Republic of the Philippines
DEPARTMENT OF AGRICULTURE
Office of the Secretary
Elliptical Road, Diliman, Quezon City

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Department of Agriculture
Administrative Order No. **40**
Series of 1999

Subject: **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. INTRODUCTON

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 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 of 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 member 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 (CO_2)

- 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/commercially; 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 CO_2 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)

- CO_2 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 CO_2

- 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 within the chamber

- very suitable for cats which become unconscious within 90 seconds and die in 5 minutes in concentrations less than 60%

- animal(s) should remain in the container for 20 minutes after respiratory arrest to ensure death

- only one adult cat or dog should be euthanatized in the enclosure at one time

6.1.4 Primates

- euthanatized in a lethal chamber or with mask or cone

- CO_2 may be used alone or following ketamine and/or general anesthetic agents

6.2 Other Inhalation Anesthetics

6.2.1 Halothane, Methoxyflurane – may be too expensive

6.2.2 Ether – inexpensive but flammable/explosive cotton is soaked with ether then placed inside an ether jar or other suitable tightly sealed container; wire mesh is placed over the cotton to prevent contact between animal and ether; animal is then placed in the container which is then tightly shut. Unsatisfactory because death is prolonged.

6.2.3 Chloroform – NOT recommended any more: CARCINOGENIC.

6.3 Barbiturates

- sodium pentobarbital (pentobarbitone) most commonly used

- controlled substance

6.3.1 Rodents

- intraperitoneal (IP) route easier and faster; intravenous (IV) route more difficult and time-consuming

- intrathoracic and intracardiac methods may be painful and are recommended only in animals already sedated

6.3.2 Rabbits

- IV route is first choice if aural veins are to be used

- Intracardiac may be painful or slow if injection is made into pericardial space; may be useful if animal is already under anesthesia

- sodium pentobarbital is humane, safe, and efficient but consideration should be given to the chemical burden

6.3.3 Dogs and Cats

- sodium pentobarbital at three times the anesthetic dose should ensure respiratory and subsequent cardiac arrest in dogs and cats

- this drug by the IV route is the most recommended means of producing in dogs and cats

- premedication with sedative drugs by intramuscular (IM) or subcutaneous (SC) routes facilitates restraint for intravenous injection

- IP injection is reserved for fractious animals

- intracardiac injection can be used in dogs already anesthetized, or by skilled personnel in unanesthetized animals

- some euthanatizing agents (T-61^R or Buthanasia^R) may be available commercially

6.3.4 Primates

- injected by IP or IV route while animal is being held or restrained in squeeze cage

- premedication with IM or SC administration of ketamine hydrochloride facilitates the procedure

- may be combined with other anesthetic agents

6.4 Cervical or Cranial Concussion (Stunning)

- requires skill to be effective and humane

6.4.1 Rodents

- guinea pigs may be stunned with a sharp blow to the back of the neck; this procedure is usually followed by exsanguination, thoracotomy, etc.

- suitable also for mice and other small animals

- rats may be wrapped in a small towel prior to striking them behind the head or against a sink or table; primarily used in young rats

6.4.2 Rabbits

- involves striking the rabbit behind the head with a wooden or metal object or the heel of the hands as in a karate blow (rabbit punch)

- used when drug is contraindicated; avoids exogenous drugs but prevents histological studies of the brain

- objectionable to some individuals for esthetic reasons

- requires skill and does not assure death

- followed by decapitation, thoracotomy, or exsanguination

6.5 Cervical Dislocation

- requires skill to be effective and humane

6.5.1 Rodents

- very satisfactory in mice, can be used for other animals weighing less than 250 gm e.g. young rats; used only if a few mice are to be sacrificed

- thumb, first finger, a pencil, a piece of wood, or metal object is placed against the back of the neck and pressed down against a firm surface such as a table top to produce the dislocation; pressure is applied to the neck at the same time tail is pulled firmly and suddenly; the thoracic vertebrae may also be dislocated

- hamsters and guinea pigs are more difficult to euthanatize by this method due to their short necks, stronger neck muscles, and loose skin over the neck and shoulders; an alternate method consists of grasping them over the head from the cranial direction and/or giving the body a quick snap as a whip.

