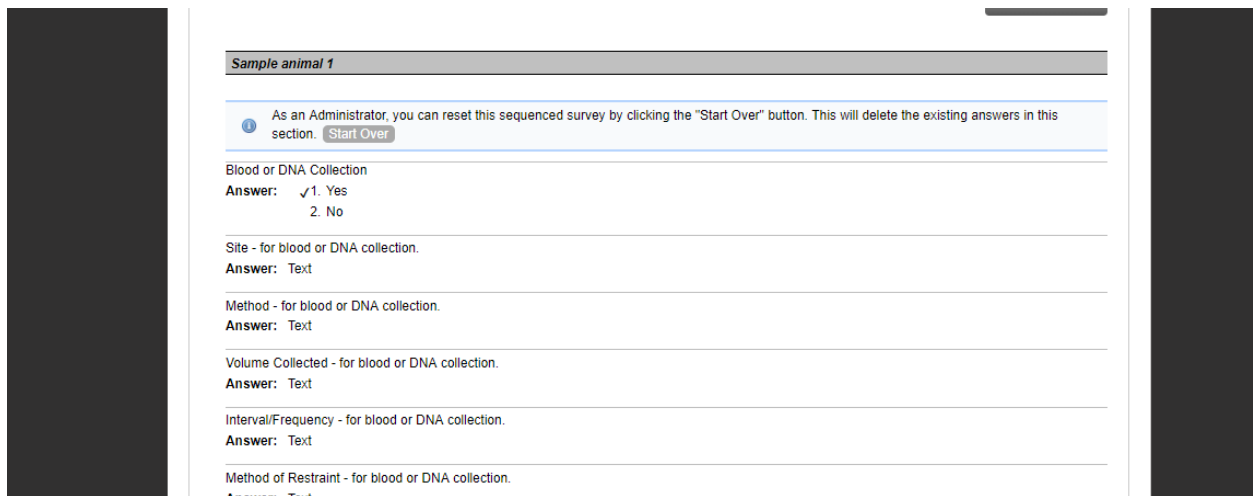


Sample Protocol for Research – Lab Animal Protocols

The attached document contains potential questions that could be asked in the Mentor IACUC system while completing your application.

Please note:

- Application Sections will be generated based on the answers you give on the first page (also known as the protocol page) and certain questions within the Application Sections. For example, if you choose “Research (wildlife)” for the project type, you will see questions tailored to this project type. If you choose “Euthanasia” as a procedure that will be utilized on the Animal Information section, you will see an additional Application Section specific to euthanasia.
- If you listed more than one species on the Animal Information section, you will see that some of the Application Sections contain species-specific questions. Here is an example:



The screenshot shows a form titled "Sample animal 1". At the top, there is a grey header bar with the text "Sample animal 1". Below the header, there is a blue information box with a circular icon containing the number 1. The text in the box reads: "As an Administrator, you can reset this sequenced survey by clicking the 'Start Over' button. This will delete the existing answers in this section." Below the information box, there are several sections of the form, each with a label and an "Answer:" field. The sections are: "Blood or DNA Collection" with a radio button selected for "1. Yes" and "2. No"; "Site - for blood or DNA collection." with a text input field; "Method - for blood or DNA collection." with a text input field; "Volume Collected - for blood or DNA collection." with a text input field; "Interval/Frequency - for blood or DNA collection." with a text input field; and "Method of Restraint - for blood or DNA collection." with a text input field.

- Some of the Application Sections contain sophisticated branching logic. For example, if you select that you will be using anesthesia, you will see additional questions related to that answer.

Please do not hesitate to contact the IACUC Administrator at iacuc@nku.edu or 859-572-5168 with any questions

Research - Lab Animal Protocol Example

IACUC Number 729
PI Anita Southwick
PI Type General Faculty
Department Research, Grants & Contracts
PI Institution
Co-PI's
Research Staff Donna Longworth 07/29/2019
External PIs
Review Type Review Type Not Specified
Approval Status New - Submitted
Submitted By Anita Southwick
Date Received
Date of Completion
Date Approved
Three Year Expiration Date
Proposed Start Date 07/31/2019
Date Closed
Project Type Research (lab animals)
Funding Source NIH KBRIN
Application Type New Protocol
Link to IBC Protocol

Animal Information

Common Name	Scientific Name	Source	Pain/Distress	Total Used
	Sample animal 1	approved vendor xyz	C	400

Strain/Stock:

Sex: M

Age: 45

Which of the following procedures will be utilized for this protocol?

