ANIMAL CARE AND USE MANUAL

Committee on the Protection of Research Subjects:
Institutional Animal Care and Use Committee

ARCADIA UNIVERSITY
450 S. Easton Road
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TABLE OF CONTENTS:

Appendices:

Supplemental Materials in Printed Manual:

Essentials for Animal Research: A primer for research personnel

Safety in Academic Chemistry Laboratories: Accident prevention for college and university students. 7th ed.

Supplemental Materials on CD-ROM:

Title and URL	Filename on CD-ROM
Arcadia University IACUC Animal Use Proposal form	IACUC-form.doc
Arcadia University Progress Report	IACUC-progress.doc
Arcadia University Termination Report	IACUC-termination.doc
"Animal Welfare Act as Amended (7 USC, 2131-2156), http://www.nal.usda.gov/awic/legislat/awa.htm	"Animal-Welfare-Act.pdf"
AWA regulations http://iacuc.ufl.edu/OLD%20Web%20Site/Animal%20Use%20Guides/AWA%20Regulations.doc	"AWA-regulations.pdf"
"Biomethodology of the rat." http://www.miami.edu/acuc/Biometh_rat.html	Biometh_rat.pdf"
"Essentials for Animal Research: A Primer for Research Personnel, 2nd Edition." Bennett, BT; Brown MJ; Schofield, JC. United States Department of Agriculture National Agricultural Library. 1994 http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm	"essentials.pdf"
"*Guide for the Care and Use of Laboratory Animals*" National Research Council, 1996, http://iacuc.ufl.edu/OLD%20Web%20Site/Animal%20Use%20Guides/NRC%20Guide%20for%20the%20Care%20&%20Use%20of%20Laboratory%20Animals.doc	"The-guide.pdf"
"Guidelines for survival rodent surgery." NIH Intramural Research Program. http://iacuc.ufl.edu/OLD%20Web%20Site/Animal%20Use%20Guides/Guidelines%20for%20Rodent%20Surgery.mht	"surgery.pdf"
"*Institutional Animal Care and Use Committee Guidebook, 2nd edition."* Applied Research Ethics National Association and Office of Laboratory Animal Welfare, 2002, http://grants.nih.gov/grants/olaw/guidebook.pdf	"IACUC-guidebook.pdf"

"*Methods and Welfare Considerations in Behavioral Research with Animals: Report of a National Institutes of Health Workshop*." Morrison AR; Evans HL; Ator NA; Hakamura RK (eds). NIH Publication No. 02-5083. National Institute of Mental Health, 2002, http://www.nimh.nih.gov/research/animals.pdf	"animals.pdf"
"*NIH – Diet Restriction in Behavioral Studies*" http://iacuc.ufl.edu/OLD%20Web%20Site/Animal%20Use%20Guides/Guidelines%20for%20Diet%20Restriction.pdf	"Diet-restriction.pdf"
"*PHS Policy on Humane Care and Use of Laboratory Animals Tutorial*" Office of Laboratory Animal Welfare, 2000 http://grants.nih.gov/grants/olaw/tutorial/index.htm	"phs-animal-tutorial.pdf
"Principles of Aseptic Surgery" http://www.miami.edu/acuc/Aseptic.html	"aseptic.pdf"
"*Public Health Service Policy on Humane Care and Use of Laboratory Animals*." Office of Laboratory Animal Welfare, 2002, http://grants.nih.gov/grants/olaw/references/phspol.htm	"PHS-policy.pdf"
"Report of the AVMA panel on euthanasia, 2000." American Veterinary Medical Association. JAVMA 28:50(669-696), 2001.	"AVMA-euthanasia-2000.pdf"
"Safety in Academic Chemistry laboratories: Accident Prevention for College and University Students, 7th Edition" American Chemical Society http://membership.acs.org/c/ccs/pubs/SACL_Students.pdf	"SACL_students.pdf"

Preface:

Mission Statement:

Arcadia University acknowledges its responsibility to protect the welfare of animal subjects involved in research performed on its premises or conducted under its authority by persons affiliated with the university. This policy is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals. In addition, this policy covers research being conducted by faculty, staff, or students of this institution working at research sites abroad. At the same time the university, as an academic institution, recognizes a special interest in promoting research and a special responsibility to see that the rights of academic freedom traditionally accorded researchers not be abridged.

Oversight of all on-campus or university-authorized research or projects that involve animal subjects will be exercised by the Institutional Animal Care and Use Committee (IACUC). The composition of the committee will comply with government guidelines for membership of institutional review boards and of institutional animal care and use committees. All members are appointed by the President and, in the case of the faculty members, upon the recommendation of Faculty Council.

The President of the College may disapprove research or projects that have previously received the approval of the committee, but the President may not approve what has not been approved by the committee.

Specifically:

1. ***Personnel Covered***: These policies apply to all faculty, staff, and students involved in animal use.

2. ***Activities Covered***: These policies apply to all research, research training, experimentation, biological testing, teaching, and related activities.

3. ***Animal Species Covered***: These policies apply to all live vertebrate animals.

IACUC Duties:

1. To establish guidelines, criteria and procedures, in accord with university policies, to protect the welfare of animal subjects in all research and projects performed on the premises of the college or undertaken under its authority.

2. Review at least once every six months the institution's program for humane care and use of animals.

3. Establish a training program to ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct the proposed activities.

4. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals in research, teaching, and testing. Conduct continuing review of each previously approved, ongoing activity at yearly intervals, including a complete review at least once every three years.

4. Review concerns involving the care and use of animals at the institution. The Committee is authorized to suspend any activity involving animals deemed deficient or not in with the specifications set forth in the Arcadia University IACUC policy.

5. Inspect at least once every six months all of the institution's animal facilities, including satellite facilities.

6. Prepare and submit reports of the IACUC evaluations, inspections, and recommendations to the Institutional Official and assist in the preparation of the annual reports to accrediting agencies.

Regulatory Authorities:

A. Arcadia University recognizes and will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals; including the Animal Welfare Act (7 USC, 2131-2156 with all amendments 1970, 1976, 1985, 1990) and the Health Research Extension Act of 1985 (Public Law 99-158).

B. Arcadia University is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training." (**Appendix I**)

C. Arcadia University acknowledges and accepts responsibility for the care and use of animals involved in research, teaching, and testing. As partial fulfillment of this responsibility, Arcadia University will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.

D. Arcadia University has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

E. Arcadia University *maintains an Animal Welfare Assurance (***A4424-01***), approved by the Office of Laboratory Animal Welfare (OLAW), of the Public Health Services. The assurance indicates the University's compliance with the program requirements of the Guide. OLAW is responsible for the general administration and coordination of PHS policy regarding animal care and use. Federal awarding units may not make an award for a project involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance on file with OLAW, and the responsible institutional official has provided verification of approval by the IACUC. All records that directly relate to applications, proposals, and proposed changes in animal care and use reviewed by IACUC must be maintained for at least three years after completion of the research and must be accessible to the OLAW with reasonable notice.*

IACUC Membership

A. Definition

The Institutional Animal Care and Use Committee, or IACUC, is a committee appointed by the University President. The IACUC has certain federally mandated responsibilities, such as review of protocols and periodic evaluations of the program of animal care and use, including inspections of facilities.

B. IACUC Organization

1. University President: The IACUC is appointed by and answers to the President of the University.

2. Institutional Official: The *Institutional Official* is a formally designated senior official with the authority to administer the program of animal care and use, and to make commitments on behalf of the institution to ensure compliance with the PHS Policy. The Institutional Official relies on the IACUC to oversee the program, to develop plans to correct program deficiencies, to address concerns that may arise regarding the institution's use of animals, and to make recommendations with regard to the program. Through semiannual reports to the Institutional Official and open channels of communication, the IACUC keeps the Institutional Official informed of the status of the program and alerts the Official to potential noncompliance with the PHS Policy. Documents submitted to OLAW, such as an Animal Welfare Assurance, annual report, or reports of noncompliance, are submitted by the IACUC, through the Institutional Official, and should bear his or her signature as the official responsible for animal welfare at the institution.

3. The IACUC is appointed committee with responsibility of enforced self-regulation to ensure that the policies and procedures of responsible animal care and use are followed.

4. Veterinarian:
   A veterinarian with small animal and laboratory animal experience from outside of the institution serves on the IACUC. In this capacity he reviews all protocols involving animals for research, testing, or instruction. He is involved in the semi-annual program review, inspection of facilities. In addition, he provides consultative services in the development of research and training protocols, anesthetics, analgesics and other animal use related techniques. He has the authority to euthanize any animal suffering pain or distress not described in the IACUC approved protocol and to temporarily suspend activities and report any incidents involving inappropriate use or care of animals directly to the IACUC. He also reports directly to the Institutional Official. Twenty-four hour emergency veterinary coverage is available through his veterinary practice or associates. Although the veterinarian serves as a voting member of the IACUC, he also reports directly to the Institutional Official in his capacity as supervising veterinarian.

5. Animal Research Coordinator - administrator who is responsible for overall supervision of animal research at the university, especially in relation to federal guidelines and regulations; with this designation, the Associate Dean for Research, Scholarly and Creative Activities will coordinate all research regulations as the Animal Research Coordinator. This is currently an explicit responsibility of the Institutional Official.

6. Faculty Animal Care Representative – A faculty member who is a practicing scientist with experience working with animals. This appointment to COPRS is made by the President of the University to represent issues related to animal research (formerly the Animal Care Supervisor).

7. Animal Laboratory Administrative Assistant - staff member who manages administrative tasks associated with the laboratories, such as supplies and student workers. This position is appointed by Animal Research Coordinator.

C. Committee Structure:

C. 1. Membership

The President of the University upon recommendation of Faculty Council will appoint the chairman of the IACUC, a vice-chair, and the members for 3 year terms. At a minimum, the composition of the committee must fulfill the PHS Policy membership requirements and include a faculty animal care representative, a non-scientist, a veterinarian, and a non-affiliated layperson. The Institutional official (Associate Dean for Research, Scholarly and Creative Activities) is appointed to the IACUC in an *ex officio* capacity.

Faculty representatives:

A. **Scientist* - a practicing scientist experienced in research involving animals.

B. Faculty Animal Care Representative - faculty member who is appointed to COPRS to represent issues related to animal research

C. *Nonscientist - a member whose primary concerns are in a non-scientific areas (e.g. ethicist, lawyer, member of the clergy).

In addition to faculty members appointed to the IACUC, the committee will also be composed of

D. **Veterinarian* - a veterinarian with direct or delegated program responsibility.

E. **Non-affiliated member* - The USDA Animal Welfare Regulations intend that the individual not affiliated with the facility provide representation for general community interests in the proper care and treatment of animals. The 1996 *Guide* further specifies that the nonaffiliated member should not be a laboratory animal user.

F. Institutional Official: University representative responsible for reporting to the Office of Laboratory Animal Welfare, serves on the IACUC in an ex officio capacity.

*PHS Policy Membership Requirements:

C. 2. Qualifications on IACUC Members

A. Committed to the ethical and scientifically sound conduct of research, testing, or teaching involving animals.

B. Completion of training required for investigators.
including: Animal Use Level 1
Occupational Health and Safety

C. Thorough review and knowledge of policies and procedures for the use of animals in research, testing, and teaching activities at Arcadia University.

IACUC Meetings

A. Meeting Schedule: The IACUC will meet at least monthly during the academic year. Additional meetings may be called by the Chair as deemed necessary.

B. Quorum: A quorum of the IACUC will be a majority of all appointed members. Committee decisions will be made by a simple majority of appointed members. In the event of an opinion differing from the majority, a minority report should be included in the Committee minutes. Minority reports should also be included in the semi-annual reports to the Institutional Official.

C. Subcommittees: Subcommittees of the IACUC may be created by a vote of the full committee and charged with conducting IACUC business including facility inspections and summer review of protocols.

D. Committee activities outside of the standard academic year: A subcommittee will be created composed of current and past IACUC members to conduct necessary business outside of the normal academic year. The committee will be composed of at least the chair or vice-chair of the IACUC, one additional faculty representative, and the veterinarian. All decisions made by this sub-committee composed solely of these three individuals must be unanimous.

E. Records:

E. 1. Record Keeping Requirements:

This institution will maintain for at least three years:

1. A copy of the Animal Welfare Assurance and any modifications thereto, as approved by PHS.

2. Minutes of IACUC meetings, including records of attendance, activities of the committee, committee deliberations, and minority views.

3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.

4. Records of semiannual IACUC reports, semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction and recommendations (including minority views) as forwarded to the Institutional Official.

5. Records of accrediting body determinations.

E. 2. Record Keeping Duration:. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

E. 3. Record Format: Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the *Guide* and with commonly accepted professional standards.

E. 4. Record Access: All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

Program Review:
A. Program Review Schedule:

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. The IACUC procedures for conducting semiannual program evaluations are:

a. A subcommittee of the IACUC is appointed by the Chairperson to conduct the Program Review. The subcommittee will be composed of at least 3 members, including the veterinarian, and an animal scientist.

B. **Criteria for review**: Members of the subcommittee complete the attached IACUC Semi-Annual Program Review form (**Appendix II**). This form includes all items listed in the Guide and upon completion is reviewed by the full Committee and forwarded to the Institutional Official for review.

C. Recommendations: Make written recommendations to the Institutional Official (Associate Dean for Research, Scholarly and Creative) regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are:

a. The IACUC will formulate at convened or non-convened meetings any recommendations to the institutional official.

b. The IACUC chair will forward all Committee recommendations to the Institutional Official (Associate Dean for Research, Scholarly and Creative Activities).

Training Program

Need for personnel Training:

It is the responsibility of Arcadia University to ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities. The development and implementation of a training program are usually performed by the IACUC, the veterinary staff, and investigators using animals. Program content is governed by legal requirements and by specific scientific activities conducted at the institution.

All individuals involved with the use and care of animals must complete both the appropriate level of "Animal Care and Use Training" and "Occupational Health and Safety Training." Certification of completion of these training programs is valid for 1 year, and must be completed prior to beginning any animal care or use. Valid certification is also a requirement for approval of animal use proposals.

A. Animal Care and Use Training:

The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is attached (**Appendix III**). Training covers the appropriate selection of animal models, methods to minimize the number of animals needed to obtain valid results, steps to minimize pain and distress as well as procedures for submitting protocols and changes in protocols to the IACUC. Training is also given on sources of acceptable alternatives to animal use, IACUC guidelines on pain and distress, the reporting of allegations concerning animal welfare, as well as other IACUC recommendations. In addition, experienced members of the IACUC provide mechanisms for protocol specific training and certification for investigators staff and students.

IACUC Animal Use Levels:

The IACUC recognizes that there will be a wide range in skills and responsibilities of individuals based on the types of animal care, treatment, or use activities that the individual will be completing. Therefore, the Arcadia University IACUC has created different levels of Animal Users-based on responsibilities and provides training based on these specific needs.

Level 1 Animal User:

Responsibilities: These individuals have minimal contact with live animals, but are involved in caring for the animal (providing food, water, clean housing, and monitoring health). These individuals will need general background on regulations, routine care and handling, and standard policies regarding the use of laboratory animals.

