MIDWESTERN UNIVERSITY
OFFICE OF RESEARCH AND SPONSORED PROGRAMS

IACUC – IL - ANIMAL USE PROTOCOL FORM (AUP)

NOTE: This completed form must be received no later than the first of the month in order to insure consideration at the Institutional Animal Care and Use Committee (IACUC) monthly meeting). Fill out this form and email it to ORSP **(ncronk@midwestern.edu**) for review.

I. GENERAL INFORMATION

PRINCIPAL INVESTIGATOR(S):

DEPARTMENT/COLLEGE:

PROJECT TITLE:

PROTOCOL STATUS:

☐ New

☐ Triennial Renewal of IACUC file # **If this protocol is a three-year renewal, complete and attach APPENDIX 3**

☐ Major amendment to IACUC file # (please underline the modifications to the original protocol) (ORSP only) Amendment #

PROTOCOL TYPE

☐ Education
☐ Non-funded Research
☐ Funded Research – Funding Agency:

EMERGENCY CONTACT - Who should be contacted in case of an animal emergency?

Name:
Office Phone #
Cell Phone #

II. PERSONNEL INFORMATION – *NOTE: MWU requires for all personnel engaged in animal research to be properly trained and qualified through experience in order to conduct the work humanely. Non-trained personnel will not be granted access to the animal facility. Contact our Manager of the Animal resources for information on required training.*

A. LIST ALL PERSONS INVOLVED IN THIS PROTOCOL. List the PI first

Name / Title	Role in the protocol (what procedures will each person be doing?)	Experience / Training

III. ANIMAL INFORMATION - This section must be completed for each species used.

A. SPECIES:

B. STRAIN:

C. TOTAL # OF ANIMALS TO BE USED FOR THE ENTIRE THREE YEARS OF PROTOCOL:

D. SEX:

E. AGE OR WEIGHT RANGE:

F. SOURCE (e.g., commercial, donated, captured from wild):

G. ARE THE ANIMALS GOING TO BE KEPT (HOUSED AND USED) INSIDE THE MWU CENTRALIZED VIVARIUM?

☐ Yes. Proceed to section IV.

☐ No. List all labs / rooms outside of the MWU centralized vivarium where you intend to keep or use live animals in connection with the animal use covered under this protocol.

NOTE: If animals are to be kept in a lab for more than 12 hours, this will be defined as a housing area and must meet all the standards of the same, including, possibly, central management.
This list is for IACUC information to assure each location is inspected semi-annually. Listing rooms here does not assure approval of this space for use.

Building	Room #	Max length of stay	Method of transportation	Purpose

IV. PROJECT DESCRIPTION

A. LAY SUMMARY - Please provide a brief (300 words or less) synopsis in layman's terms of proposed research -

B. BACKGROUND INFORMATION - scientific hypothesis, rationale and purpose specific aims and experiments/ tests planned per aim (1 page max) -

C. DETAILED EXPLANATION OF THE USE OF ANIMALS PER AIM /EXPERIMENT – Provide:

- A clear concise sequential description of the procedure(s) involving the use of animals. It is critical to provide for each procedure a detailed sequence of events that effectively describes what happens to the live animals.
- Number/groups of animals intended to use per aim/experiment. Flow charts, diagrams or tables are strongly recommended to explain the experimental design -

NOTE: Do not provide detailed description of surgical procedures and drug treatments in this section as they will be addressed later.

D. RATIONALE FOR THE APPROPRIATENESS OF THE SPECIES SELECTED – Provide a justification of the selected species and number of animals to be used -

V. CATEGORY OF PAIN OR DISTRESS

- Only one (the highest) category of pain or distress should be indicated.

☐ CATEGORY **B** – Animals bred, conditioned or held for use in teaching, testing, research, but not yet used for such purposes. *(NOTE: If tail snips are necessary for genotyping, this*

category is not appropriate).

☐ CATEGORY **C** – Procedures that involve no or only very brief pain or distress, with no need for or use of pain relieving drugs.

