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| --- |
| **INSTRUCTIONS: Read carefully and respond appropriately. PUT N/A FOR ALL NOT APPLICABLE ITEMS. Submit the completed application to the IACUC office at** **jbaker@westernu.edu****. Contact Ms. Jennifer Baker IACUC Office, at 909-469-5606 if you have any questions.** |

**WESTERN UNIVERSITY OF HEALTH SCIENCES**

## Institutional Animal Care and Use Protocol Application

*\*\*For IACUC Use Only\*\**

Protocol #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Type of protocol: [ ] New

 [ ] Full Renewal; Old Protocol #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expiration Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DO NOT USE THIS FORM FOR BREEDING OR AQUATIC SPECIES PROTOCOLS**

1. Title of Project or Course:

2. Principal Investigator (one name only):

3. Department/College:

4. Office phone: Email: Emergency Off-Campus #:

Completed forms are for internal use only and are **not** to be distributed outside Western University without written permission from the IACUC or the Vice President for Research. Violation of this policy could result in suspension of the protocol.

The use of audio or video recording devices **of any kind**, including cell phone cameras, cameras and tape recorders, in any Western University owned or leased animal facility is **strictly prohibited** unless the recording is approved by the IACUC in conjunction with the performance of IACUC-approved activities within the animal facility or research laboratories where animals are housed, used or euthanized for tissue collection. Any photography or recording not described in an IACUC-approved protocol must have the written permission of the Institutional Official, in consultation with the IACUC, which must be produced upon request by Animal Facility staff or the IACUC Chair before admittance to the facilities will be permitted. **Violation of this policy may result in suspension of privileges for the principal investigator & their laboratory personnel.** Your signature on this application acknowledges that you are aware of this policy.

**Declarations and Signatures**

*As the Principal Investigator on this protocol, I accept full* **responsibility** *for, and agree to abide by, this protocol. I also understand and agree to the following:*

1. I will abide by all applicable local, state and federal laws and regulations and WesternU policies and procedures.

2. Deviations from an approved protocol or violations of applicable policies, guidelines or laws could result in immediate suspension of the protocol.

3. The attending veterinarian or designee must be consulted in the planning of any research or procedural changes that may cause more than momentary or slight pain or distress to the animals.

4. All experiments involving live animals will be performed under my supervision or that of another qualified scientist. All listed personnel will be trained and certified in the proper humane methods of animal care and use prior to conducting experiments.

5. Emergency veterinary care will be administered to animals showing evidence of discomfort, ailment or illness.

6. Information provided in this protocol is accurate to the best of my knowledge. If funded by an extramural source, the protocol accurately reflects all currently planned procedures involving animals described in the proposal to the funding agency.

7. Modifications to the protocol will be submitted to and approved by the IACUC prior to initiation of such changes.

8. The experimental design has been refined to minimize the invasiveness of the proposed procedures.

9. The proposed research does not unnecessarily duplicate previous experiments.

Principal Investigator Signature Date

Dean/Dept Chair Signature Date

5. Using **lay** **terminology**, provide a non-technical synopsis of this project/course. **LIMIT TO 250 WORDS.**

6. Does this protocol involve the use of controlled substances *in vivo* or *in vitro*?

 No; ; Skip to the next section.

 Yes; ; Answer the following.

 The PI or a collaborator **named on this protocol** must have a current DEA registration to use controlled substances *in vivo* or *in vitro*, without which the protocol will not be reviewed. A link to the application form may be found [here](https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp).

 i) Provide the name & contact information of the DEA registrant: Name

 Office Phone:  Email:

 ii) Will you be using a Schedule I controlled substance *in vivo* or *in vitro*?

 No;

 Yes; ; You must have a current DEA registration **AND** approval from the [Research Advisory Panel of California](http://oag.ca.gov/research/guide), without which the IACUC will not approve the protocol.

 iii) Have you completed the on-line Controlled Substances training?

 No; ; Click [here](https://elearning.westernu.edu/training/login/?redirect_to=%2Ftraining%2F&reauth=1) to access the training course on eLearning. You will need a user name and password to access the site.