Training: Level 1 Animal Users will

- Receive a copy of the Arcadia University "Animal Care and Use Manual"
- Complete the "*PHS Policy on Humane Care and Use of Laboratory Animals Tutorial*" located in **Appendix IV** or online at: http://grants.nih.gov/grants/olaw/tutorial/index.htm
- Read the following chapters in *"Essentials for Animal Research: A Primer for Research Personnel, 2nd Edition*." Located in Supplemental materials or online at: http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm
  - Chapter 1 – Regulations and Requirements
  - Chapter 2 – Alternative Methodologies

Chapter 3 – Animal Care and Use: A Non-experimental Variable
- Pass the IACUC "Level 1 Animal Care and Use Certification Exam"

Certification: Level 1 Animal Users will receive certification documenting the successful completion of the Level 1 training requirements. This certification is valid for 1 year. Individuals must have current certification status prior to beginning work with animals.

Level 2 Animal User:

Responsibilities: These individuals will have all of the responsibilities of the Level 1 Animal Users, but will also be involved in simple animal procedures such as behavioral testing, injections, specimen collection, or euthanasia. These individuals need hands-on training on the relevant protocols.

Training: Level 2 Animal Users will
- Complete all of the requirements for Level 1 Animal Care User
- Read the following chapters in *"Essentials for Animal Research: A Primer for Research Personnel, 2nd Edition*." Located in Supplemental materials or online at:
  http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm
  Chapter 7 – euthanasia
- Read relevant scholarly articles or standard protocols related to their procedures
- if requested by the IACUC, demonstrate proficiency in the technique or protocol to a IACUC assigned trainer (Veterinarian, Faculty Animal Care Representative, or IACUC designate)

Certification: Level 2 Animal Users will receive a letter from the IACUC-assigned trainer documenting the techniques and procedures that the user is certified to complete. This certification is valid for 1 year. Individuals must have current certification status prior to conducting these techniques. If techniques are needed beyond the current certification, proficiency will need to be demonstrated prior to using the new techniques.

Level 3 Animal User:

Responsibilities: These individuals will have all of the responsibilities of the Level 1 and Level 2 Animal Users, but will also be involved in advanced animal procedures such as anesthesia and surgical procedures. These individuals need hands-on training on the relevant protocols.

Training: Level 3 Animal Users will
- Complete all of the requirements for Level 1 and Level 2 Animal Care User
- Read the following chapters in *"Essentials for Animal Research: A Primer for Research Personnel, 2nd Edition*." Located in Supplemental materials or online at:
  http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm
  Chapter 4 – Principles of Anesthesia and Analgesia
  Chapter 5 – Principles of Aseptic Surgery
  Chapter 6 – Perioperative Care
- Read relevant scholarly articles or standard protocols related to their procedures
- if requested by the IACUC, demonstrate proficiency in the technique or protocol to

a IACUC assigned trainer (Veterinarian, Faculty Animal Care Representative, or IACUC designate)

Certification: Level 3 Animal Users will receive a letter from the IACUC-assigned trainer documenting the techniques and procedures that the user is certified to complete. This certification is valid for 1 year. Individuals must have current certification status prior to conducting these techniques. If techniques are needed beyond the current certification, proficiency will need to be demonstrated prior to using the new techniques.

B. Occupational Health and Safety Program:

An effective occupational health and safety program must encompass all personnel that have contact with animals based on the *Occupational Health and Safety in the Care and Use of Research Animals*, published in 1997 by the National Research Council. Depending on the species of animal or the amount of animal exposure, the program may not affect all personnel equally.

1. Risk Assessment: The principal investigator must identify to the IACUC the species being used and any additional risks or concerns. Each individual working with animals or animal tissues on the protocol must sign a statement (**Appendix V**) saying that they have read and understood both the protocol and a description of zoonotic information and other concerns with the species they are using (**Appendix VI**).

Allergies: Allergies to animals are common and it is estimated that 15-20% of personnel exposed to animals for extended periods of time will develop symptoms of allergies. Symptoms of allergies may include:

allergic rhinitis: hay fever-like symptoms of runny nose and sneezing
allergic conjunctivitis: irritation of eye resulting in red eye and tearing
atopic dermatitis: redness to skin, inflammation, edema, hives, rash
asthma: restricted breathing, difficulty catching breath, wheezing

Persons with a history of allergies or asthma should attempt to avoid direct contact with animal substances on the skin by wearing gloves and a laboratory coat, and washing their hands frequently. Individuals with respiratory symptoms may consider wearing a surgical mask.

2. Hazard Identification: Researchers are expected to evaluate and determine appropriate levels of precautions for the safe usage of all materials used in their experiments. At a minimum, researchers are expected to discuss MSDS safety ratings and personal protection equipment needs with students and technicians. A hazard identification and risk plan should be documented and made available to all research personnel in the laboratory.

Use of biohazardous agents will be evaluated by a University Biosafety Committee prior to submission of a protocol to the IACUC. The review of the protocol must include a description of the biohazardous materials, risks involved with use of the material, and precautions that must be taken with the material. Documentation of training for laboratory personnel in the safe and proper use of the agents is required.

3. Personnel training: All laboratory personnel must
   - Read the following chapters in *"Safety in Academic Chemistry laboratories: Accident Prevention for College and University Students, 7th Edition"*
     Located in Supplemental materials or online at:
     http://membership.acs.org/c/ccs/pubs/SACL_Students.pdf
     Chapter 1 – Your responsibility for Accident Prevention
     Chapter 2 – Guide to Chemical Hazards
     Chapter 4 – Safety Equipment and Emergency Procedures
   - Pass the IACUC "Occupational Health and Safety Certification Exam"
   - Complete the Animal Users Risk Assessment Form (*Appendix V*).

   Certification: Animal Users will receive certification documenting the successful completion of the Occupational Health and Safety training requirements. This certification is valid for 1 year. Individuals must have current certification status prior to beginning work with animals.

4. Personal Protective Equipment (PPE): Gloves, masks, goggles, and lab coats are provided for laboratory personnel depending upon the area in which they are working.

5. Personal Hygiene: Personnel are not permitted to eat, drink, use tobacco products, or apply cosmetics in the animal rooms or laboratories.

6. Pre-employment medical evaluation: Students, staff, and faculty at Arcadia University are expected to have a current physical and MMR1, MMR2, tetanus, hepatitis 1, 2, 3, and PPD vaccinations.

7. Procedures for reporting and treating injuries: All work related injuries are reported to the campus **Department of Public Safety (emergency number 2999)** and the **Campus Wellness Center (2966),** and if appropriate to local **Emergency Medical Services through 911**. A Public Safety Officer trained in first aid is immediately dispatched to the location and will be involved in collecting information for a formal report. Depending on the severity of the incident, the injured individual will be referred to the Campus Wellness Center or be transported by ambulance to Abington Memorial Hospital.

Protocol Review Process

The Arcadia University IACUC has oversight over all research, research training, experimentation, biological testing, teaching, and related activities conducted on live vertebrate animals. The type of live animal activity determines the level of review that must occur prior to the initiation of the work. ***No animal experimentation, conditioning, manipulation, or other use is permitted at Arcadia University without written IACUC approval.***

All activities involving live vertebrate animals in teaching with classrooms or laboratories, including demonstrations, are subject to same levels of IACUC review as research projects.

Undergraduate and Graduate students must have a faculty sponsor who will provide instruction, mentoring, and assurance that all Arcadia University policies will be followed prior to approval of an animal use protocol.

A. Protocol Review Categories:

A faculty member or student with faculty mentor contemplating a research project will use a flow chart of questions about animal research project In order to determine the required level of review.

Flow chart for determining level of review for use of animal subjects.	
1. Are the subjects of this study animals or humans?	1A. Humans – Proceed to Institutional Review Board information to determine procedures for obtaining approval for study. 1B. Animals – Proceed to 2.
2. Does the study involve biohazardous or radioactive materials?	2A. YES –Review by the University's Biohazard Committee must occur before review by the full IACUC. 2B. NO – Proceed to 3.
3. Are animals alive or dead?	3A. Dead – experiments using non-living materials are considered exempt. 3B. Alive – Proceed to 4.
4. Are animals vertebrates?	4A. No – Experiments on invertebrate animal species, bacteria, and protozoa are considered exempt. 4B. Yes – subjects are vertebrate animals – Proceed to 5.
5. Will the animal subjects used in the research will be subjected to pain or discomfort beyond that entailed in routine laboratory maintenance	5A. No – Observational studies are considered exempt. 5B. YES – Empirical and manipulative studies of animals need to be reviewed. Proceed to 6.
6. Are any of the protocols used in the experiment new or have not been approved by the IACUC within the past 3 years?	6A. No – Experiments using protocols previously approved by the IACUC are eligible for expedited review. 6B. YES – New protocols or protocols that have not been approved in the past 3 years must be reviewed by the full IACUC

B. Review of use of Biohazardous and Radioactive materials in Laboratory animals.
Biohazardous materials are defined as those materials having known or suspected carcinogenic, teratogenic, or mutagenic properties. All activities using biohazardous materials must be reviewed and approved by the Arcadia University Biohazard Committee prior to submission for review of the protocol to the full IACUC. The Biohazard Committee will evaluate the plan for minimizing exposure to hazardous materials by the investigators and non-research individuals. A plan will also need to include a strategy for the safe disposal of waste materials.

Arcadia University does not currently have a Nuclear Regulatory Commission license so no use of radioactive materials is permitted on campus. Experiments using radioactive materials off-site must be approved by the host institution prior to review by the full IACUC.

C. Exempt from Review: Activities that involve the use of dead animals (preserved specimens used for dissection or anatomical study); non-vertebrates (bacteria, protozoa, and invertebrate animal species are exempt); or animal tissue or cells obtained from an outside source (continuous cell lines, ***note: sacrificing an animal for obtaining primary cultures is not exempt***) are exempt from review. If an animal used in the research will not be subjected to pain or discomfort beyond that entailed in routine laboratory maintenance (simple observational studies), then the research need not be reviewed. Nevertheless, the Principal Investigator should submit a brief letter to the IACUC stating the intended use of the animals or materials, the sponsor of the activity, and the proposed methods for obtaining the material. The Principal Investigator should also keep records of the procurement of all animal tissues and/or cells regardless of source.

Activities involving observations of live vertebrate animals within their natural habitat in the wild or non-invasive exhibits (ornamental fish tanks or zoological enclosures) without investigator intervention are considered exempt from review.

D. Expedited Review:
The IACUC conducts expedited review of protocols that are non-painful or for those using previously IACUC-approved procedures. The expedited committee is composed of one current member of the IACUC from outside of the investigators department, and two current, former, or similarly qualified members of the IACUC from the investigators department. The composition of the Expedited (or Departmental) committee must be approved by the full IACUC prior to convening to make decisions. Each member of the expedited committee receives a copy of the protocol. Members are given five working days to review the protocol. Any member of the expedited committee can require modifications in order to secure approval. If the protocol is not approved unanimously after modification, it will be reviewed by the full IACUC.

A protocol that is the same as a previously approved protocol, but is being submitted to a different sponsor, resubmitted to the same sponsor, or being renamed, may also receive expedited review and approval. The principal investigator need only complete the first part of the IACUC application (in particular, listing the protocol number of the previously approved application) and submit the remaining elements of the application package. The Chair of the

IACUC will review this application and the previously approved protocol and if they are indeed the same, the protocol will be approved.

E. Standard Protocol Review

All activities (research, testing, and teaching) involving vertebrate animals that are not considered exempt or eligible for expedited review must be submitted to the full IACUC for approval prior to the commencement of the activity.

E.1. Proposal Format:

All proposals for the use of animals must include the information in the IACUC submission form (**Appendix VII**). The proposal must contain descriptions of the following:

a. the species and approximate number of animals to be used.

b. the rationale for involving animals, and for the appropriateness of the species and numbers to be used.

c. procedures designed to assure that discomfort or injury to animals will be limited to that which is unavoidable and that analgesic, anesthetic, and tranquilizing drugs will be available and used where indicated and appropriate to minimize discomfort and pain.

d. the proposed use of the animals

e. any euthanasia method to be used.

E.2. Criteria for IACUC Review and Approval of Protocols

In order to be approved by the committee, research involving animals must satisfy all of the following requirements (from IV. C.1.a.-g. of the PHS Policy). If members of the committee do not feel competent to judge a particular proposal, advice can be sought from individuals with appropriate experience.

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, unless a deviation is justified for scientific reasons in writing by the investigator.

E.3. Review Procedure:
Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are:

a. The chair of the IACUC receives all protocols and screens them for compliance with administrative requirements, readability, and completeness. The chair than distributes these protocols to all Committee members for review.

b. The IACUC conducts convened meetings to review protocols, discuss inspection results, formulate recommendations, if any, to the Institutional Official (Associate Dean for Research, Scholarly, and Creative Activities), and conduct any other necessary business. The presence of a majority of voting members (or designated alternates) constitutes a quorum. Painful protocols and those involving procedures not previously IACUC-approved are reviewed in the convened meetings. One week prior to the meeting, each IACUC member receives from the IACUC chair, copies of the protocols being presented. At the meeting, each protocol is reviewed and discussed, then the Committee votes on protocol approval.

c. Under some circumstances where the Committee feels the need to obtain additional information, the investigator may be invited to the IACUC meeting to discuss their protocol. Investigators are requested to leave the room during the final discussion and vote on the protocol. Investigators are then informed of the results of the vote.

d. Committee members who are affiliated with the protocol in any way that presents a potential conflict of interest will recuse themselves from the meeting room during final discussions and voting on the protocol. Committee members that have recused themselves because of a conflict may not be counted in the establishment of a quorum.

e. Voting: Protocols may be approved, disapproved, or tabled by a vote of a quorum of the Committee. (Section VII.E.4) In some cases, the committee may find that the protocol is approvable on certain conditions. Final approval for those cases is withheld until a designated reviewer determines that the conditions have been met. A simple majority vote of the IACUC is required for approval.

E.4. Review Outcomes:

Approved as Submitted: This action indicates that the protocol has the approval of the committee and no further revisions or changes are required. The principal investigator will be sent an approval notice within five working days that includes additional information regarding his or her responsibility in regard to activation, continuing review and notification of any changes and/or problems with the protocol.

The approval period of the protocol is generally for three years. However, approval to conduct the protocol is given for one full calendar year from the date of approval. If the study is ongoing, the researcher will need to submit a progress report and a request for continuance approximately 1 month before the approval expires.

Note that if you wish to change any aspect of the study, such as procedures, consent forms, or the investigators, please communicate your requested changes in writing to the chair of the IACUC. New procedures or changes cannot be initiated until Committee approval has been given.

Revise and Resubmit: This action indicates that the committee has concerns with the protocol such that it can not be approved without revisions. The investigator will be sent a letter within five working days describing the reasons for tabling the study and outlining the necessary revisions for reconsideration by the IACUC. A revised copy of the protocol must be submitted to the IACUC chair within 30 days from the date of notification. The changes to the protocol must also be described point-by-point in a cover letter. Revisions in letter form will not be accepted for the re-review of tabled protocols. If the revised protocol is not submitted within 30 days, the protocol will be reviewed as a new submission.