6.5.2 Rabbits

- rabbits weighing less than 1 kg can be held by the legs at the waist with one hand, while the head is held in the other and the neck is overextended

- the technique may also be used while the rabbit is held in lateral recumbency on a table or flat surface

6.6 Decapitation

- performed with the use of guillotine

- unpleasant and dangerous to the operator but useful for pharmacological studies or for special studies in which drugs are contraindicated

- objectionable to many people

- equipment must be thoroughly cleaned before the next animal is decapitated

- head must be completely served from the body

- more difficult to use in guinea pigs, hamsters, and mice than in rats; also used in rabbits

6.7 Exsanguination

- used in animals (usually rabbits and guinea pigs) that have high titers of antibodies

- performed only AFTER anesthetization

- isolation of the carotid artery or venipuncture via the intracardiac route are means of withdrawing blood

6.8 Air by the Intravenous Route

- 5-50 mL/kg produces rapid death that may be accompanied by convulsions, opisthotonos, pupillary dilatation, and vocalization

- mostly used in rabbits

- NOT recommended in unanesthetized animals

6.9 Chloral Hydrate and Magnesium Sulfate

- given intravenous to cats and dogs to effect; animals MUST be sedated first

6.10 Ethanol 70%

- for use in mice and rats only; 70% concentration is usually used

- initially proposed by Dr. Roger Lord of the Queensland (Australia) Institute of Medical Research, Herston, Queensland (CCAC Research 16(1); 1991,1992- January)
- mode of action: works as a depressant like CO_2
- humane, inexpensive, very simple - - Dr. Lord
- may be utilized in instances where barbiturate drugs are normally used
- readily available
- injected intraperitoneally

Section 7. ADMINISTRATIVE SANCTIONS

7.1 Authorization shall be revoked under the following conditions:

7.1.1 Failure to subscribe to or conduct the Animal Technician Training Program

7.1.2 Misrepresentation of any material fact in the animal care and use program description and the reports of the ACUC

7.2 Re-application after revocation

An entity whose Authorization was revoked can only re-apply for Authorization after one (1) year from the date of revocation.

Section 8. SEPARABILITY CLAUSE

In case any provision of these rules and regulations is declared to be contrary to law or unconstitutional, the other provisions that are not affected shall thereby remain valid and effective.

Section 9. REPEALING CLAUSE

All Administrative Orders, rules and regulations and other Administrative issuance or parts thereof, inconsistent with the provisions of this Administrative Order, are hereby repealed or modified accordingly.

Section 10. TRANSITORY PROVISIONS/GRACE PERIOD

The current conduct of scientific procedures using animals shall be allowed pending the establishment of the infrastructures and mechanisms for authorization/registration/certification and until the issuance of a denial of authorization with reference to the initial application for authorization.

Section 11. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

EDGARDO J. ANGARA
Secretary

Annex A

Guide for Institutional Animal Care and Use Committees (IACUC)

1. Objective

   This Guide describes the composition, functions and obligations, and the review/inspection process to be followed by Institutional Animal Care and Use Committees (IACUC)

2. General Considerations

   2.1 All proposed scientific procedures shall be approved by the IACUC before they can be carried out on live animals.

   2.2 The review of the IACUC shall be guided by the principles of the 3R's of Russell and Burch and other pertinent guiding principles such as the International Guiding Principles for Biomedical Research Involving Animals (CIOMS). See attachments.

   2.3 In reviewing the protocols, the IACUC shall use a Protocol Review Form which include standard information that focuses on the welfare and use of the monkeys. The review is specifically on animal care and use, not a review or evaluation of the entire merit of the study/procedures. The review must not interfere with scientific objectives. The review must be flexible and not burdensome. It must avoid delaying the conduct of scientific procedures.

   2.4 Should recommendations or modifications be suggested, the principal investigator/responsible person must be given the opportunity to discuss/ explain the concerned procedures.

   2.5 Because of the commercial nature of some studies/procedures, confidentiality is invoked. Data, protocols, reports and records of discussions must be kept confidential.

   2.6 A record of the IACUC meetings, attendance, deliberations, decisions, actions and other relevant review/inspection/approval documents shall be archived for at least five (5) years.

3. Composition of the IACUC

   3.1 The IACUC is 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 (1) experienced in scientific procedures involving animals

- a public member not affiliated with the institution and preferably with concern for animal welfare

- any additional member may be appointed provided he/she possesses the aforementioned qualifications.

