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**Institutional Animal Care and Use Committee**

**Protocol Application for the Use of Animals**

**~ All requested information is required by** [**PHS**](http://grants.nih.gov/grants/olaw/references/phspol.htm) **and** [**USDA**](https://www.aphis.usda.gov/animal_welfare/downloads/bluebook-ac-awa.pdf) **Regulations ~**

***Make sure to refer to the Instructions when completing this application.***

**REQUIRED SECTIONS**

1. **Principal Investigator Assurance Statement**
2. **General Information**
3. **Personnel**
4. **Personnel Qualifications**
5. **Animal Information/USDA Category of Animal Use**
6. **Holding and Procedure Room Information**
7. **Lay Summary**
8. **Experimental Design**
9. **Euthanasia/Disposition of Animals**
10. **IACUC Policies, Procedures and Guidance**
11. **Refinement, Reduction, Replacement**

**PROCEDURAL APPENDICES**

**Check “yes” for those** [**appendices**](https://animal.research.wvu.edu/protocols) **that need to be completed for your protocol and check “no” for those appendices that do not apply to your protocol. Include applicable appendices with your protocol submission. Please submit all forms in Word format.**

 **YES** **NO**

**Appendix A Surgery and Management of Surgical Pain and Distress**[ ] [ ]

**Appendix B Other Non-Surgical Procedures** [ ] [ ]

**Appendix C Use of Drugs in Animals (non-euthanizing agents)** [ ] [ ]

**Appendix E Breeding Animals** [ ] [ ]

**Appendix F Transgenic/Knock-out Animals** [ ] [ ]

**Appendix G Category E Justification** [ ] [ ]

**Appendix H Physical Restraint** [ ] [ ]

**Appendix I Use of Biological or Infectious Materials in Animals** [ ] [ ]

**Appendix J Use of Radioactive Materials in Animals** [ ] [ ]

**Appendix K Satellite Housing Request** [ ] [ ]

**Appendix L Protocol Renewal Progress Report** [ ] [ ]

**Appendix N Additional Species** [ ] [ ]

**Appendix O Single Housing (only needed if there WILL be animals singly housed)** [ ] [ ]

**Appendix R Field Work** [ ] [ ]

**Appendix S Food / Water Changes for Study Purposes** [ ] [ ]

***BE SURE TO ATTACH ALL APPLICABLE PROCEDURAL APPENDICES!***

**Return your application and all required appendices to the IACUC Office:** **IACUC@mail.wvu.edu**

1. **Principal Investigator Assurance**

**As the Principal Investigator (Instructor), I certify that I will adhere to all WVU Animal Care and Use Committee (WVU ACUC) regulations. I am responsible for assuring that all animal related procedures follow accepted practices as detailed in Federal (Animal Welfare Act, Public Health Services Policy, etc.) and State laws, and as detailed in WVU ACUC policies, OLAR SOPs and as promulgated by the Institutional Official. I assume responsibility to assure that all personnel listed are properly** [**trained**](https://animal.research.wvu.edu/training) **in all procedures detailed in this protocol that are assigned to them, including the criteria for euthanasia. I assume responsibility for ensuring that all personnel involved in this project are informed of the Occupational Health hazards and appropriately trained. I also understand that any changes to the project(s) involving the live animals described in this protocol must be reviewed and approved by the WVU IACUC before implementation.**

**Principal Investigator Date**

*This must be signed by the Principal Investigator* ***OR sent to the IACUC office from the PI’s email address.***

1. **General Information**

|  |  |
| --- | --- |
| **Principal Investigator:**   |  |
| **PI Title:**       | **PI E-mail:**       |
| **PI Phone:**       | **PI Fax:**       |
| **Department:**       | **PO Box:**       |
| **Contact Person:**       | **Contact E-mail:**       |
| **Contact Phone:**       | **Contact Fax:**       |

**Project title:**

**Type of protocol:** [ ]  **Maintenance** [ ] **Research** [ ] **Service**

(check all that apply) [ ]  **Teaching** [**indicate subject & course#(s)**]

