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Northeastern University protocol for use of vertebrate animals in instruction or research

Northeastern University Institutional Animal Care and Use Committee

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Northeastern University Protocol for Use of Vertebrate Animals in Instruction or Research

1. Please complete this form in full. All items must be addressed. If an item is "not applicable," so state.
2. The original formatting of the protocol form must be maintained, especially page breaks and the content of the questions.
3. If the project involves surgery, complete and attach a *Surgical Addendum Form*.
4. If the project is for instruction, complete and attach an *Instructional Addendum Form* along with a complete copy of the laboratory exercise.
5. Please forward the original typewritten or computer generated forms and thirteen (13) double sided copies of protocol, addenda and any attachments to the DLAM/IACUC Administrative Office in room 012 in the Mugar Life Sciences Building.
6. Please submit for each protocol, a copy of Section F or animal section of the grant supporting this work(only for original grant submission)

Principal Investigator: _____ **Title:** _____

Contact Person*:

Name: _____ **Title:** _____

Address: _____

Phone: _____ **Fax:** _____ **Cell #:** _____ **E-mail:** _____

Project Title

* Contact person is the individual who will be contacted regarding an animal's health or disposition when morbidity requires action. All correspondence from the IACUC will be sent to the PI.

Double Click Text Boxes to Mark

Vertebrate animals are to be used in this protocol for: Research; Instruction (Attach Instructional Addendum)

This protocol is a: New Project; Renewal, old protocol number:

Does this protocol involve surgery? No Yes, complete and attach Surgical Addendum.

For Instructional Protocols list course number and name:

For Research Protocols list:

Source of funding: _____

Grant submission date: _____

For existing grants list identification #: _____

Will this protocol be used for a grant submission? No Yes,

Submission of this protocol authorizes the IACUC to have access to the complete grant proposal which is on file with the Office of Research Administration and Finance.

Protocol has been compared to Vertebrate Animal Section (if Applicable) of the Grant by: _____

Do Not Write Below This Line

Approval of the Animal Care and Use Committee

IACUC Protocol Number

Chair (or designate), IACUC

Date

Rev: 12/2010

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SECTION A: PERSONNEL INVOLVED IN THE PROTOCOL

1. In Table 1 list all personnel, include faculty, postdoctoral fellows, students, and any other personnel, who will work with vertebrate animals on this project. Indicate their phone number, email address, and whether or not the person is enrolled in the Occupational Health and Safety Program and has taken the NU-IACUC & DLAM On-Line Training Course. It is required that each person working with animals at Northeastern University participates in these two programs. Failure to participate will result in the loss of the privilege to work with animals at Northeastern University. Please contact the DLAM Office to initiate this process.

In Table 2, indicate the experience of each individual (in years) for each procedure listed in the protocol that they will perform or be involved with.

Table 1

Name	Contact Phone Number	Email Address (NU email only)	Entered in the Occupational Health & Safety Program (Yes or No)	Entered in the NU-IACUC & DLAM Investigator Training Program (Yes or No)

2. Federal law requires that this Committee evaluate the training and qualifications of personnel who intend to use live animals in research or teaching. Federal and state law requires all research personnel to be appropriately qualified to conduct work with animals. Personnel must, at a minimum: 1) understand the basic needs of each species they utilize; 2) use proper techniques when handling each species and select methods that minimize animal distress; 3) provide proper pre- and post-procedural care to animals; 4) use aseptic surgical techniques, when applicable; and 5) select and use anesthetics and tranquilizers appropriate for each species, when applicable. In the table, please indicate the years of experience each person has with the species *and* with the techniques separately for each of the rows. If DLAM staff will perform any of the animal procedures, please indicate. Please list personnel below and use their initials in the relevant rows and columns of the table. The Principal Investigator must be included in the table. Please number each person as exemplified in the first row. The boxes can be enlarged, if necessary. Under "PROCEDURES", fill in the specific procedures that will be performed under this protocol. It is suggested that the specific procedure(s) performed in this protocol be written into the "Procedures" column in Table 2 below.

Table 2

<u>PROCEDURES</u>	<u>NAME</u>	<u>YRS. W/SPECIES</u>	<u>YRS. W/TECHNIQUES</u>
A. Animal handling/ Breeding	1) 2) 3) 4)	1) 2) 3) 4)	1) 2) 3) 4)
B. Agent administration			
C. Sample collection			
D. Animal surgery			
E. Animal euthanasia			

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Other – <i>please list</i>			
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3. From the individuals listed above, please indicate the person primarily responsible for monitoring the care and health of the animals.