- Answer:**
- 1. Invasive or surgical procedures
 - 2. Experimental/hazardous agents or chemical use (non-anesthetic/non-analgesic)
 - 3. Pain and/or distress
 - 4. None of the above

Will this species be housed at NKU?

- Answer:**
- 1. Yes
 - 2. No

	Sample animal 2	approved vendor xyz	D	45
--	-----------------	---------------------	---	----

Strain/Stock:

Sex: F

Age: 45

Which of the following procedures will be utilized for this protocol?

- Answer:**
- 1. Invasive or surgical procedures
 - 2. Experimental/hazardous agents or chemical use (non-anesthetic/non-analgesic)
 - 3. Pain and/or distress
 - 4. None of the above

Will this species be housed at NKU?

- Answer:**
- 1. Yes
 - 2. No

Personnel Qualifications

PIs	Position
Anita Southwick	Staff
Responsibilities: Administer anesthesia, Animal husbandry, Behavioral procedures, Draw blood/Perform injection, Perform euthanasia, Perform surgery, Post-operative care, Other	
Research Associates	Position
Donna Longworth	Staff
Responsibilities: Animal husbandry	

Questions

✓
The **NKU IACUC Standard Operating Procedures** will be followed by personnel trained and experienced in nonmedical care, handling, and use of the animals listed under this protocol.

✓ The PI has completed all required training within the required timeframe.
All research personnel, including students, will have completed the required training prior to beginning work on this protocol.

✓
The PI and all research personnel (including students) listed on this protocol have completed and submitted the **Animal Contact Assessment** form.

Could any individuals listed on this protocol come in contact with human blood or potentially infectious materials related to potential Hepatitis B exposure?

Answer: ✓1. Yes. As PI, I will verify the completion of Bloodborne Pathogens for all individuals who could come in contact with human blood or potentially infectious materials related to potential Hepatitis B exposure.
2. No

Will DEA scheduled drugs (see <https://www.dea.gov/drug-scheduling>) be used for this protocol?

Answer: ✓1. Yes. Please describe.
2. No

Text

Please select one:

Answer: ✓1. Medical care for animals housed at NKU will be available and provided by the NKU IACUC approved Veterinarian.
2. This protocol will not use the NKU IACUC approved Veterinarian. The **NKU IACUC Veterinarian Exception Form** will be uploaded into Mentor IACUC before submitting the application.
3. Wildlife will remain in the wild and therefore do not require veterinary care. Wildlife that remain at field sites are not required to have medical care provided by veterinary staff.

✓ As the PI, I understand that I am required to submit a revised protocol if any of the approved procedures are changed.

✓
As the PI, I understand that any failure to comply with the provisions of the Animal Welfare Act and the requirements of the **PHS Guide for the Care and Use of Laboratory Animals**, as implemented by the NKU IACUC, may result in the suspension of my animal studies. I hereby provide assurance that the people doing the research are properly trained and qualified and that this work is not unnecessarily duplicative. If toxic materials are to be used in this research project, I have notified the **NKU Department of Safety and Emergency Management**.

Scientific Justification - Research (lab or wildlife)

Questions

Summarize the goals of the proposed research. Use non-technical language that a layperson can understand.

Answer:

Text

Provide a rationale for use of the animals. Explain in language that a layperson can understand and cite reference sources.

Answer:

Text

What are the probable benefits of this work to human or animal health, the advancement of knowledge or the good of society?

Answer:

Text

Explain why computer simulation, in vitro biological systems or audiovisual demonstration are not acceptable alternatives to the use of animals in this project.

Answer:

Text

Justify use of the animal species listed for this protocol. Describe the biological characteristics of the animal that are essential to the proposed study. Include evidence of experience with the proposed animal model and manipulation.

Answer:

Text

Specifically address why fewer animals cannot be used.

Answer:

Text

Summarize your latest literature review.

Answer:

Text

List the date/s of the most recent literature review.

Answer: Text

What years were searched (from – to) for the literature review?

Answer: Text

What databases were used for literature review?

Answer: Text

What keywords and search strategy were used for the literature review?

Answer: Text

Indicate that this activity does not unnecessarily duplicate previous work.

Answer:

Text

Procedures - Non-Wildlife (non-invasive/non-surgical)

Sample animal 1

Blood or DNA Collection

Answer: ✓ 1. Yes
2. No

Site - for blood or DNA collection.

