establishing and maintaining an effective, comprehensive program (also see Appendix A). An effective program relies on strong administrative support and interactions among several institutional functions or activities, including the research program (as represented by the investigator), the animal care and use program (as represented by the veterinarian and the IACUC), the environmental health and safety program, occupational-health services, and administration (e.g., human resources, finance, and facility-maintenance personnel). Operational and day-to-day responsibility for safety in the workplace,

however, resides with the laboratory or facility supervisor (e.g., principal investigator, facility director, or veterinarian) and depends on performance of safe work practices by all employees.

### **Hazard Identification and Risk Assessment**

Professional staff who conduct and support research programs that involve hazardous biologic, chemical, or physical agents (including ionizing and nonionizing radiation) should be qualified to assess dangers associated with the programs and to select safeguards appropriate to the risks. An effective occupational health and safety program ensures that the risks associated with the experimental use of animals are reduced to acceptable levels. Potential hazards—such as animal bites, chemical cleaning agents, allergens, and zoonoses—that are inherent in or intrinsic to animal use should also be identified and evaluated. Health and safety specialists with knowledge in appropriate disciplines should be involved in the assessment of risks associated with hazardous activities and in the development of procedures to manage such risks. The extent and level of participation of personnel in the occupational health and safety program should be based on the hazards posed by the animals and materials used; on the exposure intensity, duration, and frequency; on the susceptibility of the personnel; and on the history of occupational illness and injury in the particular workplace (Clark 1993).

### **Personnel Training**

Personnel at risk should be provided with clearly defined procedures for conducting their duties, should understand the hazards involved, and should be proficient in implementing the required safeguards.

Personnel should be trained regarding zoonoses, chemical safety, microbiologic and physical hazards (including those related to radiation and allergies), unusual conditions or agents that might be part of experimental procedures (including the use of genetically engineered animals and the use of human tissue in immunocompromised animals), handling of waste materials, personal hygiene, and other considerations (e.g., precautions to be taken during personnel pregnancy, illness, or decreased immunocompetence) as appropriate to the risk imposed by their workplace.

### **Personal Hygiene**

It is essential that all personnel maintain a high standard of personal cleanliness. Clothing suitable for use in the animal facility and laboratories in which animals are used should be supplied and laundered by the institution. A commercial laundering service is acceptable in many situations; however, appropriate arrangements should be made to decontaminate clothing exposed to potential hazards. Disposable gloves, masks, head covers, coats, coveralls, and shoe covers might be desirable in some circumstances. Personnel should wash their hands and change clothing as often as necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility. Personnel should not be permitted to eat, drink, use tobacco products, or apply cosmetics in animal rooms.

### **Facilities, Procedures, and Monitoring**

Facilities required to support occupational health and safety concerns associated with animal care and use programs will vary. Because a high standard of personal cleanliness is essential, facilities and supplies for meeting this obligation should be provided. Washing and showering facilities appropriate to the program should be available. Facilities, equipment, and procedures should also be designed, selected, and developed to provide for ergonomically sound operations that reduce the potential of physical injury to personnel (such as might be caused by the lifting of heavy equipment or animals

and the use of repetitive movements). Safety equipment should be properly maintained and routinely calibrated.

The selection of appropriate animal-housing systems requires professional knowledge and judgment and depends on the nature of the hazards in question, the types of animals used, and the design of the experiments. Experimental animals should be housed so that potentially contaminated food and bedding, feces and urine can be handled in a controlled manner. Facilities, equipment, and procedures should be provided for appropriate bedding disposal.

Appropriate methods should be used for assessing exposure to potentially hazardous biologic, chemical, and physical agents where the possibility of exceeding permissible exposure limits (PELs) exists (CFR 1984b).

### **Animal Experimentation Involving Hazards**

In selecting specific safeguards for animal experimentation with hazardous agents, careful attention should be given to procedures for animal care and housing, storage and disbursement of the agents, dose preparation and administration, body-fluid and tissue handling, waste and carcass disposal, and personal protection. Special safety equipment should be used in combination with appropriate management and safe practices. As a general rule, safety depends on trained personnel who rigorously follow safe practices.

Institutions should have written policies governing experimentation with hazardous biologic, chemical, and physical agents. An oversight process (such as use of a safety committee) should be developed to involve persons who are knowledgeable in the evaluation of hazards and safety issues. Because the use of animals in such studies requires special considerations, the procedures and facilities to be used should undergo review for specific safety concerns. Formal safety programs should be established to assess the hazards, determine the safeguards needed for their control, ensure that the staff has the necessary training and skills, and ensure that the facilities are adequate for the safe conduct of the research. Technical support should be provided to monitor and ensure compliance with institutional safety policies.

The Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) publication *Biosafety in Microbiological and Biomedical Laboratories* (1993) and the National Research Council (In press) recommend practices and procedures, safety equipment, and facility requirements for working with hazardous biologic agents and materials. Facilities that handle agents of unknown risk should consult with appropriate CDC personnel about hazard control and medical surveillance.