3.2 The institutional management designates all members.

3.3 The veterinarian usually serves as the chairperson and a secretary is appointed to record the contents of the discussions and prepare the reports.

3.4 If necessary, the chairperson can request any expert to attend the Committee meetings or review protocols.

3.5 A term of membership shall be one (1) year but it is possible for the same personnel to be re-appointed for the following term.

4. Functions and obligations of the IACUC

The functions and obligations of the IACUC shall be to:

- evaluate and approve the Animal Care and Use Program (ACUP) and the protocols of scientific procedures

- monitor and review the implementation of the ACUP and scientific procedures

- submit an annual report on the status and implementation of the ACUP

- revoke any approval on the basis of non-compliance to the approved program/protocol despite repeated appeals on its violations

- provide necessary technical recommendations and guidelines/references (e.g., a list of recommended anesthetics, analgesics, and tranquilizers with dose ranges for monkeys)

5. Protocol Review Process

5.1 The principal investigator/responsible person shall submit the accomplished Protocol Review Form (Appendix 1) at least one week before the commencement date of the study/procedures.

5.2 The Chairperson of the IACUC shall assign the study/procedure under one of the following categories:

Category 1: Procedures of Low or Mild Severity –

including the taking of small or infrequent blood samples; skin irritation tests with substances expected to be only mildly irritant; conventional minor surgical procedures under anesthesia such as laparoscopy, small superficial tissue biopsies or cannulation of peripheral blood vessels; and other procedures which will be terminated before the animal shows more than minor changes from normal behavior.

Category 2: Procedures of Medium or Moderate Severity -

including much of the screening and development of potential pharmaceutical agents, toxicity tests avoiding lethal endpoints, and most surgical procedures, provided that suffering can be controlled by reliable post-operative analgesia and care.

Category 3: Procedures of High or Substantial Severity -

Including procedures that result in a major departure from the animal's usual state of health or well-being. These include acute toxicity procedures where significant morbidity or death is an endpoint; some efficacy tests of anti-microbial agents and vaccines; some models of disease and major surgery where significant post-operative suffering may result.

5.3 Category 1 procedures are for expedited review by the IACUC chairperson.

5.4 Category 2 procedures are for expedited review by the IACUC chairperson and 1 or 2 other members of the committee assigned by the chairperson

5.5 Category 3 procedures are for full review by a quorum of the IACUC, but not by less than 3 members.

5.6 The IACUC members are informed by the IACUC Chairperson of the action taken on the protocol. Copies of the Protocol Review Form (Animal Care and Use Statement) and protocol review comments are attached to the memorandum.

5.7 The principal investigator/responsible person is furnished a copy of the consolidated protocol review comments, which he or she shall act upon for the approval of the protocol to be granted. **No study/procedure can be conducted without prior approval.** In case of revisions, the principal investigator shall submit the revised parts of the protocol to the IACUC Chairperson for evaluation.

5.8 For Category 3 procedures, approval means approval of the majority of the quorum present.

5.9 No member may participate in the review or approval of a procedure in which the member has a conflicting interest (e.g., direct involvement in the project) except to provide information requested by the IACUC.

5.10 Regardless of category, all IACUC members, except those subject to Section 5.8, shall sign the Certificate of Approval (Appendix 2).

5.11 If the IACUC revoked an approval, based on a majority decision of a quorum of a convened IACUC meeting, the Institutional Official in consultation with the IACUC shall review the reasons for revocation, take appropriate corrective action and report that action and the full circumstances of the revocation to the Animal Welfare Division.

6. Animal Care and Use Program (ACUP) Review/Inspection Process

6.1 The IACUC evaluates the ACUP, at least once annually, according to the following inspection items

- veterinary care
- personnel qualifications and training
- animal environment, housing and management
  physical environment, behavioral management and husbandry
- veterinary medical care
  animal procurement and transportation, preventive medicine, surgery, pain, analgesia, anesthesia, euthanasia

6.2 Each IACUC member shall list down his or her perceived deficiencies (that could be programmatic and facility-related) in the ACUP.