Answer: Text

Method - for blood or DNA collection.

Answer: Text

Volume collected - for blood or DNA collection.

Answer: Text

Interval/Frequency - for blood or DNA collection.

Answer: Text

Method of Restraint - for blood or DNA collection.

Answer: Text

Animal Identification

Answer: 1. Yes
 2. No

Which types animal identification will be used?

Answer: 1. Banding
 2. Micro-tattooing
 3. Microchip
 4. Ear-tagging
 5. Ear-punching
 6. Toe-clipping (altricial neonates only)
 7. Other. Please specify.

Text

Special diets

Answer: 1. Yes
 2. No

Please explain the special diet details.

Answer:

Text

Describe the feeding schedule.

Answer:

Text

Do you plan on documenting intake and weight?

Answer: 1. Yes
 2. No. Please explain why you will not document intake and weight.

What are the possible consequences of the diet change?

Answer:

Text

Will footpad injection be used?

Answer: 1. Yes
 2. No

Describe the method for footpad injection (e.g., needle size, name of solution and concentration, justify the need for these injections, and describe the methods for monitoring and treating any related pain/distress.

Answer:

Text

Will the protocol use or produce monoclonal or polyclonal antibodies?

Answer: 1. Yes, describe below.
 2. No

Text

Will the protocol use tumor production procedures?

Answer: 1. Yes
 2. No

Describe any tumor production procedures being utilized.

Answer:

Text

Describe the monitoring schedule per week.

Answer:

Text

Sample animal 2

Blood or DNA Collection

Answer: 1. Yes
 2. No

Animal Identification

Answer: 1. Yes
 2. No

Special diets

Answer: 1. Yes
 2. No

Will footpad injection be used?

Answer: 1. Yes
 2. No

Will the protocol use or produce monoclonal or polyclonal antibodies?

Answer: 1. Yes, describe below.
 2. No

Will the protocol use tumor production procedures?

Answer: 1. Yes
 2. No

Questions

Food or water restriction.

Answer: 1. Yes
 2. No

Describe the restriction regimen, the duration of the regimen, and how frequently the animals will be weighed during period of food or water

restriction.

Answer:

Text

Provide reference sources regarding the use of these schedules by others or by the PI.

Answer:

Text

Does the protocol involve the production or rederivation of transgenic animals?

Answer: 1. Yes. Please describe.
 2. No

Text

Will non-standard methods of transportation be utilized?

Answer: 1. Yes. Please explain.
 2. No

Text

How will animals be disposed of?

Answer: 1. Euthanized
 2. Other. Please specify.

Will there be other non-invasive/non-surgical procedures relevant to this protocol?

Answer: 1. Yes. Please describe.
 2. No

Text

Invasive or Surgical Procedures

Questions

This project involves:

Answer: 1. Surgical procedures (non-terminal or terminal)
 2. Non-surgical invasive procedures

Does this protocol involve multiple survival surgeries? Please note multiple survival surgeries are discouraged. If this protocol involves multiple survival surgeries please justify.

Answer: 1. Yes. Please note multiple survival surgeries are discouraged. If this protocol involves multiple survival surgeries please justify.
 2. No

Text

Please select the type of surgical procedures.

Answer: 1. Major
 2. Minor
 3. Terminal

Where will the surgical and post-op records be maintained?

Answer: Text

Where will the surgical procedures take place?

Answer: 1. FH 171 C
 2. FH 171 D

3. FH 171 E

4. Other. Please explain.

Please describe the surgical procedure including a description of the surgical site and ancillary care (e.g., fluid administration, maintenance of body temperature) provided during the procedure.

Answer:

Text

Please provide the following information for the anesthetic:

- Name
- Dose range
- Route
- Expected duration of efficacy for each dosing
- Supplemental dose

Answer:

Text

Will you be using gas anesthesia?

- Answer:** 1. Yes
2. No
-

Select the method that will be used:

- Answer:** 1. Vaporizer with scavenger system
2. Drop box method
3. Other. Please describe.
-

How will the anesthesia effects be monitored? Check all that apply.

- Answer:** 1. Respiration rate
2. Corneal reflex
3. Muscle relaxation
4. Blood pressure
5. Mucous membrane color
6. Pulse oximeter
7. Positive toe pinch
8. Other. Please describe.

Text

Describe how the surgical site will be prepared.