☐ CATEGORY **D** – Procedures involving potential pain or distress for which appropriate anesthetics, analgesics, or tranquilizers are given. *(NOTE: Contact Veterinary Resources (Dr. Emma Liechty – eliech@midwestern.edu) for suggestions on "appropriate" agents as needed).*

☐ CATEGORY **E** – Painful or distressful procedures for which drugs to relieve the pain or distress are withheld because they would adversely affect the research study. *(NOTE: STRONG SCIENTIFIC JUSTIFICATION MUST BE GIVEN FOR ANY RESEARCH FALLING UNDER THIS CATEGORY).*

VI. ALTERNATIVES AND DUPLICATION

A. IF EITHER CATEGORY OF PAIN OR DISTRESS **D** OR **E** IS CHECKED, YOU **MUST** PROVIDE DOCUMENTATION OF AN ELECTRONIC SEARCH TO:

1. Explore for alternatives to animal use.
2. Explore alternatives to painful procedures that may cause more than momentary or slight pain or distress to the animal.
3. Ensure proposed experiments are not redundant.

The minimal written narrative should **include the databases searched and other sources consulted** (e.g. a professional organization, such as the AMA, or a veterinarian), **the date of the database search, the years covered by the search, and the major key words and/or search strategy used**. The narrative should be such that the IACUC can readily assess whether the search topics or other sources consulted were appropriate and whether the database search was sufficiently thorough. *If an alternative exists but is not used, provide specific scientific justification for the decision.*

Databases searched:
Date of search (years covered):
Key words:
Findings of search:

B. DOES THIS RESEARCH REPLICATE PREVIOUS WORK?

☐ No. Proceed to section VII.

☐ Yes. Explain why the replication is necessary:

VII. RESEARCH PROCEDURES – Check all that apply.

A. WILL ANIMALS BE IMMUNIZED FOR ANTIBODY PRODUCTION?

☐ No. Proceed to section B.

☐ Yes. Complete the following table:

Injection:

Volume of injectate	Adjuvant	Route	Min. Frequency	Max. # of injections

Collection: If terminal, check here ☐ otherwise complete the following:

Route	Max. Volume	Min. Frequency	Max. # of collections

B. WILL TISSUES (BLOOD INCLUDED) BE HARVESTED (other than for antibody production)?

☐ No. Proceed to section C.

☐ Yes. **Complete and attach Appendix 1.**

C. WILL FOOD OR WATER BE RESTRICTED?

☐ No. Proceed to section D.

☐ Yes.

- What are the restriction parameters? Provide scientific justification:
- How will you monitor for negative effects of food/water restriction (include information on how you will account for animal growth)?

D. WILL NON-PHARMACEUTICAL GRADE DRUGS/REAGENTS BE ADMINISTERED?

☐ No. Proceed to section E.

☐ Yes. List and provide scientific justification:

E. WILL ANIMALS BE EXPOSED TO **ANY** SUBSTANCES (except analgesics, and anesthetics) OR PHYSICAL AND/OR ENVIRONMENTAL STRESS AS PART OF THE RESEARCH BUT NOT AS A TREATMENT REQUIRED BY THE VETERINARIAN?

☐ No. Proceed to section F.

☐ Yes. **Complete Appendix 4a.**

F. WILL ANIMALS BE USED FOR BEHAVIORAL STUDIES?

☐ No. Proceed to section G.

☐ Yes. Describe possible effects on animal wellness:

G. WILL ANY ANIMALS HAVE ANY IMPLANTED DEVICE?

☐ No. Proceed to section H.

☐ Yes. Provide details of the implant:

H. WILL ANY ANIMALS HAVE AN IMPLANTED DEVICE CHRONICALLY EXTERIORIZED (e.g., thermocouple, cannula, and electrode) THROUGH THE SKIN?

☐ No. Proceed to section I.

☐ Yes. Describe animal care and housing measures to maintain the animal health and welfare:

I. WILL ANIMALS UNDERGO PHYSIOLOGIC MEASUREMENTS (e.g., blood pressure, telemetry, electrophysiology, etc.)?

☐ No. Proceed to section J.

☐ Yes. Describe special procedures and provide scientific justification:

J. WILL ANIMALS BE USED FOR BREEDING?

☐ No. Proceed to section K.