Special facilities and safety equipment are needed to protect the animal-care and investigative staff, other occupants of the facility, the public, animals, and the environment from exposure to hazardous biologic, chemical, and physical agents used in animal experimentation. Facilities used for animal experimentation with hazardous agents should be separated from other animal housing and support areas, research and clinical laboratories, and patient-care facilities and should be appropriately identified; and access to them should be limited to authorized personnel. Such facilities should be designed and constructed to facilitate cleaning and maintenance of mechanical systems. A properly managed and used double corridor facility or barrier entry system is an effective means of reducing cross-contamination. Floor drains should always contain liquid or be sealed effectively by other means. Automatic trap priming can be provided to ensure that traps remain filled.

Hazardous agents should be contained within the study environment. Control of airflow (such as through the use of biologic-safety cabinets) that minimizes the escape of contaminants is a primary barrier used in the handling and administration of hazardous agents and the performance of

necropsies on contaminated animals (CDC 1995; Kruse and others 1991). Special features of the facility-such as airlocks, negative air pressure, air filters, and redundant mechanical equipment with automatic switching-are secondary barriers aimed at preventing accidental release of hazards outside the facility and work environment.

Exposure to anesthetic waste gases should be limited. This is usually accomplished by using various scavenging techniques. If ether is used, personnel safety should be ensured by proper use of signs and by using equipment and practices to minimize risks associated with its explosiveness.

### **Personal Protection**

Personal protective equipment should be provided, and other safety measures should be adopted when needed. Animal-care personnel should wear appropriate institution-issued protective clothing, shoes or shoe covers, and gloves. Clean protective clothing should be provided as often as necessary. If it is appropriate, personnel should shower when they leave the animal-care, procedure, or dose-preparation areas. Protective clothing and equipment should not be worn beyond the boundary of the hazardous-agent work area or the animal facility. Personnel with potential exposure to hazardous agents should be provided with personal protective equipment appropriate to the agents (CFR 1984c). For example, personnel exposed to nonhuman primates should be provided with such protective items as gloves, arm protectors, masks, and face shields. Hearing protection should be provided in high-noise areas. Personnel working in areas where they might be exposed to contaminated airborne particulate material or vapors should be provided with suitable respiratory protection (CFR 1984c).

### **Medical Evaluation and Preventive Medicine for Personnel**

Development and implementation of a program of medical evaluation and preventive medicine should involve input from trained health professionals, such as occupational-health physicians and nurses. Confidentiality and other medical and legal factors must be considered in the context of appropriate federal, state, and local regulations.

A health-history evaluation before work assignment is advisable to assess potential risks for individual employees. Periodic medical evaluations are advisable for people in some risk categories. An appropriate immunization schedule should be adopted. It is important to immunize animal-care personnel against tetanus. In addition, pre-exposure immunization should be offered to people at risk of infection or exposure to such agents as rabies or hepatitis B virus. Vaccination is recommended if research is to be conducted on infectious diseases for which effective vaccines are available. Specific recommendations can be found in the CDC and NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (1993). Pre-employment or pre-exposure serum collection is advisable only in specific circumstances as determined by an occupational health and safety professional (NRC In press). In such cases, identification, traceability, retention, and storage conditions of samples should be considered and the purpose for which the serum samples will be used must be consistent with applicable state laws and consistent with the Federal Policy for the Protection of Human Subjects (Federal Register 56(117): 28002-28032, June 18, 1991).

Zoonosis surveillance should be a part of an occupational-health program (CDC and NIH 1993; Fox and others 1984; NRC In press). Personnel should be instructed to notify their supervisors of potential or known exposures and of suspected health hazards and illnesses. Clear procedures should be established for reporting all accidents, bites, scratches, and allergic reactions (NRC In press).

Nonhuman-primate diseases that are transmissible to humans can be serious hazards. Animal technicians, clinicians, investigators, predoctoral and postdoctoral trainees, research technicians, consultants, maintenance workers, security personnel, and others who have contact with nonhuman primates or have duties in nonhuman-primate housing areas should be routinely screened for

tuberculosis. Because of the potential for Cercopithecine herpesvirus 1 (formerly Herpesvirus simiae) exposure, personnel who work with macaques should have access to and be instructed in the use of bite and scratch emergency-care stations (Holmes and others 1995). A procedure should be established for ensuring medical care for bites and scratches.