Disapproval as Submitted: This action occurs when the committee determines that the risks of the procedure outweigh any benefit to be gained. The investigator will be sent a letter describing the reasons for disapproving the study. The investigator may discuss the Committee's review with the Chairperson and/or submit a revised protocol for re-review at the next scheduled meeting.

E.5. Notification:

a. The Chair of 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 within 5 working days of the meeting.

b. The IACUC chair generates and sends a letter or an e-mail communicating the results of the Committee action and forwards this to the investigators. Records of this communication are maintained within the IACUC files.

c. An official copy of the minutes of each meeting is distributed to inform the Institutional Official of all actions taken by the IACUC.

F. Duplicate Review

The Office of Laboratory Animal Welfare (OLAW), NIH, and the USDA Animal and Plant Health Inspection Service have agreed as part of the "NIH Initiative to Reduce Regulatory Burden" that an animal use protocol does not need to be reviewed by more than one IACUC(NOT-OD-01-017; February 12, 2001).

If an Arcadia University Faculty member, Staff member, or student is involved in an animal study at another institution, all of the live animal work is conducted at that institution, and the

project has received approval from that institution's IACUC; then the project does not need to be approved by the Arcadia University IACUC. A copy of the approved IACUC protocol from the other institutions should be submitted and kept on file by the Arcadia University IACUC.

If an Arcadia University Faculty member, Staff member, or student is involved in an animal study at another institution, cell or tissues samples are obtained from live animals at the collaborating institution but analyzed at Arcadia University, and the project has received approval from that institution's IACUC; then the project does not need to be approved by the Arcadia University IACUC. A copy of the approved IACUC protocol from the other institutions should be submitted and kept on file by the Arcadia University IACUC.

If an Arcadia University Faculty member, Staff member, or student is involved in an animal study in collaboration with another institution, the project has received approval from that institution's IACUC, but some of the live animal housing or experimental work is conducted at Arcadia University; then the Arcadia University IACUC may either require its own review and approval of the protocol or may vote to accept the collaborating institutions approved protocol.

G. Amendments:
Any proposed modification to an approved protocol must be approved by the IACUC prior to implementation. This includes, but is not limited to, changes to procedures, housing requirements, pre- or post-operative care, euthanasia, the addition of animals, or the addition or deletion of personnel. Investigators who wish to initiate a change in a protocol must submit a letter to the Chair of the IACUC describing in detail the proposed modifications, justification for the proposed changes, and any effects that the modifications may have on the animal(s). The chair may decide that the amendment represents significant procedural changes that require the submission of a new IACUC protocol. Amendments may be approved by the Chair of the IACUC on an ad-hoc basis.

H. Continuing Review
a. Proposals will be approved for a three year interval. The investigator will have to seek reapproval during the three years if the procedures are altered significantly. At the end of the third year, the investigator must submit the proposal for review even if the procedures are the same.

b. Federal regulations and University policy require that all activities involving the care and use of animals be reviewed at least annually. To this end, each principal investigator of an approved IACUC protocol must complete a Periodic Report Form **(Appendix VIII**) each year prior to the anniversary date of the initial IACUC approval. The Periodic Report Form solicits information regarding the number of animals used in the previous year, whether there have been any changes to the protocol, whether there have been any complications or pre-mature deaths associated with the protocol, and whether the protocol is currently active.

c. The chair of the IACUC will send the Periodic Report Form to each principal investigator two months prior to the anniversary date and, if necessary, a second notice will be sent one month prior to the anniversary date. The completed form must be returned to the chair of the IACUC no later than two weeks prior to the anniversary date. Otherwise, the protocol will be

administratively inactivated and animals will no be released for research. Proposals that are approved in the summer will be reviewed prior to the end of the academic year.

d. The Periodic Report Form is reviewed by the IACUC at its monthly meetings. If there are no problems, the protocol may remain active for another year. If problems are observed or suggested, further investigation by the IACUC may be necessary and suspension or termination of the protocol may be required. The investigator will be notified in writing regarding the outcome of the IACUC review of the Periodic Report Form.

I. Renewal

Generally, IACUC protocols are approved for a three year period. To renew a protocol after the three year period, the principal investigator usually needs to submit a full application and follow the standard review process. However, the protocol for a multi-year project that extends beyond three years for which there has been no or little change to the protocol may not need to be pre-reviewed (at the discretion of the chair).

If the project meets the requirements for expedited review, the review may be carried out by the chairperson of COPRS or by an experienced member of the Committee designated by the chairperson. In reviewing the project, the reviewers may exercise all the authority of COPRS except that they may not disapprove the project. A project may be disapproved only after full review by COPRS.

J. Termination or Inactivation of Protocol

As noted above, protocols are generally approved for a three year period. A protocol may be terminated or inactivated by the principal investigator at any time during this approval period by notifying the IACUC in writing or, as part of the continuing review process, by completing the appropriate section of the periodic report form, or by completing the project termination form (**Appendix IX**). A protocol may also be administratively inactivated by the IACUC if the principal investigator fails to submit the Periodic Report Form as required by the annual continuing review process.

Process for responding to animal welfare concerns.

The IACUC will review concerns involving the care and use of animals at the institution.

A. Ongoing Review of Animal Protocols:

Members of the IACUC may takes steps to ensure that the observed use of animals is consistent with the approved protocol for the project, through periodic unannounced inspections of animal facilities.

a. Animal Care personnel are encouraged to report any concerns to the IACUC.

b. Protocols that appear to have a high risk of causing animal pain, discomfort or distress are monitored by the IACUC, with random visits to the animals in question.

B. Addressing Animal Welfare Concerns:
Reporting of animal Welfare concerns: Signs are placed in prominent locations in the vivarium and in animal laboratories, directing individuals to report concerns regarding animal welfare to the Institutional Official, the IACUC chair, or the Attending Veterinarian. The names of these individuals, their office location, and telephone numbers are listed on the sign (**Appendix X**).

Potential infractions of the Guide or of the Animal Welfare Act that are reported by any source will be investigated immediately by a designated IACUC member, who will then recommend a course of action to the Committee. In the event that the Committee cannot be convened in time to address a situation of urgency, the Chair of the Committee will communicate directly with the investigator and inform the Institutional Official.

C. Suspension of Animal Activities:
The Committee or Chair of the Committee are authorized to suspend any activity involving animals deemed deficient or not in compliance with guidelines set forth in Arcadia University IACUC Policy.

The IACUC procedures for suspending an ongoing activity are:

1. Potential infractions of the Guide or of the Animal Welfare Act that are reported to the Committee will be investigated immediately by a designated IACUC member, who will then recommend a course of action to the Committee. In the event that the Committee cannot be convened in time to address a situation of urgency, the Chair of the Committee will communicate directly with the investigator and inform the Institutional Official (Associate Dean for Research, Scholarly and Creative Activities) of any action.

2. Depending on the urgency of the situation, an ongoing activity may be suspended by a majority vote of a quorum of the Committee, by the Committee Chair, by an attending veterinarian, and/or by the Institutional Official (Associate Dean for Research, Scholarly and Creative Activities)

3. Any suspension of any ongoing activity will be immediately communicated to the Institutional Official and to the primary investigator.

4. Suspensions of activities involving animals will be reported to OLAW by the Institutional Official after the IACUC has voted upon it.

Animal Environment, Housing, and Management

"Proper housing and management of animal facilities are essential to animal well-being, to the quality of research data and teaching or testing programs in which animals are used, and to the health and safety of personnel A good management program provides the environment, housing, and care that permit animals to grow, mature, reproduce, and maintain good health; provides for their well-being; and minimizes variations that can affect research results. Specific operating practices depend on many factors that are peculiar to individual institutions. Well-trained and motivated personnel can often ensure high-quality animal care, even in institutions with less than optimal physical plants or equipment." (Guide, p. 21)

A. Primary Enclosure

The primary enclosure (cage) should provide a suitable microenvironment for the normal physiologic and behavioral needs of the animals. This environment should permit normal movement, the ability to remain clean and dry, and access to appropriate food and water. The majority of rats at Arcadia University are housed in standard plastic or polycarbonate solid bottom cages (60 x 20 x 19 cm), with a metal or wire lid.

B. Space Recommendations:

Rats are housed in cages following the regulations established in the Guide, Table 2.1:

	Weight (grams)	Floor area/ animal in^2 (cm^2)	Rats per standard cage
rats	<100	17 (110)	6
	Up to 200	23 (149)	4
	Up to 300	29 (187)	3
	Up to 400	40 (258)	2
	Up to 500	60 (387)	1
	> 500	>70 (>451)	1

C. Husbandry

1. Food:

"*Animals should be fed palatable, noncontaminated, and nutritionally adequate food daily or according to their particular requirements unless the protocol in which they are being sued requires otherwise*." (The Guide, page 38). Arcadia University uses a standard rodent diet approved by the subcommittees of the National Research Council Committee on Animal Nutrition from a reputable dealer.

Unopened bags of food must be stored off the floor on a rack. Unused, open bags of food must be stored in vermin-proof containers (generally 55 gallon Rubbermaid trashcans with a sealable lid). Food should be checked on a daily basis for contamination.

Feeders should allow easy access to food and minimize potential contact and contamination with urine or feces. Arcadia University uses metal or wire cage tops with built in feeders.

2. Water:
Animals "*should have access to potable, uncontaminated drinking water according to their particular requirements."* (The Guide, page 40). Arcadia University uses tap water provided using standard glass bottles with rubber stoppers and metal sipper tubes.

Water bottles, rubber stoppers, and sipper tubes should be checked daily to ensure maintenance, cleanliness, and operation. Water bottles should be drained and refilled or replaced at least once every other day. If the water bottles are drained and refilled, the bottle should be returned to the appropriate cage to minimize the potential for microbiological cross-contamination.

Water bottles, rubber stoppers, and sipper tubes should be cleaned and sterilized at least once per week.

3. Bedding:
Arcadia University uses untreated softwood shavings and chips as bedding.

Unopened containers of bedding must be stored off the floor on a rack. Unused, open bags of bedding must be stored in vermin-proof containers (generally 55 gallon Rubbermaid trashcans with a sealable lid). Unused bedding should be checked prior to use for presence of moisture or contamination.

Bedding should allow for the animals to remain clean and dry between cage changes. Care should be taken to prevent contact between the bedding and the water tubes to prevent leakage into the cage.

"Soiled bedding should be removed and replaced with fresh materials as often as is necessary to keep the animals clean and dry." "There is no absolute minimal frequency of changing bedding, but it typically varies from daily to weekly." Bedding is provided in sufficient quantity to keep the animals dry. Soiled bedding is changed as necessary, but at least once a week. If bedding becomes wet and/or matted it is changed more frequently. In general, cages with multiple animals are changed biweekly. Unless approved by the IACUC for specific experimental purposes (e.g. postpartum period), the bedding should be changed no less frequently than once per week.

4. Cleaning and Disinfecting:

"*Solid-bottom caging, bottles, and sipper tubes usually require sanitation at least once a week.*" (The Guide, 43)
Cages, bottles, and wire lids are washed weekly using a Basil Equipment Corporation Model CW3500 Cage and Bottle washer maintained by Pharamacol Research Laboratories. The machine runs through a normal cycle using a high temperature Alkadet 3 wash and two rinses. The sanitizing agent currently used in the cage and bottle washer is Alkadet 3 from Pharmacol Research Laboratories, Naugatuck, CT.

D. Secondary Enclosures:

Each animal room has its own set of cleaning implements; including brooms, dustpans, mops, buckets, and rags. Each animal room is to be swept daily. At a minimum, the floors are mopped with a Lestoil and water solution weekly. Walls are cleaned at least monthly with a Lestoil and water solution.

E. Waste Disposal:

1. Soiled Bedding and Refuse
Soiled bedding and refuse is collected and sealed in large plastic garbage bags. These bags are collected daily by the Facilities Department for incineration off-site.

2. Animal Carcasses
Animal carcasses are stored in a freezer until periodic removal with other biohazard infectious waste by contract with the appropriate vendor (currently Stericycle Inc.). Removal of the waste occurs throughout the year on an as needed basis dependent upon the amount of waste generated.

3. Hazardous Wastes
No hazardous materials have been used with animals in the recent past, and there is no current plan to use hazardous materials with animals in the future. If animals are exposed to hazardous materials a plan will be created prior to IACUC approval for the proper disposal of wastes utilizing a current contract with the appropriate vendor (currently Clean Harbor) for the removal of hazardous chemical wastes from campus.

F. Pest Control
The University has a contract with Ecolab for pest control services. Ecolab conducts periodic inspections of Boyer Hall, including the animal facilities, and makes recommendations for dealing with any identified pest problems. Ecolab is also available on an as-needed basis for concerns that arise between scheduled visits. Prior to pest treatment, Faculty sponsors of research projects are notified by the Facilities Department.

G. Emergency, Weekend, and Holiday Care
At least once a day (including weekends and Holidays) a member of the Research Staff or Animal Care Personnel will visually inspect each animal to assess animal health and well-being, appropriate food and water. Contact information for Faculty sponsors of research projects is available in the animal housing rooms. In the event of a problem or concern the individual inspecting the animals will contact the Faculty sponsor, who will make a decision regarding appropriate action. This may involve returning to campus to conduct their own assessment of the circumstances or contacting the on-call veterinarian.

H. Identification and Records:
Cage cards are maintained for each animal documenting (1) IACUC protocol number; (2) unique animal identifier number or code; (3) source of animal; (4) name and contact information for investigator; (5) relevant dates, such as date of arrival or date of birth; and (6) special experimental information such as diet restriction.

Investigators are expected to maintain detailed records for each animal documenting (1) source of animal; (2) relevant dates, such as date of arrival, date of birth, date of experimental procedures; (4) animal disposition.

Veterinary Medical Care:

A. Animal Procurement:
Animals are purchased from a reputable vendor approved by the IACUC. Currently animals are obtained from Charles River Laboratory and Harlan.

B. Preventive Medicine:

1. Quarantine and Stabilization:
a. Receiving and Initial Evaluation Procedures
When animals are received from the source (Charles River) they are transferred to standard cages during which time they are examined with regard to appearance, weight, and behavior. Animals which appear sick, underweight, or abnormal behavior (lethargic or hyperactive) are brought to the attention of the faculty member in charge. There is normally no official quarantine procedure since all animals are obtained from the same supplier.

b. Isolation Facilities and Procedures for Ill Animals
There are currently no isolation facilities available for ill animals. In general, ill animals are euthanized to minimize potential pain or discomfort.

c. Periods for Physiologic, Psychologic, and Nutritional Stabilization
Animals are allowed to acclimate to the Arcadia Animal facilities for a minimum of one week prior to the start of experimental procedures. During that time, the animals may begin nutritional stabilization (food restriction) or psychologic conditioning (isolated, group, or enriched housing).

