Preamble

The Development of knowledge necessary for the improvement of the health and well-being of humans and other animals requires in-vivo experimentation with a wide variety of animal species. For research to be valid and reliable, laboratory animals subjected to in-vivo experimentation must be healthy and their well-being must be preserved throughout a whole experimental protocol.

In the 1980s, the US Government established through its “Public Health Service” (PHS) a set of rules and regulations called the “PUBLIC HEALTH SERVICE POLICY” (PHS Policy) on the “Humane Care and Utilization of Laboratory Animals, Used in Research, Training and Testing”. Since then it has been a rule that every research entity appoints a special committee called “The Institutional Animal Care and Use Committee” (IACUC). The function of this committee is to make sure that the PHS Policy is being implemented and to provide a framework for conducting research in accordance with the PHS Policy.

The AUB Faculty of Medicine has long considered animal-based biological research as vital to at least two major components of its mission:

1. Educating and training students, physicians, scientists and specialists.
2. Generating novel knowledge for a better understanding of biology and disease.

In parallel with its sister institutions in the US, the AUB faculty of Medicine has established an “Institutional Animal Care and Use Committee” to make sure that laboratory animals used in research, teaching, testing and training at AUB are treated in accordance with the “US Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research and Training”.

Introduction

It is the policy of the American University of Beirut that any teaching, testing, training or research endeavor involving the use of vertebrate animals be conducted in a manner compliant with the U.S. Animal Welfare Act, the U.S. Public Health Service Policy and the Guide for the Care and Use of Laboratory Animals, Research Council, NIH.

Accordingly the IACUC of the American University of Beirut:

- **Accepts and implements as mandatory** the U.S. Government Principles for the [Utilization and Care of Vertebrate Animals Used in Testing, Teaching, Research and Training](https://crdd.osdd.net/curc/cancers/other/pubs/np1996.pdf)
- **Implements** the requirements of the [Guide for the Care and Use of Laboratory Animals](https://crdd.osdd.net/curc/cancers/other/pubs/np1996.pdf), National Research Council, ed.1996
- **Complies** with:
  - US [Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals](https://crdd.osdd.net/curc/cancers/other/pubs/np1996.pdf), National Institutes of Health (NIH) policy
  - [Animal Welfare Act](https://www.phs.gov/)
  - Other applicable statutes and regulations concerning the care and use of laboratory animals as determined by the IACUC.
U. S. Government Principles for the Care and Utilization of Vertebrate Animals Used in Testing, Research, and Education

The Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training were prepared by the US Government Interagency Research Animal Committee, which was established in 1983. The committee's principal concerns are the conservation, use, care, and welfare of research animals. Its responsibilities include information exchange, program coordination, and contributions to policy development.

I. 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.

II. 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.

III. 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.

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

V. 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.

VI. 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.

VII. 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.

VIII. 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 I, by an appropriate review group such as an Institutional Animal Research Committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

Functions of the Institutional Animal Care and Use Committee
As an agent of the Institution, the IACUC shall, with respect to the Policy on Humane Care and Use of Laboratory Animals:

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;

2. Inspect at least once every six months all of the Institution’s animal facilities (including satellite facilities, if any) using the Guide as a basis for evaluation;
3. Prepare reports of the IACUC evaluations conducted as required by I-1 and I-2 above, and submit the reports to the Institutional Official**. (NOTE: The reports shall be updated at least every six months upon completion of the required semiannual evaluations and shall be maintained by the Institution. The reports must contain a description of the nature and extent of the Institution’s adherence to the Guide*** and the PHS Policy and must identify specifically any departure from provisions of the Guide and the PHS Policy and must state the reasons for each departure.)

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 related to the care and use of animals as specified below;

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. Suspend an activity involving animals not in accordance with the specifications set forth.

**Review of Research Projects**

1. In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall confirm that the research project or a modification to a previously approved research project is consistent with the Guide unless acceptable justification for a departure from the Guide is presented. Further, the IACUC shall determine that the research project 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 sacrificed 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 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, and approved by the IACUC.

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 conflict of 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 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.

4. The IACUC shall conduct continuing review of activities covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with paragraph I-1 above.

5. 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 Guide or in accordance with paragraph II 1a-g above. 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.

6. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension and take appropriate corrective action.

The Principal Investigator: Institutional Duties and Responsibilities

Operating Standards

In compliance with the above, the Principal Investigator (PI) has the following responsibilities: He/she must:

- have a working knowledge of the rules and regulations governing the care and use of laboratory animals.
- be familiar with the factors that affect the selection, acquisition and maintenance of experimental animals and be aware of the ethical and social issues involved with the use of animals in biomedical research
- design the research protocol so as to utilize the least number of animals needed to provide reliable data. Details of the statistical basis on which the number of animals is determined should be included in the application to the IACUC.
• ensure that all personnel involved in research projects using animals have:
  – Successfully completed animal care and use training
  – Enrolled in appropriate occupational health programs
  – Received proper training in techniques used for the experimental procedure
• use animals that are lawfully acquired in compliance with an approved animal protocol
• not initiate any research, testing, or instructional project involving the use of vertebrate animals unless this protocol has IACUC approval and training of the staff involved in the care and use of laboratory animals has been completed
• ensure that the use of hazardous agents utilized with or in animals is done so as to be compliant with University Policy and in accordance with all applicable laws and regulations
• make certain that:
  – Students using animals for training, testing or research do so under the direct supervision of an experienced teacher or investigator
  – Animals are treated humanely, properly fed, and their surroundings are kept in a sanitary condition
  – Anesthetics and analgesics, appropriate to the experimental design, are used to eliminate unnecessary pain during scientific procedures
  – Postoperative care of animals in survival surgery is such as to minimize discomfort and pain as well as maintain health and well-being
• ensure that all animals are observed daily for signs of illness, injury or abnormal behavior and when found, the attending veterinarian is immediately contacted
• ensure that all applicable records and logs are properly documented.
• ensure that animals are euthanized, using the American Veterinary Medical Association Panel on Euthanasia (AVMA) approved methods, at the conclusion of the scientific protocol. Examples of approved methods of euthanasia are as follows:
  - Carbon dioxide inhalation
  - Anesthetic overdose
  - Cervical dislocation or decapitation under anesthesia

Contact the IACUC office with any questions concerning regulations or protocol procedures.