**Protocol Classification:** [ ] **New**

 [ ] **Renewal\* Current Protocol #:**       \*Progress Report required

 [ ] **Amendment Amendment # (if known):**

**Collaborations:** Check here if this protocol involves collaboration with another organization? [ ]

**Funding Source (NIH, NIA, NSF, VA, foundation, departmental, etc.)**

**All funding updates should be submitted ASAP as an amendment during the 3-yr life of protocol.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Source | Grant number | OSP # | Funding period | Active or Pending |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

1. **Personnel**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Department | Procedures | Email |
|       |       |       |       |
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 |  |

1. **Personnel Qualifications**
2. **List the qualifications of all personnel on this protocol who will be responsible for each procedure and/or for training others on the procedures. Please note that the qualifications/experience should be related to the procedures listed in this protocol.**

1. **All people working on this protocol must follow the WVU Occupational Health policies for working with or near animals. Are all of the listed personnel on this protocol, including the PI, enrolled in the WVU Occupational Health and Safety Program?**

[ ] **Yes** [ ] **No**

**If no, indicate which personnel are not enrolled and why.**

*If you know of any people who will be in close proximity of the work you will be doing with/on animals but are not listed on this protocol, PLEASE contact the IACUC office, (304) 293-1050. It is very important that WVU and the IACUC identify ALL personnel who may need to work around animals so that a risk assessment can be completed to be sure that allergies, etc. will not negatively impact their health.*

1. **COI: Please ensure that the Principal Investigator, the Co-Investigators and all other key personnel listed on this protocol have filed an annual Disclosure of Interest in Research (DOIR) form**.

For further assistance in fulfilling this requirement, contact Joy Edwards at 304-293-5475.

***NOTE – Any personnel add forms submitted as amendments in the future will be added by the IACUC office after this page.***

1. **Animal Information**

***BE SURE TO READ INSTRUCTIONS for definitions of pain categories!***

***\*If Category E is indicated, you must complete*** [***Appendix G***](https://animal.research.wvu.edu/protocols)

1. **Will any of the animals be exposed to any of the following? Check yes or no for each.**

**YES NO**

[ ] [ ]  **Prolonged restraint (>30 minutes) of unanesthetized animals (See Appendix H)**

[ ] [ ]  **Food and/or food access changes for study purposes (See Appendix S)**

[ ] [ ]  **Water and/or water access changes for study purposes (See Appendix S)**

[ ] [ ]  **Special diet or water for study purposes (See Appendix S)**

[ ] [ ]  **Reverse light cycle**

[ ] [ ]  **Changes to enrichment or no enrichment**

[ ] [ ]  **More than momentary pain or unrelieved pain**

[ ] [ ]  **Aversive methods (e.g., forced swim)**

1. **SPECIES #1**

|  |
| --- |
| Scientific and/or Common Name:       |
| Strain/Stock/Breed:       |
| Sex:       |

*Indicate the total number of animals to be used in each pain category (see* ***BELOW*** *for category definitions):*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pain Category: | B | C | D | E\* | B+C+D+E= |
| Animal number for 3 yrs.: |       |       |       |       |       |
| Provide a justification for the chosen pain category/categories: |       |

1. **SPECIES #2**

|  |
| --- |
| Scientific and/or Common Name:       |
| Strain/Stock/Breed:       |
| Sex:       |

*Indicate the total number of animals to be used in each pain category (see* ***BELOW*** *for category definitions):*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pain Category: | B | C | D | E\* | B+C+D+E= |
| Animal number for 3 yrs.: |       |       |       |       |       |
| Provide a justification for the chosen pain category/categories: |       |

**Pain Category Definitions:**

**B** – Animals used for breeding or other purposes where no experimental manipulations are required.

**C** – Animals will undergo procedures or experience conditions that would not normally cause more than momentary or slight pain or distress, including animals that will be euthanized because they are considered “extraneous”.

**D** – Animals may potentially experience more than momentary or slight pain or distress and will receive some corrective measures, such as anesthetics, analgesics, or tranquilizers during or after the procedure.

