

[BAI ADMINISTRATIVE ORDER NO. 40-99, August 02, 1999]

RULES AND REGULATIONS ON THE CONDUCT OF SCIENTIFIC PROCEDURES USING ANIMALS

Pursuant to Republic Act No. 8485, otherwise known as the "Animal Welfare Act of 1998", the following rules and regulations are hereby promulgated for the information, guidance and compliance of all concerned:

Section 1. Introduction

1.1 The purpose of these rules and regulations is to institute the basic systems, organizations and practices in all laboratory animal care and use establishments to safeguard the welfare of animals used in scientific procedures. The intention is to grant authorization to conduct scientific procedures. The intention is to grant authorization to conduct scientific procedures using animals to any concerned entity based mainly on the acceptability of their Animal Care and Use Program and the existence of an Institutional Animal Care and Use Committee (IACUC). There is no intention to evaluate or review individual scientific procedures or protocols at the Animal Welfare Committee level. Such evaluation or review is best assumed by the IACUC in adherence to the principles of self-regulation.

1.2 Applicable guidelines and principles including: (1) Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, National Research Council, USA; (2) PALAS Code of Practice for the Care and Use of Laboratory Animals in the Philippines, and (3) The International Guiding Principles for Biomedical Research Involving Animals, Council for International Organizations of Medical Sciences, are considered as support documents. From time to time, additional guidance may be issued on specific issues. A Guide for Institutional Animal Care and Use Committees (ANNEX A) is an integral part of this document.

1.3 The following shall be exempted from the requirements:

1.3.1 A clinical test on animals for evaluating a veterinary product in accordance with regulatory requirements or standard procedures.

1.3.2 The conduct of recognized veterinary procedures such as any therapy, prophylaxis, diagnostic or disease surveillance procedures directly necessary or desirable for the welfare of the animal or animal population. Examples are:

- giving established medicines (e.g., antibiotics, anthelmintics, analgesics) orally or by

injection

- anesthetizing or sedating prior to further therapy (e.g., surgery) or diagnostic evaluation (e.g., x-ray)
- performing corrective surgical procedures
- vaccinating against rabies, distemper or other infectious diseases
- taking blood or other tissue samples for diagnosis/disease testing.

1.3.3 The conduct or recognized agricultural practices such as castration, genetic engineering or embryo manipulation, unless they form part of an experiment.

Section 2. Definition of Terms . — For purposes of these rules and regulations, the following definitions shall apply:

2.1 Animal refers to any live vertebrate animal, whether in a domestic or wild state, which is used or intended for use in scientific procedures.

2.2 Scientific Procedures refer to any activity which entails manipulation of animals for the following purposes:

- a) biomedical researches, experiments, studies, or investigations
- b) teaching and instruction
- c) product (food, drugs, agrochemicals and cosmetics) testing
- d) production of antisera or other biologicals

2.3 Manipulation refers to interfering with the normal physiological, behavioral or anatomical integrity of the animal by deliberately:

- a) exposing it to any parasite, microorganism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition;
- b) subjecting it to enforced activity, unusual restraint, abnormal nutrition or surgical procedures;
- c) depriving it of usual care.

These may have the effect of causing an animal pain, suffering, distress or lasting harm. These terms include death, disease, injury, physiological or psychological stress, significant discomfort or any disturbance to normal health, whether immediately or in the long term.

Section 3. Authorization/Registration/Certification

3.1 Any private or government entity (i.e., person, partnership, organization, establishment, firm, cooperative, corporation, association including medical, dental, allied, research, academic and/or scientific institutions) must secure from the Bureau of Animal Industry,

Department of Agriculture, Authorization to conduct scientific procedures using animals.

3.2 Application for Authorization or renewal thereof shall be made by the entity in such form and manner as may be prescribed from time to time by regulations.

3.3 A processing fee of P100.00 shall be paid upon application.

3.4 The revocation of the authorization of any entity may be appealed to the Animal Welfare Committee.

Section 4. Requirements for Authorization. — The entity shall be required to submit a duly accomplished "Application for Authorization" form (ANNEX B) accompanied by the following documents:

4.1 Description of the Animal Care and Use Program (ACUP) (ANNEX C) signed by the duly licensed veterinarian representing the entity.

4.2 Animal Care and Use Program Accreditation Certificate issued by a duly recognized body or association such as the Philippine Association for Laboratory Animal Science (PALAS).

4.3 Animal Technician Training Program on laboratory animal care and use.

4.4 Certification of Assurance that an Institutional Animal Care and Use Committee (IACUC) is in existence in the establishment.

The IACUC shall be composed of at least three (3) members:

- a licensed veterinarian (preferably with sufficient training and experience in laboratory animal science or medicine or in the use of the species in question)
- one experienced in scientific procedures involving animals
- a public member not affiliated with the institution and preferably with concern for animal welfare
- any additional members may be appointed provided he/she possesses the aforementioned qualifications.

The functions and obligations of the IACUC shall be to:

- evaluate and approve the ACUP and the protocols of scientific procedures
- monitor and review the implementation of the ACUP and scientific procedures through the conduct of facility inspections
- submit an annual report on the status and implementation of the ACUP to the BAI.

Section 5. Renewal of Authorization

5.1 The Authorization shall be valid for 2 years and is renewable thereafter. Renewal shall be based on a Compliance Evaluation of the entity.

5.2 Application for renewal of the Authorization shall be made at least 1 month prior to the expiration of the Authorization.

Section 6. Euthanasia . — Euthanasia is defined as the process of inducing painless death to pets. It has rapidly gained acceptance in many aspects of scientific procedures. It should be done rapidly and humanely and must occur with the least fear, anxiety, pain and distress to the animals. Consideration must be given to how the animal is handled immediately prior to and during the procedure.

The euthanasia of animals should always be done away from public view.

6.1 Carbon Dioxide (CO₂)

- Satisfactory for several species if used in an uncrowded chamber —> safe, humane, economical, rapid
- relatively safe for operator but must be used in a well-ventilated room
- favored when investigators want to avoid the use of chemicals on animals and if a large number of animals are to be sacrificed
- available locally/commercial; initial expense may be high since the gas cylinder may have to be purchased but some companies loan out the cylinders; gas gauge not necessary but cylinder must be fitted with valves for control of gas release
- should be at least 40% concentration (commercial grade is 99%)
- Since (CO₂) is heavier than air, opening should be on top; container may be a specially constructed lethal chamber or a simple plastic bag
- filling container first before placing animals inside may improve efficiency
- dry ice may also be used but contact between the animals and the ice must be avoided

6.1.1 *Small rodents* (mice, rats, hamsters, guinea pigs)

- CO₂ is ideal for rodents since several animals can be euthanatized at the same time
- animals are placed in a large chamber or plastic bag which is subsequently filled with CO₂
- newborn may be more resistant than adults

6.1.2 *Rabbits*

- concentrations of 40-100% are safe and effective

6.1.3 *Dogs and Cats*

- concentration should at least be 40% preferably 70%
- some stress may be encountered depending on the means of delivery and the concentration