
Draft Guidelines for use by Ethics Review Committees that review research proposals involving “Animal Participants”

In general research involving ‘animal participants’ should not be conducted unless such research has been reviewed and approved by an appropriate institutional Ethics Review Committee. As such these guidelines are intended to serve as guidance to committees that review such proposals. They apply to any research involving “Animal Participants”, including research on live animals, identifiable animal material and/or data.

1. Institutional Ethics Review Committee (ERC)

- 1.1.
 - a. It is desirable that institutional ERCs that review research involving ‘animal participants’ consists of at least one veterinary surgeon and/or a representative from an animal welfare organization.
 - b. When volume of research involving ‘animal participants’ reviewed by a committee does not warrant permanent presence of such members, there should be provision for co-opting such members when required.
- 1.2.
 - a. It is the duty of the committee to ensure that research procedure(s) carried out on ‘animal participants’ are appropriate and humane prior to granting approval.
 - b. The institutional ERC has the rights to supervise any project that it has approved (including field visits without prior notice) and withdraw the approval given previously if the committee finds that the study is being carried out unethically.

2. Investigator(s) /Researcher(s)/ Scientists

- 2.1.
 - a. The research team may include investigator(s) such as animal technicians, research technicians, healthcare professionals, veterinary clinicians, maintenance workers and other personnel.
 - b. All the investigator(s) must be scientifically qualified to utilize animals for research purpose and must have knowledge appropriate for their job description including knowledge of applicable ethical guidelines.
 - c. The members of the research team should have the following basic competencies:
 - i. ability to differentiate normal and abnormal behavioral characteristics of animals to be used in the research.
 - ii. awareness of potential risks/hazardous events that could arise as a consequence of the study to animals (research participants and others), humans (research team personnel and society) and the nation as a whole.
 - d. The welfare of the animal must be the primary consideration of the research team and researchers must monitor (keep records) the animals' welfare (including maintenance of psychological well-being of the research animals) throughout the course of an investigation to ensure continued justification for the research.
- 2.2.
 - a. It is the responsibility of the principle investigator to ensure that all members of the research team are familiar with ethical guidelines and that their role and

responsibilities in the research team are consistent with their competence, training and experience on research involving animals.

- b. The principle investigator is responsible for the conditions under which animals are kept during and after research even when the animals are being housed in an animal house.
- 2.3.
- a. A veterinary surgeon must be a member of the research team where there is a possible reason to believe that an injury or death to the animal may occur.
 - b. 2.2.a may be waved when an animal house used to house the animals have the routine services of a veterinary surgeon.

3. Study design

- 3.1. Any Research involving ‘animal Participants’ should not be approved, unless the scientific purpose of the research including objective(s), rationale and design of the study are clearly justified (based on documentation of literature reviews, prior observations, approved laboratory and animal studies) on the basis that it would advance knowledge for the welfare of humans and /or animals and has adequate potential significance to justify the use of animals.
- 3.2. No study should be granted ethics approval unless the following are clearly justified:
- a. The use of ‘animal participants’ (Why it can’t be carried out with non animal alternatives).
 - b. Species of animals used (species chosen for study should be compatible with the objective(s) and the possibility of using other species, etc. should be addressed).
 - c. The number of animals required (through a valid statistical design – the number should be as low as possible).
 - d. The animal facility where this research is to be conducted.
 - e. Post-experimental care of animals.
- 3.3. No study should be approved where there is a strong reason to believe that death or disabling injury may occur to “animal participants” unless the potential scientific merits are clearly justified.

4. Experimental procedure - pain and discomfort

- 4.1. The research team personnel must treat the animals with kindness, respect and great care, understanding that the “animal participants” including bees, birds, etc., have sufficient organization to have their own basic drives, desires, and intentions and by this research we interfere with their effort to fulfill their destinies.
- 4.2. The institutional ERC must pay attention to the following when granting ethics clearance.
- a. The study must be conducted in a manner which would avoid discomfort, pain, illness and trauma to “animal participants”. If this is unavoidable, the discomfort and pain must be minimized with the assumption that procedures that would produce pain in humans will also do so in other animals. Therefore alternative

methodological and procedural techniques, which avoid or minimize illness, pain, trauma and discomfort has to be considered always.