**E\*** - Animals may potentially experience more than momentary pain or distress and will not receive a corrective measure, such as anesthetics, analgesics or tranquilizers or other therapies to alleviate pain or distress.

**6. Holding and Procedure Room Information**

**A. Check preferred buildings/locations for animals to be *housed/held* for 24 hours or more.**

[ ]  **HSC**

[ ]  **LSB**

[ ]  **BRNI**

[ ]  **FARF** (Farm Animal Research Facility)

[ ]  **Davis College of Agriculture** ([ ]  Stewartstown, [ ]  Organic Farm, [ ]  Agronomy Farm,

[ ]  Wardensville, [ ]  Willow Bend, [ ]  Reedsville)

[ ]  **Potomac State College**

[ ]  **WVU Tech**

[ ]  **Satellite** ([Appendix K](https://animal.research.wvu.edu/protocols) must be completed and submitted for satellite requests)

[ ]  **Other, specify**:

**B. List all buildings/locations where animal *procedures* will be performed.**

**You do NOT have to list animal housing rooms.**

|  |  |  |
| --- | --- | --- |
| Building/Site\*  | Room\*\* | Procedures to be performed here |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

**\*Buildings** – HSC, LSB, BRNI, FARF, Stewartstown Farm, Wardensville (Reymann Memorial) Farm, Willow Bend Farm, Potomac State College, Reedsville Farm, or other site (e.g., wildlife/capture location).

**\*\*Rooms** – Room numbers in buildings above or specific buildings (e.g., Pole Barn, Dairy Barn, Sheep Barn, etc.)

1. **Lay Summary**
2. **Provide a brief (≤250 words) but complete lay summary of the proposed use of animals.**

1. **Indicate the benefit of your research to society, human health, animal health or the advancement of science.**

1. **Experimental Design ~Do not include procedure specifics in this section~**
2. **Give a scientific description of the project and the use of animals in it. Be sure to include discussion of each point detailed in the instructions AND a sequential schema for animal use from acquisition to final disposition.**

1. **Justify the number of animals requested and describe how the numbers of experimental animals were obtained based on experimental requirements, not convenience or cost. *Note that these numbers need to be consistent with section 5.***

1. **Euthanasia/Disposition of Animals**
2. **Describe the method(s) for euthanasia. List agents, dose ranges and route in the chart below if applicable. When required, describe a secondary method/verification of euthanasia that will be used to ensure death. NOTE: each euthanasia method you use only needs to be indicated once in the chart, based on the PRIMARY CAUSE of death.**

|  |  |
| --- | --- |
| Inhalant | Secondary Method/Verification of Euthanasia(e.g., cervical dislocation, decapitation, bilateral thoracotomy, vital organ removal) |
| [ ]  CO2 | [ ]  from tank: 30-70% chamber vol/min |       |
| [ ]  Other      Justify       |       |
| [ ]  Isoflurane | [ ]  4-5% to effect[ ]  Other       |       |
|
| [ ]  Other  |      Justify       |       |

|  |  |
| --- | --- |
| Injectable | Secondary Method/Verification of Euthanasia(e.g., cervical dislocation, decapitation, bilateral thoracotomy, vital organ removal, exsanguination, pithing) |
| [ ]  Pentobarbital |  |
|  [ ]  standard dose range per species (see Formulary) [ ]  non-standard dose       |       |
| [ ]  Other       |       |