4. Please list the person in your laboratory primarily responsible for training individuals in the use of and handling of research animals. If you would prefer DLAM perform this function, please indicate below:

Laboratory _____ **DLAM Will**
Trainer: _____ **Train:**

5. Please include any additional, relevant information pertaining to the personnel listed above:

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SECTION B: SPECIES INFORMATION

1. Species and number to be used: Please do not deliberately overestimate the numbers required. The numbers requested must be justified for the experiments planned (see question 4 following). Estimates of average daily census are to help DLAM plan housing. Please discuss your requirements with the DLAM staff. If a researcher maintains a breeding colony for their experiments, the NU-IACUC requires investigators to report annually on the *Animal Protocol Annual Review Form* all rodent-breeding-colony-animal production.

	<u>Species 1*</u>	<u>Species 2</u>	<u>Species 3</u>	<u>Species 4</u>
Animal species to be used: (e.g., mouse, rat, rabbit)				
Total number of animals to be used for this project:				
Average daily census				

(Maximum initial protocol approval = 3 years)

* If additional space is required, please attach document.

Where will the animals be housed?

Location of research and/or laboratory exercise:

a. Provide the choice of species, strain, ages, sex and number of animals requested to be used; please provide an experimental plan with the number of animals in each experimental group. You are encouraged to include tables or flowcharts...

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b. Justify the use of animals, the choice of species and the number of animals used. Please include a brief description of the statistical analyses, including tests, power and probability levels utilized to justify the requested numbers. When providing justification for the choice of species, also describe why this species is the desired model, and if alternatives to the use of animals were considered.

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SECTION C: PAIN AND DISCOMFORT; AVOIDING UNNECESSARY DUPLICATION

Federal* and Northeastern University IACUC guidelines mandate that all procedures involving animals must avoid or minimize discomfort, distress, and pain to animals. This section is designed to summarize information related to this mandate.

* See USDA Policy 12 at: <http://www.aphis.usda.gov/ac/policy/policy12.html>

1. CATEGORIES OF PAIN/DISTRESS. Please fill in the number of animals to be used in each category and check all boxes that apply.

CATEGORY C:

Animals used in this category for research and/or teaching purposes experience no more than slight or momentary pain or distress, and no pain-alleviating drugs are used.

	<u>Species 1*</u>	<u>Species 2</u>	<u>Species 3</u>	<u>Species 4</u>
Number of animals to be used under this pain category:				

CATEGORY D:

Animals used in this category for research and/or teaching purposes *may* experience accompanying pain or distress for which appropriate anesthetic, analgesic, or tranquilizing drugs are used.

	<u>Species 1*</u>	<u>Species 2</u>	<u>Species 3</u>	<u>Species 4</u>
Number of animals to be used under this pain category:				

CATEGORY E:

Animals used in this category for research and/or teaching purposes experience *significant UNALLEVIATED pain or distress*. You must justify in detail under **Section C, Question 7**, why appropriate anesthetic, analgesic, or tranquilizing drugs are not to be used.

	<u>Species 1*</u>	<u>Species 2</u>	<u>Species 3</u>	<u>Species 4</u>
Number of animals to be used under this pain category:				

* If additional space is required, please attach additional pages.

Please check boxes below that apply for all categories:

- | | |
|--|---|
| <input type="checkbox"/> Holding the animals | <input type="checkbox"/> Blood sampling |
| <input type="checkbox"/> Observation | <input type="checkbox"/> Tattooing |
| <input type="checkbox"/> Simple injection | <input type="checkbox"/> Physical examination |
| <input type="checkbox"/> Breeding | <input type="checkbox"/> Euthanasia followed by tissue harvest |
| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Non-recovery surgery |
| <input type="checkbox"/> Recovery surgery | <input type="checkbox"/> Debilitating tests |
| <input type="checkbox"/> Anesthesia followed by euthanasia | <input type="checkbox"/> Exposure to burning, heat, freezing or cold |
| <input type="checkbox"/> Induction of anatomical or physical deficit | <input type="checkbox"/> Monoclonal antibody production |
| <input type="checkbox"/> Laparoscopy or needle biopsy | <input type="checkbox"/> Polyclonal antibody production |
| <input type="checkbox"/> Exposure of blood vessels | <input type="checkbox"/> Short term physical restraint |
| <input type="checkbox"/> Implantation of chronic catheters, electrodes, or other devices | <input type="checkbox"/> External or internal application of foreign, electrodes, or other devices toxic, irritative, pathogenic agents |
| <input type="checkbox"/> Electric shock | <input type="checkbox"/> Disease |
| <input type="checkbox"/> Forced exercise | <input type="checkbox"/> Physical or psychological trauma |
| <input type="checkbox"/> Denial of: <input type="checkbox"/> Food <input type="checkbox"/> Water <input type="checkbox"/> Sleep <input type="checkbox"/> Space | <input type="checkbox"/> Induction of behavioral stress |

