

Office of Research Services



THE UNIVERSITY OF LETHBRIDGE

animal WELFARE approval form – Research

*Complete, sign, and send* ***an electronic copy*** *of the Animal Welfare Approval Form, and supporting documentation, to the* *Animal Welfare Coordinator**. Applications received* ***two weeks prior to the next Animal Welfare Committee meeting will be considered at that meeting.***

**CONFIDENTIAL**

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| **Consult the Canadian Council on Animal Care (CCAC) *Guide to Care and Use of Experimental Animals, Ethics of Animal Investigation*, and pertinent guidelines before completing this form (**[**http://www.ccac.ca/**](http://www.ccac.ca/)**).****For appendices, guidelines and forms visit the** [**Research Services**](https://www.uleth.ca/research/animal-welfare-guidelines-forms) **website.**  | **For Research Services use only:** |
| Protocol: # |
| *Date Approved:* |
| Principal Investigator: |

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| PART I - ADMINISTRATIVE INFORMATION |

*This information is collected under the authority of the Alberta Post-secondary Learning Act and will be used for administrative purposes associated with the review of your animal welfare protocol. It will be treated in accordance with the privacy protection provisions of Part 2 of the Alberta Freedom of Information and Protection of Privacy Act. Questions about the collection, use or disclosure of your personal information collected on this form can be directed to Danika Dorchak, Office of Research & Innovation Services, University of Lethbridge, Lethbridge, Alberta, T1K 3M4, Phone: (403) 382-7198, Email:* *animal.ethics@uleth.ca* *.*

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| **Principal Investigator (PI)** | **Department** | **email address** |
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| **Business Phone** | **Home Phone** | **Cell Phone** |
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| **Co-Investigator(s)** | **Department** | **email address** |
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| **24 hour emergency contact** | **Business Phone** | **Cell Phone** |  |
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| **alternate Emerg Contact** | **Business Phone** | **Cell Phone** |
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| Project Title |  |

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| [ ]  **NEW Application** | [ ]  **RENEWAL of Protocol #**  |  |
| [ ]  **MAJOR Modification requiring a complete application** | [ ]  **PILOT** [ ]  **New Direction in Existing Protocol** |
|  |  [ ]  **Not Related to an Existing Protocol** |
| Click or tap to enter a date. | Click or tap to enter a date. |
| **Proposed Start Date of Research** | **Expected Date of Completion** |

*For multi-year projects, approval will only be granted for one year and for the number of animals required for that period. Each additional year must be approved through an annual protocol renewal submission, for up to three additional years.*

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| PART II - PROJECT PERSONNEL & QUALIFICATIONS |

**A: INDIVIDUALS INVOLVED IN ANIMAL USE AND THEIR TRAINING**

**Identify the individual and their position (e.g. faculty, research assistant, postdoctoral fellow, veterinarian, technician, undergraduate, graduate or doctoral student, etc.) involved in animal handling, and indicate their training or relevant experience. Mark with an “x” the** [**Institutional Animal User Training Program (IAUTP)**](http://www.uleth.ca/research/institutional-animal-user-training-program-iautp) **training they have received. If relevant, indicate the type of “Other Training Received”. Under Procedures, indicate the relevant number from the list below:**

1. **Meeting CCAC standards of animal husbandry and housing**
2. **Providing daily care of animals**
3. **Reporting ill/injured/dead animals to veterinarian**
4. **Performing surgical procedures**
5. **Performing other invasive procedures**
6. **Monitoring recovery from surgery**
7. **Administering analgesics**
8. **Performing euthanasia**
9. **Maintaining animal logbook**
10. **Maintaining restricted drug logbook**
11. **Performing behavioural tests**
12. **Performing field work and meeting accepted standards with respect to field work**
13. **Oversight and overall management of approved study**

