
**CHAPTER VII:
POLICY ON HUMANE
CARE AND USE OF
ANIMALS**

POLICY ON THE HUMANE CARE AND USE OF ANIMALS

I. Policy:

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

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

- *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.
- *Animal Welfare Assurance* - The documentation from an institution assuring institutional compliance with this Policy.
- *Guide - Guide for the Care and Use of Laboratory Animals*, National Academy Press, 1996, Washington, D.C., or succeeding revised editions.
- *Institution* - Any public or private organization, business, or agency (including components of Federal, state, and local governments).
- *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.
- *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.
- *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. 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.

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. The program description must include the following:

1. 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;
2. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy;
3. 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;
4. 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;

5. The procedures which the IACUC will follow to fulfill the requirements set forth in this Policy;
6. The health program for personnel who work in laboratory animal facilities or have frequent contact with animals;
7. 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;
8. 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
9. Any other pertinent information requested by OLAW.

B. Institutional Status

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

1. **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. 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.
2. **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

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| <p>the IACUC evaluation shall be submitted to OLAW with the Assurance.</p> | |
| <p>C. Institutional Animal Care and Use Committee (IACUC)</p> | |
| <ol style="list-style-type: none"> 1. The Chancellor through the Vice Provost for Research appoints 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. 2. The Assurance must include the names, position titles, and credentials of the IACUC chairperson and the members. The committee consists of not less than five members, and shall include at least: <ol style="list-style-type: none"> a. 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.); b. One practicing scientist experienced in research involving animals; c. One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and d. 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. e. 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. | <ol style="list-style-type: none"> 2. Inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the <i>Guide</i> 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 (Vice Provost for Research); (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 <i>Guide</i> and this Policy and must identify specifically any departures from the provisions of the <i>Guide</i> 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 |
| <p>D. Functions of the Institutional Animal Care and Use Committee (IACUC)</p> | |
| <p>As an agent of the institution, the IACUC shall with respect to PHS - conducted or supported activities:</p> | |
| <ol style="list-style-type: none"> 1. Review at least once every six months the institution's program for humane care and use of animals, | |

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.

E. Review of PHS-Conducted or Supported Research Projects or any other use of vertebrate animals

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. 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 non-medical 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.
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. 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.

F. 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.

G. 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.

H. 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; 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*; 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. The Office of Laboratory Animal Welfare

(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

UAA Institutional Animal Care and Use Committee (IACUC)

The UAA Institutional Animal Care and Use Committee (IACUC) was established by the Chancellor and charged with oversight of all animal use at the University of Alaska Anchorage. The primary purpose of this committee is to ensure compliance with national policies protecting the welfare of laboratory and field research animals. These policies, regulations, and guidelines include, but are not limited to: the Animal Welfare Act, Public Health Service Policies, the Health Research Extension Act, Acceptable Field Methods of Mammalogy, Guidelines for the Use of Wild Birds in Research, Guidelines for the Use of Fishes in Field Research, Guidelines for the Use of Live Amphibians and Reptiles in Field Research, and the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. Responsible conduct of animal research requires knowledge of the requirements and empathy towards the animals we use. Details on UAA's IACUC can be found at

www.uaa.alaska.edu/research/ric/iacuc/index.cfm.

The UAA Animal Care Program is detailed in this institution's *Assurance of Compliance with PHS Policy on the Humane Care and Use of Laboratory Animals*. This *Assurance* describes the basic functioning of the IACUC committee and the lines of authority at UAA, and can be found online at

www.uaa.alaska.edu/research/ric/iacuc/document_s.cfm.

In order to clarify issues specific to UAA, the IACUC periodically issues policy statements. These policy statements are intended to address controversial or poorly understood issues. Our page on *frequently asked questions* (see www.uaa.alaska.edu/research/ric/iacuc/policy.cfm) may also provide valuable information about your responsibilities. Please contact Dr. Eric Murphy, IACUC chair, at afesm@uaa.alaska.edu or Joanne Thordarson, compliance administrator, at anjkt@uaa.alaska.edu if you cannot find the information you need.