Answer:

Text

Select the appropriate surgical sterilization procedures:

- Answer:** 1. Chemical sterilant
2. Steam autoclave sterilization
3. Sterile from manufacturer
4. Gas sterilization (e.g., ethylene oxide)
5. N/A Terminal surgery
6. Other. Please describe
-

Will batch surgery be performed?

- Answer:** 1. Yes. Describe the technique that will be used for batch sterilization (glass bead sterilization or other techniques).
2. No

Text

Please specify the suture material and location on the animal.

Answer:

Text

Will the skin sutures or staples be removed within 14 days?

- Answer:** 1. Yes
 2. No. Please justify.
 3. Not applicable. Please explain
-

How will post-operative pain be monitored and managed if present?

Answer:

Text

Describe the clinical signs of pain.

Answer:

Text

Describe the observation schedule.

Answer:

Text

Will drugs be used to minimize pain, discomfort or distress?

- Answer:** 1. Yes
 2. No. Give specific details as to why pain-relieving drugs will not be used and cite reference sources. Describe any non-pharmaceutical procedures that will be used to minimize pain and distress.
-

If an analgesic will be used, provide the following information:

- Name
- Dose range
- Route
- Expected duration of analgesic efficacy for each dosing
- Supplemental dose

Answer:

Text

Will animals be monitored until returning to consciousness?

- Answer:** 1. Yes
 2. No. Please explain why not and/or describe the alternate plan.

Text

What post-operative supportive care will be provided?

- Answer:** 1. Supplemental health. Please describe.
 2. Fluid therapy. Please describe.
 3. Other. Please describe.

Text

Do you anticipate the possibility of sudden death during the post-operative period?

- Answer:** 1. Yes. Describe, and discuss steps taken to minimize sudden death.
 2. No

Text

Will a second surgical procedure be required?

- Answer:** 1. Yes
 2. No
-

Please select the type of surgical procedures for the second surgery.

- Answer:**
1. Major
 2. Minor
 3. Terminal

Where will the surgical and post-op records be maintained?

Answer: Text

Where will the surgical procedures take place for the second second surgery?

- Answer:**
1. FH 171 C
 2. FH 171 D
 3. FH 171 E
 4. Other. Please explain

Text

Please describe the second surgical procedure including a description of the surgical site and ancillary care (e.g., fluid administration, maintenance of body temperature) provided during the procedure.

Answer:

Text

Please provide the following information for the anesthetic for the second surgery:

- Name
- Dose range
- Route
- Expected duration of efficacy for each dosing
- Supplemental dose

Answer:

Text

Will you be using gas anesthesia for the second surgery?

- Answer:**
1. Yes
 2. No

Select the method that will be used:

- Answer:**
1. Vaporizer with scavenger system
 2. Drop box method
 3. Other. Please describe.

How will the anesthesia effects be monitored for the second surgery? Check all that apply.

- Answer:**
1. Respiration rate
 2. Corneal reflex
 3. Muscle relaxation
 4. Blood pressure
 5. Mucous membrane color
 6. Pulse oximeter
 7. Positive toe pinch
 8. Other. Please describe.

Describe how the surgical site will be prepared for the second surgery.

Answer:

Text

Select the appropriate surgical sterilization procedures for the second surgery:

- Answer:**
1. Chemical sterilant
 2. Steam autoclave sterilization

3. Sterile from manufacturer
4. Gas sterilization (e.g., ethylene oxide)
5. N/A Terminal surgery
6. Other. Please describe

Text

Will batch surgery be performed for the second surgery?

- Answer:**
1. Yes. Describe the technique that will be used for batch sterilization (glass bead sterilization or other techniques).
 2. No

Please specify the suture material and location on the animal for the second surgery.

Answer:

Text

Will the skin sutures or staples be removed within 14 days?

- Answer:**
1. Yes
 2. No. Please justify.
 3. Not applicable. Please explain

Text

How will post-operative pain be monitored and managed if present for the second surgery?

Answer:

Text

Describe the clinical signs of pain for the second surgery.

Answer:

Text

Describe the observation schedule for the second surgery.

Answer:

Text

Will drugs be used to minimize pain, discomfort or distress for the second surgery?

- Answer:**
1. Yes
 2. No. Give specific details as to why pain-relieving drugs will not be used and cite reference sources. Describe any non-pharmaceutical procedures that will be used to minimize pain and distress.

Text

Will animals be monitored until returning to consciousness for the second surgery?

- Answer:**
1. Yes
 2. No. Please explain why not and/or describe the alternate plan.