- b. Procedures which cause pain, stress, privation or death should be used only when an acceptable alternative procedure is unavailable.
 - c. Procedures involving more than momentary pain or slight aversive stimulation, which can not be relieved by medication or other acceptable methods, can be undertaken only when the objectives of the research cannot be achieved by any other method. These will be performed with appropriate pain management (including sedation, analgesia or anesthesia - relevant to the species etc.) compatible with the goal of the research.
 - d. Research studies which require prolonged aversive conditions or produce tissue damage or metabolic disturbances are strongly discouraged. These include prolonged exposure to extreme environmental conditions, experimentally induced prey killing, or infliction of physical trauma or tissue damage etc.
 - e. When conducting a study, which is intentionally designed to examine aversive conditions with greater justification, the parameters of stimulation of pain should be optimized to minimal levels, with out affecting the objective(s) of the research.
- 4.3 If a researcher diagnoses signs of pain on experimental animals, which was not anticipated, he/she should immediately contact the institutional ERC for necessary guidance.

5. Surgery and anesthesia

- 5.1. Any surgical procedures and anesthetization on animals should be conducted only by a veterinary surgeon. Approval may be given for others who are scientifically qualified and trained to do so, under the direct supervision of an attending veterinary surgeon.
- 5.2. Multiple surgical procedures on the same animals are strongly discouraged. However approval may be given with valid scientific justification considering the nature of the research, the nature of the surgery or the well-being of the animal.
- 5.3. Description of pre-surgical planning and evaluation procedures (including the individual responsibilities of the members of the surgical team according to their competency), surgical technique(s) and equipment to be used have to be incorporated in the proposal. Proper aseptic methods must be used.
- 5.4. Special considerations regarding anesthetic agents.
 - a. Best suited anesthetic methods should be selected appropriate to the species, clinical and humane aspects and research needs.
 - b. Procedures involving the use of paralytic agents without reduction in pain sensation should be avoided as far as possible.

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- c. Use of muscle relaxants or paralytics alone during surgery, without general anesthesia, is unacceptable and is to be avoided.
 - d. Studies of pain on animals paralyzed with a neuromuscular blocking agent can not be carried out without a general anesthetic or an appropriate surgical procedure that eliminates sensory awareness.
- 5.5. When the surgical procedure is likely to cause greater discomfort beyond the provided analgesia/anesthesia, and unless there is a specific justification not to do so, animals should be maintained under complete anesthesia during the whole surgical procedure.
- 5.6. Proper postoperative monitoring and care, in addition to food and housing, analgesics and antibiotics should be provided (if necessary) to animals in order to minimize discomfort and pain and to prevent infection and other undesirable consequences.

6. Animal house (Animal facility) and Research environment

- 6.1. A structurally well designed animal facility and proper management of which play a vital role not only on the welfare of animals but also the welfare of the research team personnel and the quality of research.
- 6.2. Animals have to be provided with adequate quality and quantity palatable, non contaminated and nutritionally balanced food and non contaminated drinking water considering the animal's daily requirements and the research goal. In addition attention should be paid to provide sufficient number of feeders and waterers to the facility and on their filling, refilling and cleaning and their arrangement in the facility (eating habit also to be considered).
- 6.3. The feed for the normal animals (unless it is required and ethical approval obtained) should be free from medicines, antibiotics, etc. and feed is to be given according to a time table
- 6.4. The animal facility to be designed according to the:
- a. goal of the research,
 - b. species, strain and breed of the animal selected,
 - c. sex, age, social grouping and behavior of the animal selected and
 - d. sensitivity to environmental changes
- 6.5. The animal facility must contain sufficient space, ventilation, proper instrumentation and mechanisms for noise management to ensure that animals are provided with humane care and healthful conditions during the research.
- 6.6. The animal house has to be cleaned regularly to maintain animal and human hygiene.
- 6.7. Records of the facility should be maintained to ensure that it has been inspected on a regular basis

7. Acquisition of animals – law and rights

- 7.1. All animals, which are not bred in the same research facility, must be acquired lawfully.
- 7.2. When using a healthy animal for the research, a health certificate from a veterinary surgeon should be obtained to ensure the good health status of the animal after a complete investigation.
- 7.3. During the course of the research involving “animal participants”, the person in charge (if applicable) of an animal has the liberty to bring the experiment to an end at any point if he/she believes that continuation of the experiment is harmful.
- 7.4. The use of wild animals for research purpose needs more justification and permission from relevant authorities.
- 7.5. Animals to be captured from the wild should be trapped in a humane manner.
- 7.6. The retention and use of animals shall be in every case in compliance with laws that are in effect at that time.