☐ Yes. Provide scientific justification and assure breeding comply with the IACUC standard procedures packet for animal housing/overcrowding (see table below):

K. SPECIAL HOUSING CONSIDERATIONS - ***NOTE: all research animals must be housed and used within the Animal Facility. If they are to be transported out of the central animal facility into the investigator's laboratory, prior IACUC approval is required.***

K.1 Are the animals to be housed under a 12/12 light/dark cycle?

☐ Yes. Proceed to section K.2.

☐ No. Provide scientific justification:

K.2 Are the animals to be group housed?

NOTE: Social housing is a regulatory requirement for all species, unless scientific justification for single housing is approved. If some portion of the experiment requires single housing, but group housing would be acceptable for portion, then this must be described.

☐ Yes. Proceed to section K.3.

☐ Yes, but only for a portion of the experimental procedure. Provide details and scientific justification:

☐ No. Provide scientific justification:

K.3 Are the animals to be housed in presence of standard enrichment (e.g. nesting material, crawl balls, igloos/fast tracks)?

NOTE: The standard enrichment is required unless scientifically justified otherwise.

☐ Yes, for any or all. Proceed to section K.4.

☐ Yes, but only for a specific type of enrichment. Please indicate which one and provide scientific justification:

☐ No. Provide scientific justification:

K.4 Are the animals subjected to a diet different from the standard one in use in the animal facility?

☐ No. Proceed to section L.

☐ Yes. Provide specification on the diet and justification:

L. WILL ANY ANIMALS NEED TO BE INDIVIDUALLY IDENTIFIED?

☐ No. Proceed to section M.

☐ Yes. Describe the marking technique to be used, why that technique was chosen, how it will be performed, and on what age range of animals

M. WILL ANIMALS UNDERGO NON-SURGICAL PROCEDURES THAT REQUIRE ANESTHESIA?

☐ No. Proceed to section N.

☐ Yes. Describe special procedures and complete the chart below:

ANESTHETIC REGIMEN:

Drug and concentration	Dose	Route

Describe measures used to assess that the animal is fully anesthetized before proceeding with the procedure:

N. WILL ANIMALS UNDERGO SURGERY?

☐ No. Proceed to section O.

☐ Yes. **Complete and attach Appendix 2.**

O. WILL ANIMALS POSSIBLY EXPERIENCE ADVERSE CLINICAL SIGNS INTENTIONALLY OR AS A POSSIBLE SIDE EFFECT OF THE STUDY?

☐ No. Proceed to section VIII.

☐ Yes. Complete the following and proceed to section VIII:

Possible Clinical Effect	Probability of Occurrence	Treatment

VIII. CONTROLLED SUBSTANCES

Does this protocol involve the use of controlled substances (e.g., ketamine, pentobarbital, androgens, diazepam, buprenorphine)?

☐ No. Proceed to section IX.

☐ Yes. List all controlled substances:

IX. END POINT CRITERIA

Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering (some common criteria could be weight loss ≥ 15%, loss of appetite or mobility, lethargy, failure to groom, unkept appearance, open sores/ necrotic skin lesions, signs of distress/pain, etc.):

X. EUTHANASIA

A. WHICH EUTHANASIA METHOD WILL BE USED?

☐ CO_2 euthanasia by gradual inflow method as used in the Animal Facility.

☐ Overdose of chemical anesthetics. Include name and dose.

Name	Dose

☐ Pentobarbital euthanasia solution iv or ip. Include pentobarbital dose and route of administration.

Name	Dose	Route

☐ Physical method (e.g. exsanguination) under anesthesia. Complete the chart below for administration of general anesthetic(s)

Name	Dose	Route

☐ Cervical dislocation as a primary method of euthanasia without anesthesia.

NOTE: The approved designated trainer for this method must be observed and verified by either the AF manager or Attending Veterinarian.

☐ Decapitation as a primary method of euthanasia without anesthesia. Provide scientific justification:

NOTE: The approved designated trainer for this method must be observed and verified by either the AF manager or Attending Veterinarian.

☐ Other: Describe and present justification. If the method does not follow current AVMA guidelines, then further justification is needed:

B. NAME(S) AND QUALIFICATIONS OF PERSON(S) PERFORMING A PHYSICAL METHOD EUTHANASIA:

Name	**Qualification/ Experience**

C. WHICH CONFIRMATION (SECONDARY) METHODS OF EUTHANASIA WILL BE USED?

☐ Bilateral thoracotomy

☐ Decapitation

☐ Vital tissue harvest (inclusive of heart and/or lungs and/or brain)

☐ Cervical dislocation

☐ Other?

