AMENDMENT: CHANGES IN PROCEDURES

CHANGES IN PROCEDURES FOR AN APPROVED PROTOCOL

Current Protocol Registry Number:	
Project Title:	Click here to enter text.

1. PRINCIPAL INVESTIGATOR INFORMATION

Principal Investigator: Click here to enter text., Click here to enter text.
Campus Box: Click here to enter text.
Position/Title: Click here to enter text.
Department/College: Click here to enter text.
Office/Cell Phone #:
Email Address: Click here to enter text.

> This application is used to request changes in animal species, number, or methods and procedures associated with the animal use protocol specified above. It is also used to request a change in the Principal Investigator (PI) responsible for work under that protocol.

Indicate the purpose(s) of this request by checking the box(es) that apply. If your revisions are extensive, you may be asked to submit a new protocol.

- [ ] Animal subjects (species, strain, or animal number) [Go to Section 2]
- [ ] Location (building, room) for housing, surgery, or non-surgical procedures. [Go to Section 3]
- [ ] Nonsurgical procedure or treatment. [Go to Sections 4, 6, 7]
- [ ] Surgery (survival, non-survival) or intraoperative procedure. [Go to Sections 5, 6, 7]
- [ ] Intraoperative, post-surgical, or post-procedural care and monitoring. [Go to Sections 8 A,B,C]
- [ ] Humane endpoints. [Go to Section 8 D]
- [ ] Use of hazardous agents (biological, chemical, radiological, laser). [Go to Section 9]
- [ ] Method of euthanasia. [Go to Section 10]
- [ ] Change of Principal Investigator or Principal Investigator animal handling role. [Go to Section 11]
- [ ] Other change in animal use activity. [Go to Section 12]

2. CHANGE IN ANIMAL SPECIES NUMBER

To add additional species, click on the + at the end of each box.

SPECIES	NUMBER CURRENTLY APPROVED	ADD OR DELETE	NUMBER TO BE ADDED / DELETED
Click here to enter text.		☐ ADD ☐ DELETE	
Click here to enter text.		☐ ADD ☐ DELETE	
Click here to enter text.		☐ ADD ☐ DELETE	
Click here to enter text.		☐ ADD ☐ DELETE	
Click here to enter text.		☐ ADD ☐ DELETE	

2.A. JUSTIFICATION FOR ADDED SPECIES

Address each added species individually.

To add additional species, click on the + at the end of each box.

SPECIES	Click here to enter text.
This additional species was selected for the study because of the following attributes (select all that apply):	
☐	A large database exists allowing comparisons with previous data.
Explain:	Click here to enter text.
☐	The anatomy or physiology is uniquely suited to the study proposed.
Explain:	Click here to enter text.
☐	The lowest species on the phylogenetic scale that is suitable for the proposed study.
Explain:	Click here to enter text.
☐	Other attributes:
Explain:	Click here to enter text.

2.B. JUSTIFICATION FOR ADDITIONAL ANIMALS

Address each species individually.

To add additional species, click on the + at the end of each box.

SPECIES:	Click here to enter text.
The number of additional animals requested for this protocol is based on the following (select all that apply):	
☐	The number needed to offset an earlier underestimate of animal requirements.
Explain:	Click here to enter text.
☐	The number required to populate new or expanded experimental groups.
Explain:	Click here to enter text.
☐	A new or revised statistical estimate of the number required to achieve statistical significance.
Explain:	Click here to enter text.
☐	A new or revised estimate of the number necessary to achieve the goals of the study in the absence of a statistical estimate.
Explain:	Click here to enter text.

		The number necessary to obtain additional tissue or other material for testing or analysis.
Explain:		Click here to enter text.
		The number required to provide additional technical training or practice for the number of trainees expected.
Explain:		Click here to enter text.

TABLE 2.C.1. POST-WEANING ANIMALS (ONLY)

To add additional species, click on the + at the end of each box.