|  |  |
| --- | --- |
| Physical | Secondary Method/Verification of Euthanasia(e.g., bilateral thoracotomy, vital organ removal, exsanguination, pithing, delivery of potassium chloride) |
| [ ]  Cervical dislocation (may be used with small birds, poultry, mice, immature rats (<200g) and rabbits) |
|  [ ]  under deep anesthesia Anesthesia used, route and dose:       |        |
|  [ ]  without anesthesia Scientific Justification:        |  |
| [ ]  Decapitation (may be used with rodents and rabbits in research, and poultry in agriculture) |
|  [ ]  under deep anesthesia Anesthesia used, route and dose:       | N/A |
|  [ ]  without anesthesia Scientific Justification:        | N/A |
| [ ]  Under deep anesthesia: Anesthesia used, route and dose:       |
|  [ ]  Exsanguination Route/site of blood removal:       Volume of blood removed:       |
|  [ ]  Perfusion \*note: if tissue collection occurs PRIOR to perfusion, you will LIKELY need to submit an Appendix A for non-survival surgery [ ]  formalin/paraformaldehyde [ ]  saline/buffer [ ]  other       |
|  [ ]  Vital organ removal [ ]  heart [ ]  brain [ ]  liver [ ]  other       |
|  [ ]  Thoracotomy |
|  [ ]  Other       |
| [ ]  Captive Bolt | **Secondary Method**(e.g., potassium chloride administration IV rapidly, exsanguination, pithing):       | **Verification of Euthanasia**:       |
| [ ]  Other       |       |       |

1. **Provide scientific justification for euthanasia methods that are not described as “acceptable” by the** [**AVMA Guidelines on Euthanasia, 2020**](https://www.avma.org/sites/default/files/2020-01/2020-Euthanasia-Final-1-17-20.pdf)**.**

1. **Describe disposition of animals, if other than by euthanasia.**

**10.** **Policies, Procedures, and Guidelines**

**Check one of the three boxes, “YES”, “NO” or “N/A” (not applicable) for each policy or SOP listed below, based on the work that is proposed in this protocol. If “NO” is checked for any of the policies or SOPs, you must include a justification\*.**

**Find all current polices here:** [**https://animal.research.wvu.edu/policies-and-guidelines**](https://animal.research.wvu.edu/policies-and-guidelines)**.**

1. **Approved IACUC Policies, Guidelines and SOPs**

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | N/A | IACUC Policy, SOP and Guidelines |
| [ ]  | [ ]  | [ ]  | **Acclimation of Newly Acquired Animals** |
| [ ]  | [ ]  | [ ]  | **Acquisition of Agricultural Animals** |
| [ ]  | [ ]  | [ ]  | **Acquisition and Disposition of Biomedical Research and Teaching Animals** |
| [ ]  | [ ]  | [ ]  | **Administration of Substances to Research and Teaching Animals** |
| [ ]  | [ ]  | [ ]  | **Aquatic Vertebrate Guidelines** |
| [ ]  | [ ]  | [ ]  | **Autoclave Validation and Sterile Pack Processing** |
| [ ]  | [ ]  | [ ]  | **Biomedical Research Involving Changes to Food or Fluid** |
| [ ]  | [ ]  | [ ]  | **Blood Collection – Maximum Volumes and Fluid Replacement** |
| [ ]  | [ ]  | [ ]  | **Breeding and Weaning of Mice and Rats** |
| [ ]  | [ ]  | [ ]  | **Certification, Maintenance and Use of Equipment Used for Inhalation Anesthesia in Animals** |
| [ ]  | [ ]  | [ ]  | **Environmental Enrichment for Animals** |
| [ ]  | [ ]  | [ ]  | **Euthanasia by Decapitation or Cervical Dislocation** |
| [ ]  | [ ]  | [ ]  | **Euthanasia Guidelines** |
| [ ]  | [ ]  | [ ]  | **Field Studies** |
| [ ]  | [ ]  | [ ]  | **Guidelines for Aging Animals** |
| [ ]  | [ ]  | [ ]  | **Hazardous Chemicals Used with Animals** |
| [ ]  | [ ]  | [ ]  | **Multi-Dose and Mixed-Substance Container Labeling, Use and Expiration** |
| [ ]  | [ ]  | [ ]  | **Multiple Survival Surgeries in the Same Animal** |
| [ ]  | [ ]  | [ ]  | **Non-Pharmaceutical Grade Substances Used in Animals** |
| [ ]  | [ ]  | [ ]  | **OLAR ABSL-2 Use in Animals** |
| [ ]  | [ ]  | [ ]  | **Pain and Distress Recognition – Humane Endpoints** |
| [ ]  | [ ]  | [ ]  | **Prevention and Management of Fighting (Aggression) in Mice** |
| [ ]  | [ ]  | [ ]  | **Prolonged Restraint of Animals** |
| [ ]  | [ ]  | [ ]  | **Q Fever** |
| [ ]  | [ ]  | [ ]  | **Reporting Adverse Events/Unexpected Outcomes Policy** |
| [ ]  | [ ]  | [ ]  | **Reporting Animal Welfare Concerns and Whistleblower Protections** |
| [ ]  | [ ]  | [ ]  | **Residue Avoidance in Research Using Food-producing Agricultural Animals** |
| [ ]  | [ ]  | [ ]  | **Satellite Housing Policy** |
| [ ]  | [ ]  | [ ]  | **Social Housing of Research Animals** |
| [ ]  | [ ]  | [ ]  | **Surgery Guidelines for Rodents** |
| [ ]  | [ ]  | [ ]  | **Surgery Guidelines for USDA Regulated Species** |
| [ ]  | [ ]  | [ ]  | **Toe Clipping for Animal Identification** |
| [ ]  | [ ]  | [ ]  | **Transportation of Animals used in Biomedical Research and Teaching** |
| [ ]  | [ ]  | [ ]  | **Tumor Development Endpoints for Euthanasia in Rodents** |
| [ ]  | [ ]  | [ ]  | **Use of Radioactive Materials in Animal Studies** |
| [ ]  | [ ]  | [ ]  | **Veterinary Recommendations for Anesthesia and Analgesia** |