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2. Does this protocol involve surgery? (If no continue to question 3) Yes No
- a. Indicate the building and room number in which the surgery will be performed: _____
- b. Will the animals recover from surgery? Yes No
- c. Will multiple surgeries be performed on one animal? Yes No
If "Yes," please refer to the *NU-IACUC Policy on Multiple Major Survival Surgeries*.
3. Does this protocol involve mechanical restraint? Yes No
(Brief holding by hand for injection, transport, etc. does not classify as restraint.)

If "yes," describe and justify.

4. Will the procedures in the protocol cause more than momentary or slight pain, discomfort, or distress to the animal? Yes No

➤ Before responding, please note:

- You must check "Yes" on question C4 if the protocol involves Recovery Surgery or Restraint.
- If the protocol involves only observation, breeding, simple injections, venipuncture or euthanasia followed by tissue collection, you may check "No" on question C4. (See Section C1).
- Federal Guidelines require that most other procedures, including Antibody Production, require you to check "Yes" on question C4. (See Categories D and E in Section C1).

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5. What methods and sources have you used to consider alternatives* to procedures that cause more than momentary or slight pain or distress to the animals.

* Alternatives or alternative methods are generally regarded as those that incorporate some aspect of replacement, reduction, or refinement of animal use in pursuit of the minimization of animal pain and distress consistent with the goals of the research. These include methods that use non-animal systems or less sentient animal species to partially or fully replace animals (for example, the use of an in vitro or insect model to replace a mammalian model), methods that reduce the number of animals to the minimum required to obtain scientifically valid data, and methods that refine animal use by lessening or eliminating pain or distress and, thereby, enhance animal well-being. Potential alternatives that do not allow the attainment of the goals of the research are by definition, not alternatives. (USDA policy 12).

a. List journals that you review regularly and other methods used to review the most recent literature that would help with this protocol.

b. List meetings you attend annually that would help with this protocol.

c. List the literature searches you have carried out for alternatives to each painful procedure. The search must be presented in the form of a **narrative description**. At a minimum the search should include the following:

- The date the search was performed
- The time period covered by the search. This cannot be a single date; it must be a date range.
- The name(s) of the databases searched
- The keywords, the search string/strategy used and the number of references that were found (i.e. *mouse and anesthesia and alternative:104 References*)
 - “Alternative” must be used in each search string because the search is for alternatives to painful procedures.
 - If the protocol involves surgery, the keywords must include the name of the surgery to be performed.

Date Search Performed:	
Time Period Covered by Search:	
Database(s) Searched:	
Key Words:	
Search Strings:	References
1)	
2)	
3)	
4)	
5)	
6)	

Narrative for Search for Alternative to Painful Procedures:

d. List other sources and methods (i.e. professional consultants, etc.).

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6. Summarize the procedures and circumstances that may cause discomfort, pain, or injury. Describe procedures designed to assure that pain and discomfort to the animals will be limited to that which is unavoidable for the conduct of scientifically valuable research. You must list all anesthetic, analgesic and tranquilizing drugs to be used, their doses, the duration of administration, and the criteria for administering or withholding these drugs. State the nature and frequency of **observations to evaluate pain/distress** of the animals during the course of the research and humane experimental endpoints.

7. If it is necessary to withhold, for scientific reasons, analgesic or anesthetic agents during procedures that could cause significant pain or discomfort, specify the duration of time you will withhold these agents and justify.

SECTION D: DESCRIPTION OF ALL PROCEDURES INVOLVING LIVE ANIMALS

1. Will this protocol involve the use of *in vivo* and/or *ex vivo* infectious organisms? Yes No

If “Yes,” has approval been received from the University Biological Safety Committee? Yes No
A copy of the approval letter must be filed with the DLAM office prior to initiating animal studies.