ADULT SPECIES:	Click here to enter text.	AGE OR WEIGHT RANGE:		ADDITIONAL NUMBER REQUIRED:	
NUMBER OF ADDITIONAL ANIMALS IN USDA CATEGORIES:					
CATEGORY B: (breeding animals)			CATEGORY D: (procedures using anesthesia/analgesia)		
CATEGORY C: (non-painful procedures)			CATEGORY E: (painful procedures without anesthesia/analgesia)		
SOURCE OF THE ANIMALS:					
Note: for animals transferred from another DU protocol, provide PI name and protocol number:					
PI NAME:		Click here to enter text.	IRBNet NUMBER:		

2.C. DISTRIBUTION OF ADDITIONAL ANIMALS OVER USDA PAIN AND DISTRESS CATEGORIES.

Complete the table below.

TABLE 2.C.A. PRE-WEANING/NEONATAL/EMBRYONIC ANIMALS (ONLY)

To add additional species, click on the + at the end of each box.

PRE-WEANING SPECIES:	Click here to enter text.	AGE OR WEIGHT RANGE:		ADDITIONAL NUMBER REQUIRED:	
NUMBER OF ADDITIONAL ANIMALS IN USDA CATEGORIES:					
CATEGORY B: (breeding animals)			CATEGORY D: (procedures using anesthesia/analgesia)		
CATEGORY C: (non-painful procedures)			CATEGORY E: (painful procedures without anesthesia/analgesia)		
SOURCE OF THE ANIMALS:					
Note: for animals transferred from another DU protocol, provide PI name and protocol number:					
PI NAME:		Click here to enter text.	IRBNet NUMBER:		

3. CHANGE IN LOCATION FOR APPROVED ANIMAL USE ACTIVITY

ADD/DELETE:	BUILDING:	ROOM:	ASSOCIATED ANIMAL USE ACTIVITY:	SPECIES INVOLVED:
☐ ADD ☐ DELETE	Click here to enter text.	Click here to enter text.	☐ housing > 12 hours ☐ housing < 12 hours ☐ survival surgery ☐ non-survival surgery ☐ non-surgical procedures ☐ hazardous agent use ☐ breeding colony	Click here to enter text.

State the reason(s) for the change(s) in location(s) for approved animal use activities:
Click here to enter text.

4. CHANGE IN NON-SURGICAL PROCEDURE

In addition to Section 3, you will also need to fill out Section 5 and Section 6.

4.A. ADDED OR ALTERED NON-SURGICAL PROCEDURE(S)

4.A.1. Describe the non-surgical procedure(s) to be added to this protocol or explain how existing procedures are to be altered. If new animal groups are involved, define group sizes and specify how each group will be tested or used. If testing or use of individual animals occurs over time, define the timeline for experimental events.
Click here to enter text.

4.A.2 Are the added or altered procedures expected to cause pain, but for which pain-relieving anesthetics and/or analgesics will not be provided?
☐ Yes   ☐ No

If you selected 'YES' please complete the following:

a. Identify the treatment groups and specify the number of animals in each group that will not be provided with pain relief.
Click here to enter text.

b. Detail the scientific reason that requires the withholding of anesthetics and/or analgesics for pain relief.
Click here to enter text.

4.B. MONITORING AND HUMANE ENDPOINTS FOR ADDED ALTERED PROCEDURES.

4.B.1. Monitoring of animal condition will be:

☐ as described in the approved protocol
☐ as detailed in section 7 of this form

4.B.2. Monitoring endpoints will be observed:

☐ as described in the approved protocol
☐ as detailed in section 7 of this form

4.C. DELETED PROCEDURE(S)

4.C.1. Specify any existing non-surgical procedures that should be deleted from this protocol.
Click here to enter text.

5. CHANGE IN SURGICAL PROCEDURE

In addition to Section 5, you will also need to fill out Section 6 and Section 7.

5.A. ADDED OR ALTERED SURVIVAL SURGERY PROCEDURE(S)

5.A.1. Describe the survival surgery procedure(s) to be added to this protocol or explain how existing survival surgery procedures are to be altered. If new animal groups are involved, define group sizes and specify how each group will be tested or used. If testing or use of individual animals occurs over time, define the timeline for experimental events.
Click here to enter text.

5.A.2. Will the added or altered survival surgery cause any animal to experience more than one survival surgery procedure?

