Sub-Code for Research Involving Animals

NATIONAL HEALTH RESEARCH ETHICS COMMITTEE OF NIGERIA

FEDERAL MINISTRY OF HEALTH
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1. Introduction

The *National Health Research Ethics Committee's* (NHREC*'s)* definition of animal is ''Any live non-human vertebrate''.

All researchers conducting research on animals for whatever purpose must provide all information outlined in this appendix to their Institutional Health Research Ethics Committee for review and approval.

2. Alternatives to Painful Procedures

The NHEC definition of painful procedure is 'ány procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in a human being to which that procedure is applied."

2.1 If the research proposed is likely to cause pain in the animal, the research protocol must include a narrative on the methods and sources the researcher used to determine that alternatives were not available to the painful/distressful procedure or procedures that is proposed in the experiment, including those procedures in which pain/distress is alleviated.

2.2 The narrative must include: databases searched or other sources consulted, date of the search, years covered by the search, key words and/or search strategy used, and a discussion of what alternatives were considered but not used.

3. Literature Search for Unnecessary Duplication

3.1 The research proposal must provide information - databases searched, keywords or search strategy used, period of search, and date search was performed - describing the database search to ensure that the current proposal is not duplicating previous experiments.

4. Rationale for Using Animals

4.1 The research proposal must provide a justification for using animals in the proposed research. State alternatives to animal use that were considered and explain why these alternatives cannot be used to obtain the research objectives (e.g., computer modeling, cell cultures).

5. Species Identification and Rationale:

5.1 The researcher must provide the species name and if applicable the strain, stock or breed of animals to be used in the proposal. State the strain or stock of mice, rats or guinea pigs to be used. State the breed if dogs, cats or rabbits to be used.

5.2 In the proposal, the researcher must provide a justification for using this particular animal model and include a discussion of the unique morphological and physiological characteristics of this animal model which makes it the best choice for this project citing verifiable and appropriate literature.

6. Number of Animals Used

The research protocol must list the number of: experimental groups, animals in each group and the total animals used by species. Also, using the definition of "painful procedure" presented above:

6.1 State the common names and number of animals in this proposal which will experience no more than slight or momentary pain or distress.

6.2 State the common names and numbers of animals in this proposal which will experience pain or distress that will be relieved with anesthetics and/or analgesics.

6.3 State the common names and numbers of animals in this proposal which will experience pain or distress that will not be relieved with anesthetics and/or analgesics.

7. Rationale for the Number of Animals Required

7.1 The research protocol must list the total number of animals to be used in this research. Include animals necessary for controls, technique development, expected losses, etc. Describe the statistical methodology used to determine that at least the minimum number of animals is used to obtain valid scientific results.

7.2 State the statistical test(s) used to determine sample size and the rationale for using that specific test.

7.3 Describe the strategy intended to evaluate the data.

8. Experimental Design

The researcher must outline the scientific plan and direction of experimentation.

8.1 Provide a complete description of the experimental design of the project to include a summary table of experimental groups and a flowchart indicating sequence of experimental events.

8.2 Describe the experimental design of each experiment separately if several experiments or sequential studies are included in the proposal.

8.3 Procedures that may cause more than momentary or slight pain must be performed with appropriate sedation, analgesia, or anesthetic, unless justified for scientific reasons in writing.

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

8.5 Living conditions must be species-appropriate, contribute to the health and comfort of the animals, and be overseen by a veterinarian or other trained scientist.

8.6 Procedures must avoid or minimize discomfort, distress, and pain to animals consistent with sound research design.

8.7 Necessary medical care must be provided by a qualified veterinarian.

8.8 Personnel conducting procedures must be appropriately qualified and trained in those procedures.

9. Technical Methods

9.1 The research proposal must state the frequency of animal observation once experimental procedures start and describe health status assessment criteria used.

9.2 Provide a complete description of all procedures the animals will experience to include:

i. Surgical procedures
ii. Biological samples (i.e., frequency, volume, harvest site, and collection method)

iii. Adjuvants (if using Complete Freund's Adjuvant and/or *in vivo* production of monoclonal antibodies, provide a scientific justification and state what alternatives you considered and why they were not used)
iv. Tissue sampling for DNA analysis (i.e., age of sampling, amount of tissue taken, anesthetic use)
v. Injections (i.e., agent, dosage, route, and anatomical site of administration)
vi. Prolonged restraint (additionally, justification for its use)
vii. Food or water restriction (additionally, justification for its use)
viii. Multiple major survival surgeries on the same animal (additionally, justification for its use)

10. Anesthesia/Analgesia/Tranquilization

10.1 The research proposal must describe the methods or strategies planned to effectively relieve pain and distress. If drugs are used for anesthesia, analgesia or tranquilization list the drug: name, dosage, frequency, route, and anatomical site of administration. List the observation criteria utilized to determine if the animals are experiencing pain and/or distress.

10.2 If applicable, provide an explanation for withholding anesthetic/analgesic agents from animals that will experience a painful or distressful procedure yet not receive anesthesia or analgesia.

11. Study Endpoint

11.1 State the projected study endpoint for the animals (e.g., recovery, euthanasia), which should be in line with the study hypothesis and design.

11.2 Define specific health assessment criteria used to determine early study endpoints and/or indication for euthanasia (e.g., percentage of weight loss, tumor size, number of abdominal taps, abdominal distention, anorexia, decreased activity, ruffled fur).

12. Euthanasia or Final Disposition

12.1 Describe the method of euthanasia by agent, dosage, route, and anatomical site of administration.

12.2 State the final disposition of the animals if they are not euthanized.

12.3 If administration of carbon dioxide is the proposed method of euthanasia, indicate how death will be confirmed.

12.4 Methods of euthanasia used must be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia and the relevant guideline from the Veterinary Council of Nigeria, unless a deviation is justified for scientific reasons in writing

13. Institutional Health Research Ethics Review and Approvals

13.1 In order to review a proposal that includes animal research, in addition to guidance provided in the National Code for Health Research Ethics, the must include at least

i. One doctor of veterinary medicine
ii. One practicing scientist with experience in animal research

13.2 The researcher and principal study staff must provide documentation of completing an NHREC approved training on ethics of animal research

14. Qualifications

14.1 The research proposal must include a list by name of all personnel working with animals under this proposal and all procedures, manipulations and observations each individual will perform

14.2 Provide each individual's training, experience, and qualifications to perform these duties (e.g., surgery, euthanasia, pre- and post-operative care, injections, phlebotomy, restraint).

14.3 Qualifications should include educational degrees.

15. Principal Investigator Assurances

15.1 The NHREC specifically requires written assurances from the P.I. - (this section may be copied verbatim or modified as required)

15.2 As the Principal Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

A. Painful Procedures: I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that analgesic, anesthetic, and/or tranquilizing drugs will be used where indicated and appropriate to minimize pain and/or distress to animals.

B. Animal Use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein. If a change is to be made, prior approval will be obtained from the approving Health Research Ethics Committee (HREC).

C. Duplication of Effort: I have made a reasonable, good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

D. Statistical Assurance: I assure that I have consulted with a qualified individual who evaluated the experimental design with respect to the statistical analysis, and that the minimum number of animals needed for scientific validity will be used.

E. Training: I verify that the personnel performing the animal procedures/manipulations/observations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures/manipulations.

F. Responsibility: I acknowledge the inherent moral, ethical and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to implement animal use alternatives where feasible, and conduct humane and lawful research.

(Principal Investigator Printed Name)

(Principal Investigator Signature and Date)