Please describe the infectious agents involved. Provide a description of the safety precautions that must be followed for handling the animals, their waste, and the animal carcasses

2. Will this protocol involve the use of *in vivo* and/or *ex vivo* radionuclides? Yes No

If “Yes,” has approval been received from the University Radiation Safety Committee?
A copy of the approval letter must be filed with the DLAM office prior to initiating animal studies. Yes No

Please list the isotope(s) involved.

3. Will this protocol involve the use of hazardous chemicals, carcinogens, or other hazardous substances? Yes No

Please describe the chemical(s) or hazardous agent involved. Provide a description of the safety precautions that must be followed for handling the animals, their waste, and the animal carcasses

➤ *Please address questions regarding potentially hazardous materials with the DLAM and with the Office of Environmental Health and Safety.*

4. Will this protocol involve any deviations from standard arrangements for housing and care? Yes No

These deviations include, but are not limited to: deprivation of food or water, feeding a non-standard diet, addition of materials to the food or drinking water, increased animal density per cage, or changes in frequency of cage cleaning.

If “Yes”, please describe and justify here or in an attachment if more space is required.

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5. Provide details of euthanasia for each species. If animals are not euthanized please describe their final disposition. Even if some animals are **not** euthanized, protocols must include an emergency plan in case euthanasia becomes necessary. *If a physical method of sacrifice, such as cervical dislocation or decapitation, is used without prior anesthesia or sedation, please provide scientific justification including research references.*

All/Some animals described in this protocol will be euthanized upon completion. Yes No

a. Provide primary method of euthanasia and justify the requested method(s):

If applicable, give:

Dose(mg/kg)		Route:		Volume:	
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If using CO2 or a gas anesthetic for euthanasia, provide a form of secondary euthanasia by physical means (e.g., cervical dislocation, decapitation, thoracotomy, vital organ removal):

b. What tissues from euthanized animal(s) will be available for utilization by other investigators?

c. Individual(s) responsible for administering euthanasia:

6. All/Some animals described in this protocol will NOT be euthanized upon completion. . Yes No
Please describe the fate of these animal(s). (Please note that no animal may be given away without permission from DLAM.)

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7. Provide a detailed description of the research project or instructional exercise. **Please discuss in terms understandable to the non-scientists on the committee.**
- a. Provide a brief overview of the project. Provide general information on the scientific and/or medical significance of the project and how it will contribute to the literature in your area. This must be understandable to a layperson.

- b. Provide a detailed description of the procedures involving animals. If the project is complex, you should provide an outline of all procedures performed on animals used in this protocol with adequate details so that the committee can easily understand which procedures will be performed, the length of the procedures, and the numbers of animals receiving each treatment. This includes all procedures from the time the animals arrive until the animals are sacrificed or otherwise leave Northeastern University. If the project involves instructional use, you need not duplicate here information given on the Instructional Addendum Form.

SECTION E: AUTHORIZATION

Project Title

Principal Investigator: As the individual responsible for this project, I confirm that (check boxes):

- The information contained in this protocol is true and accurate, and that, to the best of my knowledge, it conforms with Northeastern University's IACUC, NIH, USDA, and MDPH policies on the use of animals in research and teaching.*
- I have considered alternatives to the biological models used in this project and have found these other methods unacceptable on scientific or educational grounds.*
- This project does not unnecessarily duplicate previous experiments.*
- All personnel named in Section A have agreed to participate in this study and are aware of Approved procedures. All individuals who will be involved with the animals used in the project have been instructed in the humane care, handling, and use of animals, and I have reviewed their qualifications.*
- No change will be made to procedures, care, or housing without prior written notification to and approval by the Institutional Animal Care and Use Committee (IACUC).*
- I understand that failure to comply with IACUC policies and procedures will jeopardize Northeastern University's Animal Welfare Assurance on file with the NIH, and may lead to revocation of my privileges to conduct animal research at this institution.*

Principal Investigator

Date

Please submit this form bearing the original signature of the Principal Investigator.

Department Chairperson: As the Department Chair for this researcher, I confirm that I am aware that this protocol is being submitted to the IACUC. I do not make any assertions about the care and use of animals involved in this research protocol.

Department Chairperson

Date