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| **Name of Individual** | **Position** | **Procedures** | **IAUTP****Part 1****Ethics** | **IAUTP****Part 2****Handling****(List Rat, Mouse, Fish, or Bird)** | **Other Training Received****(i.e., surgical competency, biomethodology)** | **Other Training Required****(i.e., surgical competency, biomethodology)** |
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| PART III - CANADIAN COUNCIL ON ANIMAL CARE (CCAC) REPORTING REQUIREMENTS |
| A: Is the project: Surgical: [ ]  Acute [ ]  Chronic (animal will recover from surgery)Non-surgical: [ ]  Acute [ ]  Chronic (animal will be subjected to long term and/or multiple procedures) |
| B: CCAC CATEGORY OF INVASIVENESS (see APPENDIX I for more information): |
| [ ]  **B. Experiments which cause little or no discomfort or stress** [ ]  **C. Experiments which cause minor stress or pain of short duration**[ ]  **D. Experiments which cause moderate to severe distress or discomfort\*** [ ]  **E. Procedures which cause severe pain near, at, or above the pain tolerance threshold of**  **unanesthetized conscious animals** |
| C: CCAC PURPOSE OF ANIMAL USE (PAU) (see APPENDIX II for more information): |
| [ ]  **PAU 0** Animals held in **breeding colonies** that have not been assigned to a particular protocol.[ ]  **PAU 1** Studies of a **fundamental nature** in sciences relating to essential structure or function.[ ]  **PAU 2** Studies for **medical purposes**, including veterinary medicine, that relate to human or animal  diseases or disorders.[ ]  **PAU 3** Studies for **regulatory testing** of products for the protection of humans, animals, or the  environment.[ ]  **PAU 4** Studies for the **development of products** or appliances for human or veterinary medicine.[ ]  **PAU 5 Education and training** of individuals in post-secondary institutions or facilities. |
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| PART IV - ANIMALS REQUESTED |

**A: NUMBER AND TYPE OF ANIMALS REQUESTED**

**List different strains and age ranges (i.e. juveniles, adults) on separate rows.**

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| **Species (Specific and Common Names)** | **Strain\*** | **Age Range** | **Sex** | **Source of animals** | **Total for Year 1** | **Species Status****(E, T, C or I)\*\*** |
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*\* If the project involves transgenic animals, Appendix F (*[*Transgenic Information Sheet*](https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms)*) must be completed and included as an attachment to this form.*

*\*\*List species status or special considerations: Endangered (E) Threatened (T) Of Special Concern (C) Immunocompromised (I)*

**B: JUSTIFICATION FOR THE NUMBER OF ANIMALS REQUESTED**

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| **Provide the statistical significance or scientific validity to justify the number of animals requested *including the group size or range of group sizes*.** [**Reduction**](https://ccac.ca/en/three-rs/replacement-reduction-refinement.html) **of animal use should be emphasized within an appropriate experimental design, while ensuring that sufficient numbers of animals will be used to fulfill requirements for statistical significance/scientific validity (i.e., previous pilot study, statistical power analysis, resource equation analysis, expected background mortality rate (%), etc.) in the case of research projects, or for acceptance of regulatory tests. For breeding, specify how many adults are required, number of offspring produced and how *many offspring are expected to be used in experimental studies, transferred to experimental protocols or culled due to wrong genotypes.*** |
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| **PART V - LOCATION OF ANIMALS DURING PROCEDURES** |

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|  | **Animal housing room:** |  |
| **Surgical procedures room:** |  |
| **Observational procedures room:** |  |
| **Field site location (please specify):** |  |

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| PART VI – SPACE REQUIREMENTS |

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| **YES** |  | **NO** |  |
|[ ]   |[ ]  **Will the University be required to provide additional space?** |
|[ ]   |[ ]  **Has approval for this space been sought?** |
|[ ]   |[ ]  **Has approval for this space been granted?** |
|  |  |  |  |
|[ ]   |[ ]  **Are renovations required to existing space?** |
|[ ]   |[ ]  **Has approval for these renovations been sought?** |
|[ ]   |[ ]  **Has approval for these renovations been granted?** |

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| PART VII – JUSTIFICATION FOR ANIMAL USE |

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| **CCAC guidelines and University policy require that animals selected should be the appropriate species and that the minimum number be used to obtain valid results. The Three Rs** [**(replacement, reduction and refinement alternatives)**](https://ccac.ca/en/three-rs/replacement-reduction-refinement.html) **should be employed.**  |

| **A. Explain the necessity of using animals in this study and provide justification if replacement alternatives cannot be used (non-animal methods, cell-tissue culture, computer simulations, audio-visual teaching methods, the replacement of sentient animals with animals of lower sentiency, etc.).** |
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| **B. Describe the characteristics of the animal that make the species or strain appropriate for the research or testing objectives, i.e. structural, behavioural, physiological, biochemical or other features or considerations** |
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| PART VIII – SCIENTIFIC MERIT, FUNDING SOURCE & PERMITS |

**Is this project:**

[ ]  **Research** [ ]  **Testing** [ ]  **Research and Testing**

**SCIENTIFIC MERIT:**

**The Canadian Council on Animal Care requires that each research proposal has been evaluated and shown to have** [**scientific merit**](http://www.ccac.ca/Documents/Standards/Policies/Scientific_merit_and_ethical_review_of_animal-based_research.pdf) **through independent peer review before approving the project. The AWC must receive confirmation that the protocol is part of a research program or project that has been found to have scientific merit before the AWC can conduct the ethical review of the protocol. Please contact the Office of Research and Innovation Services if your proposal has not been evaluated for scientific merit to arrange for independent peer review.**