6.3 The IACUC members shall then deliberate on their individual findings, preferably in the presence of the animal facility manager or Institutional Official to establish a mutually agreeable plan and realistic deadline for corrections. A Summary ACUP Evaluation Document (Appendix 3) shall then be prepared. The document shall present the deficiencies classified as Minor or Significant and the corresponding expected Timeline for their correction shall be indicated. A significant deficiency is one which is or may be a threat to the health or safety of the animals, as judged by the IACUC and the Institutional Official.

6.4 The animal facility manager shall acknowledge the receipt of the Document and he shall be given the opportunity to reply in writing to the IACUC.

6.5 The animal facility manager is required to confirm in writing that they have corrected the deficiencies by the date/timeline given.

6.6 A Certificate of Approval of the ACUP (Appendix 4) shall be issued upon confirmation of the outcome of the actions taken.

6.7 If significant deficiencies are not resolved by the set correction dates, the IACUC must notify the Animal Welfare Division, Bureau of Animal Industry, within 30 working days.

6.8 The following references may be used by the ACUC as guidelines for evaluation:

- PALAS Code of Practice for the Care and Use of Laboratory Animals in the Philippines. 1993, Philippines Association for Laboratory Animal Science (PALAS).

- Guide for the Care and Use of Laboratory Animals. 1996, Institute of Laboratory Animal Resources, National Research Council, U.S.A.

7. Protocol Review Process

7.1 The principal investigator or responsible person submits the Protocol Review Form "Animal Care and Use Statement" to the IACUC Chairperson.

7.2 The IACUC Chairperson assigns the protocol to its category. Under Category 3, the principal investigator and IACUC members are informed of the schedule of the full review.

7.3 Review Process: Category 1 – by the IACUC Chairperson only
Category 2 – by the IACUC Chairperson and 1 or 2 members
Category 3 – by a quorum of the IACUC (but not less than 3 members)

7.4 The principal investigator and IACUC members are informed of the r review results:

- Memo to the PI includes copies of the Protocol Review comments
- Memo to the IACUC members includes the Protocol Review comments and the Animal Care and Use Statement.

7.5 When the IACUC reviewers made no significant comments, or after the IACUC Chairperson has been satisfied by the action taken by the principal investigator, the Protocol Review Certification shall be presented to all the members for affixing their signatures.

8. Animal Care and Use Program Inspection Process

8.1 The members of the IACUC conducts the inspection of the animal facility using the ACUP Inspection Checklist where remarks and observations are written.

8.2 After inspection, the IACUC deliberates on their findings together with the Animal Facility Manager or Institutional Official.

8.3 The IACUC prepares the "Summary of the ACUP Evaluation" Document presenting the deficiencies (minor or significant) observed. The other findings that are not necessarily considered as deficiencies are recorded in the minutes of the meeting.

8.4 The Animal Facility Manager is presented a copy of the document for his appropriate action.

8.5 The Animal Facility Manager acknowledges the receipt of the document and is given the opportunity to reply in writing to the IACUC.

8.6 The Certificate of Approval of the ACUP is issued upon confirmation of the outcome of the actions taken by the Animal Facility Manager or Institutional Official.

9. Animal Care and Use Program (ACUP) Inspection Check List

Inspection Date___________________

Items	/	Remarks
Veterinary care - Full/part time - Weekend /holiday duty		
Personnel qualifications and training - Names - Credentials - Qualifications - Training - Experience/education		

Animal care personnel - Number - Training - Certification level - Experience/continuing education			
Animal environment, hous ing and management - Physical environment (housing/cage (barrier aspects), animal space provisions/stocking densities, temperature and humidity, ventilation, pressure gradient, illumination, and noise control, monitoring and documenting - Behavioral management (environmental enrichment-structural/social) - Husbandry - Food (type, source, feeding method, quality control – storage, stock monitoring, nutritional analysis, contaminant analysis, etc.) - Water (source, treatment or purification process, supply method, quality control method - Sanitation (washing/sanitizing frequency and method for primary and secondary enclosures including corridors and support areas, and cage accessories – feeders, watering devices and distribution lines) - Emergency, weekend, and holiday care (procedure, emergency communication system			
Veterinary medical care - Disease preventive management (quarantine, stabilization, conditioning, isolation, surveillance – animal observation/monitoring, diagnosis, treatment and control of disease) - Pain, distress, analgesic, anesthesia (monitoring use of agents, training and experiences of personnel) - Euthanasia (methods, training and experiences of personnel)			

- Additional remarks may be written in another sheet of paper.