Ethical Considerations

An important ethical principle of animal use in biomedical research is that alternatives to live animals should be used whenever possible.

Documentation of a search for alternatives and an explanation for why these alternatives were not found to be suitable or how alternatives were incorporated into the experimental design is a mandatory requirement.

All animal users are encouraged to explore this and other means of improving animal welfare while still accomplishing the AUB research mission by using the Three Rs as outlined in the Table below.
**The Three R’s:**

Exploring alternatives to animal use may be accomplished by using the three Rs; **Replacement**, **Reduction**, and **Refinement** as follows:

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<th>Alternatives</th>
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| Replacement  | Replacing “higher” animals with “lower” animals. Microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals. Alternatively, live animals may be replaced with non-animal models such as:  
  - Dummies for an introduction to dissection for teaching the structure of the animal  
  - Mechanical or computer models  
  - Audiovisual aids  
  - In vitro modeling |
| Reduction    | Minimizing the number of animals needed to perform an experiment or teach a concept, using replacement whenever possible. Methods to achieve this may include:  
  - Performing pilot studies to determine some of the potential problems in an experiment before numerous animals are used  
  - Gathering a maximum amount of information from each animal, perhaps gathering data for more than one experiment concurrently  
  - Consulting with a statistician to use only the numbers of animals required to achieve significance  
  - Minimizing variables such as disease, stress, diet, genetics, etc., that may affect experimental results  
  - Performing appropriate literature searches and consulting with colleagues to ensure that experiments are not duplicated  
  - Using the appropriate species of animal so that useful data are collected |
| Refinement   | Refining experimental protocols to minimize pain or distress whenever possible. Examples of refinement may include:  
  - Using proper handling techniques and receiving adequate training prior to performing a procedure  
  - Ensuring that:  
    - Procedures to be performed on the animal are reasonable for that species  
    - Drug doses are correct and that the drugs used are not expired  
  - Identifying pain and distress and making plans for preventing or relieving it using appropriate analgesics and anesthetics for potentially painful procedures  
  - Performing:  
    - Surgeries and procedures aseptically to prevent infection  
    - Appropriate post-surgical care, including thermoregulation and fluid balance  
    - Only one single major survival surgery procedure on any one animal, whenever possible  
  - Setting the earliest possible endpoint for an experiment.  
**Explanation:** If the necessary information can be gathered before the animal experiences prolonged suffering from the experimental procedure, this should be defined as the endpoint and the animal subsequently euthanized.
In some cases, application of one alternative concept may have an adverse effect in another area (i.e. using a “lower” animal or minimizing pain or distress may require using more animals.) These issues are discussed by the IACUC and depending on the circumstances, different priorities may be set.

Protocols and Amendments: Mechanisms of Approval

Submitting New Protocols

For preliminary review, the Principal Investigator shall submit new protocols along with the required IACUC Forms to the IACUC office for review by the Committee.

- Any concerns or requested changes will be communicated to the Principal Investigator two weeks after reception of the protocol by the Committee.
- Addressing these concerns or the requested changes by the Principal Investigator does not guarantee that additional changes or clarifications will not be requested at a later time.
- The Principal Investigator modifies the protocol based on the preliminary evaluations by the IACUC and resubmits the protocol for IACUC review within one week of receiving the preliminary evaluation memo.
- The modified protocol is assigned a designated reviewer who presents his findings to the Committee for approval, further modifications of the protocol for approval, or rejection.
- If there are no concerns or requested changes, the Principal Investigator will receive an approval from the IACUC.
- New protocols with the following elements are automatically assigned for full Committee review, without preliminary review:
  - Major survival surgery (e.g. brain, chest, bone etc…)
  - Death as an endpoint
  - Unrelieved pain and distress

Submitting Amendment(s) to already approved protocols

An amendment to an already approved protocol may be submitted at any time by the Principal Investigator.

- Amendments containing the following elements will be assigned automatically for full committee review and will be processed as described under New Protocols:
  - Major survival surgery
  - Death as an endpoint
  - Unrelieved pain and distress

- If the amendment does not contain the above criteria, it is assigned to the IACUC Chair/designee for review. The IACUC Chair/designee may:
  - Approve
  - Require modifications in order to approve the amendment
  - Request full-board review

Authority of the IACUC
The IACUC has the authority to suspend animal research activities or animal research protocols under the following circumstances:

- Animals are treated inhumanely
- Researchers perform experiments that have not been previously approved by the IACUC
- Other circumstances as applicable determined by the IACUC

**References**

Public Health Service Policy on Humane Care of Laboratory Animals Used in Research, Testing and Training. (PHS)

American Veterinary Medical Association

US Government Principles for the Care and Utilization of Laboratory Animals in Research, Testing and Training.

* The American University of Beirut
** The Dean of the Faculty of Medicine or his Designee
*** The Guide for the Care and Use of Laboratory Animals