**Status of Funding:** [ ]  **Awarded Funding Start Date:** Click or tap to enter a date.

 **End Date:** Click or tap to enter a date.

[ ]  **Pending**

**Funding Agency/Source:**

**Is this project funded through a contract? Yes** [ ]  **No** [ ]

**Status of Protocol:** [ ]  **Peer-reviewed**

 **(choose 1 only)** [ ]  **Pending**

[ ]  **Non-peer reviewed**

**PRE-CLINICAL TESTING OF DRUGS:**

**Testing must been planned according to the most current regulatory requirements, using guidelines acceptable to the regulatory agency(ies) and which meet the requirements of the CCAC policy statement on: ethics of animal investigation.**

**Does your project involved pre-clinical testing of drugs? Yes** [ ]  **No** [ ]

**If yes, attach a copy of the relevant regulatory requirements.**

**PERMITS REQUIRED**

**It is the Principal Investigator’s responsibility to obtain the necessary permits.  *Permit numbers (with the exception of Health Canada Controlled Drug Exemptions) must be sent to the Animal Welfare Coordinator when they have been obtained.***

**Are federal or provincial permits required for importation, collection, and maintenance (*including Health Canada Controlled Drug Exemptions*)?**

No [ ]  Yes [ ] , Agency:

**Permit application is**: Approved [ ]  Pending [ ]  To be Submitted [ ]

**Permit Number(s)** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| PART IX – ANIMAL PROCEDURES |

**A: LIST OF PROCEDURES, MANIPULATIONS AND MANAGEMENT INVOLVED IN THIS PROTOCOL INVOLVING ANIMALS**

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| **List *all* procedures, manipulations, and/or measurements that will be performed on the animals in the appropriate category below. If a category of procedure is not required for this protocol, write N/A.** **Cite SOP numbers/titles, where appropriate.** ***The PI must ensure that they and their personnel have read and follow the pertinent SOPs.*** |

| **PROCEDURES****Including injection of compounds, experimental manipulation, etc.** | **SOP #’s**  | **Procedure Title (s) or Description**(add additional column if more than one procedure is used in each category) | **Animals involved in each procedure: species/strain and quantity** | **Distress or Pain****(B-E)\*** |
| --- | --- | --- | --- | --- |
| 1. **Restraint or handling**
 |  |  |  |  |
| 1. **INDIVIDUAL MARKING**
 |  |  |  |  |
| 1. **SURGERY**
 |  | Example: 1. Surgical Procedure A.  |  |  |
|  |  | 2. Surgical Procedure B |  |  |
| 1. **BLOOD COLLECTION**
 |  |  |  |  |
| 1. **INJECTIONS**
 |  | Example: 1. Injection A |  |  |
|  |  | 2. Injection B  |  |  |
| 1. **FOOD/WATER RESTRICTION**
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| 1. **HOUSING MODIFICATION (special accommodation)**
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| 1. **REINFORCMENT**
 |  |  |  |  |
| 1. **ADMINISTRATION OF CHEMICALS/ DRUGS/RADIOISOTOPES**
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| 1. **ADMINISTRATION OF BIOLOGICALS**
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| 1. **ANAESTHETIC/ ANALGESICS/ ANTIBIOTICS**
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| 1. **NEUROMUSCULAR BLOCKING AGENTS**
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| 1. **EUTHANASIA**
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| 1. **STANDARD HUSBANDRY (i.e. standard enrichment)\*\***
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| 1. **BEHAVIOURAL TASKS**
 |  | Example: 1. Behavioural test A |  |  |
|  |  | 2. Behavioural test B |  |  |
| 1. **OTHER**
 |  |  |  |  |
| If you need more space for animals involved, please insert new rows |  |  |  |  |

 **\* Indicate the Category for each procedure listed (refer to the Canadian Council on Animal Care’s ‘Categories of Invasiveness in Animal Experiments’, APPENDIX I).**

**\*\*Provide justification for any deviation from the normal standard of environmental enrichment offered in the animals housing unit.**

**B: SUMMARY OF DRUGS, CHEMICALS OR BIOLOGICALS**

**\*List Analgesics, anaesthetics and antibiotics FIRST (strategies to alleviate pain or distress)**

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| **Provide a description of any drugs, chemicals or biologicals to be administered. Please consult APPENDIX IVa (rats), IVb (mice) or IVc (fish).** **NOTE: All injectable drugs or chemicals must be sterile and, if given parenterally, administered with sterile equipment (i.e. needles, syringes). Proper storage and disposal is essential. Drugs must not be past the expiration date. Please note that this information must be provided for** **tissue-based procedures that are included in approved animal welfare protocols.** |