The University's goal is to foster a supportive environment for high quality research, education,

and service while ensuring that all use of live vertebrates is adequately justified and conducted by knowledgeable people using the most appropriate methodology. In acknowledgement of the scientific and ethical responsibility of the University for the humane care of animals, and in the interest of ensuring the high quality of university research and educational pursuits, the principles and procedures below have been established. Additional details and all relevant forms and training are on the IACUC website at www.uaa.alaska.edu/research/ric/iacuc/index.cfm

Section 1: General Principles

The following nine “Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training” have been prepared by the U.S. Interagency Research Animal Committee and are herewith adopted to apply equally to all institutional and research use of animals, whether carried out solely within University resources, or with the assistance of extramural funds. These are the cornerstone for all the regulations, guidelines, and policy statements addressing the humane care and use of live vertebrates in a research, teaching, or diagnostic setting. Everyone engaged in the use of live vertebrates at UAA should read and understand these basic principles. 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. 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.

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. 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. 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. 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. 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. 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. 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.

Section 2: UAA IACUC Review Procedures and Delegation of Review Authority

It is the obligation of each individual intending to use live vertebrate animals in testing, research, or training (faculty, staff, or student) to bring the proposed activity to the attention of the UAA’s IACUC for review and approval prior to the initiation of the activity. The Investigator shall submit an electronic copy of the Assurance of Animal Care form (available at www.uaa.alaska.edu/research/ric/iacuc/forms.cfm) to the IACUC Chair, Dr. Eric Murphy, at least two weeks prior to scheduled IACUC committee meetings. The committee usually meets monthly (see website). If a more timely review is necessary, the IACUC may conduct designated review. In this procedure, the researcher requests rapid review by the committee and the chair reviews the proposal to see if designated review is appropriate. If the chair determines that designated review is appropriate, the proposal is submitted to the entire committee with a request for the committee to review the proposal within a week and let the chair know if they approve of or disagree with the use of the designated review for

the proposal. If any committee member requests a full review, then the designated review is cancelled, and the proposal must undergo full review. If no one on the committee objects, then the chair will designate a single reviewer for the proposal. This reviewer will make recommendations to the chair for approval or refer the proposal back to the full committee for a full review. Use of designated review is at the discretion of the IACUC. No activities involving the use of vertebrate animals shall be initiated nor shall such animals be obtained until the proposal has received committee approval.

The formal actions of the IACUC upon reviewing a proposals shall be as follows:

Approval – indicates that the applicant may obtain animals and begin research, and that the project meets IACUC standards for the care and use of vertebrate animals

Approval withheld pending – Indicates that the approval of the committee has been withheld, pending revisions of specific points. Animals may not be obtained or used until all the outlined provisions have been submitted to and approved by the committee

Disapproval – Indicates that the proposed activity does not meet university or federal guidelines for the care and use of vertebrate animals. Animals may not be obtained, nor can any activity proceed. The investigator shall have the opportunity to respond in person or in writing to the committee. If the IACUC gives a proposed project an *Approval Withheld Pending* status, the investigator must contact the IACUC Chair regarding the required action within sixty (60) days, or the proposal will be withdrawn from further committee action and considered to be Disapproved.

The IACUC approves the protocols for a period of three years, pending successful annual review. In the reviews at the end of each year, the principal investigator must provide the committee with a brief summary of the research conducted in the past year, a table detailing the numbers and species used, and a statement assuring the committee that the investigator is familiar with the definition of significant changes, and that no such changes have occurred.

After the third report is submitted (end of year three), the principal investigator must submit a

new protocol form and have the procedures reviewed again, as if it were a new protocol. If the IACUC refuses to approve the use of animals in an ongoing research project, the IACUC will provide the investigator with a statement as to the reasons for the disapproval and, if necessary, will make recommendations for changes in the proposed animal care and use which would lead to approval by the IACUC. It shall be the responsibility of the PI to report any modification in the description of animal use activity or personnel involved in the activity to the IACUC prior to such changes. It is not sufficient to notify the IACUC of significant changes in protocol or personnel solely in the annual report.

Investigators and the Institutional Official will be formally notified in writing of committee actions. The Municipality of Anchorage (Alaska) enforces an ordinance restricting the importation, sale, and possession of rats within its political boundaries. Before a project involving the use of rats may be approved, it is the responsibility of the principal investigator to negotiate an agreement with the Municipality's Department of Health and Human Services, Division of Environmental Health. A copy of the letter from the Municipality of Anchorage, acknowledging and detailing this agreement, must accompany the protocol. Under no circumstances are rats to be purchased until such an agreement is in place and the protocol has been approved by the IACUC(811).