________________________________ Date ____________________

Annex B

APPLICATION FOR AUTHORIZATION

(For the Conduct of Scientific Procedures Using Animals)

1. Name of Entity: ______________________________

2. Address : ______________________________
____

3. Telephone Nos. : ____________________ Fax Nos.: ______________

4. Name and Position of Representative Person:

____
Last Name First Name Middle Name

Position : ______________________________

5. Description/Profile of Entity (attach organizational chart):

6. Purposes of the conduct of Scientific Procedures (encircle one or more):

   a. Biomedical research, experiment, studies, investigation (including pre-clinical research)
   b. Teaching and instruction
   c. Product testing
   d. Production of antisera or other biologicals

7. Identify the Key Institutional Representatives (including the ACUC Chairperson, veterinarians, and researchers):

I certify that the statements made herein are correct and true.

______________________	______________________
Signature of representative	Signature of head of Institution
Date :______________________	Date: ______________________

Note: This application should be accompanied by the requirements stipulated in Section 4 of the Administrative Order.

Annex C

DESCRIPTION OF INSTITUTIONAL ANIMAL CARE AND USE PROGRAM

A. Institutional Policies and Responsibilities

1. Monitoring the Care and Use of Animals

a. Institutional Animal Care and Use Committee (s) (IACUC)

1) State who appoints the committee and who is the institutional official for animal care and use.

2) Describe composition (names, degrees, affiliation), frequency of meetings, and responsibilities of the committee.

3) Describe the frequency with which the committee reviews the animal care and use program and facilities and provide a copy of the last report of this review.

4) Describe other procedures for monitoring care and use of animals.

b. Animal Care and Use Protocols (A blank copy of your institution's protocol review from should be provided as an attachment)

Describe the process for reviewing and approving scientific procedures protocols including the review of research and teaching proposals and ongoing studies. Describe how protocols that have a potential to cause pain or distress to animals are reviewed and controlled or overseen.

c. Multiple Major Survival Surgical Procedures

Note: One survival surgical procedure followed by a nonsurvival procedure is not included in this category

1) Describe the institution's policy regarding multiple major survival surgery on a single animal.
2) Describe the time allowed between procedures on the same animal.

2. Veterinary Care

a. Describe the institutional arrangement for providing adequate veterinary care. Give the veterinarian's name, list responsibilities, and how the veterinarian(s) is(are) involved in monitoring the care and use of laboratory animals. If employed part-time or as a consultant, note the frequency and duration of visits.

b. Describe <u>others' roles</u> in providing veterinary care.

3. Personnel Qualifications and Training

a. Animal Resource Professional/Management/Supervisory Personnel (including the veterinary personnel named above)

List name(s), credentials, qualifications, training, experience, and continuing education. (*Please do not provide curriculum vitae of personnel).*

b. Animal Care Personnel

Note the number of animal care personnel (a list of names need not be included) and summarize their training, certification level and type, experience, and continuing education opportunities provided.

B. <u>Animal Environment, Housing and Management</u>

1. Physical Environment

a. Housing

Describe the <u>cage and pen environment</u> (include general descriptions of composition (materials), condition, flooring, special ventilation or barrier aspects, access to food and water).

b. Animal Space Provisions

Describe <u>references and considerations</u> used to determine adequate cage or pen size or housing/stocking densities.

c. Temperature and Humidity

Provide <u>method and frequency for assessing</u>, monitoring, and documenting animal room or housing area temperature and humidity.

d. Ventilation (for air-conditioned facilities only)

Provide method and frequency for assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients.

e. Illumination

Describe lighting system, intensity, photoperiod, automatic control (yes/no), windows (yes/no)

f. Noise

Describe design features and methods used to control/reduce/ prevent excessive noise in the animal facility

2. Husbandry

a. Food

1) Describe type and source of food stuffs

2) Describe how food is provided to various species (*ad libitum,* limited amounts, types of feeders).

3) Describe special food quality control procedures including storage condition, procedures for rotating stock, monitoring milling dates, nutritional quality, chemical contaminants, etc.

b. Water

1) Describe source, treatment or purification process, and how provided to the animals (pans, bottles with sipper tubed, automatic watering, etc.).