## REFERENCES

- AVMA (American Veterinary Medical Association). 1995. Accredited programs in veterinary technology. Pp.236-240 in 1995 AVMA Membership Directory and Resource Manual. 44th ed. Schaumburg, Ill.: AVMA.
- Bryant, J. M. 1980. Vest and tethering system to accommodate catheters and a temperature monitor for nonhuman primates. *Lab. Anim. Sci.* 30(4. Part I):706-705.
- Byrd, L. D. 1979. A tethering system for direct measurement of cardiovascular function in the caged baboon. *Am. J. Physiol.* 236:H775-H779.
- CCAC (Canadian Council on Animal Care) 1993. Guide to the Care and Use of Experimental Animals. Vol. 1.2nd ed. E. D. Olfert, B. M. Cross, and A. A. McWilliam, eds. Ontario, Canada: Canadian Council on Animal Care. 211 pp.
- CDC (Centers for Disease Control and Prevention and NIH (National Institutes of Health). 1993. Biosafety in Microbiological and Biomedical Laboratories. 3rd ed. HHS Publication No. (CDC) 93-8395, Washington, D.C.: U.S. Government Printing Office.
- CDC (Centers for Disease Control and Prevention) and NIH (National Institutes of Health). 1995. Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets. Washington, D.C.: U.S. Government Printing Office.
- CFR (Code of Federal Regulations). 1984a. Title 10; Part 20, Standards for Protection Against Radiation. Washington, D.C.: Office of the Federal Register.
- CFR (Code of Federal Regulations). 1984b. Title 29; Part 1910, Occupational Safety and Health Standards; Subpart G. Occupation Health and Environmental Control, and Subpart Z. Toxic and Hazardous Substances. Washington, D.C.: Office of the Federal Register.
- CFR (Code of Federal Regulations). 1984c. Title 29: Part 1910. Occupational Safety and Health Standards; Subpart I. Personal Protective Equipment. Washington, D.C.: Office of the Federal Register.
- CFR (Code of Federal Regulations). 1985. Title 9 (Animals and Animal Products), Subchapter A (Animal Welfare). Washington, D.C.: Office of the Federal Register.
- Clark, J. M. 1993. Planning for safety: biological and chemical hazards. *Lab Anim.* 22:33-38.
- Fox, J. G., C. E. Newcomer, and H. Rozmiarek. 1984. Selected zoonoses and other health hazards. Pp.614-648 in *Laboratory Animal Medicine*. 3. G. Fox, B. 3. Cohen, and F.M. Loew, eds. New York: Academic Press.
- Grandin, T. 1991. Livestock behavior and the design of livestock handling facilities. Pp.96-125 in *Handbook of Facilities Planning*. Vol.2. Laboratory Animal Facilities. New York: Van Nostrand. 422 pp.

Holmes, G. P., L. E. Chapman, J. A. Stewart, S. E. Straus, 3. K. Hilliard, D. S. Davenport, and the B Virus Working Group. 1995. Guidelines for the prevention and treatment of B-virus infections in exposed persons. *Clin. Infect. Dis.* 20:421-439.

IRAC (Interagency Research Animal Committee). 1985. U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. *Federal Register*, May 20, 1985. Washington, D.C.: Office of Science and Technology Policy.

Kreger, M. D., 1995. Training Materials for Animal Facility Personnel: AWIC Quick Bibliography Series, 95-08. Beltsville, Md.: National Agricultural Library.

Kruse, R. H., W. H. Puckett, and J. H. Richardson. 1991. Biological safety cabinetry. *Clin. Micro. Reviews* 4:207-241.

McNamee, G. A., Jr., R. W. Wannemacher, Jr., R. E. Dinterman, H. Rozmiarek, and R. D. Montrey. 1984. A surgical procedure and tethering system for chronic blood sampling, infusion, and temperature monitoring in caged nonhuman primates. *Lab. Anim. Sci.* 34(3):303-307.

Morton, W. R., G. H. Knitter, P. M. Smith, T. G. Susor, and K. Schmitt. 1987. Alternatives to chronic restraint of nonhuman primates. *J. Am. Vet. Med. Assoc.* 191(10):1282-1286.

NIH (National Institutes of Health). 1990. Guidelines for Diet Control in Behavioral Study. Bethesda, Md.: Animal Research Advisory Committee. NIH.

NRC (National Research Council). 1990. Important laboratory animal resources: selection criteria and funding mechanisms for their preservation. A report of the Institute of Laboratory Animal Resources Committee on Preservation of Laboratory Animal Resources. *ILAR News* 32(4):A1-A32.

NRC (National Research Council). 1991. Education and Training in the Care and Use of Laboratory Animals: A Guide for Developing Institutional Programs. A report of the Institute of Laboratory Animal Resources Committee on Educational Programs in Laboratory Animal Science. Washington, D.C.: National Academy Press. 152 pp.

NRC (National Research Council). In press. Occupational Health and Safety in the Care and Use of Research Animals. A report of the Institute of Laboratory Animal Resources Committee on Occupational Safety and Health in Research Animal Facilities. Washington, D.C.: National Academy Press.

**Animal Care and Use Protocol Review Application**  
**Institutional Animal Care and Use Committee**  
**Southern Utah University**

(Required for Use of Non-Human Vertebrate Animals in Teaching and Research)

Protocol Title: _____ _____	
PI or Faculty Sponsor: _____	
Signature: _____	Date: _____
Department: _____	Email address: _____
Campus Mailing Address: _____ _____	
Phone: _____	Fax: _____
Protocol Starting Date: _____	Ending Date: _____
IACUC may approve protocols for up to three years duration. However, animal continuation reports are required for each year of the protocol approval period.	
Proposed animal use is for (check the appropriate box):	
<b><u>Laboratory and Classroom Settings</u></b>	<b><u>Field Settings</u></b>
Faculty Research	Faculty Research
Student Research	Student Research
Teaching: Course Number(s)	Teaching: Course Number(s)
Mail the signed original of this application to:	
Valerie Cheeseman	Phone: 435-865-8175
Director, Office of Sponsored Research & Grants	Email: <a href="mailto:cheeseman@suu.edu">cheeseman@suu.edu</a>
304-C Administration Bldg. (The Milton & Steven Bennion Bldg.)	
Southern Utah University	
351 W. University Blvd.	
Cedar City, Utah 84720	
Application Deadlines: IACUC applications must be made at least two weeks prior to a regularly scheduled IACUC meeting. For meeting dates, please contact: <a href="mailto:smetanka@suu.edu">smetanka@suu.edu</a> (Committee Chair)	
This space for IACUC	
IACUC Protocol: _____	Date Approved: _____
Date Received: _____	Date disapproved: _____
Date Reviewed: _____	Chair of IACUC: _____

All Persons Using Animals (list responsible person first. For teaching protocols, class lists are not required.