1. **IACUC-Approved CORE Facility SOPs**

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | N/A | SOP |
| [ ]  | [ ]  | [ ]  | **Animal Models and Imaging Facility (AMIF) SOP** |
| [ ]  | [ ]  | [ ]  | **Inhalation Facility SOP** |
| [ ]  | [ ]  | [ ]  | **Rodent Behavior Core (RBC) SOP** |
| [ ]  | [ ]  | [ ]  | **Superovulation of Female Mice for Embryo Collection SOP** |

1. **\*Justification as to why one or more of the above policies cannot be followed:**

1. **For each Guideline, Policy or SOP for which I have checked “YES”, I affirm that I have read it and will follow it as written.** [ ]  **Agree** [ ]  **Disagree**

**11.** **Replacement, Reduction and Refinement of Use of Animals**

1. **Replacement**
2. **Provide a justification for using animals rather than non-animal alternatives.**

1. **Justify the need for each species that you selected.**

1. **Reduction**
2. **Does this proposed project unnecessarily duplicate previous work?** [ ]  **Yes** [ ]  **No**

**If yes, justify:**

***If this project involves pain categories B or C, SKIP 11C!***

***If this project involves categories D or E, fill out section 11C based on species being used!***

1. **Refinement**

***Non-USDA-regulated species*** *(typically mice, rats and birds used for biomedical/behavioral research and farm animals used for agricultural or food/fiber research) must complete question #1.*

***USDA-regulated species*** *(any warm-blooded vertebrate animal used for research except for mice, rats and birds and agricultural animals used for food/fiber research) must complete questions #2-#5.*

1. ***Non-USDA-regulated species –* Summarize why alternative(s) to potentially painful/distressful procedures cannot be used for this study.**

1. ***USDA-regulated species –* List/describe the procedures in this protocol that may potentially lead to pain and/or distress in animals.**

1. ***USDA-regulated species –* Complete two database searches that specifically look for alternatives to the potentially painful or distressful procedures listed in section 11.C.1.**

|  |  |  |
| --- | --- | --- |
|  | 1st search | 2nd search |
| Database searched: |       |       |
| Date of search: |       |       |
| Publication dates: |       |       |
| Boolean operators & search words used: |       |       |
| Number of hits per search: |       |       |

1. ***USDA-regulated species –* Based on this search, are there any alternatives to painful or distressful procedures that have been described in any of the proposed projects that would be compatible with your experimental design?**

 [ ]  **Yes**  [ ]  **No**

1. ***USDA-regulated species –* Regardless of whether you found alternatives or not, you must summarize the findings of the results obtained by the search for alternatives to painful or distressful procedures that was performed above.**