 Yes;

 iv) Disposal of unwanted or expired controlled substances must be done through a Reverse Distributor. A list of DEA-registered Reverse Distributors may be found [here](http://www.rld.state.nm.us/uploads/filelinks/a5bdc4c0017d4bf294dd2cbfea6f294e/reversedistributor.pdf). Refer to IACUC [Policy 2014-050](http://www.westernu.edu/bin/research/iacuc/policies/policy_2014_050_controlled_substances.pdf) for more information on controlled substances.

7. Is this a **3-year full renewal**?

 No; ; Skip to the next section.

 Yes; ; Answer the following.

 a) Have you acquired or used any animals for this project so far? No  Yes

 b) How many unused animals, if any, are left over from the previous protocol?

 The numbers of animals requested in this renewal **must** include all unused animals from the previous protocol. Otherwise, explain.

 c) List each goal, specific aim and/or hypothesis **from the original protocol** and indicate if it/they have been completed, are in progress or not yet started. **List the number of animals used for each specific aim that has been completed or is in progress.**

 d) Describe any adverse effects or unanticipated problems encountered including higher than expected mortality/morbidity regardless of cause.

 i. How were these effects/problems resolved?

8. Proposed and Approved Funding Sources (grant, contract, fellowship, training, career development). List all funding sources for this protocol. For each funding source, provide the following information, if known.

 Source:

 Submitted or Approval Date:

 Title (if different from protocol title):

 Fund number (if known):

9. For each person, including the PI and off campus personnel, involved in this study who will have contact with animals or animal tissues, provide:

 a) their name, email address and phone number,

 b) their **role, responsibilities and specific duties** in this project,

 c) a description of their animal **training relevant to their duties** in this project.

10. (a) If working with mice or rats, list all personnel named in item 9 who have taken WesternU’s on-line training on the Barrier Facility and either on the Use of Mice in Research or the Use of Rats in Research.

 (b) If not working with mice or rats, list all personnel named in item 9 who have taken WesternU’s on-line training on the Barrier Facility.

11. Summary of Animals Requested:

\*Pain/Distress Categories (The Attending Veterinarian must be immediately consulted if pain or distress

 exceeds the anticipated level or interventional control is not possible.):

 C – No pain or distress, slight or momentary pain or distress

 D – Pain or distress; drug relieved

 E – Pain or distress; no relief provided. Must provide scientific justification in Section 12.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Species/ Strain |       |       |       |       |       |
| Total Number Requested\* |       |       |       |       |       |
| Sex (indicate #of ♂ & ♀) |       |       |       |       |       |
| Age or Weight |       |       |       |       |       |
| Pain or Distress Category |       |       |       |       |       |
| Housing Location (Bldg. & Rm No.) |       |       |       |       |       |
| Vendor/Source |       |       |       |       |       |
| If additional species are requested, provide information here:       |

\*For 3-year full renewals, this number must include the number of animals reported in item 7 above unless fewer animals are requested.

Signs of acute pain:

* Guarding (attempting to protect, move away or bite)
* Vocalization (crying out when palpated or forced to use affected area)
* Self-harm (licking, biting, scratching, shaking or rubbing)
* Repetitive or stereotypical behaviors such as pacing, persistent circling, flipping, etc.
* Prolonged recumbency
* Depression (reluctance to move or difficulty in rising)
* Abnormal appearance (tucked abdomen, hunched, facial distortion or persistent squinting)

 a) If transferring animals from an off-campus investigator, an Animal Transfer Form and health report must be submitted and approved prior to protocol approval. The Animal Transfer Form may be obtained from the Office of the IACUC at 469-5619. The health report is to be obtained by the PI from the exporting institution prior to transfer of any animals.

12. Provide justification for non-use of analgesia and anesthesia for animals in Pain Category E above.

 Include sources for documentation.

13. Provide the location where each experiment or procedure will be conducted.

14. Project Description (Use lay terminology to the extent practical)

a. What are the goals, specific aims and hypotheses of this project/course? **Include potential benefits to scientific knowledge.**

b. Provide a detailed description of exactly what will be done to the animals during this project/course **and a table listing all control and experimental groups and the numbers of animals required per group as determined in Item 11**.