Name and Department

Email

Phone

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Unusual Conditions of Use and Care:

Yes No

\_\_\_\_\_ \_\_\_\_\_ Collaboration with another university? If yes, specify: \_\_\_\_\_

\_\_\_\_\_ \_\_\_\_\_ Animal exposure to biohazards?

\_\_\_\_\_ \_\_\_\_\_ If so, what agent(s): \_\_\_\_\_

\_\_\_\_\_ \_\_\_\_\_ Animal exposure to radiological hazards?

\_\_\_\_\_ \_\_\_\_\_ Isotope(s) \_\_\_\_\_ Radiological activity: \_\_\_\_\_

\_\_\_\_\_ \_\_\_\_\_ Will animals be used outside of approved animal facilities?

\_\_\_\_\_ \_\_\_\_\_ If so, what location? \_\_\_\_\_

\_\_\_\_\_ \_\_\_\_\_ Are there any other animal health concerns that might result from the proposed research? If yes, specify in the protocol.

\_\_\_\_\_ \_\_\_\_\_ Will the implementation of this protocol directly or indirectly result in Unusual health risks for humans? If yes, specify in the protocol.

Funding:

Is this research externally funded? YES \_\_\_\_\_ NO \_\_\_\_\_ PENDING \_\_\_\_\_

If externally sponsored, list sources below:

PI \_\_\_\_\_ Funded by: \_\_\_\_\_

Grant title: \_\_\_\_\_

PI \_\_\_\_\_ Funded by: \_\_\_\_\_

Grant title: \_\_\_\_\_

PI \_\_\_\_\_ Funded by: \_\_\_\_\_

Grant title: \_\_\_\_\_

For funded projects, are contents of this protocol the same as those described in the funding application? YES \_\_\_\_\_ NO \_\_\_\_\_

If externally funded, submit a copy of the grant application narrative to the IACUC Committee with this application.

Animal Use Summary for Duration of Protocol Approval Period

Pain/Distress Categories:

- Minimal (USDA Category C) = no pain/distress and no use of pain-relieving Drugs (routine procedures [ e.g. injections and blood sampling]).
- Moderated (USDA Category D) pain/distress for which appropriate anesthetic Analgesic, or tranquilizing drugs are used.
- Unmoderated (USDA Category E) pain/distress for which the use of Appropriate anesthetic, analgesic or tranquilizing drugs are withheld due to Adverse effects on procedures, results or interpretation.

Answer for each species. Indicate applicable USDA category. Answer for first year of use. Subsequent years of the protocol will be addressed on the annual continuation report form. For Field Studies, **attach Field Study Supplement**.

Species of animal (& common name)	Pain/Distress Category	Total animals*	Surgery (yes/no)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

\*If total is unknown, include minimum and maximum number.

Required Signatures

- All people using animals under my direction will be trained to use appropriate methods and will read and agree to comply with this protocol.
- All animal use will be in accordance with the guidelines set forth in Animal Care Policy in the SUU Policy and Procedures Manual.

PI or Faculty Sponsor

\_\_\_\_\_ Date: \_\_\_\_\_  
 Department Chair or Dean

\_\_\_\_\_ Date: \_\_\_\_\_

### **Animal Protocol Preparation Instructions:**

Answer questions 1-7 below. If more space is needed attach additional pages. Clearly number each item as listed below. If references are used, list full reference citation.

1. Acquisition of Animals:

- a. Where will the animals be procured?
- b. Who is the responsible receiving party?
- c. What is the protocol for delivery? Include what measures have been take to ensure that the animals are delivered when a responsible party can receive them.
- d. How will animals be moved between and within facilities? Specify what methods will be used to minimize stress, injury and chance of escape.

NOTE: The Director of the Animal Care and Use Program must be notified at least two weeks before procurement. Procurement is contingent upon the availability of housing and physical plant limitations.

2. Rationale:

- a. What is the purpose and value of the research? For classroom and teaching use, include a description of the goals of the course and the relationship to the protocol.
- b. Is this a duplication of previous research? If yes, explain.
- c. Why must animals be used? Are there alternatives?
- d. Why is this species being used?
- e. Provide a justification for the number of animals used and explain procedures for determining the total number of animals.

### 3. Procedures:

Describe all experimental procedures using animals. Include detailed information about all aspects of animal use, for example:

- a. Environment in which experiments will be conducted.
- b. Experimental manipulations
- c. Chemical and pharmaceutical manipulations (include dose, frequency, route of administration, etc.)
- d. Food deprivation (or any unusual feeding patterns).
- e. Animal handling.
- f. Animal transportation from housing site to experimental site.

