

GUIDE TO INVESTIGATORS USING ANIMALS FOR RESEARCH

This *Guide* is intended to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles. These recommendations are based on published data, scientific principles, expert opinion, and experience with methods and practices that have proved to be consistent with high-quality, humane animal care and use.

Cardinal Principle Underlying Use of Animals for Research

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.

Institutional Animal Ethics Committee (IAEC)

All procedures carried out on nonhuman animals will be reviewed by AU's IAEC to ensure that the procedures are appropriate and humane. The committee shall have representation from within the institution and from the local community as stipulated by the Committee for the Purpose of Control and Supervision on Animals (CPCSEA).

Functions of IAEC

1. Supervision and evaluation of the animal care and use program
2. Inspection of animal house facilities
3. Submission of reports to responsible institutional officials
4. Review of proposals submitted for use of animals in research, testing, or education.
5. The review of proposals shall seriously consider whether the use of animals in a given protocol could be replaced by other experimental approaches such as *in vitro* studies or computer modeling.
6. Establishment of a mechanism for receipt and review of concerns involving the care and use of animals at AU.

IAEC Meetings

1. The IAEC shall meet as often as necessary to fulfill its responsibilities, but at least once every 6 months.
2. Records of committee meetings and of results of deliberations should be maintained.
3. The committee should review the animal care program and inspect the animal facilities and activity areas at least once every 6 months. After review and inspection, a written report, signed by the members, should be sent to the responsible administrative officials of the institution and to CPCSEA.

Personnel Handling Animals and Using Animals for Research

Qualifications and Training

Personnel who care for or perform procedures on animals must be qualified to do so. When students propose to use animals for research, such work shall be conducted only after undergoing appropriate training.

Hazards and Safeguards

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

All personnel shall maintain a high standard of personal cleanliness. Appropriate arrangements should be made to decontaminate clothing exposed to potential hazards. Disposable gloves, masks,

head covers, coats, coveralls, and shoe covers may be required in some situations. Personnel should wash their hands and change clothing as often as necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility. Personnel should not be permitted to eat, drink, use tobacco products, or apply cosmetics in animal rooms.

Guidelines for Researchers

1. Prior approval shall be obtained from IAEC for research on animals. The proposals shall include the following aspects:
 - Rationale and purpose of the proposed use of animals.
 - Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
 - Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation.
 - Adequacy of training and experience of personnel in the procedures used.
 - Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
 - Postprocedure care.
 - Method of euthanasia and disposal of dead animals.
2. Experimentation on animals shall be conducted only by or under the close supervision of qualified and experienced persons.
3. Unnecessary duplication of experiments shall be avoided. Conduct of multiple major operative procedures.
4. Animals used in research and teaching shall be procured only from a registered breeder.
5. The procurement, transport, maintenance, and use of animals must in all cases comply with the regulations of the IAEC and the CPCSEA.
6. Laboratory animals are to be provided with humane care and hygienic environment.
7. Animals used in research and education must be housed, fed, and maintained in a manner appropriate for their species and their condition. They should also be given appropriate veterinary care.
8. Use of appropriate experimental procedures, species, quality, and number of animals.
9. Avoidance or minimization of discomfort, distress, and pain in concert with sound science.
10. Studies involving surgeries or other painful procedures must include an explanation of steps taken to mitigate pain and distress, including the types and dosage of anesthetics and post-operative analgesics to be used. Curarizing agents are not anesthetics; if these are proposed to be used, evidence must be provided that anesthesia of suitable grade and duration will be employed. Drugs that produce muscle paralysis are not anesthetics. They must never be used alone for surgical restraint, only when animals are under anesthesia. Analgesics and other techniques should be used to minimize discomfort and pain except when the intervention would compromise experimental goals. Unnecessary duplication of experiments shall be avoided. Conduct of multiple major operative procedures shall be avoided.
11. Occasionally, protocols include procedures that have not been previously encountered or that have the potential to cause pain or distress that cannot be reliably controlled. Such procedures might include physical restraint, multiple major survival surgery, food or fluid restriction, use of adjuvants, use of death as an end point, use of noxious stimuli, skin or corneal irritancy testing, allowance of excessive tumor burden, intracardiac or orbital-sinus blood sampling, or the use of abnormal environmental conditions. Relevant objective information regarding the procedures and the purpose of the study should be sought from the literature, veterinarians, investigators, and others knowledgeable about the effects on animals. If little is known regarding a specific procedure, limited pilot studies designed to assess the effects of the procedure on the animals, shall be conducted under IAEC supervision.
12. Establishment of experimental end points.