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| **Animal** | **Agent** | **Purpose** | **Route****(PO, SC, IM, IP, intra-cranial, water-borne)**  | **Dose****(mg/kg)** | **Concentration (mg/ml)** **and** **Total Volume (ml)** | **Frequency****(per day & # of days)** | **Storage (i.e. refrigeration)** | **Disposal Method** | **Health Canada Exemption Required\*** |
|  |  | **Analgesic**  |  |  |  |  |  |  |  |
|  |  | **Anaesthetic** |  |  |  |  |  |  |  |
|  |  | **Antibiotic** |  |  |  |  |  |  |  |
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**\*The *Application Form for an Exemption to Use a Controlled Substance for Scientific Purposes* can be found here:** [**Health Canada Exemption Application**](http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/applic-scien-eng.php)

**C. EXPECTED OR POTENTIAL ANIMAL HEALTH CONCERNS OR RISKS (Please consult the** **University Veterinarian** **prior to completing this section.)**

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| **Agent *(excluding analgesics, anesthetics, or antibiotics)*** | **Expected Clinical Effects – indicate whether special care or management is required** | **Possible Side Effects – indicate whether special care or management is required** | **Pain and/or Distress experienced by the animal as a result of this administration.**  | **Measures to alleviate pain and/or distress resulting from administration of this agent.** |
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**D: DETAILED DESCRIPTION OF ALL PROCEDURES, MANIPULATIONS AND/OR MEASUREMENTS INVOLVING ANIMALS**

**The Animal Protection Act, Animal Protection Regulation, and the CCAC require that complete information be supplied about all manipulations involving animals. The primary mandate of the Animal Welfare Committee (AWC) is to review protocols from the perspective of the ethical use and humane treatment of animals.**

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| **1. Provide a lay summary, outlining the objectives of the proposed project, written so that all members of the Animal Welfare Committee, including community and non-user faculty representatives, have enough information to understand the protocol.** **2. Provide a brief rationale for each procedure, manipulation and/or measurement.****3. Explain in detail the procedures/experimental design.****4. Provide a table or flowchart detailing the timeline of the procedures, manipulations and /or measurements on individual animals or groups of animals.****5. Describe strategies for care to alleviate pain, distress, and discomfort. Include post-operative care, and special procedures used. Specify the criteria that will be used to assess the level of analgesia/anesthesia required. NOTE: Specific requirements for anesthesia, and surgical procedures are outlined in APPENDIX Va (rodents) or Vb (fish).****6. Specify the monitoring schedule during the procedure(s) and recovery.****For field studies (COI D & E), include the Field Study details (APPENDIX VIII) in this protocol.** **For projects involving transgenic animals, complete the Transgenic Information Sheet (APPENDIX IX).**[**GENERAL INFORMATION AND APPENDICES ARE AVAILABLE HERE**](https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms) |
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| PART X – CLINICAL AND/OR ANIMAL USE HUMANE ENDPOINT [PART X MUST BE ACCESSIBLE TO ANIMAL USERS AND ANIMAL CARE STAFF AT ALL TIMES] |

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| **In the course of an experiment, animals may experience expected (or unexpected) effects. Compliance with the CCAC guidelines clearly places responsibility on everyone involved in the care and use of animals to ensure that animals do not undergo *“unnecessary pain and suffering”*. This section is aimed at identifying appropriate humane endpoints and providing guidance for suitable treatment of animals who have reached humane endpoint.****All protocols, even non-invasive ones, must identify humane endpoints to ensure that any animals requiring treatment are treated and that animals are not simply kept indefinitely.** **Humane Endpoint is defined as the point at which an experimental animals’ pain and/or distress is terminated, minimized, or reduced, by taking actions such as terminating a painful procedure, giving treatment to relieve pain and/or distress, or euthanizing the animal humanely. *Do not confuse the humane endpoint with the intended point at which you gather scientific data (experimental endpoint)*. Selection of the humane endpoint by the investigator should involve consultation with the laboratory animal veterinarian and the animal care committee. PIs should refer to the** [***CCAC guidelines on: choosing an appropriate endpoint in experiments using animals for research, teaching and testing***](http://ccac.ca/Documents/Standards/Guidelines/Appropriate_endpoint.pdf)**. The University Veterinarian, under the authority of the AWC and the Veterinary Professions Act, has ultimate responsibility to deal with situations of pain and distress (**[**AWC Authority**](https://www.uleth.ca/research/animal-welfare-committee)**).** |