2. Surveillance, Diagnosis, Treatment, and Control of Disease:

a. Program: All animals are observed daily during normal feeding and watering. Any animals exhibiting abnormal health or behaviors are reported to the faculty advisor/sponsor for the research project. The faculty member evaluates the animal and determines the appropriate response. When animals are deemed to require veterinary care, the faculty advisor contacts the veterinarian to schedule evaluation and possible treatment. A copy of all medical records are maintained by both the veterinarian and faculty advisor/sponsor.

b. Diagnostic Resources: Arcadia University does not maintain on-site diagnostic facilities.
We utilize diagnostic services through Charles River Laboratories to monitor colony health.
Every six months, serum samples from two sentinel rats are submitted for the ASSESMENT-level profile. This series of tests includes SEND, PVM, SDAV, KRV, H-1, REO, MPUL, RPV, RMV, TMEV, LCMV, and MAV.

C. Surgery:

1. Surgical Monitoring
All surgical plans are evaluated by the IACUC with special attention by the veterinarian. Surgical procedures are conducted by the Ph.D.-level investigator who monitors all aspects of pre-surgery, surgery, and post-surgery procedures.

2. Presurgical Planning

All animal surgical procedures are developed in collaboration with the investigator and veterinarian. At a minimum the planning involves pre-surgical preparation, decision on anesthesia, surgical design, post-surgical care, and euthanasia plan.

3. Training Program

Currently surgical procedures are only conducted by Ph.D.-level investigators who have completed training elsewhere. There is currently no plan for undergraduate students to conduct surgical procedures, although they may assist in portions of the protocols (anesthesia) under the direct supervision of the investigator. In the future, if another individual is approved for conducting surgery they will undergo extensive training by the investigator and be certified as proficient after observation by the veterinarian.

4. Major and Minor Procedures

Major surgical procedures are defined as those that involve penetration and exposure "*of a body cavity or produces substantial impairment of physical or physiological functions*." Minor surgical procedures are those protocols that do not fulfill these criteria.

5. Aseptic Procedures

Rat surgeries are conducted using aseptic practices. Counter or table-top surfaces are cleaned with bleach prior to surgery. Areas of incision are shaved and then cleaned with 70% ethanol. Autoclave sterilized instruments are used. These instruments may be cleaned with 70% ethanol during the procedure as needed. Surgical personnel wear gloves and lab coats during the procedures. Animals are monitored until they have completed recovered from exposure to anesthesia prior to being returned to their home cage.

D. Pain, distress, and anesthesia

1. Pain and distress categories:

The researcher is responsible for making an informed judgment on the category of pain and/or distress experienced by animals in the study. In addition, members of the IACUC and the veterinarian use their judgment in determining if the category assigned appears appropriate.

The IACUC follows the specific categories defined by the USDA such that:

Category	Definition	explanation
C:	No pain or distress beyond that involved in the restraint, injections, or collection of samples.	This level corresponds to procedures similar to those expected in a human medical office visit and would include such procedures as obtaining blood samples through venipuncture.
D:	potential for pain or distress but relief is provided by analgesics and/or sedatives as appropriate.	This level corresponds to procedures that if conducted on a human would involve analgesics or anesthetics. Examples of these procedures would include all surgeries. These procedures must be approved by the veterinarian prior to IACUC approval.
E:	pain or distress not relieved by sedatives or analgesics.	This level corresponds to well-documented and designed studies of limited pain or stress in which providing sedatives or analgesics would interfere with the results of the study. These procedures must be approved by the veterinarian prior to IACUC approval.

2. IACUC Guidelines for Avoiding Unnecessary Pain or Distress

The Institutional Animal Care and Use Committee requires that "…*The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources… used to determine that alternatives were not available."* [Federal Animal Welfare Act (9 CFR 2.31(d)iii]. In these circumstances, the investigator must complete a special form describing why alternatives are not possible under these circumstances.

All protocols in which animals are subjected to any level of pain or distress are carefully reviewed by the veterinarian. In addition, the review of these studies generally requires a much more detailed justification including references to peer-reviewed journal articles and a well-designed experimental plan.

3. Agents Used for Each Species

All protocols requiring analgesia or anesthesia must be reviewed and approved by the veterinarian prior to IACUC approval. It is recommended that a researcher communicate with the veterinarian prior to submitting a protocol to develop an appropriate plan and avoid a delay in IACUC review and approval. Any surgical procedures involving anesthetic gases should be completed in a well-ventilated room or under a hood.

Potential anesthetics approved for use are:

Sodium Pentobarbital – 40 mg/kg body weight i.p.
Methoxyfluorane – inhalation
Ether - inhalation

E. Euthanasia

The only animals being euthanized are rats. The two procedures for euthanasia are CO2 asphyxiation or anesthesia overdose.

1. CO2 asphyxiation

When a large number of animals are to be euthanized without the need for tissue collection, several animals will be placed into a chamber and the chamber will be filled with CO2. Euthanasia will be confirmed and the animals stored in the freezer prior to disposal.

2. Anesthesia overdose

If animals are being euthanized and tissues are to be collected, the animals will first be deeply anesthesized and the relevant tissues collected. Depending upon the tissues being collected, cardiac puncture will be completed either prior to or after tissue collection.

F. Drug Storage and Control

Drugs are stored in a large safe located in Boyer 118 or locked cabinets within individual laboratories. Each researcher is responsible for maintaining records related to use of drugs; including quantity of drug used or prepared, animal doses administered, and expiration dates. Each researcher is responsible for ensuring that drugs and reagents are within their date of expiration. A new annual chemical inventory plan implemented by the University may assist in identifying expired drugs.

Report on Animal Use Program
A. Animal Facility Inspections:
The IACUC will appoint a subcommittee to 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.

IACUC members or designated subcommittee will make unannounced inspection tours of the animal facilities at least twice annually. They will conduct repeat visits as needed to any area where deficiencies have been found and communicated to ensure that any recommended changes have been implemented. During these site visits, the IACUC members will review each facilities program and documentation.

The Arcadia University program of animal care and use will include attention to:

- aspects of the physical plant where animals are housed such as location, components, construction, management, and operation;
- the physical and social environment of the animals;
- animal husbandry which encompasses food, water, bedding, sanitation, waste disposal, and pest control;
- animal identification, genetic monitoring, and animal health records; and
- daily observation of and care for animals, including weekends and holidays.

B. Facilities Report:
The Committee will relay to the responsible administrator deficiencies noted during inspections. The committee will work with the responsible administrator to develop a plan and timeline for correction of the deficiencies or for an explanation why the deficiencies cannot be corrected within the timeline. The Committee will require deficiencies that potentially compromise animal welfare to be corrected as soon as possible. Results of the inspections will be recorded in the IACUC minutes. The minutes will be provided to the Institutional Official.

Reporting Requirements:
The IACUC will prepare reports of the IACUC evaluations and submit the reports to the Institutional Official (Associate Dean for Research, Scholarly, and Creative Activities□□□□). The IACUC process for developing reports and submitting them to the Institutional Official is to assign a subcommittee of members to prepare the report and to have the completed report approved by the entire committee before final submission.

A. Minutes: Meeting minutes will be prepared and submitted to the Institutional Official and stored in the IACUC archive.

B. Semi-Annual Reports: The IACUC will report to the Institutional Official:

1. The results of the biannual review the institution's program for humane care and use of animals
2. A summary of activities related to the care and use of animals in research, teaching, and testing.
3. The results of the inspection of the animal facilities.

C. Submission of reports to accrediting agencies: The IACUC will assist the Institutional Official in the preparation of annual reports to the appropriate accrediting agencies. This includes but is not limited to:

A. Animal Welfare Assurance

B. Annual Reports to PHS OLAW (or equivalent subsequent office). This report includes:

1. Any change in the status of the institution (*e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked*), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.

2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official (Associate Dean for Research, Scholarly, and Creative Activities- John R. Hoffman, PhD□□□□).

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

A. Any serious or continuing noncompliance with the PHS Policy.

B. Any serious deviations from the provisions of the Guide.

C. Any suspension of an activity by the IACUC.

4. Reports filed under shall include any minority views filed by members of the IACUC.

Appendices:

Supplemental Materials in Manual:

Essentials for Animal Research: A primer for research personnel

Safety in Academic Chemistry Laboratories: Accident prevention for college and university students. 7th ed.

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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

TABLE OF CONTENTS

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, shall 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 shall 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 shall not be construed to prescribe methods of research.

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

"(b)

(1) Guidelines of the Secretary under subsection (a)(3) shall 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 shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall 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 shall-

"(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) shall include any minority views filed by members of the committee.

"(c) The Director of NIH shall 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 shall 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 shall 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 shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall 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 shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall 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 shall 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 shall be submitted to the Office of Laboratory Animal Welfare (OLAW), Office of the Director, National Institutes of Health.[1] The Assurance shall 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 shall 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 shall 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.[2] 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;[3]

   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.[4] 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 shall be submitted to OLAW with the Assurance.

3. Institutional Animal Care and Use Committee (IACUC)

a. The Chief Executive Officer shall 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.[5]

b. The Assurance must include the names,[6] position titles, and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall 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 shall 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;[7]

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;[8] (NOTE: The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall 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 shall 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 shall 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.[9] Further, the IACUC shall 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.[10]

2. Prior to the review, each IACUC member shall 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 shall 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, shall 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 shall 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 shall 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 shall 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.[11] 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 shall 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 shall 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 shall 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 shall state the modifications, if any, required by the IACUC. The verification shall 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 shall constitute a declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in

accordance with IV.A. of this Policy. The authorized IACUC shall 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 shall submit the Assurance to OLAW.

E. Recordkeeping Requirements

1. The awardee institution shall 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 shall 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 shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall 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, shall 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;[12] 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, shall 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, shall 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*;[13] or

c. any suspension of an activity by the IACUC.

4. Reports filed under IV.F. of this Policy shall 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 shall 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.

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Appendix II. IACUC Semi-Annual Program Review Form
ARCADIA UNIVERSITY
SEMIANNUAL PROGRAM REVIEW CHECKLIST

Semiannual Program and Facility Review Report

Date:

Members in attendance

Deficiency Category (S or M)	*	Location	Deficiency & Plan for Correction	Responsible Party	Correction Schedule & Interim Status	Date Complete

S = *significant deficiency,* **M** = *minor deficiency (a significant deficiency is or may be a threat to animal health or safety)*

Check if repeat deficiency

Appendix II. IACUC Semi-Annual Program Review Form
ARCADIA UNIVERSITY
SEMIANNUAL PROGRAM REVIEW CHECKLIST

INSTITUTIONAL POLICIES AND RESPONSIBILITIES

DATE:

1. IACUC MEMBERSHIP AND FUNCTIONS	A	M	S
- at least 5 members, appointed by CEO			
- members include veterinarian, scientist, non-scientist, and non-affiliated non-lab animal user			
- responsible for oversight and evaluation of institution's program			
- reports to Institutional Official (IO)			
- conducts semiannual evaluations of institutional animal care and use program			
- conducts semiannual inspections of institutional animal facilities			
- reviews and investigates concerns about animal care and use at institution			
- procedures for review, approval and suspension of animal activities			
- procedures for review & approval of significant changes to approved activities			
- policies for special procedures (e.g. restraint, multiple survival surgery, fluid restriction)			
2. IACUC RECORDS AND REPORTING REQUIREMENTS			
Reports to Institutional Official (IO)			
- reports of semiannual program reviews & facility inspections are submitted to IO			
- include minority IACUC views			
- describe departures from *Guide* or PHS Policy and reasons for departure			
- distinguish significant from minor deficiencies			
- include plan and schedule for correction of each deficiency identified			
Reports to Office of Laboratory Animal Welfare (OLAW)			
- reports include any minority IACUC views			
- annual report to OLAW documents program changes & dates of IACUC semiannual review			
- promptly advises OLAW of serious/ongoing *Guide* deviations or *PHS Policy* noncompliance			
- promptly advises OLAW of any suspension of activity by the IACUC			
Reports to United States Department of Agriculture (USDA)			
- annual report contains required information			
- reporting mechanism in place for IACUC-approved exceptions to the regulations and standards			
- reports within 15 days failure to adhere to timetable for correction of deficiencies			
- reports suspension of activity by the IACUC to USDA and any Federal funding agency			
Records			
- minutes of IACUC meetings and semiannual reports maintained for 3 years			
- IACUC review documentation maintained for 3 years after end of study			
- IACUC review of activities involving animals includes all required information			
3. VETERINARY CARE (See also next section - Veterinary Medical Care)			
- institutional arrangement for veterinarian with training or experience in lab animal medicine			
- veterinary access to all animals			
- provision for backup veterinary care			
- must provide guidance on handling, immobilization, sedation, analgesia, anesthesia, euthanasia			
- must provide guidance/oversight on surgery programs and oversight of postsurgical care			
- veterinary authority to oversee all aspects of animal care and use			

***A** = acceptable; **M** = minor deficiency; **S** = significant deficiency (is or may be a threat to animal health or safety)

Appendix II. IACUC Semi-Annual Program Review Form
ARCADIA UNIVERSITY
SEMIANNUAL PROGRAM REVIEW CHECKLIST

INSTITUTIONAL POLICIES AND RESPONSIBILITIES

DATE:

4. PERSONNEL QUALIFICATIONS AND TRAINING	**A**	**M**	**S**
- institution has established and implemented an effective training program			
- includes professional/management/supervisory personnel			
- includes animal care personnel			
- includes research investigators, instructors, technicians, trainees, students			
Training program content			
- humane practices of animal care (e.g. housing, husbandry, handling)			
- humane practices of animal use (e.g. research procedures, use of anesthesia, pre- & post-operative care)			
- research/testing methods that minimize numbers necessary to obtain valid results			
- research/testing methods that minimize animal pain or distress			
- use of hazardous agents, including access to OSHA chemical hazard notices where applicable			
5. OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL			
Institutional program for a safe and healthy workplace			
- program is established and implemented			
- covers *all* personnel who work in laboratory animal facilities			
- based on hazard identification and risk assessment			
- personnel training (e.g. zoonoses, hazards, pregnancy/illness/immunosuppression precautions)			
- personal hygiene procedures (e.g., work clothing, eating/drinking/smoking policies)			
- procedures for use, storage & disposal of hazardous biologic, chemical, and physical agents			
- specific procedures for personnel protection (e.g., shower/change facilities, injury prevention)			
Program for medical evaluation and preventive medicine for personnel			
- pre-employment evaluation including health history			
- immunizations as appropriate (e.g. rabies, tetanus) & tests			
- zoonosis surveillance as appropriate (e.g. Q-fever, tularemia, Hantavirus, plague)			
- procedures for reporting and treating injuries, including bites etc.			

