



Northeastern University

NU-IACUC Forms

Institutional Animal Care and Use Committee

January 01, 2004

Northeastern University supplement A: animal use protocol addendum

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DLAM USE ONLY: Amendment No.: _____ Date _____ Approved: _____
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**Northeastern University Supplement A
Animal Use Protocol Addendum**

Only the Principal Investigator listed on the protocol is permitted to make changes to a protocol. Please note that certain changes to protocols may affect other aspects of that protocol, and that this should be reflected in this addendum. Addenda to protocols require Institutional Animal Care and Use Committee (IACUC) review and approval. The IACUC reserves the right to determine whether proposed changes are substantive or not, and to request further information or a new protocol application, as appropriate. When submitting an addendum, the Principal Investigator is required to review all of the details of the original protocol to assure the IACUC that all unamended details remain identical to the original protocol.

I. GENERAL INFORMATION

- A. Principal Investigator: _____ Title: _____
- B. Contact person*: *(if changed from original submission)*
 Name: _____ Title: _____
 Address: _____
 phone: _____ fax: _____ Cell #: _____ e-mail: _____
- C. Protocol # & 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.

II. PROPOSED MODIFICATIONS

- Change in personnel *(complete Sections III, and XII) If adding personnel only, submit sections I, II, III, & XI*
- Number of animals used *(complete Sections IV and XII)*
- Species of animal used *(complete Sections IV, IX, XI, and XII)*
- Procedure used *(complete Sections V, VI, VII, VIII, IX, X, XI, and XII)*

III. CHANGE IN PERSONNEL

- A. In Table 1 list all new personnel, include faculty, postdoctoral fellows, students, and any other personnel, who will work with vertebrate animals on this project. Indicate their contact 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 they will perform or be involved with.

Table 1

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

Table 2

Procedure: (i.e. type of surgery, perfusion, etc)	Personnel Involved (list multiple personnel in box per procedure)	Species	Experience with Procedure (Years)

2. Please indicate the person primarily responsible for monitoring the care and health of the animals. (if different from the original protocol)

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3. 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 Trainer: _____ DLAM Will Train:

B. Delete:

Name(s): _____

IV. ANIMAL USE AND JUSTIFICATION

A. Check applicable box(es):

- Additional animals
 Change in species

1. Animal species to be used:
(e.g., mouse, rat, rabbit)
2. Total number of animals to be used for this project:
(maximum initial protocol approval = 3 years)

<u>Species 1</u>	<u>Species 2</u>	<u>Species 3</u>	<u>Species 4</u>

B. Assessment of animal pain and or/distress

Number of animals used

Species 1 Species 2 Species 3 Species 4

(place **each** animal species listed above in a **single** category)

1. Number of animals to be used in procedures with minimal, momentary, or no pain or distress (USDA/NU Category C):
2. Number of animals that will receive appropriate anesthetics, tranquilizers, or analgesics to alleviate pain and/or distress (USDA/NU Category D):*
3. Number of animals that will experience pain and/or distress without alleviation (USDA/NU Category E):*

	<u>Species 1</u>	<u>Species 2</u>	<u>Species 3</u>	<u>Species 4</u>
1. Number of animals to be used in procedures with minimal, momentary, or no pain or distress (USDA/NU Category C):				
2. Number of animals that will receive appropriate anesthetics, tranquilizers, or analgesics to alleviate pain and/or distress (USDA/NU Category D):*				
3. Number of animals that will experience pain and/or distress without alleviation (USDA/NU Category E):*				

C. Justification for additional animals: Please justify why more animals are needed and provide an experimental plan with the number of animals in each experimental group:

D. Justification for change of species, etc.: *(if applicable)*

V. CHANGE IN PROCEDURES

A. Procedure to be added/changed:

B. Describe and justify: *(include adverse effects)*

VI. DUPLICATION AND CONSIDERATION OF ALTERNATIVE METHODS

This section is required for a new procedure.

A. Duplication:

- These experiments have not been conducted previously.
- Previously performed experiments were inconclusive.
- Although similar experiments have been performed, these studies extend our knowledge. *(explain below)*
- None of the above apply. *(provide specific justification below)*

B. Alternative Methods Verification for USDA Category D & E Protocols:

Database Search:

Painful/Distressful Procedure: *(describe)*

Date Search Performed: _____ Database(s) searched: _____

Time Period covered _____ No. of references reviewed: _____
by Search: _____

Key words: _____

Repeat the search for each procedure.

C. Narrative statement that non-animal alternatives were evaluated: *(Provide a brief assurance that alternative non-animal models do not exist.)*

VII. THERAPEUTIC RESTRICTIONS

*This section is only applicable for a **new procedure**. In an emergency, animals will be treated to relieve suffering and preserve life, or if necessary, euthanized. Investigators will be contacted prior to diagnostic testing, therapy, or euthanasia whenever possible. In the event that contact is not possible, please respond below, and list restrictions on therapy where applicable:*

A. No therapeutic restrictions exist.

B. Do not use the following medications (e.g., corticosteroids, antihistamines, antibiotics):

C. If emergency euthanasia is necessary, please save the following specimens: (**NOTE: Special arrangements must be made by the responsible investigator with DLAM before onset of the project. Unless otherwise noted, specimen will be placed in DLAM refrigerator for a maximum of 3 days.**)

VIII. SPECIAL CONSIDERATIONS

*This section is applicable for a **new procedure** and may be requested for **change in species**.*

A. What **adverse effects** may occur as a result of these experiments to the animals? (Describe distress, pain, significant discomfort, morbidity, etc.) If adverse effects occur, how will they be alleviated?

B. State the nature and frequency of **observations to evaluate pain/distress** of the animals during the course of the research.

IX. EUTHANASIA OR FINAL DISPOSITION

*This section is applicable for a **new procedure** and **change in species**. What method or agent (including dosage in mg/kg and route of administration) will be used to sacrifice animals? Provide details for each species. If animals are not euthanized please describe their final disposition.*

X. LOCATION(S) OF PROPOSED WORK/EXPERIMENTS INVOLVING LIVE ANIMALS

This section is required for a new procedure.

A. Are live animals ever removed from the DLAM Animal Facilities? Yes No

If Yes, please respond to the following:

Purpose for which room will be used	Building/Room Number	Longest period of time the animals would be present
<input type="checkbox"/> Sacrifice/tissue harvest		
<input type="checkbox"/> Non-surgical survival procedures		
<input type="checkbox"/> Survival surgery		
<input type="checkbox"/> Non-survival surgery		
<input type="checkbox"/> Other (specify):		

XI. QUALIFICATIONS

*This section is applicable for **change in personnel, change in procedure and change in species**. 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.*

Check off the appropriate responses below:

- I, as Principal Investigator, certify that **all personnel** who will be performing animal procedures under this protocol have the knowledge and skills enumerated above, as well as the appropriate training and experience with all the procedures conducted on animals described in the protocol.
- The following individuals will contact the IACUC Administrative Officer (x 3958) to arrange for information and/or training needed to fulfill all the requirements stated above: (use additional pages as necessary)

Name

1.

2.

XII. SIGNATURE

This section is required for all changes.

Principal Investigator

Date

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