 If using IACUC-approved Western University Standard Operating Procedures (SOPs), provide the procedure codes here and **UPLOAD A COPY TO** [**www.irbnet.org**](http://www.irbnet.orgA) **ALONG WITH THIS APPLICATION**. Note any deviations from the SOPs and attach a copy of each SOP.

c. Provide the following information for all drugs, chemicals, toxins, infectious agents, viral vectors, cell lines or radioactivity to be given or applied to the animals*.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Generic Name** | **Pharma-ceutical****Grade** **(Y/N)\*** | **Controlled****Substance?****(Y/N) &****Schedule** | **Purpose** | **Dose** | **Volume** | **Interval** | **Route** |
| **Euthanizing Agent** |  |  |  |  |  |  |  |
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 \*If No, explain.

d. If paralytic agents/neuromuscular blockers are used, justify their use and describe how the absence of pain and the absence of consciousness will be assessed.

15. Literature Search – A literature search must be performed to determine that (i) this study/course does not unnecessarily duplicate previous work, (ii) there are no alternatives to the use of live animals, and (iii) there are no alternatives to procedures that may cause more than momentary or slight pain or distress to the animals (Pain Categories D and E above).

a. Date of Search (**must be within the last 2 months of submission**):

b. Identify databases used (**minimum of 2 required**): (e.g., PubMed, Biological Abstracts, Animal Welfare Information Center, Altweb).

c.Keywords used in search (Must include name of animal species & model. The USDA recommends not including the term “alternatives”. An explanation is given [here](https://www.nal.usda.gov/awic/3Rs-terms-examples)):

d. Years covered in search (a minimum of the last 10 years):

e. Federal regulations (9 CFR 2.31) require investigators to assure the following. Please check the appropriate boxes. For any unmarked boxes, explain.

 \*\*To select a check box, **double click** the box and select “Checked” under Default Value.

 [ ]  There are no alternatives to the use of live animals.

 [ ]  Procedures involving animals will avoid or minimize discomfort, distress and pain to the animals.

 [ ]  There are no alternatives to procedures that may cause more than momentary or slight pain or distress to the animals as in Pain Categories D and E above.

 [ ]  This study/course does not unnecessarily duplicate previous work.

16. Reduction and Replacement of Animals

a. How does the experimental or course design assure the use of the fewest animals? Justify the numbers of animals requested with a sample size calculation, citation of similar work or other means. This should agree with the numbers in the table requested in item 11.

b. Can this project/course be done using a lower species or a non-animal model?  Yes; explain why it is not being used   No; how was this determined?

17. Will you be using non-WesternU owned animals?

  No; Skip to the next section.

  Yes; Answer the following.

 Attach a sample copy of an Owner Consent Form describing the use of the animals, the potential benefits and adverse effects or risks and any alternative methods or procedures that might be available.

 a. Will normal routine veterinary care be altered in any manner, including treatment options, sample collections etc.?

  No

  Yes; explain.

 b. Will the owner be involved in all treatment decisions?

  No; explain.

  Yes

 c. Will there be any deviation from standard husbandry conditions appropriate to the species?

  No

  Yes, explain.

 d. What criteria will warrant premature removal from the study?

 e. Who will monitor morbidity? List at least two persons (primary and back-up)

18. Animal Care for Western University Owned Animals - Although the Animal Care Facility personnel will provide daily care of the animals including weekends and holidays, **the PI is ultimately responsible for ensuring the wellbeing of the animals under this protocol** (except during a natural disaster).

 **Pomona and Lebanon Campuses**: Contact the Attending Veterinarian, Dr. Willie Bidot, as soon as possible at 787-447-4993 (phone or text) in the event of any unexpected illness, debilitation or death of an animal. Failure to do so could result in actions being taken by the IACUC.

 **Lebanon Campus:** The emergency phone number for the Coordinator of Animal Resources is 541-259-0355 (phone or text).

1. Will anyone other than the Animal Care Facility personnel be providing daily animal care, including weekends and holidays?

  No

  Yes. Provide their names, titles and off campus emergency phone numbers.

1. Will you be using something other than standard rodent lab chow provided by the Animal Care Facility?

  No

  Yes, describe.

1. Will water be provided *ad libitum*?

  No; justify.

  Yes

**Body weights for food or fluid restricted animals must be recorded at least weekly along with a daily written health record for each animal and kept in the animal room.**

1. Will you be using something other than standard corncob, hardwood chips or Alpha Dri bedding provided by the Animal Care Facility?

  No

  Yes; describe.