Notes:

***A** = acceptable; **M** = minor deficiency; **S** = significant deficiency (is or may be a threat to animal health or safety)

Appendix II. IACUC Semi-Annual Program Review Form
ARCADIA UNIVERSITY
SEMIANNUAL PROGRAM REVIEW CHECKLIST

VETERINARY MEDICAL CARE

DATE:

1. PREVENTIVE MEDICINE/ANIMAL PROCUREMENT & TRANSPORTATION	**A**	**M**	**S**
- evaluation of animal vendors			
- procedures for lawful animal procurement, evaluation of animals, & transport			
- procedures for quarantine, stabilization			
- policies on separation by species, source, health status			
- policies for isolation of sick animals			
- program of surveillance, diagnosis, treatment and control of disease			
- availability of diagnostic resources for preventive health program			
- provision for emergency, weekend and holiday veterinary care			
2. SURGERY			
- procedures for monitoring surgical anesthesia and analgesia			
- pre-surgical plan (e.g. identify space, supplies, conduct pre-op exam, define post-op care)			
- appropriate training or experience of personnel in surgery & anesthesia			
- major procedures distinguished from minor			
- use of effective aseptic procedures for survival surgery			
- implemented procedures for use of surgical facility			
- implemented procedures for using/scavenging volatile anesthetics			
- effective procedures for sterilizing instruments & monitoring expiration dates on sterile packs			
- documentation of post-operative monitoring and care			
3. PAIN, DISTRESS, ANALGESIA, AND ANESTHESIA			
- guidelines for assessment and categorization of pain			
- IACUC guidelines for avoiding unnecessary pain and distress			
- appropriate anesthetics, analgesics, tranquilizers used for each species			
- special precautions for the use of paralytics			
- veterinary input in the choice of drugs			
4. EUTHANASIA			
- compliance with current AVMA Panel on Euthanasia unless approved by the IACUC			
- guidance provided on appropriate methods for each species			
- training available for personnel in humane methods of euthanasia			
5. DRUG STORAGE AND CONTROL			
- safe, secure, storage arrangement			
- record keeping meets regulations			
- procedures exist for ensuring drugs are within expiration date			
Notes:			

***A** = acceptable; **M** = minor deficiency; **S** = significant deficiency (is or may be a threat to animal health or safety)

Appendix II. IACUC Semi-Annual Program Review Form
ARCADIA UNIVERSITY
SEMIANNUAL PROGRAM REVIEW CHECKLIST

ANIMAL HOUSING & SUPPORT AREAS

DATE:

	*A	M	S	NA
ANIMAL HOUSING AND SUPPORT AREAS				
Location: Animal areas separate from personnel areas, separation of species, separation by disease status.				
Construction: Corridors, doors, windows, floors, drainage, walls, ceiling, HVAC, power, lighting, noise				
Room: temperature, humidity, ventilation, illumination, noise control				
Cage: sanitation, cleaning tools, food/water access, security, safety				
Food: feeding schedule & procedures, contamination, vendor quality control,				
Food: storage in sealed containers, expiration date labeling, vermin control, rotation of stocks				
Water: ad libitum unless justified, QC procedures				
Bedding: species appropriate, QC procedures				
Sanitation: frequency of bedding changes, cleaning & disinfection, monitoring				
Waste disposal: procedures for collection, storage & disposal of waste; animal carcasses				
Pest control: regularly scheduled, documented program for control of rodent and insect pests				
Emergency, weekend & holiday animal care: provision for, accessible contact information				
Animal identification and records: cage/rack cards contain required information				
Storage: food and bedding, supplies, drugs and biologics, waste material, hazardous material.				
CAGE WASH				
Sufficient space for workload				
Traffic flow clean to dirty with no contamination of clean equipment by dirty equipment				
Insulation and/or sound attenuation present as needed				
Utilities are appropriate				
Ventilation meets heat and humidity load and Guide requirements				
Safety features (SOP's, warning signs, eyewash station) are in use				
Cagewash temperatures are monitored & records are available				
Appropriate clean cage storage				
ASEPTIC SURGERY				
General considerations				
-location minimizes traffic/ contamination				
Appropriate drug storage, control, expiration date monitoring				
Safe sharps disposal system				
Adequate records of anesthesia and perioperative care				
Aseptic procedures in use for all survival surgery				
Operating area has effective contamination control procedures				
Effective cleaning procedures and dedicated tools				
Autoclave monitoring procedures are implemented				
Notes:				

***A** = acceptable; **M** = minor deficiency; **S** = significant deficiency (is or may be a threat to animal health or safety);
NA = not applicable

Appendix II. IACUC Semi-Annual Program Review Form
ARCADIA UNIVERSITY
SEMIANNUAL PROGRAM REVIEW CHECKLIST

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Appendix III. IACUC Animal Care and Use training.

Animal Care and Use Training

Arcadia University is required by Federal Regulations to provide training for all personnel involved in the use and/or care of live vertebrate animals in research, testing and teaching.

Specifically, the Animal Welfare Act as Amended (7 USC, 2131-2156) Section #13 states:

(d) Training of scientists, animal technicians, and other personnel involved with animal care and treatment of research facilities. Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility as required by the Secretary. Such training shall include instruction on--

(1) the humane practice of animal maintenance and experimentation;

(2) research of testing methods that minimize or eliminate the use of animals or limit animal pain or distress;

(3) utilization of the information service at the National Agricultural Library, established under subsection (e); and

(4) methods whereby deficiencies in animal care and treatment should be reported.

In addition,
USDA Regulations (9 CFR 2:32 Federal Register 54 (168) Thursday, August 31, 1989) require that the institution make available training in:

1. *"Humane methods of animal maintenance and experimentation, including:*
    i. *The basic needs of each species of animal*
    ii. *Proper handling and care for the various species of animals used by the facility*
    iii. *Proper pre-procedural and post-procedural care of animals and*
    iv. *Aseptic surgical methods and procedures*
2. *The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress*
3. *Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility*
4. *Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility.*
5. *Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:*
    i. *on appropriate methods of animal care and use*
    ii. *on alternatives to the use of live animals in research*
    iii. *that could prevent unintended and unnecessary duplication of research involving animals*
    iv. *regarding the intent and requirements of the [Animal Welfare] Act."*

In order to comply with the aforementioned Federal requirements, a training program has been established which consists of specific training on guidelines for the use of animals in research, techniques of animal research, and hands-on demonstration of competencies.

Appendix III. IACUC Animal Care and Use training.

IACUC Animal Use Levels:
The IACUC recognizes that there will be a wide range in skills and responsibilities of individuals based on the types of animal care, treatment, or use activities that the individual will be completing. Therefore, the Arcadia University IACUC has created different levels of Animal Users-based on responsibilities and provides training based on these specific needs.

Level 1 Animal User:

Responsibilities: These individuals have minimal contact with live animals, but are involved in caring for the animal (providing food, water, clean housing, and monitoring health). These individuals will need general background on regulations, routine care and handling, and standard policies regarding the use of laboratory animals.

Training: Level 1 Animal Users will
- Receive a copy of the Arcadia University "Animal Care and Use Manual"
- Complete the "*PHS Policy on Humane Care and Use of Laboratory Animals Tutorial*" located in Appendix IV or online at: http://grants.nih.gov/grants/olaw/tutorial/index.htm
- Read the following chapters in *"Essentials for Animal Research: A Primer for Research Personnel, 2nd Edition*." Located in supplemental materials or online at: http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm
  - Chapter 1 – Regulations and Requirements
  - Chapter 2 – Alternative Methodologies
  - Chapter 3 – Animal Care and Use: A Non-experimental Variable
- Pass the IACUC "Level 1 Animal Care and Use Certification Exam"

Certification: Level 1 Animal Users will receive certification documenting the successful completion of the Level 1 training requirements. This certification is valid for 1 year. Individuals must have current certification status prior to beginning work with animals.

Level 2 Animal User:

Responsibilities: These individuals will have all of the responsibilities of the Level 1 Animal Users, but will also be involved in simple animal procedures such as behavioral testing, injections, specimen collection, or euthanasia. These individuals need hands-on training on the relevant protocols.

Training: Level 2 Animal Users will
- Complete all of the requirements for Level 1 Animal Care User
- Read the following chapters in *"Essentials for Animal Research: A Primer for Research Personnel, 2nd Edition*." Located in Supplemental materials or online at: http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm
  - Chapter 7 – euthanasia
- Read relevant scholarly articles or standard protocols related to their procedures
- if requested by the IACUC, demonstrate proficiency in the technique or protocol to a IACUC assigned trainer (Veterinarian, Faculty Animal Care Representative, or IACUC designate)

Certification: Level 2 Animal Users will receive a letter from the IACUC-assigned trainer documenting the techniques and procedures that the user is certified to complete. This certification is valid for 1 year. Individuals must have current certification status prior to conducting these techniques. If techniques are needed beyond the current certification, proficiency will need to be demonstrated prior to using the new techniques.

Level 3 Animal User:

Responsibilities: These individuals will have all of the responsibilities of the Level 1 and Level 2 Animal Users, but will also be involved in advanced animal procedures such as anesthesia and surgical procedures. These individuals need hands-on training on the relevant protocols.

Training: Level 3 Animal Users will

- Complete all of the requirements for Level 1 and Level 2 Animal Care User
- - Read the following chapters in *"Essentials for Animal Research: A Primer for Research Personnel, 2nd Edition*." Located in Supplemental materials or online at:
  http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm
  Chapter 4 – Principles of Anesthesia and Analgesia
  Chapter 5 – Principles of Aseptic Surgery
  Chapter 6 – Perioperative Care
- Read relevant scholarly articles or standard protocols related to their procedures
- if requested by the IACUC, demonstrate proficiency in the technique or protocol to a IACUC assigned trainer (Veterinarian, Faculty Animal Care Representative, or IACUC designate)

Certification: Level 3 Animal Users will receive a letter from the IACUC-assigned trainer documenting the techniques and procedures that the user is certified to complete. This certification is valid for 1 year. Individuals must have current certification status prior to conducting these techniques. If techniques are needed beyond the current certification, proficiency will need to be demonstrated prior to using the new techniques.

Appendix III. IACUC Animal Care and Use training.

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http://grants.nih.gov/grants/olaw/tutorial/index.htm

A tutorial for new animal care and use committee members, institutional administrators, investigators, animal care personnel, veterinarians, or others who are interested in learning about the PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/phspol.htm).
Comments and suggestions about this tutorial are welcome and should be sent to: olaw@od.nih.gov.

web posting: 2000/03/27
captured and converted to pdf: 2005/07/14

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

Table of Contents

INTRODUCTION

- Health Research Extension Act of 1985
- Office of Laboratory Animal Welfare
- Applicability of the PHS Policy

Health Research Extension Act of 1985

The Health Research Extension Act of 1985 (Public Law 99-158; http://grants.nih.gov/grants/olaw/references/hrea1985.htm) provides the legislative mandate for the PHS Policy (http://grants.nih.gov/grants/olaw/references/phspol.htm). It directs the Secretary of Health and Human Services to establish guidelines for the proper care and treatment of animals used in research, and for the organization and operation of animal care committees. The law requires that the guidelines address appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia, and appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals. The requirements for reporting minority views of animal care committee members, for Animal Welfare Assurances, and for instruction or training in methods that limit the use of animals or limit animal distress, are all embodied in this Act. The PHS Policy implements the Health Research Extension Act of 1985.

Office of Laboratory Animal Welfare (OLAW)

The Office of Laboratory Animal Welfare (http://grants.nih.gov/grants/olaw/olaw.htm), or OLAW (formerly the OPRR Division of Animal Welfare) implements the PHS Policy. While OLAW is located organizationally at the National Institutes of Health (http://www.nih.gov/) in Bethesda, Maryland, OLAW's responsibility for laboratory animal welfare extends beyond NIH to all PHS supported activities involving animals.

Specific OLAW responsibilities include:

- implementation of the PHS Policy;
- interpretation of the PHS Policy;
- negotiation of Animal Welfare Assurances;
- evaluation of compliance with the PHS Policy; and
- education of institutions and investigators receiving PHS support.

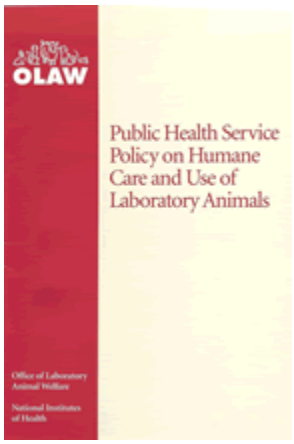
From time to time OLAW issues policy guidance, interpretation, or general notices regarding the PHS Policy, which may be accessed through an Index (http://grants.nih.gov/grants/olaw/references/pubartindex.htm).

Another educational OLAW activity is the cosponsorship of animal welfare workshops (http://grants.nih.gov/grants/olaw/workshop.htm) that are held in different locations across the country each year.

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

Applicability of the PHS Policy

The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the Public Health Service (PHS; http://phs.os.dhhs.gov/ophs/default.htm). PHS agencies include:



- Agency for Health Care Policy Research; http://www.ahcpr.gov/

- Agency for Toxic Substances and Disease Registry; http://atsdr1.atsdr.cdc.gov:8080/atsdrhome.html

- Centers for Disease Control and Prevention; http://www.cdc.gov/

- Food and Drug Administration; http://www.fda.gov/fdahomepage.html

- Health Resources and Services Administration; http://www.hrsa.gov/

- Indian Health Service; http://www.ihs.gov/

- National Institutes of Health; http://www.nih.gov/

and

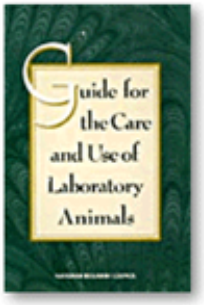
- Substance Abuse and Mental Health Services Administration; http://www.samhsa.gov/

DOCUMENTS RELEVANT TO THE PHS POLICY

- Guide for the Care and Use of Laboratory Animals
- United States Government Principles for the Utilization and Care of Vertebrate Animals
- Animal Welfare Regulations
- Report of the AVMA Panel on Euthanasia

Compliance with the PHS Policy requires familiarity with each of these documents. This section describes each one and its relevance to the PHS Policy.

Guide for the Care and Use of Laboratory Animals



The *Guide for the Care and Use of Laboratory Animals* (http://www.nap.edu/readingroom/books/labrats/) is a widely accepted primary reference on animal care and use. The seventh and latest edition of the *Guide*, published in 1996, was written under the auspices of the Institute for Laboratory Animal Research (http://dels.nas.edu/ilar/) of the National Academy of Sciences (http://www4.nationalacademies.org/nas/nashome.nsf).

The 1996 *Guide* demonstrates a shift toward performance standards which emphasize outcomes, as opposed to engineering standards which are prescriptive and may not allow sufficient flexibility or professional judgment to deal with unique circumstances. Recommendations in the *Guide* are based on published data, scientific principles, expert opinion, and experience with methods and practices that are consistent with high-quality, humane animal care and use. Extensive references found at the end of each chapter are key features of the *Guide*.

The *Guide* is intended to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. Included in the *Guide* are descriptions of institutional responsibilities and professional standards. Institutional responsibilities include monitoring animal care and use, provisions for veterinary care, training for personnel, and the establishment of an appropriate occupational health and safety program. Professional standards encompass the animal environment, animal husbandry and management, veterinary care, and design and construction of animal facilities.

Familiarity with the standards and recommendations of the *Guide* is important because the PHS Policy mandates that institutions use the *Guide* as a basis for developing and implementing an animal care and use program.

United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

The PHS Policy implements nine U.S. Government Principles that are the foundation for humane care and use of laboratory animals in this country. These principles were developed by the Interagency Research Animal Committee and adopted in 1985 by the Office of Science and Technology Policy (http://www.ostp.gov/index.html). The principles are:

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 shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall 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.