4. Husbandry:

Include information for the first year only. You will be asked to address subsequent years use on the annual continuation form. (Note: This section should only be filled out for those animals that are held for more than 12 hours).

- a. Where will the animals be housed and used?
- b. Who is responsible for daily care?
- c. What feeding regimen will be used?
- d. What cleaning regimen (method and frequency) will be used?
- e. Provide type of housing used and number of animals per unit.
- f. Describe the temperature, humidity and light requirements of the animals and how those requirements will be met.

Species	Total animals per semester	Maximum daily census	Initial date of animal use	Ending date of animal use
Animal use location	Animal housing location	Housing is in an approved facility? (yes/no)	Animal Care by IACUP Staff? (yes/no)	

## 5. Disposition of Animals:

Include a description of how animals will be disposed of at the end of use.

- a. For transfer to another protocol of same investigator, provide approved protocol number.
- b. For transfer to another researcher at SUU, provide name and approved protocol number.
- c. For transfer to another researcher/institution, provide name of individual or entity receiving the animals, how the transfer will be handled and how the animals will be used following the transfer.
- d. For euthanasia describe the method to be used as well as the methods by which death will be confirmed before the disposal of the animals. All euthanasia methods should comply with the 2000 Report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia:  
<http://www.avma.org/resources/euthanasia.pdf>
- e. For adoption, submit an adoption form at the time of adoption.
- f. For release into the wild, provide location as well as all pertinent information regarding the animals' ability to survive as well as their environmental impact.

## 6. Pain/Distress

### For Moderated and Unmoderated Pain/Distress Categories:

- g. These categories have the potential for more than momentary or slight pain or distress. Include a description of the methods used to assess pain and a written narrative describe the methods and sources used to determine that alternative procedures (i.e., less painful or distressful) are not available. Investigators might consult with staff veterinarian, Dr. \_\_\_\_\_ or other sources which such as the Animal Welfare information Center at email : AWIC@NAL. USDA.GOV or other relevant sources. The narrative might include information similar to that in the following sample:

I have performed the following database searches (insert database titles and key words used). Based on (insert number) of years of experience in this field in conjunction with periodic consultation of bibliographic sources (insert titles) and a number of other references including journals (insert titles), I believe there is no alternative to performing this potentially painful/distressing procedure. Based on the aforementioned references and my experience, this (insert species) animal model is the most appropriate for conducting research.

- h. Provide a list of anesthetics (including paralytics) and other drugs. Include dosage, routes, and frequency of administration.

- i. For Unmoderated Pain/Distress Category ONLY

Provide written explanation of the procedures producing pain or distress for any portion of the protocol and the reason drugs can not be used to fully alleviate pain/distress. Include the species, number of animals affected and the criteria used for determining from the experimental view point or the timely intervention for removal of animals from the pain and distress. Investigator(s) may be requested to attend an IACUC meeting to discuss proposed research.

### 7. Training of Personnel

Describe how personnel who perform animal anesthesia, surgery or other experimental manipulations are qualified through training and/or experience to accomplish these tasks in a humane and scientifically acceptable manner. If any personnel are in need of training, indicate who will train them prior to personnel's use of the animals.

**Public Health Service Policy on Humane Care  
and Use of Laboratory Animals**  
OFFICE OF LABORATORY ANIMAL WELFARE  
Amended August, 2002

---

**PREFACE**

This 2002 reprint of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals reflects the August 7, 2002 PHS Policy amendment permitting institutions with PHS Animal Welfare Assurances to submit verification of Institutional Animal Care and Use Committee (IACUC) approval for competing applications or proposals subsequent to peer review but prior to award (67 FR 51289). New footnotes (6 and 12) are incorporated to provide institutions with the option of coding the names of IACUC members in materials routinely submitted to the Office of Laboratory Animal Welfare (OLAW). Citations and addresses are also updated in this reprint, and language specifying that information be submitted on institutional letterhead or in letter form is eliminated to allow for electronic submission of information to OLAW in the future.

OLAW, which has responsibility for the general administration and coordination of the Policy, provides specific guidance, instruction, and materials to institutions that must comply with the Policy. For supplemental materials please contact OLAW at the National Institutes of Health, RKL1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982 (for express or hand delivered mail, use zip code 20817) or visit the OLAW website at <http://grants.nih.gov/grants/olaw/olaw.htm>.

This reprint includes the Health Research Extension Act of 1985, Public Law 99-158, "Animals In Research" (November 20, 1985), which provides the statutory mandate for the PHS Policy. Also included in this reprint are the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. The U.S. Principles were promulgated in 1985 by the Interagency Research Animal Committee and adopted by U.S. Government agencies that either develop requirements for or sponsor procedures involving the use of vertebrate animals. The Principles were incorporated into the PHS Policy in 1986 and continue to provide a framework for conducting research in accordance with the Policy.

OFFICE OF LABORATORY ANIMAL WELFARE  
OFFICE OF EXTRAMURAL RESEARCH  
NATIONAL INSTITUTES OF HEALTH

**Health Research Extension Act of 1985**  
**Public Law 99-158**  
**November 20, 1985, "Animals in Research"**

Sec.495.