8. Post research procedures

- 8.1. The research should be terminated when,
 - a. the goal is reached or
 - b. continuation will result in injury or suffering to the ‘animal participants’
- 8.2. When the use of an animal is no longer required by an experimental protocol or procedure alternative uses of the animals should be considered. Such uses should be compatible with the goals of research and the welfare of the animal (not multiple surgeries).
- 8.3. If death occurs, the body/carcass has to be disposed in an acceptable way, approved by the institutional ERC, considering relevant legislation, health issues, environmental, and aesthetic concerns.
- 8.4. The return of wild-caught animals to the field can carry substantial risks, both to the formerly captive animals and to the ecosystem. Animals reared in the laboratory should not be released.

9. Transportation of animals

- 9.1. Acquired animals should be transported in a humane way by providing sufficient food, water, ventilation, space and facilities to prevent unnecessary discomfort and pain to the animals, according to the species, breed, caging/housing facilities, mode of transport and climatic conditions, etc.

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- 9.2. Other factors to be considered
 - a. Minimize transit time
 - b. Health certificate to be obtained at the point of transportation and destination (if healthy animals are used)
 - c. Quarantine procedures when reach the country
 - d. Provide stabilizing time for newly received animals

10. Euthanasia

- 10.1. If the study requires the death of an animal or painful or stressful outcome or irreparable injury is anticipated at the conclusion of the research the most humane, reliable and safe euthanasia method (appropriate for the species to ensure immediate death) consistent with the study must be used.
- 10.2. Euthanasia must be carried out quickly and painlessly in the environment which is free from fear and anxiety under the supervision of an attending veterinary surgeon.
- 10.3. Procedures in which the animal is anesthetized and insensitive to pain throughout the experiment must be euthanized before regaining consciousness
- 10.4. An animal observed to be in a state of severe distress or chronic pain that cannot be relieved and is not essential to the purposes of the research should be euthanized immediately.
- 10.5. No animal shall be discarded until its clinical death is confirmed.
- 10.6. Euthanasia should be performed in a separate location considering human and animal psychological well being.

11. Field Research

- 11.1. Any field research should not disturb their populations, sensitive ecosystems and ethnologies. Every effort should be made to minimize potential harmful effects of the study on the population and on other plant and animal species in the area.
- 11.2. Research conducted in populated areas should be done with respect for the property and privacy of the inhabitants of the area.

12. Other aspects

- 12.1 The adverse events have to be informed to the relevant authorities and necessary compensation has to be paid (if applicable).

13. Educational use of animals

- 13.1. Animals can be used for laboratory exercises as well as classroom demonstrations as instructional aids. This also needs ethics approval from the institutional ERC.
- 13.2. Some procedures that can be justified for research purposes may not be justified for educational purposes. Always consideration should be given to the possibility of using non animal alternatives .

Definitions and Terminology

“research” in relation to an animal means an experiment, procedure, test or study in which an animal is used and includes subjecting an animal to surgical, medical, psychological, biological, chemical or physical treatment.

“animal” means any living being other than a human-being and includes a domestic animal, a farm animal, an animal in captivity, a wild animal, a companion animal, a stray animal, food animal, fish, etc.

“pain” includes distress and mental and /or physical suffering

“veterinary surgeon” means a Veterinary Surgeon registered under the Veterinary Surgeons and Practitioners Act No. 46 of 1956 and includes a Veterinary Practitioner

“welfare” includes the health, safety and well-being of an animal or human

“person in charge of an animal" means a person who a) owns or has a lease, license or other proprietary right to or over the animal; or b) has custody of the animal lawfully or otherwise

References

1. Ethical Guidelines for the Care and Use of Animals in Health Research in Nepal: Nepal Health Research Council (NHRC)
2. Ethical obligation when using laboratory Animals: Medical Research Institute
3. Bestly conduct: Ethical Issues in Animal Experimentation: Arthur L. Caplan chapter4,page246 -254

Web Resources

1. Guidelines for Ethical Conduct in the Care and Use of Animals developed by the American Psychological Association (APA)
2. Report of the Law commission on the draft Animal welfare bill, Sri Lanka
3. NUREMBERG CODE : Reprinted from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182..* Washington, D.C.: U.S. Government Printing Office, 1949
4. World Medical Association Declaration of Helsinki

Credits

This document was drafted by Dr. Vajira H. W. Dissanayake, Dr. T. Chenthuran and Dr. Mangala Gunathilake and presented for discussion at the “Workshop on developing national guidelines for protection of “animal participants” in research” organized by the Ethics Review Committee, Faculty of Medicine, University of Colombo.

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