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

*For guidance throughout these Principles, the reader is referred to the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute for Laboratory Animal Research, National Academy of Sciences.

Animal Welfare Regulations

The Animal Welfare Act (AWA), initially enacted in 1966 and amended in 1970, 1976, 1985, 1990, and 2002, is the principal Federal statute governing the sale, handling, transport and use of animals. The United States Department of Agriculture (USDA; http://www.usda.gov/) , Animal and Plant Health Inspection Service (APHIS; http://www.aphis.usda.gov/)/Animal Care (AC; http://www.aphis.usda.gov/ac/) implements the AWA through the Animal Welfare Regulations found in the Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3 (http://www.access.gpo.gov/nara/cfr/waisidx_98/9cfrv1_98.html).

The AWA applies to all species of warm blooded vertebrate animals used for research, testing, or teaching, except farm animals used for agricultural research. The Farm Security and Rural Investment Act of 2002 amendments to the regulations that implement the AWA currently also exempt birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research.

The 1985 amendments to the AWA (Public Law 99-198, the Improved Standards for Laboratory Animals Act) were considered a watershed for laboratory animal welfare because for the first time the AWA clarified humane care, minimization of pain and distress, consideration of alternatives, institutional animal care and use committees, psychological well-being of primates, and exercise for dogs.

Compliance with the Animal Welfare Regulations, as applicable, is an absolute requirement of the PHS Policy.

Through a formal Memorandum of Understanding (http://grants.nih.gov/grants/olaw/references/finalmou.htm), USDA, FDA and NIH cooperate with one another to facilitate implementation of, and foster institutional compliance with, the Animal Welfare Regulations and the PHS Policy.

Report of the AVMA Panel on Euthanasia

The PHS Policy requires that euthanasia be conducted in a manner that is consistent with the professional guidance for relieving pain and suffering of animals found in the Report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia (Report; http://www.avma.org/resources/euthanasia.pdf). This Report is updated from time to time; the most recent version is dated 2000.

The Report discusses only methods and agents supported by data from scientific studies. It emphasizes professional judgment, technical proficiency, and humane handling of the animals. Deviations from the Report are permitted by the PHS Policy only if the IACUC determines that they are justified for scientific reasons.

TERMS AND CONCEPTS

- Program of Animal Care and Use
- Institutional Official
- Animal Welfare Assurance
- Enforced Self-Regulation

Program of Animal Care and Use

The PHS Policy not only addresses the humane use of animals, but the entire institutional *program of animal care and use*. There are many components to a program and although no two institutional programs are identical, all programs are expected to include:

- designation of an Institutional Official;
- appointment of an Institutional Animal Care and Use Committee (IACUC);
- administrative support for the IACUC;
- standard IACUC procedures;
- arrangements for a veterinarian with authority and responsibility for animals;
- adequate veterinary care;
- formal or on-the-job training for personnel that care for or use animals;
- an occupational health and safety program for those who have animal contact;
- maintenance of animal facilities; and
- provisions for animal care.

The next section, Animal Programs, describes in detail each component of a program of animal care and use.

Institutional Official

The *Institutional Official* is a formally designated senior official with the authority to administer the program of animal care and use, and to make commitments on behalf of the institution to ensure compliance with the PHS Policy.

The Institutional Official relies on the IACUC to oversee the program, to develop plans to correct program deficiencies, to address concerns that may arise regarding the institution's use of animals, and to make recommendations with regard to the program. Through semiannual reports to the Institutional Official and open channels of communication, the IACUC keeps the Institutional Official informed of the status of the program and alerts the Official to potential noncompliance with the PHS Policy.

Documents submitted to OLAW, such as an Animal Welfare Assurance, annual report, or reports of noncompliance, are submitted by the IACUC, through the Institutional Official, and should bear his or her signature as the official responsible for animal welfare at the institution.

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

Animal Welfare Assurance

Before the PHS may award a grant or contract that involves the use of animals, the recipient institution and all performance sites involving or using animals must have on file with OLAW an approved Animal Welfare Assurance.

The Assurance is the cornerstone of a trust relationship between the institution and the PHS. Included in the Assurance are:

- a commitment that the institution will comply with the PHS Policy, with the *Guide for the Care and Use of Laboratory Animals*, and with the AWA and the Animal Welfare Regulations;
- a description of the institution's program for animal care and use; and
- the designation of the Institutional Official responsible for compliance.

A Sample Assurance is available to aid institutions in developing an Assurance in accord with the PHS Policy. Assurances should only be submitted to OLAW upon receipt of a request from OLAW.

Enforced Self-Regulation

The PHS Policy is based on a concept of *enforced self-regulation*. Once an institution has prepared an Animal Welfare Assurance and the Assurance has been approved by OLAW, the institution is in a position to regulate itself. This concept is described as *enforced self-regulation* because if the institution fails to self-regulate, the approval of the Assurance may be restricted or withdrawn by OLAW.

The concept of enforced self-regulation encompasses:

- institutional commitment through an Assurance;
- the designation of an Institutional Official authorized to assume the obligations imposed by the PHS Policy;
- regular monitoring of the program for animal care and use by an Institutional Animal Care and Use Committee (IACUC);
- IACUC review of protocols that involve the use of laboratory animals;
- institutional identification and correction of deficiencies;
- institutional reporting to OLAW;
- performance standards wherever possible; and
- use of professional judgment.

A program of animal care and use includes multiple components that work synergistically to support activities involving laboratory animals. This section includes descriptions of each of six different components that collectively constitute a program of animal care and use.

The Institutional Animal Care and Use Committee

The Institutional Animal Care and Use Committee, or IACUC, is a committee appointed by the Chief Executive Officer of the institution. The IACUC has certain federally mandated responsibilities, such as review of protocols and periodic evaluations of the program of animal care and use, including inspections of facilities. The IACUC Guidebook (http://grants.nih.gov/grants/olaw/GuideBook.pdf), published in 1992 by OPRR and the Applied Research Ethics National Association (ARENA; http://www.primr.org/arena.html), is a recommended manual for IACUCs.

The membership and functions of the IACUC are described in detail in the next section - The IACUC

IACUC Procedures

An important component of a program is the IACUC's use of standardized procedures, sometimes referred to as SOPs or standard operating procedures. Typically, each institution will develop its own procedures, following Federal guidelines, to address:

- the conduct of IACUC semiannual program evaluations;
- IACUC inspection of animal facilities;
- protocol review;
- the handling of concerns about animal care or use;
- treatment of whistle blowers (required by the Animal Welfare Regulations; http://www.aphis.usda.gov/ac/9CFR99.html);
- maintenance of IACUC records; and
- development of reports to the Institutional Official.

Many IACUCs also develop institutional policies regarding animal use, e.g., prolonged physical restraint, multiple major survival surgeries, and food or fluid restriction.

Veterinary Care

"Adequate veterinary care must be provided, including access to all animals for evaluation of their health and well-being." (1996 *Guide*, p.12)

Arrangements for veterinary care will depend on the institution and the size of the animal program. Consultant or part-time veterinary services may be appropriate for small programs with limited numbers of animals. Under all circumstances, there must be a direct channel of open communication between the Institutional Official and the veterinarian.

The veterinary care program should contain the following components:

- access to all animals and periodic assessment of animal well-being;
- appropriate facilities, personnel, equipment, and services;
- treatment of diseases and injuries, and the availability of emergency, weekend and holiday care;
- guidelines for animal procurement and transportation;
- preventive medicine;
- presurgical planning, training, monitoring, and postsurgical care;
- relief of pain including choice of analgesics, anesthetics, and tranquilizers;
- euthanasia; and
- drug storage and control.

The attending veterinarian must have the authority to implement the veterinary care program, and to oversee the adequacy of all other aspects of animal care and use, e.g, animal husbandry, nutrition, sanitation practices, zoonosis control, and hazard containment.

The 1996 *Report of the American College of Laboratory Animal Medicine on Adequate Veterinary Care in Research, Testing and Teaching* (http://www.aclam.org/pub_adquate_care.htm) is a recommended reference on the topic of veterinary care.

Personnel Qualifications and Training

It is the responsibility of the institution to ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities. The PHS Policy explicitly requires that training includes research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress.

The development and implementation of a training program are usually performed by the IACUC, the veterinary staff, and investigators using animals. Program content is governed by legal requirements and by specific scientific activities conducted at the institution.

A number of self-instructive audiovisual materials and manuals are available. The American Association for Laboratory Animal Science (AALAS; http://www.aalas.org/) offers formal training and certification programs. The USDA Animal Welfare Information Center (AWIC; http://www.nal.usda.gov/awic/) has information on many materials and programs, and a loan program for items in its library. *Education and Training in the Care and Use of Laboratory Animals: A Guide for Developing Institutional Programs* (http://hayato.med.osaka-u.ac.jp/index/guide/inform/regulation/usadocs/educnrc.txt), developed in 1991 by the Institute for Laboratory Animal Research (http://dels.nas.edu/ilar/), Committee on Educational Programs in Laboratory Animal Science, is a comprehensive reference on this subject.

Occupational Health and Safety

"An occupational health and safety program must be part of the overall animal care and use program....The program will depend on the facility, research activities, hazards, and animal species involved." (*Guide*, p.14)

An effective occupational health and safety program must encompass all personnel that have contact with animals. Depending on the species of animal or the amount of animal exposure, the program may not affect all personnel equally.

Minimally, the program should include:

- pre-placement medical evaluation;
- identification of hazards to personnel and safeguards appropriate to the risks;
- appropriate testing and vaccinations;
- training of personnel regarding their duties, hazards, and safeguards;
- policies and facilities that promote cleanliness; and
- provisions for treating and documenting job-related injuries and illnesses.

Occupational Health and Safety in the Care and Use of Research Animals (http://www.nap.edu/catalog/4988.html), published in 1997 by the National Research Council, includes helpful guidelines and references for establishing and maintaining an effective and comprehensive program.

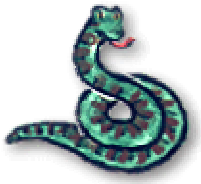
Animal Facilities and Husbandry

"Proper housing and management of animal facilities are essential to animal well-being, to the quality of research data and teaching or testing programs in which animals are used, and to the health and safety of personnel." (*Guide*, p. 21)

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

A program of animal care and use will include attention to:

- aspects of the physical plant where animals are housed such as location, components, construction, management, and operation;
- the physical and social environment of the animals;
- animal husbandry which encompasses food, water, bedding, sanitation, waste disposal, and pest control;
- animal identification, genetic monitoring, and animal health records; and
- daily observation of and care for animals, including weekends and holidays.



THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

- Membership
- Semiannual Program Reviews and Facility Inspections
- Protocol Review
- Addressing Animal Welfare Concerns
- Suspension of Animal Activities

Membership

The membership of the IACUC includes:

- at least five members;
- one veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution;
- one practicing scientist experienced in research with animals;
- one member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy); and
- one member who is not affiliated with the institution other than as a member of the IACUC.

The USDA Animal Welfare Regulations (http://www.aphis.usda.gov/ac/publications.html) intend that the individual not affiliated with the facility provide representation for general community interests in the proper care and treatment of animals. The 1996 *Guide* further specifies that the nonaffiliated member should not be a laboratory animal user.

Semiannual Program Reviews and Facility Inspections

The IACUC monitors the animal care and use program by conducting thorough reviews of the program and inspections of the animal facilities. These program review and facility inspections must occur at six-month intervals, or semiannually. The standards in the *Guide* are used by the IACUC as the basis for conducting its evaluations and inspections.

The program review encompasses institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC record keeping and reporting procedures. It should also include a review of the adequacy and appropriateness of the veterinary medical care program, the training program for personnel, and the occupational health and safety program.

The facility review is a physical inspection of all buildings, rooms, areas, enclosures and vehicles (including satellite facilities in which animals are housed for more than 24 hours) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical

manipulation. The Animal Welfare Regulations apply to animal study areas where animals are maintained for more than 12 hours (applicable only to species covered by the Regulations).

The IACUC submits documentation of its program evaluation and facility inspections, including any recommendations, in semiannual reports to the Institutional Official. These reports describe any program or facility deficiencies, distinguish significant deficiencies from minor deficiencies, and include plans and schedules for correcting each deficiency. A *significant deficiency* is defined as one that is or may be a threat to animal health or safety.

A Sample Semiannual Program and Facility Review Checklist (http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm) is available to assist IACUCs in performing this task. OLAW encourages institutions to make use of this checklist or to develop one of their own.

Note that the semiannual IACUC reports to the Institutional Official should only be submitted to OLAW if requested, or if the institution is submitting a new or renewal Animal Welfare Assurance to OLAW and is not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). However, if serious or continuing deviations from the *Guide* or PHS Policy are identified, they should be reported to OLAW promptly. The next section - Reports and Record Keeping - describes PHS Policy reporting requirements in greater detail.

Protocol Review

The IACUC oversees the specific use of animals by formally reviewing protocols, either at a convened meeting of a quorum (simple majority), or through the use of *designated reviewers*.

The use of designated reviewer(s) may occur only after the entire IACUC is provided with a list of the protocols to be reviewed, and each member provided an opportunity to call for full committee review of any protocol. If full committee review is not requested, at least one member of the IACUC, designated by the chair and qualified to conduct the review, may review the protocol and have the authority to approve, require modifications, or request full committee review.

The criteria that the IACUC considers in its review of protocols are delineated at IV.C.1.a.-g. of the PHS Policy. These criteria must be applied initially, i.e., before an animal activity begins, and at appropriate intervals, but at least once every three years.

Significant changes to a protocol after it has been approved require further review by the IACUC. It is useful for IACUCs to develop guidelines for investigators in order to eliminate potential ambiguity about what constitutes a significant change. Examples of the kinds of changes that are generally considered significant are changes:

- in the objectives of a study;
- from nonsurvival to survival surgery;

- in the invasiveness of a procedure or discomfort to an animal;
- in species or in the approximate number of animals used;
- in the Principal Investigator;
- in anesthetic agent(s), or the use or withholding of analgesics (not intended to limit the clinical judgment of the veterinarian in treating individual animals); or
- in the method of euthanasia.

Addressing Animal Welfare Concerns

The IACUC has a mandate to evaluate concerns regarding the care and use of animals at the institution. Concerns may be raised by staff or employees of the institution, individuals in the community, or even members of the IACUC. It is a good idea for the IACUC to develop guidelines or procedures for handling allegations of mistreatment or noncompliance before such allegations are raised. The IACUC should also be cognizant of the rights of whistle blowers under the AWA, which prohibits discrimination against or reprisal for reporting violations of regulations or standards under the AWA.

Suspension of Animal Activities

The IACUC is empowered to suspend a project if it finds violations of the PHS Policy, *Guide*, Assurance, or Animal Welfare Regulations. Suspension may occur 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. Further, the IACUC must consult with the Institutional Official regarding the reasons for the suspension. The Institutional Official is required to take appropriate corrective action, and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly.