(a) The Secretary, acting through the Director of NIH, will establish guidelines for the following:

- "(1) The proper care of animals to be used in biomedical and behavioral research.
- "(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph will require-
  - "(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and
  - "(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines will not be construed to prescribe methods of research.

"(3) The organization and operation of animal care committees in accordance with subsection (b).

(1) Guidelines of the Secretary under subsection (a)(3) will require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

"(2) Each animal care committee will be appointed by the chief executive officer of the entity for which the committee is established, will be composed of not fewer than three members, and will include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

"(3) Each animal care committee of a research entity will-

"(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

"(B) keep appropriate records of reviews conducted under sub-paragraph (A); and

"(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) will include any minority views filed by members of the committee.

"(c) The Director of NIH will require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on the date of enactment of this section-

"(1) assurances satisfactory to the Director of NIH that-

"(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

"(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

"(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract. Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection will be promulgated in accordance with the notice and comment requirements of such section.

"(d) If the Director of NIH determines that-

"(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

"(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

"(3) no action has been taken by the entity to correct such conditions; the Director of NIH will suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

"(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential."

## **U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training**

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles will be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official will ensure that these principles are adhered to:

I. The transportation, care, and use of animals should be in accordance with the [Animal Welfare Act \(7 U.S.C. 2131 et. seq.\)](#) and other applicable Federal laws, guidelines, and policies.\*

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care will be provided as indicated.

VIII. Investigators and other personnel will be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements will be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

\*For guidance throughout these Principles, the reader is referred to the [Guide for the Care and Use of Laboratory Animals](#) prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

---

# Public Health Service Policy on Humane Care and Use of Laboratory Animals

## I. Introduction

It is the Policy of the Public Health Service (PHS) to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities (hereinafter referred to as activities) conducted or supported by the PHS. The PHS endorses the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" developed by the Interagency Research Animal Committee. This Policy is intended to implement and supplement those Principles.

## II. Applicability

This Policy is applicable to all PHS-conducted or supported activities involving animals, whether the activities are performed at a PHS agency, an awardee institution, or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals will comply with this Policy, or provide evidence to the PHS that acceptable

standards for the humane care and use of the animals in PHS-conducted or supported activities will be met. No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this Policy, unless the individual makes other arrangements with the PHS. This Policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the [Animal Welfare Act](#), and other Federal statutes and regulations relating to animals.

## III. Definitions

A. *Animal* - Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

B. *Animal Facility* - Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

C. *Animal Welfare Act* - Public Law 89-544, 1966, as amended, (P.L. 91-579, P.L. 94-279 and P.L. 99-198) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the [Code of Federal Regulations \(CFR\), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3](#), and are administered by the U.S. Department of Agriculture.

D. *Animal Welfare Assurance or Assurance* - The documentation from an institution assuring institutional compliance with this Policy.

E. *Guide* - [Guide for the Care and Use of Laboratory Animals](#), National Academy Press, 1996, Washington, D.C., or succeeding revised editions.

F. *Institution* - Any public or private organization, business, or agency (including components of Federal, state, and local governments).

G. *Institutional Official* - An individual who signs, and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.

H. *Public Health Service* - The Public Health Service or PHS currently includes the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

I. *Quorum* - A majority of the members of the Institutional Animal Care and Use Committee (IACUC).

#### **IV. Implementation by Institutions**

##### A. Animal Welfare Assurance

No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with this Policy. Assurances will be submitted to the Office of Laboratory Animal Welfare (OLAW), Office of the Director, National Institutes of Health.<sup>1</sup> The Assurance will be signed by the Institutional Official. OLAW will provide the institution with necessary instructions and an example of an acceptable Assurance. All Assurances submitted to the PHS in accordance with this Policy will be evaluated by OLAW to determine the adequacy of the institution's proposed program for the care and use of animals in PHS-conducted or supported activities. On the basis of this evaluation OLAW may approve or disapprove the Assurance, or negotiate an approvable Assurance with the institution. Approval of an Assurance will be for a specified period of time (no longer than five years) after which time the institution must submit a new Assurance to OLAW. OLAW may limit the period during which any particular approved Assurance will remain effective or otherwise condition, restrict, or withdraw approval. Without an applicable PHS-approved Assurance no PHS-conducted or supported activity involving animals at the institution will be permitted to continue.

##### 1. Institutional Program for Animal Care and Use

The Assurance will fully describe the institution's program for the care and use of animals in PHS-conducted or supported activities. The PHS requires institutions to use the [\*Guide for the Care and Use of Laboratory Animals\*](#) (*Guide*) as a basis for developing and implementing an institutional program for activities involving animals.<sup>2</sup> The program description must include the following:

- a. a list of every branch and major component of the institution, as well as a list of every branch and major component of any other institution, which is to be included under the Assurance;
- b. the lines of authority and responsibility for administering the program and ensuring compliance with this Policy;
- c. the qualifications, authority, and responsibility of the veterinarian(s) who will participate in the program and the percent of time each will contribute to the program;

d. the membership list of the Institutional Animal Care and Use Committee(s) (IACUC) established in accordance with the requirements set forth in IV.A.3. of this Policy;<sup>3</sup>

e. the procedures which the IACUC will follow to fulfill the requirements set forth in this Policy;

f. the health program for personnel who work in laboratory animal facilities or have frequent contact with animals;

g. a synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care, treatment, or use;

h. the gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and

i. any other pertinent information requested by OLAW.