2) Methods of quality control including monitoring for contaminants.

c. Bedding

Describe type (s), how used, and how selected for various species

d. Sanitation

1) Bedding Change

Describe frequency of contact and non-contact bedding changes for each species and cage type (solid bottom or suspended) or pen.

2) Cleaning and disinfection of primary enclosures

Note the washing/sanitizing frequency and method for each of the following:

a) solid bottom cages
b) suspended wire bottom or slatted floor cages
c) cage tops (wire and, if applicable, filtered)
d) cage pans under suspended cages
e) play pens, floor pens, stalls, etc.
f) corrals for primates or outdoor paddocks for livestock

3) Cleaning and disinfection of secondary enclosures

a) Describe animal room cleaning frequency, procedures (floors, walls, ceilings, ducts, exposed pipes, and fixtures), methods (hose, high pressure washer, vacuum cleaner, hand brushing, mopping, etc.) and cleaning/sanitizing agent(s) (generic name) used.

b) Describe the corridor and support area cleaning frequency and procedures and cleaning/sanitizing agents (generic name) used.

c) Describe the procedures for sanitizing cleaning implements such as mops and mop buckets

4) Sanitation of Cage Equipment

a) Describe sanitation procedures and frequency for feeders.

b) Describe sanitation procedures and frequency for watering devices such as bottles, sipper tubes, bowls, automatic watering systems (distribution lines, connection coils), etc.

e. Emergency, Weekend, and Holiday Care

1) Describe procedures for providing weekend and holiday care. Indicate who (e.g. regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

2) Describe procedure for contacting responsible animal care and/or veterinary personnel in case of an emergency.

C. Veterinary Medical Care

1. Preventive Medicine

a. Quarantine, Stabilization and Isolation

1) Describe the initial animal receipt and evaluation procedures for each species.

2) Describe quarantine facilities and procedures for each species

3) Describe isolation facilities and procedures for ill animals

4) Describe periods for physiologic, psychologic, and nutritional stabilization followed.

5) Describe program for separation of animals by species, source, and health status. If not maintained separately, describe circumstances where mixing occurs and rationale for mixing.

b. Surveillance, Diagnosis, Treatment, and Control of Disease

1) Describe procedure and identify person(s) responsible for daily observation of animals for illness or abnormal behavior, their training for this responsibility, and procedure for reporting observations (written or verbal).

2) Describe procedure for providing veterinary medical care to ill animals and note the chain of command for and mode of communicating (written and verbal) information to the veterinarian regarding sick animals.

3) Describe preventive medicine and animal health monitoring program

4) Describe clinical laboratory and diagnostic resources/ capabilities

2. Pain, Distress, Analgesia, and Anesthesia

a. Describe how the use of anesthetics and analgesics is monitored and by whom

b. Note training and experience required to perform anesthesia

3. Euthanasia

a. Describe methods used for each species.

c. Describe training and experience of personnel carrying out euthanasia procedures.

D. Physical Plant

1. Functional Areas

a. Describe the general arrangement of the animal facilities (conventional, clean/dirty corridor, etc.)

b. Note specialized types of available animal housing spaces such as barrier or hazard containment (infectious, radioactive, chemical), or facilities designed specially for housing certain species of animals such as pens for dogs, pigs, sheep, nonhuman primates, etc.

c. Note the following necessary support areas of the animal care program, including the number of rooms and total square meters available for each activity.

1) quarantine for rodents and rabbits
2) quarantine for random source animals such as dogs, cats, and nonhuman primates
3) isolation for sick animals
4) aseptic surgery
5) food storage
6) bedding storage
7) cage washing and sanitizing
8) clean cage storage
9) laboratory for diagnosis and control of laboratory animal diseases

2. Construction Guidelines

a. Exterior Windows

Describe presence of exterior windows in animal rooms that allow natural photoperiods or public observation into the room.

b. Floors

Describe composition and present condition of floors in animal facilities.

c. Walls

Describe composition and present condition of walls in animal housing and use areas and in sanitization areas.

d. Ceilings

Describe composition and present condition of ceilings in animal housing and use areas and in sanitization areas.

e. Ventilation and Air Conditioning (VAC)

Describe the performance aspects of the VAC system. Use the form enclosed.

f. Power and Lighting

1) Note if emergency power is provided for the animal facility and if so, what electrical services it maintains in the event the primary power source fails.