XI. CERTIFICATION BY PRINCIPAL INVESTIGATOR(S)

I certify that, to the best of my knowledge, the information provided in protocol is complete and

accurate and the work will be performed as described here and approved by IACUC.

I certify that the activities described in this protocol do not unnecessarily duplicate previous experiments and are consistent with animal welfare regulations and standards for animal use described by the USDA (9CFR Parts I, II, III) and by the PHS (Guide for the Care and Use of Laboratory Animals).

I agree that any significant changes in my ongoing research protocol must first be submitted to the IACUC for appropriate review and approval.

I will ensure that all personnel involved in animal use related to this protocol have reviewed the protocol and have been properly trained in all the procedures described therein.
I will ensure that all personnel named on this protocol will have access to a copy of the approved protocol at any time they need it for reference to approved methods.

I will ensure that all personnel involved in animal use are trained for facility access by Animal Facility personnel or designee before any personnel involved with protocol are allowed to enter the animal facility and work with animals.

I will ensure that any use of photography or videography of animals, animal procedures, or gross anatomical tissues are for research purposes only and have been approved by the Associate Director of Research Operations, per the Animal Resources Department SOP #0001 "Photography/Videography of Animals used in IACUC Approved Research Projects." The PI and all personnel listed in this protocol understand that posting any photos or videos of animals to social media is never approved.

I will ensure that any adverse events or unexpected outcomes are reported to the IACUC per the IACUC Procedures and Practices SOP "Reporting Requirements and Non-Compliance."

Finally, I will ensure that all personnel have been educated as to the health risks entailed and have been offered participation in the Animal User Occupational Health Program of MWU. (A copy of the Animal User Occupational Health Program is available for review in the Office of Research and Sponsored Program Office).

_____ _____

Investigator Date

Upon notification of action by the Institutional Animal Care and Use Committee, you are authorized to place orders for animals though the Associate Director of Research Operations. Orders will be placed provided that caging and animal care can be provided.

Approved

_____ _____

IACUC Chair or Designated Member Reviewer Date

(Note this is the Official Approval Date for New Protocols and Triennial Resubmitted Protocols. Significantly Amended Protocols retain their original approval date.)

APPENDIX 1: SPECIMEN COLLECTION (attach if applicable)

A. WILL BLOOD BE COLLECTED FROM LIVE (AWAKE OR ANESTHETIZED) ANIMALS?

☐ No. Proceed to section F.

☐ Yes. Complete the following.

Site (which blood vessel)	Volume (ml)	% BW	Max. # of collections	Min. Interval

B. WILL ANESTHETICS, SEDATIVES, OR OTHER DRUGS BE USED DURING BLOOD COLLECTION?

☐ No. Proceed to section C.

☐ Yes. Complete the following.

Drug	Dose	Route	Purpose

C. DESCRIBE THE METHODS USED TO DRAW THE BLOOD INCLUDING PHYSICAL RESTRAINT, IF ANY:

D. PROVIDE SCIENTIFIC JUSTIFICATION FOR BLOOD COLLECTION AND FREQUENCY OF IT (REFER TO THE AIMS/EXPERIMENTS OF YOUR PROTOCOL)

E. WHO WILL DRAW THE BLOOD?

Name	**Qualification/ Experience**

F. WILL OTHER TISSUES OR BODY FLUIDS BE COLLECTED FROM LIVE (AWAKE OR ANESTHETIZED) ANIMALS?

☐ No. Appendix 1 is completed.

☐ Yes. Complete the following. Surgical procedures should be fully described in Appendix 2.

Tissue/Fluid	Site and Method	Max # of collections	Min Interval

G. WILL ANESTHETICS, SEDATIVES, OR OTHER DRUGS BE USED DURING TISSUE/BODY FLUID COLLECTION?

☐ No. Proceed to section H.

☐ Yes. Complete the following.