## 2. Institutional Status

Each institution must assure that its program and facilities are in one of the following categories:

Category 1 - Accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or another accrediting body recognized by PHS.<sup>4</sup> All of the institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1. and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy.

Category 2 - Evaluated by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1. and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy. The most recent semi-annual report of the IACUC evaluation will be submitted to OLAW with the Assurance.

## 3. Institutional Animal Care and Use Committee (IACUC)

a. The Chief Executive Officer will appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.<sup>5</sup>

b. The Assurance must include the names,<sup>6</sup> position titles, and credentials of the IACUC chairperson and the members. The committee will consist of not less than five members, and will include at least:

(1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution (see IV.A.1.c.);

(2) one practicing scientist experienced in research involving animals;

(3) one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and

(4) one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.

c. An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b.(1)-(4) of this policy may fulfill more than one requirement. However, no committee may consist of less than five members.

## B. Functions of the Institutional Animal Care and Use Committee

As an agent of the institution, the IACUC will with respect to PHS - conducted or supported activities:

1. review at least once every six months the institution's program for humane care and use of animals, using the [Guide](#) as a basis for evaluation;<sup>7</sup>

2. inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the [Guide](#) as a basis for evaluation;

3. prepare reports of the IACUC evaluations conducted as required by IV.B.1. and 2. of this Policy, and submit the reports to the Institutional Official;<sup>8</sup> (NOTE: The reports will be updated at least once every six months upon completion of the required semiannual evaluations and will be maintained by the institution and made available to OLAW upon request. The reports must contain a description of the nature and extent of the institution's adherence to the [Guide](#) and this Policy and must identify specifically any departures from the provisions of the [Guide](#) and this Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC International or another accrediting body recognized by PHS, the report should identify those facilities as such.)

4. review concerns involving the care and use of animals at the institution;

5. make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training;

6. review and approve, require modifications in (to secure approval) or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals as specified in IV.C. of this Policy;

7. review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and

8. be authorized to suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy.

### C. Review of PHS-Conducted or Supported Research Projects

1. In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with this Policy. In making this determination, the IACUC will confirm that the research project will be conducted in accordance with the [Animal Welfare Act](#) insofar as it applies to the research project, and that the research project is consistent with the [Guide](#) unless acceptable justification for a departure is presented.<sup>9</sup> Further, the IACUC will determine that the research project conforms with the institution's Assurance and meets the following requirements:

a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

d. The living conditions of animals will be appropriate for their species and 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 being maintained or studied.

e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

g. Methods of euthanasia used will be consistent with the recommendations of the [American Veterinary Medical Association \(AVMA\) Panel on Euthanasia](#) (PDF), unless a deviation is justified for scientific reasons in writing by the investigator.<sup>10</sup>

2. Prior to the review, each IACUC member will be provided with a list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals will be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, will review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

3. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

4. The IACUC will notify investigators and the institution 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. If the IACUC decides to withhold approval of an activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5. The IACUC will conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.

6. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the [Animal Welfare Act](#), the [Guide](#), the institution's Assurance, or IV.C.1.a.-g. of this Policy.<sup>11</sup> The IACUC may suspend an activity 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.

7. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

8. Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

#### D. Information Required in Applications-Proposals for Awards Submitted to PHS

##### 1. All Institutions

Applications and proposals (competing and non-competing) for awards submitted to PHS that involve the care and use of animals will contain the following information:

- a. identification of the species and approximate number of animals to be used;
- b. rationale for involving animals, and for the appropriateness of the species and numbers used;
- c. a complete description of the proposed use of the animals;
- d. a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- e. a description of any euthanasia method to be used.

Non-competing applications and contract proposals for other than full and open competitions need not repeat the information required by IV.D.1.a.-e. if the information was complete in the last competing application or proposal and there are no significant changes to that information. However, the application or proposal must contain a statement to that effect. If there are significant changes in the information, then the application or proposal must specifically identify them and state the reasons for the changes.

## 2. Institutions That Have an Approved Assurance

Applications or proposals (competing and non-competing) covered by this Policy from institutions which have an approved Assurance on file with OLAW will include verification of approval (including the date of the most recent approval) by the IACUC of those components related to the care and use of animals. For competing applications or proposals only, such verification may be filed at any time prior to award unless specifically required earlier by the funding component. If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification will state the modifications, if any, required by the IACUC. The verification will be signed by an individual authorized by the institution, but need not be signed by the Institutional Official.

## 3. Institutions That Do Not Have an Approved Assurance

For applications and proposals covered by this Policy from institutions that do not have an approved Assurance on file with OLAW, the signature of the official signing for the applicant organization will constitute a declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution will prepare the Assurance as instructed by OLAW and in accordance with IV.A. of this Policy. The authorized IACUC will review those components of the application or proposal as required by IV.C. of this Policy. Upon IACUC approval of those components of the application or proposal the institution will submit the Assurance to OLAW.