☐ no, individual animals will be exposed to only a single surgical procedure
☐ yes, the change will cause some individual animals to be subjected to more than one survival surgery

5.A.3. Please describe how the multiple survival surgeries, including any that may have occurred prior to entering this study, are interrelated components of this protocol and why they are necessary to achieve the scientific objective.
Click here to enter text.

5.B. ADDED OR ALTERED NON-SURVIVAL SURGERY PROCEDURE(S)

5.B.1. Describe the non-survival surgery procedure(s) to be added to this protocol or explain how existing non-survival surgery procedures are to be altered. If new animal groups are involved, define group sizes and specify how each group will be tested or used. If testing or use of individual animals occurs over time prior to this non-survival procedure, define the timeline for experimental events.
Click here to enter text.

5.C. MONITORING AND HUMANE ENDPOINTS FOR ADDED OR ALTERED SURGERY.

5.C.1. Monitoring of animal condition will be:

☐ as described in the approved protocol
☐ as detailed in section 7 of this form

5.C.2. Humane endpoints will be observed:

☐ as described in the approved protocol
☐ as detailed in section 7 of this form

5.D. DELETED SURGICAL PROCEDURE(S)

5.D.1. Specify an existing survival or non-survival surgical procedures that should be deleted from this protocol.

Click here to enter text.

6. PURPOSE AND SCIENTIFIC BENEFIT OF ADDED OR ALTERED PROCEDURE

6.1. This section must be filled out in addition to either Section 3 or Section 4.
State the relationship of added procedure(s) to the purpose of the study described in Section B1 of the approved protocol.

Click here to enter text.

6.2. State how the added procedure(s) will contribute to the scientific benefit of the study described in Section B2 of the approved protocol.

Click here to enter text.

7. LITERATURE SEARCH FOR ALTERNATIVES

This section must be filled out in addition to either Section 4 or Section 5.
Alternatives that decrease the potential for pain must be considered whenever potentially painful procedures are proposed, even when the use of pain-relieving drugs is planned. Please provide evidence of a literature search for suitable alternatives to each added/revised potentially painful procedure.

Date literature search was performed (day, month, year): Click here to enter a date.
Years covered by the search (From – To): Click here to enter text.
Keywords used in the search: Click here to enter text.
Databases searched (check all that apply):

☐ Web of Science

☐ AGRICOLA
☐ Biological Abstracts
☐ PubMed/MEDLINE

☐ Animal Welfare Information Center
☐ Other: Click here to enter text.

☐ TOXNET
☐ SciFinder Scholar
☐ AltBib
☐ @ltWeb

☐ UC Davis Guide to Bibliographic Databases for Alternatives Searching
☐ Other: Click here to enter text.

Did the literature search reveal less painful alternatives to the potentially painful procedures that are proposed?
☐ Yes ☐ No

8. CHANGE IN ANIMAL MONITORING OR HUMANE ENDPOINTS

8.A. CHANGE IN MONITORING DURING ANESTHESIA.

8.A.1. This change applies to:
☐ Non-surgical procedures   ☐ Survival surgery   ☐ Non-survival

8.A.2. Indicate below the indices, or changes therein, that will be used to monitor the depth of anesthesia and condition of the animal while under anesthesia. Note that unless specifically deleted, indices specified in the approved protocol continue to apply.

☐ ADD ☐ DELETE :Respiratory rate/effort
☐ ADD ☐ DELETE :Mucous membrane color
☐ ADD ☐ DELETE :Body temperature
☐ ADD ☐ DELETE :Oxygen saturation
☐ ADD ☐ DELETE :Capillary refill time
☐ ADD ☐ DELETE :Heart rate
☐ ADD ☐ DELETE :Blood pressure
☐ ADD ☐ DELETE :EKG
☐ ADD ☐ DELETE :Reflex (specify): Click here to enter text.
☐ ADD ☐ DELETE :Other (specify): Click here to enter text.
☐ ADD ☐ DELETE :Other (specify): Click here to enter text.

8.A.3. For added indices, specify the frequency at which they will be recorded:
Click here to enter text.

8.A.4. For deleted indices, state the reason previously approved indices will no longer be used:
Click here to enter text.