| **A. Provide a brief summary outlining the objectives of the proposed project (you may want to copy and paste Part IX D #1 from above).** |
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| **B. Please identify the experimental endpoint for the animals (i.e., the point at which the animal will reach the end of the study and will be euthanized).**  |
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| **C. Describe any clinical conditions or abnormalities which might signal the need for veterinary care, termination of experimental procedures or euthanasia (i.e., the humane intervention point). (See APPENDIX VIa (rodents) or VIb (fish) for most likely clinical conditions).** |
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| **D. Please provide an outline (including the frequency of assessment) for your animal welfare assessment plan. (See APPENDIX XI for instructions and assessment scoring sheet).** |
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| **E. An animal showing signs of sickness, pain, distress, or suffering must be assessed at least three times per 24 hour period. Indicate who will monitor the animals and record the assessments.** |
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| **F. Animals that die unexpectedly or are euthanized at humane endpoint may be submitted for post-mortem examination by the University Veterinarian. Describe any special instructions for sample collection at the time of euthanasia.** |
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| PART XI – SAMPLES TO BE TAKEN FROM LIVE ANIMALS (NOT post mortem tissue collections)– for blood collection volume and frequency, see APPENDIX X |

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| **Animal** | **Sample** | **Site & Method of Collection** | **Amount** | **Frequency** |
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| PART XII – FATE OF ANIMALS |

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| [ ]  **Transferred to another project (provide details):** |
| [ ]  **Euthanized (indicate methods of killing and disposal of carcasses or quote appropriate SOP#):** |
| [ ]  **Released to the wild (indicate the length of time they are held):** |
| \_\_ | **Immediately following live trapping** |
| \_\_ | **Following captivity (explain the measures taken to ensure that animals can be returned to the wild successfully):** |

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| PART XIII – HAZARDS TO STAFF |

**Animal welfare approval is contingent upon review of the hazards to staff.**

**To assess these hazards, a** [**Hazard Assessment Report**](http://www.uleth.ca/risk-and-safety-services/hazard-management) **must be completed, and submitted to Safety Services and the Research Ethics Officer for review. This report is available from** [**Safety Services**](http://www.uleth.ca/risk-and-safety-services/hazard-management). **If you have questions regarding completion of the Hazard Assessment Report, contact Safety Services.**

**Is your Hazard Assessment Report submitted and up to date?**

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

**If your research involves biohazards or radioisotopes, contact Safety Services for Biosafety Committee or Radiation Safety Committee review. Please select one of the choices for the following:**

**Approval has been received or review requested from the:**

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| --- | --- | --- | --- |
| **Received** | **Requested** | **N/A** |  |
|[ ] [ ] [ ]  **Biosafety Committee** |
|[ ] [ ] [ ]  **Radiation Safety Committee** |

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| PART XIV – DECLARATION |

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| **Your signature below affirms that:**1. **You acknowledge responsibility for the animals and personnel in this project.**
	1. **All animals used in this project will be cared for in accordance with the CCAC, the regulations of the Province of Alberta and the University of Lethbridge Animal Welfare Committee.**
	2. **All students, staff and faculty are/will be trained to conduct the project in a humane and scientific manner.**
2. **The techniques, facilities and equipment to be used in this project conform to all applicable regulations and guidelines of:**
	1. **The CCAC, and**
	2. **Federal and local government regulations in force in Canada and/or the country in which the project is being conducted.**
3. **You have considered alternative procedures that do not involve the use of living animals.**
4. **You will use the minimum number of animals consistent with the objective of this project.**
5. **You have carefully selected the most appropriate species and/or model for this project.**
6. **The procedures described in this protocol must be followed unless an amendment to the protocol is submitted and approved. Substantial changes will require re-submission to the Animal Welfare Committee.**
7. **You will notify the Animal Welfare Committee in writing of any revisions to this protocol.**
8. **You will report the number of animals used in this project to the Animal Care Coordinator, when requested.**
9. **You will keep copies of all approved protocols, revisions and amendments in an accessible file.**

**This protocol is valid for one year from the date of approval. Multi-year projects are subject to annual review and approval. Extensions can be granted on an annual basis, up to a maximum of four years.****Following AWC approval, a protocol number will be assigned. All animals used for this protocol should be identified (e.g., on cage cards and in the log book) with the assigned protocol number.** |

[**GENERAL INFORMATION AND APPENDICES ARE AVAILABLE HERE**](https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Click or tap to enter a date.

**Principal Investigator’s Signature Date**