Text

What post-operative supportive care will be provided for the second surgery?

- Answer:**
1. Supplemental health. Please describe.
 2. Fluid therapy. Please describe.
 3. Other. Please describe.

Text

Do you anticipate the possibility of sudden death during the post-operative period of the second surgery?

- Answer:**
1. Yes. Describe, and discuss steps taken to minimize sudden death.
 2. No

Text

Does this protocol involve any non-surgical invasive procedures (e.g., catheterization)?

- Answer:** 1. Yes
 2. No

Describe the non-surgical, invasive procedures. If anesthetics or analgesics are needed, please describe why and state the name, route, and dose.

Answer:

Text

Where will the invasive, non-surgical procedures take place?

- Answer:** 1. Founders Hall. Please list room/s.
 2. Science Center. Please list room/s.
 3. Other. Please explain.

Text

Housing & Husbandry

Questions

Where will animals be housed?

- Answer:** 1. FH 180 A/B
 2. FH 180 C/D
 3. FH 185 A/B
 4. FH 187 A/B
 5. SC 132
 6. SC 162
 7. SC 361
 8. Other. Please explain.

Text

Please describe the type of caging/tanks to be used including the caging material, cage/tank dimensions and bedding material.

Answer:

Text

Will this project require special housing or husbandry procedures?

- Answer:** 1. Yes
 2. No

Please select the special housing and husbandry procedures.

- Answer:** 1. Reduced cage sizes
 2. Housing for immune-compromised animals
 3. Modified light cycles
 4. >12-hour housing outside of animal facility
 5. Overcrowding
 6. Single housed rodents
 7. No enrichment provided
 8. Wire bottom or metabolic cages
 9. Other. Please specify.

Please justify the need for the special housing and/or husbandry.

Answer:

Text

Pain/Distress and Treatment of Pain/Distress

Questions

Describe the painful or aversive procedures. Examples include blood draw, stressful stimuli, etc.

Answer:

Text

Will there be any prolonged animal restraint?

Answer: 1. Yes
 2. No

Please describe the prolonged animal restraint including the time, frequency and method of restraint.

Answer:

Text

Will drugs be used to minimize pain, discomfort or distress? Please note procedures such as injection, tattooing and blood sampling normally do not require pain relieving drugs.

Answer: 1. Yes
 2. No. Give specific details as to why pain relieving drugs will not be used and cite reference sources. Describe any non-pharmaceutical procedures that will be used to minimize pain and distress.

For the analgesic, please describe the:

- Dose range
- Route
- Expected duration of pain relief for each dosing
- Supplemental dose

Answer:

Text

Which, if any, of the following be used to prevent pain or distress?

Answer: 1. General anesthetics. Please describe.
 2. Local anesthetics. Please describe.
 3. None

Text

Will you be using gas anesthesia to manage pain or distress?

Answer: 1. Yes
 2. No

Select the method that will be used:

Answer: 1. Vaporizer with scavenger system
 2. Drop box method
 3. Other. Please describe.

How will the anesthesia effects be monitored? Check all that apply.

Answer: 1. Respiration rate
 2. Corneal reflex
 3. Muscle relaxation
 4. Blood pressure
 5. Mucous membrane color
 6. Pulse oximeter
 7. Positive toe pinch

8. Other. Please describe.

Text

What is the plan for monitoring the animal until it returns to consciousness?

Answer:

Text

What supportive care will be provided?

Answer: 1. Supplemental health. Please describe.
 2. Fluid therapy. Please describe.
 3. Other. Please describe.

Text

Experimental and/or Hazardous Agents or Chemical Use

Sample animal 1

Will any pharmaceutical, therapeutic or chemical drug treatments be utilized in this protocol? Do not include anesthetics or analgesics.

Answer: 1. Yes
 2. No

For each agent, please provide the:

- agent
- dose
- route
- vehicle
- frequency
- duration
- potential hazard

Answer:

Text

Will non-pharmaceutical grade agents be used in animals?

Answer: 1. Yes
 2. No

List and justify the use of the non-pharmaceutical grade agents.

Answer:

Text

Describe the measures taken to ensure solution sterility.

Answer:

Text

Will neuromuscular blocking agents be used?

Answer: 1. Yes
 2. No

For each, please describe the:

- agent
- dose
- route
- vehicle
- frequency
- duration

- potential hazard

Answer:

Text

Please describe the potential effect/s of each on the animal.

Answer:

Text

Provide a justification for the use of each neuromuscular blocking agent.

