The University of New England
Policies and Procedures for Animal Care and Use

(Approved by the IACUC)

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IV. Proper use of animals includes the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices and is imperative for activities at UNE. Unless justified for scientific validity investigators must consider that procedures that cause pain or distress in human beings will cause pain or distress in other animals.

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

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved must be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other appropriately trained individual experienced in the proper care, handling, and use of the species being maintained or studied. Veterinary care shall be available as needed.

VIII. 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 and training on the UNE Policies and Procedures for the Care and Use of Animals.

IX. 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 II, by an appropriate review group such as an institutional

educational information on the health risks associated with animal handling and ways to minimize the chance of developing illness as a result of prolonged animal contact. The program also offers ongoing monitoring of animal related health status. The Director of Safety and Health may be contacted for comprehensive information about the Occupational Health Program.

D. Animal Welfare Information Center and AGRICOLA

The Animal Welfare Information Center is part of the National Agricultural Library (NAL), which is located in Beltsville, MD. The Center was established in December 1986 as mandated by amendments to the Animal Welfare Act. It is the focal point for those interested in obtaining information or publications covering many aspects of animal welfare.

AGRICOLA (Agricultural On Line Access) is a bibliographic database consisting of records for literature citations of journal articles, monographs, theses, patents, software, audiovisual materials, and technical reports relating to all aspects of agriculture. Of the more than 2 million entries, one-fifth of the database is devoted to laboratory animal science, veterinary medicine, and animal production. It is accessible through the Anschutz Science Library.

The Animal Care Unit has obtained the following aids: "AGRICOLA," "Getting started on AGRICOLA," and Searching AGRICOLA for Animal Welfare." AGRICOLA workshops are also held periodically. Brochures and training schedules are available upon request from AWIC.

E. The Reduction, Refinement and Replacement of Animal Activities

1. Reduction - The numbers of animals used in research can be reduced by a thorough literature review of the proposed activities, basing animal numbers on the statistical significance required for sufficient data points, using disease free animal and sharing animal tissue whenever possible.

Literature review – No experiment using animals should be performed without a thorough review of the literature to eliminate the possibility of needless repetition and to determine the most appropriate model to answer a particular research question. Through the inter-library loan system, the campus libraries have access to literature concerning all aspects of animal experimentation. Specific information may be sought using a variety of databases including AGRICOLA, which is maintained by the National Agricultural Library. AGRICOLA is accessible online. Consult the library staff for assistance with searches.

Animal use based on requirements to achieve statistical significance – All experiments should be planned to provide sufficient data points to determine statistical significance. Using insufficient numbers of animals may require a repetition of the experiment and, therefore, may be as undesirable as using too many animals. Formulae for estimating the number of animals needed for a particular experiment may be found in Statistical Methods for Rates and Proportions 2nd ed. by Joseph L. Fleiss and Biostatistical Analysis 2nd ed. by Jerrold H. Zar or may be obtained through consultation with a biostatistician.

Disease free animals – While the cost of disease free animals, sometimes called SPF (Specific Pathogen Free), is much greater initially, the long term benefits of using such animals usually far outweigh the initial cost. Even sub clinical infections can alter an organism's responses to research-induced challenges, thereby invalidating results.

Sharing animals or tissues – In some cases, the organs, tissues, antibodies, etc. may be commercially available. Several investigators sharing the organs of a single animal reduces the number of animals necessary and the cost to the investigator.

2. Refinement refers to refining techniques or protocols to reduce stress to the animal subject.

Whenever possible, investigators should design experiments so that death is not the end point. Minor modifications of the approach to the experimental problem may allow

(2) One practicing scientist experienced in research involving animals;

(3) One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and

(4) One individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.

An individual who meets the requirements of more than one of the categories detailed above. (1)-(4) may fulfill more than one requirement. However, no committee may consist of less than five members. No more than 3 members may come from any single department.

The IACUC meets monthly or more frequently as needed. No member of the IACUC may vote on or be present for the IACUC review and discussion of a proposal in which the member has either a financial or an institutional conflict of

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;
8. Suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy.

C. Authorized IACUC Powers

The Scope of IACUC powers is limited to the care and use of live vertebrate animals at UNE in research and instructional activities, and may not exceed that which is a) expressly required by Federal, State or local regulations or b) reasonably inferred from, reasonably related to or reasonably necessary to carry out the requirements of required by Federal, State or local regulations. Accordingly the IACUC is empowered with the following actions:

1. Approve proposed animal activities as submitted to the committee;
2. Approve proposed animal activities contingent upon specific revisions;
3. Table proposed animal activities for substantive changes;
4. Disapprove proposed animal activities;
5. Review the institution's program for humane care and use of animals, using the Guide as a basis for evaluation;
6. Inspect all of the institution's animal facilities (including satellite facilities) using the Guide as a basis for evaluation;
7. Monitor animal activities for compliance with IACUC recommendations and UNE Policy and Procedures for Animal Care by any means it deems appropriate, including direct observation of the processes and procedures of animal activities, and/or appointment of a third party to undertake such observation; and to
8. Suspend or terminate animal activities, whenever the animal activities are not conducted in accordance with the IACUC's requirements, or for minor or major proposal violations, or whenever it has been associated with an unexpected harm to animal subjects if deemed appropriate by the IACUC, its designee or Institutional Official in accordance with the procedures set forth in Section III. H. 3 of this policy.