## E. Recordkeeping Requirements

### 1. The awardee institution will maintain:

- a. a copy of the Assurance which has been approved by the PHS;
- b. minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;
- c. records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
- d. records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official; and
- e. records of accrediting body determinations.

2. All records will be maintained for at least three years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC will be maintained for the duration of the activity and for an additional three years after completion of the activity. All records will be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## F. Reporting Requirements

1. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:

- a. any change in the institution's program or facilities which would place the institution in a different category than specified in its Assurance (see IV.A.2. of this Policy);
- b. any change in the description of the institution's program for animal care and use as required by IV.A.1.a.-i. of this Policy;
- c. any changes in the IACUC membership,<sup>12</sup> and
- d. notice of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the Institutional Official.

2. At least once every 12 months, the IACUC, at an institution which has no changes to report as specified in IV.F.1.a.-c. of this Policy, will report to OLAW in writing, through the Institutional Official, that there are no changes and inform OLAW of the dates of the required IACUC evaluations and submissions to the Institutional Official.

3. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a. any serious or continuing noncompliance with this Policy;
  - b. any serious deviation from the provisions of the [Guide](#),<sup>13</sup> or
  - c. any suspension of an activity by the IACUC.
4. Reports filed under IV.F. of this Policy will include any minority views filed by members of the IACUC.

## V. Implementation by PHS

### A. Responsibilities of the Office of Laboratory Animal Welfare (OLAW)

OLAW is responsible for the general administration and coordination of this Policy and will:

1. request and negotiate, approve or disapprove, and, as necessary, restrict or withdraw approval of Assurances;
2. distribute to Scientific Review Administrators of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions [[domestic](#) and [foreign](#)] that have an approved Assurance;
3. advise awarding units and awardee institutions concerning the implementation of this Policy;
4. evaluate allegations of noncompliance with this Policy;
5. have the authority to review and approve or disapprove waivers to this Policy (see V.D. of this Policy); and
6. conduct site visits to selected institutions.

### B. Responsibilities of PHS Awarding Units

PHS awarding units may not make an award for an activity involving animals unless the prospective awardee institution and all other participating institutions have approved Assurances on file with OLAW, and the awardee institution has provided verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals. If any one of these institutions does not have an approved Assurance on file with OLAW, the awarding unit will ask OLAW to negotiate an Assurance with the institution(s) before an award is made. No award will be made until all required Assurances have been submitted by the institution(s), been approved by OLAW, and the institution(s) have provided verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals.

### C. Conduct of Special Reviews/Site Visits

Each awardee institution is subject to review at any time by PHS staff and advisors, which may include a site visit, in order to assess the adequacy or accuracy of the institution's compliance or expressed compliance with this Policy.

## D. Waiver

Institutions may request a waiver of a provision or provisions of this Policy by submitting a request to OLAW. No waiver will be granted unless sufficient justification is provided and the waiver is approved in writing by OLAW.

---

### ***FOOTNOTES***

#### **Footnote 1:**

Assurances should be sent to the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health, Rockledge I, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982 (for express or hand delivered mail use zip code 20817).

#### **Footnote 2:**

This Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* and that they comply with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

#### **Footnote 3:**

The name Institutional Animal Care and Use Committee (IACUC) as used in this Policy is intended as a generic term for a committee whose function is to ensure that the care and use of animals in PHS-conducted or supported activities is appropriate and humane in accordance with this Policy. However, each institution may identify the committee by whatever name it chooses.

#### **Footnote 4:**

As of the 2002 revision of this Policy, the only accrediting body recognized by PHS is the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#).

#### **Footnote 5:**

The [Health Research Extension Act of 1985](#) requires the IACUC to be appointed by the chief executive officer (CEO) of the entity for which the committee is established. OLAW considers the CEO to be the highest operating official of the organization (such as the President of a University). If the CEO delegates authority to appoint the IACUC then the delegation must be specific and in writing. The CEO may or may not be the Institutional Official as defined by this Policy (see definition at III.G.).

#### **Footnote 6:**

Institutions may, at their discretion, represent the names of members other than the chairperson and veterinarian with program authority (see IV.A.3.), by using numbers or other symbols in submissions to OLAW. Sufficient information for OLAW to determine that all appointees are appropriately qualified must be provided. The identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

**Footnote 7:**

This Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* and that they comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

**Footnote 8:**

The Institutional Animal Care and Use Committee (IACUC) may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

**Footnote 9:**

This Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* and that they comply with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

**Footnote 10:**

[Journal of the American Veterinary Medical Association \(JAVMA\), 2001, Vol. 218, No. 5, pp. 669-696 \(PDF\)](#), or succeeding revised editions.

**Footnote 11:**

This Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* and that they comply with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

**Footnote 12:**

Institutions may, at their discretion, represent the names of members other than the chairperson and veterinarian with program authority (see IV.A.3.), by using numbers or other symbols in submissions to OLAW. Sufficient information for OLAW to determine that all appointees are appropriately qualified must be provided. The identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

**Footnote 13:**

This Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* and that they comply with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal

Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.