8.B. CHANGE IN MONITORING DURING RECOVERY FROM ANESTHESIA

8.B.1. This change applies to:
☐ Non-surgical procedures   ☐ Survival surgery

8.B.2. Indicate below the indices or changes therein, that will be used to monitor animal condition during recovery from anesthesia. Note that unless specifically deleted, indices specified in the approved protocol continue to apply.

☐ ADD ☐ DELETE :Respiratory rate/effort
☐ ADD ☐ DELETE :Mucous membrane color
☐ ADD ☐ DELETE :Body temperature
☐ ADD ☐ DELETE :Oxygen saturation
☐ ADD ☐ DELETE :Capillary refill time
☐ ADD ☐ DELETE :Heart rate
☐ ADD ☐ DELETE :Blood pressure
☐ ADD ☐ DELETE :EKG
☐ ADD ☐ DELETE :Reflex (specify): Click here to enter text.
☐ ADD ☐ DELETE :Other (specify): Click here to enter text.
☐ ADD ☐ DELETE :Other (specify): Click here to enter text.

8.B.3. For added indices, specify the frequency at which they will be recorded:
Click here to enter text.

8.B.4. For deleted indices, state the reason previously approved indices will no longer be used:
Click here to enter text.

8.C. CHANGE IN MONITORING DURING THE STUDY UNTIL TERMINATION.

8.C.1. The change applies to:
☐ Non-surgical procedures   ☐ Post-survival surgery

Indicate below the parameters, or changes therein, that will be used to detect pain, distress, or discomfort and promote the general well-being of animals during the course of the study. Monitoring of five or more parameters is recommended.

CHOOSE ADD or DELETE	MONITORING PARAMETER	FREQUENCY OF OBSERVATION
☐ ADD ☐ DELETE	Not eating or drinking (requires individual housing)	Click here to enter text.
☐ ADD ☐ DELETE	Fecal and urine output (requires individual housing)	Click here to enter text.
☐ ADD ☐ DELETE	Body weight (requires frequent weight checks)	Click here to enter text.
☐ ADD ☐ DELETE	Behavioral change (aggression, guarding, hiding)	Click here to enter text.

CHOOSE ADD or DELETE	MONITORING PARAMETER	FREQUENCY OF OBSERVATION
☐ ADD ☐ DELETE	Licking, biting, scratching or shaking of procedure site	Click here to enter text.
☐ ADD ☐ DELETE	Hair coat (ruffled fur, lack of grooming, piloerection)	Click here to enter text.
☐ ADD ☐ DELETE	Posture or ambulation (tense, tucked-up, stiff gait)	Click here to enter text.
☐ ADD ☐ DELETE	Activity level (restlessness, pacing, reluctance to move)	Click here to enter text.
☐ ADD ☐ DELETE	Facial expression (eyes dull, pupils dilated, pinning of ears)	Click here to enter text.
☐ ADD ☐ DELETE	Sweating or salivation (stressed rodents salivate excessively)	Click here to enter text.
☐ ADD ☐ DELETE	Oculonasal discharge (rats shed reddish porphyrin pigment)	Click here to enter text.
☐ ADD ☐ DELETE	Teeth grinding	Click here to enter text.
☐ ADD ☐ DELETE	Other, specify: Click here to enter text.	Click here to enter text.

For each monitoring parameter that is added, indicate the action you will take if observations suggest pain, distress, or a decline in animal well-being.
Click here to enter text.

For deleted monitoring parameters, state the reason previously approved parameters will no longer be used:
Click here to enter text.

8.D. CHANGE IN HUMANE ENDPOINTS THAT WILL PROMPT INTERVENTION TO PREVENT CONTINUED PAIN OR DISTRESS.

Humane Endpoints to be Added:
From the list below, select humane endpoints to be added that are appropriate within the context of the present study for determining when intervention for humane reasons will occur. For each endpoint added, indicate the action that will be taken should the endpoint be reached.

