# Mentor IACUC Application Section Questions

General Faculty, Staff and Student Researcher Questions

\*NOTE: This document is to serve as an aid with the questions that could be asked during submittal of a new IACUC protocol. Do not submit this word document to the IACUC. \*

[Procedure for Submitting a new IACUC Protocol in Mentor](https://inside.nku.edu/content/dam/rgc/docs/ResearchCompliance/IACUC/PoliciesandProcedures/SOP%20%231%20(IACUC)%20PI%20-%20Submitting%20a%20New%20IACUC%20Protocol.pdf)

# Project Type

* Research (lab animals)
* classroom/teaching (lab animals)
* classroom/teaching (wildlife)
* Research (wildlife)

The following categories apply to all project types of animal research. Only those in bold apply to just their specific project type category.

Application Section Question Categories

## Animal information

## Personnel qualifications

## **Scientific Justification – Research (lab or wildlife)**

## **Scientific Justification- Classroom/Teaching (wildlife and non wildlife)**

## **Procedures- Non wildlife (non invasive/non surgical)**

## **Procedures- Wildlife (non invasive/ non surgical)**

## Invasive or surgical procedures

## Housing and Husbandry

## Pain/Distress and Treatment of Pain/Distress

## Experimental and/or Hazardous Agents or Chemical Use

## Euthanasia

## Animal Info

USDA Category C, USDA Category D, USDA Category E- add species and answer following questions about each

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

* Invasive or surgical procedures
* Experimental/hazardous agents or chemical use (non-anesthetic/non-analgesic)
* Pain and/or distress
* None of the above

1. Will this species be housed at NKU?

* Yes
* no

## Personnel Qualifications

* 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.

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

* 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.
* No

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

* Yes. Please describe.
* No

**IF YES**, describe the procedures for secure storage and recordkeeping of use for scheduled drugs for each scheduled drug. Also, state the:

* Drug,
* Source,
* schedule category,
* DEA license number that covers their use on this protocol

1. Please select one:

* Medical care for animals housed at NKU will be available and provided by the NKU IACUC approved Veterinarian.
* 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.
* 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)

1. Summarize the goals of the proposed research. Use non-technical language that a layperson can understand.
2. Provide a rationale for use of the animals. Explain in language that a layperson can understand and cite reference sources.
3. What are the probable benefits of this work to human or animal health, the advancement of knowledge or the good of society?
4. Explain why computer simulation, in vitro biological systems or audiovisual demonstration are not acceptable alternatives to the use of animals in this project.
5. 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.
6. Specifically address why fewer animals cannot be used.
7. Summarize your latest literature review.
8. List the date/s of the most recent literature review.
9. What years were searched (from – to) for the literature review?
10. What databases were used for literature review?
11. What keywords and search strategy were used for the literature review?
12. Indicate that this activity does not unnecessarily duplicate previous work.

## Procedures- non wildlife (non invasive/non surgical)

1. Blood or DNA Collection?

* Yes, please describe.
* No

**IF YES,** please describe:

* the site
* method
* volume to be collected
* interval frequency
* method of restraint

1. Animal Identification?

* Yes
* No

**IF YES**, which type of animal identification will be used?

* Banding
* Micro-tattooing
* Microchip
* Ear-tagging
* Ear-punching
* Toe-clipping (altricial neonates only)
* Other. Please specify.

1. Special diets?

* Yes, please describe special diet.
* no

**IF YES**, Describe the feeding schedule.

Do you plan on documenting intake and weight?

* yes
* No, please explain why you will not document intake and weight.

What are the possible consequences of the diet change?

1. Will footpad injection be used?
   * Yes
   * no

**IF YES**, 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.

1. Will the protocol use or produce monoclonal or polyclonal antibodies?

* Yes, describe below.
* No

1. Will the protocol use tumor production procedures?

* Yes
* No

**IF YES,** describe any tumor production procedures being utilized.

Describe the monitoring schedule per week.

1. Food or water restriction.

* Yes
* no

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

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

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

* Yes
* no

**IF YES,** please provide a general description of the genetic modification, how the animals are derived, are any behavioral or physical changes expected, and the method of genotyping.