Drug	Dose	Route	Purpose

H. DESCRIBE THE METHODS USED TO COLLECT SAMPLES, INCLUDING PHYSICAL RESTRAINT, IF ANY:

I. PROVIDE SCIENTIFIC JUSTIFICATION FOR THE SAMPLE COLLECTION(S) AND FREQUENCY OF IT

J. WHO WILL COLLECT TISSUES OR BODY FLUIDS?

Name	Qualification/ Experience

APPENDIX 2: SURGICAL PROCEDURES (attach if applicable)

I. GENERAL INFORMATION

A. LIST ALL SURGICAL PROCEDURE(S) THAT WILL BE PERFORMED ON LIVE ANIMALS (e.g., gonadectomy, MCA ligation etc.)

B. ROOM/LOCATION OF SURGERY:

C. NAME(S) AND QUALIFICATIONS OF PERSON(S) PERFORMING SURGERY

Name	Qualification/ Experience

II. PRE-SURGICAL PREPARATION

PREPARATION OF INSTRUMENTS - The instruments will initially be autoclaved for 15-20 minutes, at 121 degrees Centigrade at 15 PSI. Wrapped autoclaved packs will be dated and will include a sterility indicator inside the pack. Instruments that cannot be autoclaved are either soaked in glutaraldehyde (Cidex) for 10 hours following the manufacturers label directions or sterilized by ethylene oxide or plasma H2O2 method. Any instruments sterilized with glutaraldehyde will be liberally rinsed with sterile water and placed into a sterile tray using sterile technique.

PREPARATION OF ANIMAL - The fur will be clipped from the surgical site with clippers, loose hair removed by vacuum or brush, followed by three alternating scrubs of tamed iodine (e.g., betadine) or chlorhexidine scrub and sterile water. A sterile drape will be placed on the animal.

PREPARATION OF SURGEON - Clean scrubs or lab coat, hair bonnet, and mask are required, followed by hand scrubbing and donning of sterile surgical gloves. Procedure gloves, such as supplied in the animal facilities, are not sterile.

A. WILL THE PRE-SURGICAL PREPARATION BE PERFORMED AS DESCRIBED ABOVE?

☐ Yes

☐ No. Provide a precise description of the presurgical preparation you intend to apply:

B. WILL UNSCRUBBED PERSONNEL BE PRESENT IN THE SURGICAL ROOM TO HELP MAINTAIN ASEPTIC CONDITIONS THROUGHOUT THE SURGICAL PROCEDURE?

☐ Yes

☐ No. Describe how the surgeon can guarantee performing all the surgical steps, monitoring and adjusting anesthesia, handling non-sterile material and, if applicable, moving animals while maintaining asepsis:

III. SURGICAL PROCEDURES ☐ Survival ☐ Non-survival

A. DESCRIBE AND JUSTIFY SCIENTIFICALLY **EACH** SURGICAL PROCEDURE (e.g., approach, tissue manipulation, closure):

B. WILL PRE-ANESTHETIC DRUGS BE USED?

☐ No. Proceed to section C.

☐ Yes. Complete the following.

Drug & concentration (e.g.,mg/ml)	Dose (e.g.mg/kg)	Route	Purpose

C. ANESTHETIC REGIMEN:

Drug and concentration	Dose	Route

Describe measures used to assess that the animal is fully anesthetized before proceeding with surgery:

D. ADDITIONAL PHARMACOLOGICAL AGENTS USED DURING SURGERY (include analgesics, supportive medications, and research drugs):

Drug and concentration	Dose	Route	Frequency	Purpose

E. WILL ANIMALS BE PROVIDED A SUPPLEMENTARY HEAT SOURCE TO MAINTAIN HOMEOTHERMY WHILE UNDER ANESTHESIA?

☐ No. This is a terminal (non-survival) procedure.

☐ Yes. Describe:

F. WILL ANY ANIMALS RECOVER FROM SURGERY?

☐ No. This is a terminal (non-survival) procedure - Appendix 2 is complete.

☐ Yes. Complete Section IV.

IV. POST-SURGICAL CARE

A. IS POST-OPERATIVE PAIN OR DISTRESS ANTICIPATED?

☐ No.

☐ Yes.

B. WILL ANALGESICS BE USED?

☐ No. Provide a scientific justification:

☐ Yes. Complete the following.