1. Will you be using something other than the standard caging/housing provided by the Animal Care Facility?

  No

  Yes; describe.

1. For their physical and psychological well-being, the IACUC strongly recommends that all research animals receive environment enrichment (EE).  Although the use of EE will depend on the needs or requirements of the study, scientific justification for withholding EE must be provided.  Indicate here if you do not want to use environmental enrichment and explain why. Refer to IACUC [Policy 2014-029](https://www.westernu.edu/mediafiles/research/iacuc/policies/policy_2014_029_environmental_enrichment.pdf) for more information.
2. Will you be receiving genetically or surgically modified animals from another source?

  No

  Yes. Describe any special care they may need.

1. Will animals be housed outside the animal housing facility for longer than 12 hours?

  No

  Yes; explain.

1. What will be the criteria used to warrant euthanasia or premature removal from the study/course?
2. Who will monitor morbidity and serve as contacts if problems arise? List at least two persons (primary and back-up)
3. If euthanizing animals, the IACUC **requires** pentobarbital, 100 mg/kg IP; Euthasol (390 mg pentobarbital + 50 mg phenytoin per ml), at least 5 ml/kg IP; or isoflurane 32%. If not using the required methods, justify.

19. Will survival surgical procedures be used?

  No; Skip to the next section.

  Yes

1. Your signature on this protocol indicates that you have read and will abide by IACUC [Policy 2014-025](http://www.westernu.edu/bin/research/iacuc/policies/Policy_2014_025_Survival_Surgery.pdf) – Survival Surgery on Laboratory Animals.
2. Will animals be subjected to more than one survival surgery?

  No

  Yes; justify.

c. Who will perform the surgical procedures and what are their qualifications?

d. Describe all surgical interventions, post-operative care and efforts taken to reduce post-operative pain and infection. List any drugs on the table in Item 14c.

20. Will you be using death as an endpoint (observing or studying an animal until natural death occurs)?

  No; Skip to the next section.

  Yes. Justify and describe how these animals are expected to die.

21. Other Procedures

1. Are you performing terminal tissue harvest?

  No.

  Yes. State the tissues to be collected and the purpose for collecting them.

1. Are you collecting non-terminal body fluids/specimens?

  No

  Yes

 i) List the body fluids/specimens to be collected, the amounts collected each time and the frequency.

 ii) What effect will removal of this fluid/sample have on the animals and how will any negative consequences be mitigated?

iii) Who will collect the fluids/samplesand what are their qualifications?

iv) Describe the method(s) of collection.

c. Will you be conducting immunizations or producing antibodies?

  No

  Yes

 i) Justify why in vitro methods cannot be used.

 ii) Provide the following information:

|  |  |  |  |
| --- | --- | --- | --- |
| **Site(s) of Injection** | **Route** | **Dose and Volume per Site** | **Interval Between Doses** |
|  |  |  |  |
|  |  |  |  |
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d. Will you be using physical restraint of conscious animals for more than 30 minutes?

  No

  Yes

 i) Discuss the alternatives to physical restraint, if any, and why they cannot be used.

ii) What training or conditioning is provided to the animals to adapt them to restraint?

 iii) How often will the animals be monitored?

 Animals that fail to adapt must be removed from the study. Veterinary care must be immediately provided to any animal that develops a lesion or illness resulting from restraint. In Pomona, contact the Attending Veterinarian, Dr. David Wolf at 900-747-7483. In Lebanon, contact the Attending Veterinarian, Dr. Heather Sidener, at 971-258-5537. For emergencies, call 310-869-7556 or 971-258-5537 AND the Animal Facilities Manager, Victoria Hampton (Pomona; 909-469-5610; emergency cell 909-706-8100) or Animal Resources Coordinator, Devin Drill (Lebanon; 541-259-0355) for instructions.

e. Will you be inducing a tumor?

  No

  Yes

 (i) Describe the method of induction. Include the cell line, source, dose, route and site(s) on the animal for tumor induction.

 (ii) How will the tumors affect the overall health of the animals and how will this be monitored?

 (iii) Subcutaneous masses greater than 1.5 cm (mice) or 2.5 cm (rats) in any dimension, tumor

 ulceration, impaired mobility or inability to feed or drink are all criteria for euthanasia. If not

 following these guidelines, justify. [ ]

 (iv) For species **other than mice and rats**, what criteria will be used to determine if the animals should be euthanized?