1. Will non-standard methods of transportation be utilized?

* Yes, please describe
* no

**IF YES**, please describe how animals will be transported outside of their designated facility. Describe measures that will be taken to avoid potential disease transmission to researchers and other animals.

1. How will animals be disposed of?

* Euthanized
* Other, please specify.

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

* Yes, please describe.
* no

## Invasive and Surgical Procedures

1. This project involves:

* Surgical procedures (non-terminal or terminal)
* Non-surgical invasive procedures

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

**IF YES**, please note multiple survival surgeries are discouraged. If this protocol involves multiple survival surgeries please justify. **Then continue to #3**

**If NO,** Describe the non-surgical, invasive procedures. If anesthetics or analgesics are needed, please describe why and state the name, route, and dose.  **Then Continue to #29**

1. Please select the type of surgical procedures. If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Major
* Minor
* Terminal

1. Where will the surgical and post-op records be maintained? If the protocol involves multiple surgeries, answer this question for only the first surgery.
2. Where will the surgical procedures take place? If the protocol involves multiple surgeries, answer this question for only the first surgery.

* 1.FH 171 C
* 2.FH 171 D
* 3.FH 171 E
* Other. Please explain.

1. 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. If the protocol involves multiple surgeries, answer this question for only the first surgery.
2. Please provide the following information for the anesthetic:

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

1. Will you be using gas anesthesia? If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Yes
* No

**IF YES**, Select the method that will be used: If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Vaporizer with scavenger system
* Drop box method
* Other. Please describe.

9. How will the anesthesia effects be monitored? Check all that apply. If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Respiration rate
* Corneal reflex
* Muscle relaxation
* Blood pressure
* Mucous membrane color
* Pulse oximeter
* Positive toe pinch
* Other. Please describe.

1. Describe how the surgical site will be prepared. If the protocol involves multiple surgeries, answer this question for only the first surgery.

10. Select the appropriate surgical sterilization procedures. If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Chemical sterilant
* Steam autoclave sterilization
* Sterile from manufacturer
* Gas sterilization (e.g., ethylene oxide)
* N/A Terminal surgery
* Other. Please describe

1. Will batch surgery be performed? If the protocol involves multiple surgeries, answer this question for only the first surgery.

**IF YES,** Describe the technique that will be used for batch sterilization (glass bead sterilization or other techniques).

1. Please specify the suture material and location on the animal. If the protocol involves multiple surgeries, answer this question for only the first surgery.
2. Will the skin sutures or staples be removed within 14 days? If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Yes
* No. Please justify.
* Not applicable. Please explain

1. How will post-operative pain be monitored and managed if present? If the protocol involves multiple surgeries, answer this question for only the first surgery.
2. Describe the clinical signs of pain. If the protocol involves multiple surgeries, answer this question for only the first surgery.
3. Describe the observation schedule. If the protocol involves multiple surgeries, answer this question for only the first surgery.
4. Will drugs be used to minimize pain, discomfort or distress? If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Yes
* 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 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 YES**, if an analgesic will be used, provide the following information:

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

1. Will animals be monitored until returning to consciousness? If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Yes
* No. Please explain why not and/or describe the alternate plan.

1. What post-operative supportive care will be provided? If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Supplemental health. Please describe.
* Fluid therapy. Please describe.
* Other. Please describe.

1. Do you anticipate the possibility of sudden death during the post-operative period? If the protocol involves multiple surgeries, answer this question for only the first surgery.

* Yes. Describe, and discuss steps taken to minimize sudden death.
* No

1. Will a second surgical procedure be required?

* Yes
* No

**IF NO, go to #29**

**IF YES**, please select the type of surgical procedures for the second surgery.

* Major
* Minor
* Terminal

1. Where will the surgical and post-op records be maintained?
2. Where will the surgical procedures take place for the second surgery?

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

1. 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.
2. 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

1. Will you be using gas anesthesia for the second surgery?

* Yes
* No

**IF YES**, Select the method that will be used:

* Vaporizer with scavenger system
* Drop box method
* Other. Please describe.