Drug and concentration	Dose/Volume	Frequency (every … hrs for … days)	Route

C. POST-OPERATIVE CARE:

1. Will drugs be administered (e.g., antibiotics, fluids)?

Drug and concentration	Dose/Volume	Route	Frequency	Purpose

2. What other post-operative support and monitoring will be provided, how often (in hr. time), for how long and by whom?

D. WILL ANIMALS UNDERGO MULTIPLE SURVIVAL SURGICAL PROCEDURES?

☐ No. Appendix 2 is complete.

☐ Yes. Describe which surgeries, the sequence (timeline), and frequency. Provide scientific justification:

APPENDIX 3: TRIENNIAL RENEWAL PROGRESS REPORT
(Attach if applicable)

- If this protocol is a three-year renewal, provide a brief summary (max 1 page) of the **animal experiments** conducted during the last three years.
- List the aims of your previous protocol and indicate # of animals used and unused per aim.
- If work with animals was not initiated under the previous protocol, please indicate so.

APPENDIX 4A: HAZARD IDENTIFICATION

(Attach if applicable)

(To be completed by the PI)

1. Does this research require review of recombinant or synthetic DNA/RNA being administered to animals?

☐ No.

☐ Yes. (Complete table)

Agent	Dose	Route	Purpose

2. Does this research require review of one or more infectious agents (bacteria, fungi, virus, protozoa, flatworm, round worm, prion protein) being administered to animals?

☐ No.

☐ Yes. **(Please specify any required Biological Agents User Application Form(s), Lab-specific biosafety SOP and Lab-specific ECP and complete table.)**

Agent	Dose	Route	Purpose

3. Does this research require review of one or more hazardous chemicals being administered to animal in the research aims of the protocol?

☐ No.

☐ Yes. **(Please specify any required SOPs and complete table.)**

Agent	Dose	Route	Purpose

4. Does this research require review of one or more drugs being administered to animals in the research aims of the protocol?

☐ No.

☐ Yes. **(Please specify any required SOPs and complete table.)**

Agent	Dose	Route	Purpose

5. Does this research require review of one or more radiolabeled chemicals being administered to animals in the research aims of the protocol?

☐ No.

☐ Yes. **(Please specify any required Authorized User Application and Supervised User Application(s) and complete table.)**

Agent	Dose	Route	Purpose

6. Does this research require review of one or more physical hazard, (other than radionuclides) in the research aims of the protocol? Physical hazards include, heat, cold, laser, radiation sources that are not included in question #5, trauma, injury, electric shock, physical restraint, forced exercise, etc.

☐ No.

☐ Yes. **(Please specify any required SOPs and complete table.)**

Hazard	Purpose	Justification

7. Does this research require review of the use or administration of one or more Select Agents and Toxins in this protocol?

☐ No.

☐ Yes. **(Please complete table.)**

Agent	Dose	Route	Purpose

8. Does this research require review of one or more substances being administered to animals **in the research aims of the protocol** that are not included in question #s 1→7? Substances could include food supplements, additives etc. that you may consider harmless.

☐ No.

☐ Yes. **(Please specify any required SOPs and complete table.)**

Agent	Dose	Route	Purpose

APPENDIX 4B: Approval of Lab Safety and Biosafety Hazards in IACUC Submissions

(To be completed by Biosafety and/or Radiation Safety Committee Chair)

Applicable Forms completed by PI and Approved by Biosafety/Radiation Safety Committees:

☐ Biological Agents User Application Form(s)

☐ Lab-specific Biosafety SOP

☐ Lab-specific ECP

☐ SOPs

☐ Authorized User Application

☐ Supervised User Application(s)

Does the work presented in this protocol require non-routine protective measures for the personnel working with the animals?

☐ No.

☐ Yes. (Please list additional measures.)

The PI (name of the PI) …… may initiate studies using the agent(s) listed in this protocol upon final approval from the IACUC committee.

_____

Chair of the Biosafety committee (printed or typed)

_____

Chair of the Biosafety Committee Signature/Electronic Signature Date

_____

Chair of the Radiation Safety Committee (printed or typed)

_____

Chair of the Radiation Safety Committee Signature/Electronic Signature Date