2) Give history of power failures to the animal facility. Note frequency and duration. If emergency power was not available during a power failure, describe steps taken to assure the comfort and well-being of the animals and the temperature extremes reached in the animal rooms during the failure.

3) Describe animal losses or health problems resulting from power failures (if any).

g. Noise Control

Describe physical methods for controlling excessive noise (e.g., materials used, location).

Appendix 1.

ANIMAL CARE AND USE STATEMENT
(Protocol Review Form)

I. PROCEDURE(S) OR TITLE OF RESEARCH/STUDY:

II. PURPOSE/OBJECTIVES:

III. DURATION OR TIME FRAME:

IV. RESPONSIBLE PERSON OR PRINCIPAL INVESTIGATOR:

A. NAME
B. QUALIFICATION (degree(s) or training experience)

V. BACKGROUND AND SIGNIFICANCE OF THE PROCEDURE OR RESEARCH:
(include a description of the biomedical characteristics of the animals which are essential to the proposed procedure/research and indicate evidence of experiences with the proposed animal model)

VI. DESCRIPTION OF METHODOLOGIES/EXPERIMENTAL DESIGN:
This section should establish that the proposed procedures/research are well designed scientifically and ethically. The following should be indicated or described:

A. Type of animal to be used (species)
B. Source of the animals
C. Reason/basis for selecting the animal species
D. Sex and number of animals (justify the number of animals)
E. Quarantine and/or acclimation or conditioning process
F. Animal care procedures
   1. Cage type
   2. Number of animals per cage
   3. Cage cleaning method
   4. Room temperature, humidity, ventilation and lighting
   5. Animal diet and feeding and watering method
G. Experimental or animal manipulation methods
   1. General description of animal manipulation methods (including method of conditioning)
   2. Dosing method (including frequency, volume, route, method of restraint and expected outcome or effects)
   3. Specimen or biological agent (blood, urine, etc.) collection method (including frequency, volume, route and method of restraint)

4. Animal examination procedures and frequency of examinations (including restraining method)
5. Use of anesthetics (including drug, dosage, frequency)
6. Surgical procedures (type and purpose)
   a. Where will surgery be performed
   b. Description of supportive care and monitoring procedures during and after surgery
   c. Description of measures for possible post-surgical complications
   d. Name(s) of surgeons and their qualifications and relevant experiences

7. If euthanasia of animals will be done, indicate/describe the method selected

H. Is there a non-animal model applicable for the procedure/study? If so, please provide the reasons for not using it.

I. Indicate the names and qualification of all personnel who will be responsible for conducting the procedures.

VII. DECLARATION BY THE RESPONSIBLE PERSON:

I ACCEPT RESPONSIBILITY FOR ASSURING THAT THE PROCEDURES/ STUDY WILL BE CONDUCTED IN ACCORDANCE WITH THE APPROVED PROTOCOL.

I ASSURE THAT ALL PERSONNEL WHO USE THIS PROTOCOL AND WORK WITH ANIMALS HAVE RECEIVED APPROPRIATE TRAINING/ INSTRUCTIONS IN PROCEDURAL AND HANDLING TECHNIQUES, AND ON ANIMAL WELFARE CONSIDERATIONS.

I AGREE TO OBTAIN WRITTEN APPROVAL FROM THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE PRIOR TO MAKING ANY CHANGES AFFECTING MY PROTOCOL. I ALSO AGREE TO PROMPTLY NOTIFY THE IACUC IN WRITING OF ANY EMERGENT RPOBLEMS THAT MAY ARISE IN THE COURSE OF THIS STUDY, INCLUDING THE OCCURRENCE OF ADVERSE SIDE EFFECTS.

Signature of the Responsible Person:

____ Date _________________________

Noted by the IACUC Chairman

____ Date _________________________

RECOMMENDING APPROVAL OF THE RULES AND REGULATIONS ON THE CONDUCT OF SCIENTIFIC PROCEDURES USING ANIMALS

ENRIQUE T. CARLOS
(PVMA)
Chairperson

NITA HONTIVEROS-LICHAUCO
(PAWS)
Vice-Chairperson

TEODORO A. ABILAY
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AO lab animals/
ETC/eda