REPORTS AND RECORD KEEPING

- Annual Reports to OLAW
- Reporting Noncompliance, Guide Deviations, and Suspensions
- Where to Send Reports and Assurances
- Maintaining IACUC Records

Annual Reports to OLAW

Each year, institutions submit a report to OLAW that includes:

- changes in the institution's program of animal care and use;
- changes in the membership of the IACUC;
- dates that the IACUC conducted its semiannual program evaluations and facility inspections; and
- minority IACUC views (e.g., minority opinions expressed during a semiannual evaluation or inspection, in the course of a protocol review or IACUC evaluation of animal welfare concerns, or in recommendations to the Institutional Official).

A suggested Annual Report format is available on-line (http://grants.nih.gov/grants/olaw/sampledoc/report.htm). Information may be provided using this format, or it may be submitted in a letter to OLAW. Either way, the Institutional Official and the IACUC Chairperson must sign the report.

Reporting Noncompliance, *Guide* Deviations, and Suspensions

Circumstances that must be reported to OLAW by the Institutional Official, without delay, are:

- serious or continuing noncompliance with the PHS Policy;
- serious deviations from the *Guide for the Care and Use of Laboratory Animals*; and
- IACUC suspensions.

Many institutions fulfill the requirement that such information be reported promptly by calling the Office of Laboratory Animal Welfare, Compliance Division, at 301-402-4371, and orally apprising OLAW of the situation. OLAW will usually ask the institution to follow up with a written letter upon resolution of the matter.

OLAW guidance on reporting is published in the NIH Guide for Grants and Contracts, NOT-OD-05-034 (http://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html).

Where to Send Reports and Assurances

Animal Welfare Assurances, annual reports, and reports of noncompliance, Guide deviations, and suspensions, should be sent to:

Office of Laboratory Animal Welfare
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

NOTE, for Express or Hand Delivered Mail, Use Zip Code 20817

Maintaining IACUC Records

The institution is responsible for maintaining these records:

- assurance approved by OLAW;
- minutes of IACUC meetings;
- records of IACUC activities and deliberations;
- minority IACUC views;
- documentation of protocols reviewed by the IACUC, and proposed significant changes to protocols;
- IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction; and
- accrediting body determinations.

All records are to be kept for a minimum of three years, with the exception of records that relate directly to protocols which must be kept for the duration of the activity and for an additional three years after completion of the activity.

Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the *Guide* and with commonly accepted professional standards.

ACRONYM GLOSSARY AND ADDITIONAL RESOURCES

AAALAC - Association for Assessment and Accreditation of Laboratory Animal Care International. Independent organization that accredits animal care and use programs.
http://www.aaalac.org/

AALAS - American Association for Laboratory Animal Science. Organization of laboratory animal technicians, veterinarians, and other professionals that serves society through education and the advancement of responsible laboratory animal care and use.
http://www.aalas.org/

ACLAM - American College of Laboratory Animal Medicine. Organization that establishes standards for board certification in the veterinary medical specialty of laboratory animal medicine. Board certified veterinarians are known as ACLAM Diplomates.
http://www.aclam.org/

AHRQ - Agency for Healthcare Research and Quality. Agency of the Public Health Service.
http://www.ahcpr.gov/

APHIS - Animal and Plant Health Inspection Service. Component of the USDA that administers the Animal Welfare Act. Within APHIS, Animal Care (AC; http://www.aphis.usda.gov/ac/) is the agency that is responsible for ensuring compliance with the Animal Welfare Regulations.
http://www.aphis.usda.gov/

ATSDR - Agency for Toxic Substances and Disease Registry. Agency of the Public Health Service.
http://atsdr1.atsdr.cdc.gov:8080/atsdrhome.html

AVMA - American Veterinary Medical Association. Professional organization of veterinarians.
http://www.avma.org/

AWA - Animal Welfare Act. Federal law regulating the use, sale, and handling of animals.
http://www.nal.usda.gov/awic/legislat/awa.htm

AWIC - Animal Welfare Information Center. Part of the USDA National Agricultural Library, AWIC provides information and publications on many aspects of animal welfare and alternatives to the use of animals. http://www.nal.usda.gov/awic/
http://www.nalusda.gov/

Animal Welfare Regulations - USDA regulations that implement the Animal Welfare Act.
http://www.aphis.usda.gov/ac/publications.html

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

CDC - Centers for Disease Control and Prevention. Agency of the Public Health Service.
http://www.cdc.gov/

FDA - Food and Drug Administration. Agency of the Public Health Service. http://www.fda.gov/

FOIA - Freedom of Information Act. Statute allowing the public access to certain information on file in Federal agencies.

Guide - Guide for the Care and Use of Laboratory Animals. Manual of standards for animal care and use developed under the auspices of the Institute for Laboratory Animal Research.
http://www.nap.edu/readingroom/books/labrats/

Health Research Extension Act of 1985 - Federal law that mandates the PHS Policy.
http://grants.nih.gov/grants/olaw/references/hrea1985.htm
http://grants.nih.gov/grants/olaw/references/phspol.htm

HRSA - Health Resources and Services Administration. Agency of the Public Health Service.
http://www.hrsa.gov/

IACUC - Institutional Animal Care and Use Committee. Committee charged with oversight of institutional animal care and use program. http://grants.nih.gov/grants/olaw/tutorial/iacuc.htm

IHS - Indian Health Service. Agency of the Public Health Service. http://www.ihs.gov/

ILAR - Institute for Laboratory Animal Research. Component of the National Research Council, National Academy of Sciences, responsible for developing and disseminating information on humane care and appropriate use of animals. http://dels.nas.edu/ilar/

IRAC - Interagency Research Animal Committee. Author of U.S. Principles and the focal point for coordinating Federal policies involving all animal species needed for biomedical research and testing, especially their care, use, and conservation.

NIH - National Institutes of Health. Agency of the Public Health Service. http://www.nih.gov/

OLAW - Office of Laboratory Animal Welfare. NIH office with responsibility for implementation of the PHS Policy.
http://grants.nih.gov/grants/olaw/olaw.htm
http://grants.nih.gov/grants/olaw/references/phspol.htm

OPRR - Office for Protection from Research Risks. The OPRR Division of Animal Welfare was renamed the Office of Laboratory Animal Welfare in March, 2000.

PHS - Public Health Service. Component of the Department of Health and Human Services that includes eight different agencies. http://phs.os.dhhs.gov/ophs/default.htm

Appendix IV. PHS Policy on Humane Care and Use of Laboratory Animals Tutorial
http://grants.nih.gov/grants/olaw/tutorial/index.htm

PHS Policy - PHS Policy on Humane Care and Use of Laboratory Animals. Document that implements the Health Research Extension Act of 1985, and governs activities involving animals conducted or supported by PHS agencies.
http://grants.nih.gov/grants/olaw/references/phspol.htm

Principles - United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Nine principles that provide a foundation for humane care and use of animals in the United States.
http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

SAMHSA - Substance Abuse and Mental Health Services Administration. Agency of the Public Health Service.
http://www.samhsa.gov/

USDA - United States Department of Agriculture. Federal agency responsible for implementation and enforcement of the Animal Welfare Act. http://www.usda.gov/

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Animal Users Risk Assessment Form

IACUC Protocol Number: _____
Title: _____

Working within animal facilities may expose you to a number of allergens, including animal dander, and latex. This exposure may cause or worsen allergic reactions, including asthma. If you have concerns about possible allergic reactions and /or other medial conditions, you are strongly advised to contact the Campus Wellness Center at 215-572-2966.

Working within animal facilities may expose you to a variety of other risks including exposure to infectious agents, risk of being bitten by an animal, and exposure to insects or other infestations of the animals.

1. **This protocol involves biohazardous materials.**
   ___ Yes ___ No:
   If yes, initial that you have read a statement approved by the IACUC describing the specific risks and precautions that should be taken to work with the biohazardous materials.: _____

2. **This research is conducted using rats as an animal model.**
   ___ Yes ___ No:
   If yes, initial when you have read the "Rat Zoonoses" statement:_____

3. **Have you completed the "Occupational Health and Safety" training?**
   ___ Yes ___ No:
   If yes, provide date training was completed and certification was submitted to IACUC:
   date: _____

4. **Have you completed the "Animal Care and Use" training?**
   ___ Yes ___ No:
   If yes, provide date training was completed and certification was submitted to IACUC:
   date: _____

Individuals are not permitted to work with animals until they have satisfactorily passed "Animal Care and Use" and "Occupational Health and Safety" training. Individuals must have completed training and marked "yes" to questions 2, 3, and 4 prior to beginning work in the laboratory.

I confirm that I have read and understand the above information and relevant statements on biohazards and zoonoses, and that I have satisfactorily completed training on "Animal Care and Use" and "Occupational Health and Safety."

Researcher: _____ Signature: _____
Date: _____ phone: _____ email: _____

MAJOR ZOONOSES OF RATS

PATHOGEN	TRANSMISSION	ANIMAL DISEASE	HUMAN DISEASE
Streptobacillus moniliformis, Spirillum minor (Rat bite fever, Haverhill fever)	• animal bites, ingestion of contaminated food products	• **usually a subclinical infection, but purulent lesions have been reported in some animals**	• polyarthritis, myalgias, regional lymphadenopathy, fever
Salmonellosis (most rodents)	• **fecal-oral, ingestion of contaminated products**	• malaise, dehydration, bloody diarrhea	• dehydration, vomiting, abdominal pain, nausea
Leptospirosis (most rodents)	• direct contact with contaminated urine	• infertility, fever, anorexia, anemia	• headache, myalgia, conjunctivitis, nausea
Lymphocytic Choriomeningitis (rats and hamsters)	• exposure to saliva or urine from infected animals or to infected cell lines in the lab • fomites may play a role	• viremia, viuria, and chronic wasting disease	• subclinical infection, mild flu-like symptoms • viral meningitis and encephalitis (rare)
Hantavirus (rats and mice)	• exposure to aerosols, urine, and fecal material from infected animals • fomites may play a role	• subclinical	• fever, myalgia, petechiation, abdominal pain, headache
Dermatophytosis (*Trichophyton mentagrophytes)*	• direct contact	• circular raised erythematous lesion with hyperkeratosis and hair loss	• circular raised erythematous lesions with hyperkeratosis and hair loss

ALLERGENS

Rats: Rats are among the most commonly used laboratory animals. The major sources of rat allergen exposure appear to be urine and saliva. The major rat urine allergen is *Rat n* (isoforms 1 A and 1 B). Disturbance of bedding can leave allergens airborne for 15-35 minutes. Exposure concentrations seem to be task related. Cage cleaning results in a much higher concentration of airborne allergens than does other tasks like weighing, shaving, blood collection, and urine collection.

References

Chomel, BB. 1992. Zoonoses of house pets other than dogs, cats and birds. Pediatric Infectious Disease Journal 11:479-87.
Acha, P and B Szyfres. 1989. Zoonoses and Communicable Diseases Common to Man and Animals. Pan American Health Organization, Washington DC.
Committee on Occupational Health and Safety in Research Animals Facilities, Institute of Laboratory Animal Resources, Commission of Life Sciences, National Research Council. 1997. Occupational Health and Safety in the Care and Use of Research Animals. National Academic Press. Washington, DC.
Percy, DH and SW Barthold. 1993. Pathology of Rabbits and Rodents. Iowa State University Press. Ames, Iowa.

Revised from: http://www.upenn.edu/regulatoryaffairs/animal/species.html

ARCADIA UNIVERSITY
IACUC Animal Use Proposal

To be filled in by IACUC Office ---IACUC Form 2007
IACUC Number _____ Use Level _____
Date Received _____ Date Reviewed: _____ Date Approved: _____

All protocols must be typed. Submit an original signed copy of the protocol to the Secretary, IACUC/COPRS, 107B Taylor Hall. An electronic copy should be submitted to IACUC@arcadia.edu. Written approval from the IACUC must be obtained before initiating any research, teaching, or testing involving vertebrate animals or animal by-products.

Protocol Title:

Estimated dates of protocol: From: __ _____ to _ _ (not to exceed 3 years)

New proposal: __ __

or Revision of IACUC Number __ _____ approval date ___ ____

or 3-year Resubmission of IACUC Number____ _____ approval date __ _____

Funding Sponsor/Agency_____

Principal Investigator: ___ _____

Department: ____ _____ extension: __ _____

E-mail address: __ _____ emergency contact #:_ ____

Co-Investigator _____ _____

Status (student/staff/faculty): __ _____ extension: ___ _____

E-mail address: ____ _____ emergency contact #:__ _____

Faculty Advisor (if PI is student this must be completed)_____

Species of Animals: _____weight _____ age_____

Strain: _____ Source: _____

Number of animals in each category:

Category C: No pain or distress beyond that involved in the restraint, injections, or collection of samples.	Category D: potential for pain or distress but relief is provided by analgesics and/or sedatives as appropriate.	Category E: pain or distress not relieved by sedatives or analgesics.

****

Committee Action:
Tabled: _____ Approval Pending: _____Approved: _____ Disapproved _____

Ayes: _____ Nays: _____ Abstentions: _____ Absent: _____

Chairperson of IACUC: _____ Date: _____

ARCADIA UNIVERSITY
IACUC Animal Use Proposal

1. Does the study involve animals in Humane Use Category E or F? • **IF YES**, ☐ Complete and attach IACUC Form B – Alternatives.	☐ Yes ☐ No
2. Does the study involve anesthetic, analgesic, tranquilizing, or neuromuscular blocking agents? **IF YES**, ☐ Complete and attach IACUC Form C – Anesthetic and analgesic agents	☐ Yes ☐ No
3. Does the study involve a survival surgery? **IF YES**, Complete and attach IACUC Form D - Surgery:	☐ Yes ☐ No
4. What will be the final disposition of animals? ☐ a. Transfer to different protocol : Provide Protocol IACUC approval number _____. ☐ b. Transfer to investigator: Name_____. ☐ c. Euthanasia – complete and attach form E – Euthanasia.	
5. Do you or any member of your research group, spouses or any dependent children have any interest (i.e. any property of financial interest including stock in the sponsor company, patents, trademarks, copyrights or licensing, supplemental research grants or consulting arrangements) in the test drug/product, device, or research procedure that is the subject of this study? • **IF YES, please complete a Conflict of Interest Disclosure Form available through the Arcadia University Grants Office.** Please discuss how these conflicts will be managed during the period of the trial. 4a. In addition, for industry-sponsored trials, please attach the documentation submitted to the sponsor as required by 21CFR54.1, if applicable.	☐ Yes ☐ No
6. Has the Principal Investigator and all co-investigators completed the IACUC training • **IF YES,** attach copy of certification.	☐ Yes ☐ No
7. Has the Principal Investigator and all co-investigators completed the Occupational Health and Safety training • **IF YES,** attach copy of certification.	☐ Yes ☐ No

		Check all attachments that apply:
Principal Investigator (PI) Signature		☐ Form A - Protocol Summary
Printed Name of PI:	Date:	☐ Form B – Alternatives (if Item #1 checked)
Co-Investigator's Signature		☐ Form C – Anesthetic and analgesic agents (If Item #2checked)
Printed Name of Co-Investigator:	Date:	☐ Form D – Surgery (If Item #3 checked)
Co-Investigator's Signature		☐ Form E – Euthanasia (If item 4c checked)
Printed Name of Co-Investigator:	Date:	☐ Conflict of Interest Disclosure Form (If Item #5 checked)
		☐ Copy of IACUC Animal Use certification
Co-Investigator's Signature		☐ Copy of Occupational Health and Safety certification.
Printed Name of Co-Investigator:	Date:	☐ Copy of grant application (minus appendices)
Co-Investigator's Signature		
Printed Name of Co-Investigator:	Date:	

ARCADIA UNIVERSITY
IACUC Animal Use Proposal

INVESTIGATOR'S ASSURANCE
I certify that the information provided is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the animal care and use in these proposed research/teaching activities. I agree to comply with all Arcadia University policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of animals in research, teaching, and testing including, but not limited to, the following:

- the project will be performed by qualified personnel according to the research project/protocol,
- obtain necessary review by the AU IACUC if changes are made in the research project/protocol.
- I agree to meet with my faculty advisor (if primary investigator is a student) on a regular basis to review study progress. Failure to do this could result in suspension or termination of this protocol.
- The PI is responsible for documentation of any adverse events related to the research project and notification of the faculty advisor (if primary investigator is a student), Animal Care Representative, and the Chair of AU IACUC by e-mail (iacuc@arcadia.edu) within 24 hours of incidence.