D. IACUC Member Registration with OLAW

All voting IACUC member names and qualifications are registered with the Office of Animal Laboratory Welfare. The IO or the IACUC administrator will notify OLAW within 15 working days of any changes to membership.

E. Education of IACUC Members

All new members of the IACUC will be oriented to the UNE Animal Care and Use Policies and Procedures by the IO, IACUC administrator, IACUC Chair and/or attending Veterinarian

F. Termination of Membership

An IACUC member may be terminated for serious misconduct or breach of membership duties if approved by a gross majority of voting IACUC members. This action may only be taken at a convened IACUC meeting.

G. Rules for Program Review and Facilities Inspections

The IACUC will review the animal care and use program on a semi-annual basis (every six months) to verify and ensure a quality animal care and use program. The Program Review will include an assessment of the overall functioning of the IACUC, the adequacy of UNE Policies and Procedures for Animal Care and Use, Occupational Health Program, and Veterinary procedures as outlined by OLAW. The IACUC will use the sample forms provided by OLAW to perform the Program Review.

The IACUC will inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the "Guide" as a basis for evaluation. All members are invited to participate in the semiannual facility inspections. At least two members of the IACUC, not having a conflict of interest[1], will inspect the facility and report their findings at a convened meeting. The IACUC will use OLAW's sample facility

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, unless a deviation is justified for scientific reasons in writing by the investigator.

2. Procedure for Animal Proposal Review

a. Designated Member Review

Prior to the review, each IACUC member is provided with a list of the proposed research projects to be reviewed and given the opportunity to call for Full Committee Review (FCR). Any member may obtain a written description of the research projects or the full protocol. If no member calls for FCR, then the attending veterinarian and 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. DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so.

If a protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and if any one of the reviewers requests modifications then the other reviewer must be aware of and agree to the modifications. The-5 oio (a) -10i hawe--5 (h) -10 (e0 (e) t) -5 (io) -10 (l) -4 ( ) -5 (i) -4 (s)

2. Major Protocol Violation

Major protocol violations include violations that 1) have or pose a significant risk of substantive harm to research participants, 2) damage the scientific integrity of the data collected; or 3) there is evidence of willful or knowing misconduct on the part of the investigator; or 4) the investigator(s) demonstrate other serious or continued noncompliance with federal, state or local research policy, laws or regulations (e.g. violation of DEA license conditions, engaging in certain research involving recombinant DNA without appropriate IBC registration, etc.). In such cases the following steps will be taken:

a. A fact-finding inquiry process will be initiated by the IACUC chair in cooperation with the Director of Research Integrity

A faculty investigator who disagrees with the findings or requirements of the Committee has the right to appeal the Committee's determination by filing a grievance, as provided in the Faculty Handbook. Non-faculty member investigators have the right to appeal the Hearing Committee's Decision to the IO. The Chair will forward all information gathered by the inquiry or hearing process to the IO who will consider it along with any additional information provided by the investigator. The IO's decision will be final.

V. ANIMAL INVESTIGATOR/USER RESPONSIBILITIES

A. Responsible Animal Care and Use

The University of New England is committed to the highest ethical standards of all research, care, and use of animals. It is the primary responsibility of the investigator or handler to uphold the ethical standards of research as defined in this Policy and the ethical guidelines that govern each researcher's academic discipline(s). The individual researcher is responsible for adhering to all pertinent animal protection laws and rules, and University of New England Policy regarding animal activities.

B. Ethical Decisions for Animal Use

There has been opposition to the use of animals as study subjects for biomedical research extending back to Victorian England (1). While scientists of that era acknowledged the need for animals as study subjects, they also expressed concerns about the humane use of their animal subjects (2). The major concern, then and now, is needless suffering, human or nonhuman.

There are criteria that should always guide the investigator in assessing the use of animal subjects for study.

(1) Are animals necessary for instituting the study?
(2) Is the selected animal species appropriate for the study?
(3) What is the likelihood that the model will provide accurate information to answer the question under study?
(4) Is the proposed study unique or repetitious of already well-established data?
(5) What is the cost in terms of money and numbers of animals to answer the question in relation to the potential importance of the data?

Major medical advances through the last few centuries have been very dependent on data from the study of animals including work by: Jenner, Virchow, Lister, Koch, Erlich, Pavlov, Fleming, Harvey, Bernard and Pasteur. The data from studies in a particular area are like a ladder whose exact and eventual destination cannot be appreciated fully.

There are also groups who philosophically disagree with the use of nonhumans by humans

Each individual will have to decide for him or herself whether or not it is ethical to use animals to conduct studies which may result in a significant savings in human life or alleviation of human suffering. It is also important to recognize that aesthetics and humaneness cannot easily be correlated. Many procedures that may appear aesthetically displeasing could be humanely performed without pain or discomfort. Investigators must continually be aware of and sensitive to how others may view their procedures.

With the privilege of using animals in research goes responsibility and accountability. Careful planning and use of animals in biomedical research is essential if the proposed study is to have quality and value. From the outset, the investigator must be thoroughly knowledgeable about what is already known about the problem and have a clear vision of the potential benefits that could come from the proposed study. Equally important is the

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include barbiturates and narcotics. The Department of Justice, Drug Enforcement Administration (DEA), enforces this law and requires appropriate security and record management of these substances.

X. ANIMAL DISEASE AGENTS

A. Disease Agents That Can Affect Research Results

Rodent disease agents may impact the animals, the personnel in contact with them, and the research. It is the policy of the University of New England

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