TABLE 8.D.A. HUMANE ENDPOINTS

HUMANE ENDPOINT THAT WILL PROMPT ACTION AT RIGHT	VETERINARY CONSULTATION	EUTHANASIA	OTHER ACTION (DEFINE)
☐ Infection unrelated to the protocol.	☐	☐	Click here to enter text.
☐ Signs of moderate to severe pain or distress that was not anticipated by the study plan.	☐	☐	Click here to enter text.
☐ Body weight loss exceeding 15% of free-feeding body weight relative to an age-matched reference.	☐	☐	Click here to enter text.
☐ Mutilation of operative site or other self mutilation.	☐	☐	Click here to enter text.
☐ Neurological disorders (e.g., seizures, blindness, ataxia) that were not anticipated by the study plan.	☐	☐	Click here to enter text.
☐ Cardiopulmonary disorders (e.g. sudden weakness, vascular collapse, coma) that were not anticipated by the study plan.	☐	☐	Click here to enter text.
☐ Abnormal feeding or defecation for 48 hours (e.g., decreased feed or water intake and/or decreased fecal production that is unrelated to the study plan).	☐	☐	Click here to enter text.
☐ Non-weight bearing for 72 hours (e.g., difficulty walking, inability to maintain upright posture)	☐	☐	Click here to enter text.
☐ Other (specify): Click here to enter text.	☐	☐	Click here to enter text.
☐ Other (specify): Click here to enter text.	☐	☐	Click here to enter text.

Humane Endpoints to be Deleted:
Specify humane endpoints that you wish to have deleted from the approved protocol and explain why they are no longer necessary or appropriate for determining when intervention for humane reasons should occur.
Click here to enter text.

9. CHANGE IN HAZARDOUS AGENT USE

9.A. HAZARDOUS AGENTS

9.A.1. Indicate the nature of the change(s) and the type(s) of hazardous agent(s) affected (check all that apply):

*Please confirm with the IBC Chair that change does not need to be reviewed by the IBC

☐ ADD ☐ DELETE : Human cells or fluids
☐ ADD ☐ DELETE : Active virus / bacteria / prion
☐ ADD ☐ DELETE : Attenuated virus / bacteria
☐ ADD ☐ DELETE : Recombinant DNA
☐ ADD ☐ DELETE : Carcinogens / mutagens*
☐ ADD ☐ DELETE : Toxicological agents*
☐ ADD ☐ DELETE : Other hazardous chemicals*
☐ ADD ☐ DELETE : Laser / irradiator / x-ray machines
☐ ADD ☐ DELETE : Radioactive materials
☐ ADD ☐ DELETE : Tissue fixatives (formalin, paraformaldehyde)

TABLE 9.A.A. HAZARDOUS AGENTS

To add additional agents, click on the + at the end of each box.

AGENT (IDENTIFY)	DOSE THE FREQUENCY OF ADMINISTRATION	ROUTE OF ADMINISTRATION	DURATION OF TREATMENT
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

TABLE 9.A.B. IDENTIFYING HAZARDOUS AGENTS

To add additional agents, click on the + at the end of each box.

For each added agent listed above, please address the following issues:

AGENT (identify):　　　Click here to enter text.
The standard operating procedure (SOP) for use of the hazardous agent.
Click here to enter text.
Personnel protection precautions to be used by laboratory personnel and individuals performing animal husbandry:
Click here to enter text.
Length of time the agent remains a threat to the health of the animals or humans working with the animals:
Click here to enter text.
Duration of animal survival between exposure to the agent and euthanasia:

Click here to enter text.	
Means of caging and equipment decontamination:	
Click here to enter text.	
Method of animal waste disposal:	
Click here to enter text.	
Method of animal carcass disposal:	
Click here to enter text.	

10. CHANGE IN METHOD OF EUTHANASIA

10.A. NATURE OF CHANGE IN EUTHANASIA

10.A.1. Please indicate the nature of change that is requested:

☐ Deletion of currently approved method of euthanasia from protocol
☐ Additional method of euthanasia added to the protocol

If additional method(s) of euthanasia are added to the protocol, specify method here:
Click here to enter text.

Indicate why euthanasia method to be deleted is no longer required:
Click here to enter text.

TABLE 10.A.A. GENERALLY ACCEPTABLE METHODS OF EUTHANASIA (INJECTABLE, INHALATION, PHYSICAL UNDER ANESTHESIA)

Specify the method(s) of euthanasia **to be added** below. Use a separate line for each species to which it will apply.