I acknowledge that the completion of this work occurs within the oversight of the Arcadia University Institutional Animal Care and Use Committee. This oversight includes, but is not limited to, the following:

- written IACUC approval must be obtained prior to any animal use or initiation of the project,
- revision to the protocol must be approved by the IACUC prior to implementing changes,
- renewal of the protocol is required on an annual basis (completion and submission of IACUC Form F),
- on-going protocols must be approved de novo every three years,
- failure to follow the approved protocol or AU IACUC guidelines may result in the suspension of the project or loss of Arcadia University animal use certification,
- submission of a termination report is required at the completion of the project.

I have read and understand the above.

_____ _____ _____
Principal Investigator Signature Printed Name Date

FACULTY SPONSOR'S ASSURANCE (For Undergraduate and Graduate students' projects)

By my signature as sponsor on this research application, I certify that the student or investigator is knowledgeable about the regulations and policies governing use of animals and has sufficient training and experience to conduct this particular study in accord with the approved project/protocol. In addition,

- I agree to meet with the principal investigator on a regular basis to review study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the principal investigator in solving them.
- I assure that the principal investigator will complete all required educational IACUC and Occupational Health and Safety programs as required.
- I agree to assume responsibility for the final disposition of the animals (if appropriate)
- If I will be unavailable, as when on sabbatical, leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the IRB by letter of such arrangements.

_____ _____ ___
Faculty Sponsor signature* (if principal investigator is a student) Printed Name Date

*The faculty sponsor must be a member of the Arcadia University faculty. The faculty sponsor is considered the responsible party for legal and ethical performance of the project.

Description of Project

1. How would you explain to a non-scientist the long-term or overall scientific goals of the proposed work?

2. How would you explain to a non-scientist the specific objectives of the proposed work?

3. How would you explain to a non-scientist the ways the proposed animal use might benefit human or animal health, the advancement of knowledge, or the good of society?

Number of Animals, Species, and Humane use Categories:
The Animal Welfare Act requires annual reporting of animal use according to the following categories.

Estimate the total number of animals that will be used in each Humane Use Category in the proposed study.

Humane Use Categories

	Description:	*animals requested*
C	*No or minimal pain and/or stress (with or without the use of pain-relieving agents and techniques).* No pain or distress beyond that involved in the restraint, injections, or collection of samples. For comparison, no pain relieving drugs would be given under normal circumstances for a human patient going through the same procedure.	
D	*Pain and/or stress that does not become intolerable and thereby distressful.* Potential for pain or distress but relief is provided by analgesics and/or sedatives as appropriate. The USDA regards survival and non-survival surgery to fall in this category. This category includes all procedures in which the animal may experience pain, discomfort, or distress which would be treated with the use of anesthetics, analgesics, or tranquilizers. Therefore, this category includes euthanasia via anesthetic overdose.	
E	*Pain and/or stress that reaches the level of distress.* Pain or distress not relieved by sedatives or analgesics. This category includes procedures expected to cause pain, discomfort, or distress but the administration of normal anesthetics, analgesics, or tranquilizers cannot be used without adversely affecting the experimental results.	
	Total Animals Requested	

Project Summary: Provide enough information so that the IACUC members can review the rationale and purpose of the proposed study. Detail of experimental procedures, justification of animal numbers, and training and experience of personnel completing the procedures should also be provided.

ARCADIA UNIVERSITY
IACUC Animal Use Proposal

The Institutional Animal Care and Use Committee should determine that "*…The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources… used to determine that alternatives were not available."* [Federal Animal Welfare Act (9 CFR 2.31(d)iii]

The investigator needs to examine recent scientific advances to determine if the experiment could be **refined** to make it less stressful through the use of better procedures or the use of anesthetics, analgesics, or tranquilizers. The investigator should also consider **reduction** in animal numbers, and/or **replacement** of the animal model with a species lower on the phylogenetic scale or a non-*in vivo* model.

1. Literature Search: The investigator should complete a literature search to determine that the proposed experiments do not unnecessarily duplicate previous experiments, minimize pain and distress, and alternative models are not available for the study. (Specify database(s), date searched, years covered, and keywords utilized.)

2. Review of Scientific Journals: (specify which journals)

3. Discussion with colleagues: (specify which colleagues)

4. Are alternative models or methods available that would minimize the use of living animals?
   NO / YES If yes, describe why these methods are not being used in the proposed study.

5. Does the proposed study duplicate previous work?
   NO / YES If yes, explain why duplication is necessary.

The 3 R's of Animal Research first presented by William Russell and Rex Burch indicate the need for Refinement (minimize the suffering and distress of animals), Reduction (minimize the minimal number of animals used), and replacement (substitution for conscious living higher animals of insentient)
W.M.S. Russell and R.L. Burch. The Principles of Humane Experimental Technique
http://altweb.jhsph.edu/publications/humane_exp/het-toc.htm

The Institutional Animal Care and Use Committee should determine that "*…researchers consider alternatives to painful procedures and that, with regard to painful procedures, researchers must consult a veterinarian; use adequate tranquilizers, anesthetics, and analgesics; and provide for adequate pre- and post-surgical care. Moreover, exceptions to these standards may be made only when specified by research protocol and explained in a report mandated in the Act.*" [Federal Animal Welfare Act]

Note: Undergraduate and graduate students, your faculty sponsor will be responsible for providing information for this section.

6. Will the animals be anesthetized? NO YES
   If yes:
   A. Identify the name of the agent, dose of the agent (mg of drug/kg body weight); and route of administration.

   B. What will be the maximum duration of anesthesia?

   C. How will depth of anesthesia be monitored?

   D. How will you determine if supplemental doses of anesthetic are necessary? Provide dosage and frequency of administration.

   E. Describe post-anesthetic care.

7. Will the animals receive analgesics? NO YES
   If yes
   A. Identify the name of the agent, dose of the agent (mg of drug/kg body weight); and route of administration.

   B. Describe the procedure for determining supplemental doses of analgesics. Provide dosage and frequency of administration.

8. Will the animals receive tranquilizing agents (other than already listed under anesthesia)? NO YES
   If yes, answer A and B.
   A. Identify the name of the agent, dose of the agent (mg of drug/kg body weight); and route of administration.

   B. Describe the procedure for determining supplemental doses of tranquilizing agents. Provide dosage and frequency of administration.

Will the animals receive neuromuscular blocking agents? NO YES
If yes, answer A and B.
A. Identify the name of the agent, dose of the agent (mg of drug/kg body weight); and route of administration.

B. Describe the procedure for determining the appropriate level of anesthesia in animals exposed to the paralyzing agent.

ARCADIA UNIVERSITY
IACUC Animal Use Proposal

Check Appropriate Surgery:

	Type of surgical Procedure
_____	Terminal (non-survival) surgery will be performed.
_____	Survival surgery will be performed once per animal
_____	Multiple survival surgery will be performed
_____	Non-survival second surgery will be performed

1. All survival surgery procedures must occur under aseptic conditions. Describe the physical location in the laboratory to be used for survival surgery and the methods employed to maintain aseptic conditions and technique.

2. Describe the personnel training and expertise in the surgical model, include pre-, intra-, and post-surgical experience.

3. Describe procedures for monitoring and administering appropriate levels of anesthetics and analgesics. Be sure to include how you will monitor the depth of anesthesia and how the level of anesthetic will be increased if necessary.

4. Describe the entire surgical procedure. Be sure to include preparation of the surgical site, anesthesia, surgical procedure, and post-surgical care.

5. Multiple survival Surgeries are not normally approved. Provide scientific justification for the need to conduct multiple survival surgeries.

Investigator: _____Veterinarian: _____
Signature Signature

ARCADIA UNIVERSITY
IACUC Animal Use Proposal

The Institutional Animal Care and Use Committee should determine that "*…researchers consider alternatives to painful procedures and that, with regard to painful procedures, researchers must consult a veterinarian; use adequate tranquilizers, anesthetics, and analgesics; and provide for adequate pre- and post-surgical care. Moreover, exceptions to these standards may be made only when specified by research protocol and explained in a report mandated in the Act.*" [Federal Animal Welfare Act]

1. Will the animals be euthanized? NO YES
   If yes:
   A. Identify the name of the agent, dose of the agent (mg of drug/kg body weight); and route of administration.

2. How will euthanization be confirmed?

Investigator: _____ Veterinarian: _____
Signature Signature

Appendix VIII: IACUC Progress Report

To be filled in by IACUC Office ---Form F-2004
IACUC Number _____
Date Received _____ Date Reviewed: _____ Date Approved: _____

All protocols must be typed. Submit an original signed copy of the protocol to the attn: IACUC/COPRS, c/o Dean of Undergraduate Studies and Faculty Development, Taylor Hall. An electronic copy should be submitted to IACUC@arcadia.edu. Ongoing protocols using animals must be reviewed by the IACUC every year. The protocol must receive a full *de novo* review at least once every three years.

Protocol Title: _____

IACUC Number _____ date of last approval _____
Inclusive dates covered by this report: _____ to _____

Principal Investigator: _____

Sponsoring Agency: _____

Please provide the following information for studies conducted since your last approval date.

---

1. Is the research identified above still ongoing? ___ Yes ____ No
   If no, please explain status: __ Project completed; ___ Project not funded; ___ Project withdrawn
   __ Still in proposal stage; __ Other, please explain.

2. Have all personnel (scientists, students, and technicians) working with animals in the laboratory completed the mandatory IACUC Training Programs? ___ Yes ___ No
   If yes, please attach certification of "Animal Care and Use" and "Occupational Health and Safety" training. If no, please indicate the members of the staff who have not participated, and when they plan to complete the training.

3. Have you performed any activities involving vertebrate animals during this period? __ Yes ___ No
   If yes, what species were studied? _____
   Number of animals in each category:

Category C: No pain or distress beyond that involved in the restraint, injections, or collection of samples.	Category D: potential for pain or distress but relief is provided by analgesics and/or sedatives as appropriate.	Category E: pain or distress not relieved by sedatives or analgesics.

4. Have unexpected deaths occurred in relation to this protocol? ___ Yes __ No
   Number of deaths: _____; Total number used: _____
   Please explain circumstances surrounding unexpected deaths and steps taken to alleviate the problem (Use separate sheet)

5. Have any procedures listed in the original protocol and/or last approved revision changed in any way? __ Yes __ No. If yes, furnish the complete information of changes on a separate sheet. Any deviation from previously approved procedures must be submitted to the IACUC for approval prior to implementation.

****

Principal Investigator's signature: _____ Date: _____

IACUC chairperson's signature: _____ Date: _____

Appendix IX: IACUC Project Termination Report

To be filled in by IACUC Office ---Form G-2004
IACUC Number _____
Date Received _____ Date Reviewed: _____ Date Approved: _____

All protocols must be typed. Submit an original signed copy of the protocol to the attn: IACUC/COPRS, c/o Dean of Undergraduate Studies and Faculty Development, Taylor Hall. An electronic copy should be submitted to IACUC@arcadia.edu. Ongoing protocols using animals must be reviewed by the IACUC every year. The protocol must receive a full *de novo* review at least once every three years.

Protocol Title: _____

IACUC Number _____ date of last approval _____
Inclusive dates covered by this report: _____ to _____

Principal Investigator: _____

Sponsoring Agency: _____

Please provide the following information for studies conducted since your last approval date.

---

6. Reason for termination of the project?
   If no, please explain status: __ Project completed; ___ Funding ran out; ___ Project withdrawn
   ___ course completed; __ senior thesis project: ___ master's thesis project;
   __ Other, please explain.

7. Have you performed any activities involving vertebrate animals during this period? __ Yes ___ No
   If yes, what species were studied? _____
   Number of animals in each category:

Category C: No pain or distress beyond that involved in the restraint, injections, or collection of samples.	Category D: potential for pain or distress but relief is provided by analgesics and/or sedatives as appropriate.	Category E: pain or distress not relieved by sedatives or analgesics.

8. Have you performed any activities involving vertebrate animals during the ***ENTIRE APPROVAL PERIOD***? __ Yes ___ No
   If yes, what species were studied? _____ ***Inclusive dates***: _____ to _____
   Number of animals in each category:

Category C: No pain or distress beyond that involved in the restraint, injections, or collection of samples.	Category D: potential for pain or distress but relief is provided by analgesics and/or sedatives as appropriate.	Category E: pain or distress not relieved by sedatives or analgesics.

9. Have unexpected deaths occurred in relation to this protocol? ___ Yes __ No
   Number of deaths: _____; Total number used: _____
   Please explain circumstances surrounding unexpected deaths and steps taken to alleviate the problem (Use separate sheet)

****

Principal Investigator's signature: _____ Date: _____

IACUC chairperson's signature: _____ Date: _____

Appendix X: Notice placed in animal facilities regarding Animal Welfare Concerns.

"Arcadia University acknowledges its responsibility to protect the welfare of animal subjects involved in research performed on its premises or conducted under its authority by persons affiliated with the university. This policy is applicable to all research, research training, experimentation, biological testing, and related activities involving live, vertebrate animals.

Reports of animal welfare violations or concerns can be made anonymously and without fear of reprisal.

Any concerns about the care or use of animals can be made directly to the:

Institutional Official:
The *Institutional Official* is a formally designated senior administrative official with the authority to administer the program of animal care and use, and to make commitments on behalf of the institution to ensure compliance with federal and local policies.
Associate Dean for Research, Scholarly and Creative Activities
Dr. John Hoffman
Office: Boyer 218 Phone: 215-572-2195

Chair of the Institutional Animal Care and Use Committee (IACUC):
The *IACUC* is an appointed faculty committee with responsibility of enforced self-regulation to ensure that the policies and procedures of responsible animal care and use are followed.
IACUC Chair: Dr. Marty Eastlack
Office: Health Science Center 211 Phone: 215-572-2864

Attending Veterinarian
Dr. Adam Denish
Phone: 215-333-8888