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

* Respiration rate
* Corneal reflex
* Muscle relaxation
* Blood pressure
* Mucous membrane color
* Pulse oximeter
* Positive toe pinch
* Other. Please describe.

1. Describe how the surgical site will be prepared for the second surgery.
2. Select the appropriate surgical sterilization procedures for the second surgery:

* Chemical sterilant
* Steam autoclave sterilization
* Sterile from manufacturer
* Gas sterilization (e.g., ethylene oxide)
* N/A Terminal surgery
* Other. Please describe

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

* Yes
* No

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

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

* Founders Hall. Please list room/s.
* Science Center. Please list room/s.
* Other. Please explain. List room/s or area.

## Housing & Husbandry

1. Where will animals be housed?

* FH 180 A/B
* FH 180 C/D
* FH 185 A/B
* FH 187 A/B
* SC 132
* SC 162
* SC 361
* Other. Please explain.

1. Please describe the type of caging/tanks to be used including the caging material, cage/tank dimensions and bedding material.
2. Will this project require special housing or husbandry procedures?
3. Please select the special housing and husbandry procedures.

* Reduced cage sizes
* Housing for immune-compromised animals
* Modified light cycles
* >12-hour housing outside of animal facility
* Overcrowding
* Single housed rodents
* No enrichment provided
* Wire bottom or metabolic cages
* Other. Please specify.

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

## Pain/Distress and Treatment of Pain/Distress

1. Describe the painful or aversive procedures. Examples include blood draw, stressful stimuli, etc.
2. Will there be any prolonged animal restraint?
3. Please describe the prolonged animal restraint including the time, frequency and method of restraint.
4. 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.

* Yes
* 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. 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.

1. For the analgesic, please describe the:

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

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

* General anesthetics. Please describe.
* Local anesthetics. Please describe.
* None

**IF YES**, please describe the:

* Dose range
* Route
* Length of time anesthetized
* Supplemental dose

## Experimental and/or Hazardous Agents or Chemical Use

1. Will you be using any of the following on animals?

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

**IF YES,** please describe. (If yes, please describe the: source, dose, route, duration of action, activity after elimination)

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

3. Will you be taking agents or chemicals into the field?

* Yes. How will you transport and store them safely?
* No

1. Describe the containment strategy to prevent or reduce contamination beyond the individual animal.
2. Does the study require IBC review and approval?

* Yes
* No
* Unsure - Please contact the IBC Chair before submitting the IACUC application.

## Scientific Justification – Classroom/Teaching (wildlife and non wildlife)

1. Summarize the objectives of this classroom classwork. Use non-technical language that a layperson can understand.
2. What are the probable benefits of this work to human or animal health, the advancement of knowledge or the good of society?
3. Explain why computer simulation, in vitro biological systems or audiovisual demonstration are not acceptable alternatives to the use of animals in this project.
4. 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.
5. Specifically address why fewer animals cannot be used.

## Procedures- wildlife (non invasive/non surgical)

1. Describe the fieldwork site. Upload a map on the protocol page if needed.
2. Food or water restriction?

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

Provide reference sources regarding the use of these schedules.

1. Select the required permits for the use of the requested species and/or for access to the study area.

* Federal
* State
* Local
* Other. Please specify.
* N/A. Please explain.

1. I have uploaded the required permits to this application.

* Yes
* No, permit application is in progress. Work cannot begin until permit is uploaded into Mentor IACUC.
* Not applicable

1. Will animals be brought back to NKU?
2. Will animals be housed at NKU over 12 hours?
3. How will animals be disposed of?

* Released into the wild
* Euthanized
* Other. Please specify.

1. Describe the study procedures for trapping/handling animals.
2. Describe the type of trap/handling
3. What is the duration of trapping/restraint?
4. If injuries or conditions result from pursuit, capture or manipulation, how will this be addressed?
5. Will there be other non-invasive/non-surgical procedures relevant to this protocol?

* Yes, please describe.
* No

Euthanasia

1. Where will animals be euthanized?

* Founders Hall. Please list room/s.
* Science Center. Please list room/s.
* Other. Please list location.

1. At what stage in the experiment will animals be euthanized?

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