Answer:

Text

Please describe the criteria to be used to determine if the animal is in pain, distress or discomfort and how pain, distress or discomfort should be managed should it occur.

Answer:

Text

Provide reference sources regarding the use of the drug for the intended purpose.

Answer:

Text

Please describe the frequency of monitoring.

Answer:

Text

Sample animal 2

Will any pharmaceutical, therapeutic or chemical drug treatments be utilized in this protocol? Do not include anesthetics or analgesics.

Answer: 1. Yes
 2. No

Will non-pharmaceutical grade agents be used in animals?

Answer: 1. Yes
 2. No

Will neuromuscular blocking agents be used?

Answer: 1. Yes
 2. No

Questions

Will you be using any of the following on animals?

1. Microbiological agents (bacterial, virus, fungi, etc.)
2. Human source materials (human blood, tissues/cells, etc.)
3. Recombinant DNA (rDNA)
4. Carcinogenic, hazardous or toxic agents
5. Radioactive agents

Answer: 1. Yes. Please describe.
2. No

Text

Identify the location of where the agents or chemicals will be used.

Answer:

Text

Will you be taking agents or chemicals into the field?

- Answer:** ✓1. Yes. How will you transport and store them safely?
2. No

Text

Describe the containment strategy to prevent or reduce contamination beyond the individual animal.

Answer:

Text

Does the study require IBC review and approval?

- Answer:** 1. Yes
2. No
✓3. Unsure - Please contact the IBC Chair before submitting the IACUC application.

Euthanasia

Sample animal 1

How will animals be euthanized?

- Answer:** 1. Carbon dioxide (compressed gas only)
✓2. Decapitation
3. Cervical dislocation
4. Perfusion with fixative under anesthesia. Please provide source, name, dose, and route.
5. Anesthetic overdose. Please provide source, name, dose, and route.
✓6. Other. Please describe.

Text

Will agents be used to aide in euthanasia?

- Answer:** ✓1. Yes. Please describe the agent, dose, and route.
2. No. If euthanizing by decapitation or cervical dislocation, please justify why an anesthetic cannot be administered prior to euthanasia, and describe experience with technique.

Text

Could any of the following symptoms occur as an outcome of the proposed work and would be allowed to persist for purposes of the research including at what point the animal will be euthanized?

- Weight loss
- Tumor
- Dehydration
- Neurological abnormalities
- Inability to defecate or urinate
- Respiratory distress
- Ocular abnormalities
- Impaired motor movements
- Other symptoms

- Answer:** ✓1. Yes. Please characterize the symptoms.
2. No

Text

Will animals be allowed to persist in an adverse state until the end point is met?

- Answer:** ✓1. Yes, justify below.
2. No

Text

Sample animal 2

How will animals be euthanized?

- Answer:**
1. Carbon dioxide (compressed gas only)
 2. Decapitation
 3. Cervical dislocation
 4. Perfusion with fixative under anesthesia. Please provide source, name, dose, and route.
 5. Anesthetic overdose. Please provide source, name, dose, and route.
 6. Other. Please describe.

Text

Will agents be used to aide in euthanasia?

- Answer:**
1. Yes. Please describe the agent, dose, and route.
 2. No. If euthanizing by decapitation or cervical dislocation, please justify why an anesthetic cannot be administered prior to euthanization, and describe experience with technique.

Text

Could any of the following symptoms occur as an outcome of the proposed work and would be allowed to persist for purposes of the research including at what point the animal will be euthanized?

- Weight loss
- Tumor
- Dehydration
- Neurological abnormalities
- Inability to defecate or urinate
- Respiratory distress
- Ocular abnormalities
- Impaired motor movements
- Other symptoms

- Answer:**
1. Yes. Please characterize the symptoms.
 2. No

Will animals be allowed to persist in an adverse state until the end point is met?

- Answer:**
1. Yes, justify below.
 2. No

Questions

Where will animals be euthanized?

- Answer:**
1. Founders Hall. Please list room/s.
 2. Science Center. Please list room/s.
 3. Other. Please list location.

Text

At what stage in the experiment will animals be euthanized?

Answer:

Text

- I certify that the selected euthanasia methods are consistent with current AVMA or related standards for the species to be used.

Annual Reports

Amendments

Protocol Deviations/Adverse Events

Event/Date	Status	Deviation File/Comments	Submitted By
No Protocol Deviations/Adverse Events Found			

Reviewer Comments