NOTE: Selection of CO_2 as a method of euthanasia requires all personnel listed on this protocol to complete technical training in that method.

To add additional species, click on the + at the end of each box.

SPECIES	METHOD	ANESTHETIC OR INJECTABLE AGENT/DOSE/ROUTE OF ADMINISTRATION OR TRICAINE CONCENTRATION
Click here to enter text.	☐ CO_2 inhalation chamber ☐ Decapitation under anesthesia ☐ Exsanguination under anesthesia ☐ Inhalant anesthetic gas (no ether) ☐ Injectable euthanasia agent ☐ Tricaine (MS-222) immersion	Click here to enter text.

SPECIES	METHOD	ANESTHETIC OR INJECTABLE AGENT/DOSE/ROUTE OF ADMINISTRATION OR TRICAINE CONCENTRATION
	☐ Tricaine (MS-222) applied to gills	

If CO_2 euthanasia was selected for any species, a secondary method to ensure non-recovery is required. Please select the secondary method(s) that will be used to ensure euthanasia:

☐ Bilateral thoracotomy Decapitation
☐ Tissue / organ collection.
☐ Other method to ensure death
☐ Specify tissues / organs: Click here to enter text.
☐ Specify: Click here to enter text.

TABLE 10.A.B. CONDITIONALLY ACCEPTABLE METHODS OF EUTHANASIA (PHYSICAL WITHOUT ANESTHESIA)
To add additional species, click on the + at the end of each box.

SPECIES	METHOD	SCIENTIFIC JUSTIFICATION FR PROCEDURE WITHOUT ANESTHESIA
Click here to enter text.	☐ decapitation without anesthesia ☐ cervical dislocation without anesthesia	Click here to enter text.

TABLE 10.A.C. OTHER METHODS OF EUTHANASIA (CONSISTENT WITH AVMA GUIDELINES ON EUTHANASIA)
To add additional species, click on the + at the end of each box.

SPECIES	METHOD	AGENT/DOSE/ROUTE OF ADMINISTRATION AS APPLICABLE
Click here to enter text.	Click here to enter text.	Click here to enter text.

Please explain the reason for performing euthanasia by a method other than those identified above as generally or conditionally acceptable:
Click here to enter text.

11. CHANGE IN PRINCIPAL INVESTIGATOR

11.A. CHANGE IN PRINCIPAL INVESTIGATOR (PI) RESPONSIBLE FOR PROTOCOL.

Attach a PI Agreement (Protocol Section F) executed by the new Principal Investigator. Also complete and attach a personnel qualifications form (PQF) that reflects skills, experience, and training required for the new PI's animal handling activities.

PQF is not required if a PQF that reflects appropriate skills is already on file as part of this protocol.

TABLE 10.A.A. PI CHANGES RESPONSIBLE FOR PROTOCOL

To add additional PI's click on the **+** at the end of each box.

PI CHANGE	NAME	ANIMAL HANDLING ROLE
☐ ADD ☐ DELETE	Click here to enter text.	Click here to enter text.

11.B. CHANGE IN ANIMAL HANDLING ROLE FOR PRINCIPAL INVESTIGATOR

Complete and attach an updated personnel qualifications form (PQF) that reflects skills, experience, and training required for the additional animal handling activities. (An updated PQF is not required if the PQF currently on file indicates appropriate skills for the new activities.)

TABLE 11.B.A. CHANGE IN ANIMAL HANDLING ROLE FOR PRINCIPAL INVESTIGATOR

To add additional PI's, click on the **+** at the end of each box.

NAME	ADDITIONAL ACTIVITIES	DELETED ACTIVITIES
Click here to enter text.	Click here to enter text.	Click here to enter text.

NOTE: PI Agreement (Protocol Section F) and PQF (Personnel Qualifications Form) are available in the IRBNet Library

12. OTHER CHANGES IN ANIMAL USE ACTIVITIES

12.1. Add the activities that are described in detail below.
Click here to enter text.

12.2. Delete only those activities that are specified below.
Click here to enter text.

12.3. State the reason(s) for the above change(s).
Click here to enter text.