 (v) How often will you measure and record tumor sizes?

 **As the clinical effects of internal or metastatic tumors are difficult to predict, consult with the veterinarian if you**

 **observe abnormal clinical signs or palpate internal masses.**

22. Will work be conducted off of Western University’s campuses?

  No

  Yes

a. Why must this work be conducted off campus?

b. Off campus location:

c. Off campus contact person:  Phone:

d. Who will provide veterinary care at this site and what are their qualifications:

23. Will you be using hazardous materials such as infectious agents, viral vectors, human cell lines, toxins, carcinogens (suspected or known), radioactivity or other hazardous materials?

  No

  Yes

 a) Describe each material, type of hazard, anticipated effects on the animals, monitoring procedures, etc.

 The endpoints for infectious diseases will likely be infection-specific (e.g. TB model = respiratory signs; Staph infection = skin issues). Otherwise, the non-specific signs will apply (hunched over, squinting, ruffled fur). For some infections, monitoring of body temperature may be a good indicator, such as elevated temperature in influenza and decreased temperature in Salmonella).

 b) Describe the procedures personnel must follow to ensure that accidental exposure to the material will not occur. **Include types of personal protective equipment used, occupational health considerations and specific work practice controls.**

 c) Who will care for the animals while they are considered hazardous?

 d) What information will you provide the Animal Care Facility Staff to ensure they are aware of the hazards associated with handling these animals?

 e). How will radioactive or otherwise contaminated carcasses be disposed of?

 f) Provide documentation that the PI has approval from the appropriate University committee(s) to conduct the studies described in this protocol.

 i) Institutional Biosafety: IBC #:  Expiration Date:

 Title:

 ii) Radiation Safety:

 iii) Other:

24. Will wildlife be captured?

  No

  Yes

 a. Describe the equipment and methods used, monitoring procedures for the methods used and duration of restraint.

 b. What will be the disposition of captured animals?

 c. What is the potential for capturing non-target species and what will the disposition of these animals be?

 d. How will you deal with injured target or non-target species?

 e. List any zoonotic diseases and other safety issues that may be encountered while working with the species described and explain how they will be mitigated.

 f. All persons covered by this protocol are expected to know and abide by the laws and regulations applicable in the study area, including those of any foreign soil on which the studies may be conducted.

 g. Attach a copy of any required federal, state and local permits, including those of any foreign country, that may be required.

25. Will you be transporting animals between WU facilities or between institutions?

  No

  Yes; explain.

 For transfers between institutions, submit a completed Animal Transfer Form to the Office of the IACUC (**jbaker@westernu.edu****)**. Obtain the form from the Office of the IACUC at 469-5606.

 Attach a copy of the collaborating institution’s IACUC approval.

26. Final Disposition of Animals - Mark all appropriate boxes and provide the required information.

  The animals are under the care of their private owners.

  Euthanize -- For euthanizing animals, the IACUC strongly recommends the use of one of the following:

 1) Pentobarbital, at least 100 mg per kg, IV or IP;

 2) Euthasol (390 mg pentobarbital + 50 mg phenytoin per ml), at least 5 ml/kg, IP;

 3) Isoflurane, approximately 32%, via inhalation.

 If not using one of these preferred methods, state the method and justify.

 (i) How is death confirmed?

 (ii) How will you dispose of the carcasses?

  Transferring to another protocol. Provide the protocol number to which these animals will be transferred.

Healthy animals that cannot be used in this protocol may, upon authorization of the Attending Veterinarian, be put up for adoption ([Animal Adoption Agreement](http://www.westernu.edu/bin/research/iacuc_animal_adoption_form_waiver.pdf)) or used in the IACUC’s training protocol.

 If none of the above, explain.

If this protocol expires prior to being reapproved by the IACUC, or in the event that the IACUC takes possession of the animals due to disciplinary actions, animal welfare issues or any other reason, the animals will automatically revert to the IACUC’s holding protocol. Upon re-approval of an existing protocol, the animals covered will revert back to their original protocol. In the case of a 3-year full renewal, the animals will be assigned to the new protocol. Animals confiscated by the IACUC that are not to be returned to the PI will be disposed of at the discretion of the IACUC.