|  |
| --- |
| **INSTRUCTIONS: Read carefully and respond appropriately. PUT N/A FOR ALL NOT APPLICABLE ITEMS. Submit a completed electronic copy, in Word, to** **sdominguez@westernu.edu** **AND a signed hard copy to Ms. Susan Dominguez, IACUC Office, RWC. Do NOT submit the form as a pdf file or it may be returned without review.** |

**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:

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. Controlled Substances

 a) Does this protocol involve the use of controlled substances *in vivo* or *in vitro*?

 No; ; Skip to item 6.

 Yes; ; Complete section below.

 The PI or collaborator **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.

 b) Provide the name of the DEA registrant:

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

 No;

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

 d) 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;

 e) Disposal of unwanted or expired controlled substances must be done in accordance with federal [regulations](https://www.deadiversion.usdoj.gov/drug_disposal/index.html).

 i) Will you be rendering a controlled substance *non-retrievable*? (See IACUC [Policy 2014-050](http://www.westernu.edu/bin/research/iacuc/policies/policy_2014_050_controlled_substances.pdf) for more information.)

 No

 Yes; Complete [DEA Form 41](https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf) and keep it on file with your controlled substances usage log.

 ii) Provide the names, titles/positions, and contact information for two **authorized employee witnesses** to the destruction of a controlled substance.

 Witness 1: Name:

 Title/Position:

 Phone:

 Witness 2: Name:

 Title/Position:

 Phone:

6. If this is a **3-year full renewal**, answer the following. If not, skip.

 a) 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.

 b) 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.**

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

 i. How were these effects/problems resolved?

7. Proposed and Approved Funding Sources (grant, contract, fellowship, training, career development). List all funding sources for this protocol. Include the titles and fund numbers, if known, for each funding source.

 Source:  Submitted or Approval Date:

 Title (if different from protocol title):

 Fund number (if known):

 Source:  Submitted or Approval Date:

 Title (if different from protocol title):

 Fund number (if known):

8. 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 specific **duties** in this project,

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

9. (a) If working with rodents, list all personnel named in item 8 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 rodents, list all personnel named in item 8 who have taken WesternU’s on-line

 training on the Barrier Facility.

10. Summary of Animals Requested:

 \*Pain/Distress Categories: C – No pain or distress, slight or momentary pain or distress

 D – Pain or distress; drug relieved

 E – Pain or distress; no relief provided

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Species/ Strain |       |       |       |       |       |
| 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:       |

\*The Attending Veterinarian must be immediately consulted if pain or distress exceeds the anticipated level or interventional control is not possible.

\*\*For 3-year full renewals, this number must include the number of animals reported in item 6a) 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)
* Mutilation (licking, biting, scratching, shaking or rubbing)
* Restlessness (pacing, lying down and getting up or shifting weight)
* 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.

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

 Include sources for documentation.

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

13. Project Description

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

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

c. 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 10**.

 If using approved Western University Standard Operating Procedures (SOPs), provide the procedure codes here and **ATTACH A COPY TO THIS APPLICATION**. Note any deviations from the SOPs and attach a copy of each SOP.

d. Provide the following information for all drugs, chemicals, toxins, infectious agents, viral vectors, cell lines or radioactivity to be given to the animals*.* The IACUC requires that all chemicals and other substances used in animals be of pharmaceutical-grade when available. If using non-pharmaceutical-grade substances, justify.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Generic Name (indicate species to receive each agent)** | **Controlled****Substance? (Y/N)\*****& Schedule** | **Purpose** | **Dose** | **Volume** | **Interval** | **Route** |
| **Euthanizing Agent** |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

 \*Controlled substances used under this protocol MUST be covered by a DEA license. A link to the application form may be found on the [IACUC’s website](http://www.westernu.edu/research/regulatory-affairs/research-iacuc/) under Important Forms.

 i. Provide the name and contact information of the person with a valid DEA license who will provide

 the controlled substance(s). Office phone:  Email:

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

14. 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 6 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:

d. Years covered in search:

e. Answer the following:

(i) Does this study/course unnecessarily duplicate previous work?  No

  Yes

(ii) Are there alternatives to the use of live animals? If no, explain why. If yes, explain why they aren’t being used.

(iii) Are there 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)? No If yes, explain why they aren’t being used.

15. 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 10.

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?

16. Animal Care for Non-Western University Owned Animals. If using University-owned animals, skip.

1. 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.
2. If normal routine veterinary care will be altered in any manner, including treatment options, sample collections etc., explain.
3. Will the owner be involved in all treatment decisions? If no, explain.
4. Describe any deviation from standard husbandry conditions appropriate to the species.
5. What criteria will warrant premature removal from the study?
6. Who will monitor morbidity?

17. 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 Campus**: Contact the Attending Veterinarian, Dr. Marcelo Couto, as soon as possible at 310-869-7556 (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. The emergency phone number for the Animal Care Manager is 909-706-8100 (phone or text).

 **Lebanon Campus:** Contact the Attending Veterinarian, Dr. Heather Sidener, as soon as possible at 971-258-5537 (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. The emergency phone number for the Animal Care Manager is 541-207-7196 (phone or text). If you are unable to contact either Dr. Sidener or the Animal Care Manager, contact Dr. Marcelo Couto at 310-869-7556 (phone or text).

1. Provide the names, titles and off campus emergency phone numbers of anyone other than the Animal Care Facility personnel who will provide daily animal care, including weekends and holidays.

1. If using something other than standard rodent lab chow provided by the Animal Care Facility, describe.
2. Will water be provided *ad libitum*?  If not, justify.

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

1. If using something other than standard corncob or Alpha Dri bedding provided by the Animal Care Facility, describe.
2. If using something other than the standard caging/housing provided by the Animal Care Facility, describe. .
3. For their physical and psychological well-being, the IACUC recommends that all research animals receive environment enrichment.  However, the use of environmental enrichment will depend on the needs or requirements of the study.  Refer to IACUC [Policy 2014-029](http://www.westernu.edu/bin/research/iacuc/policies/Policy_2014_029_Environmental_Enrichment.pdf) for more information.

            Indicate here if you do not want to use environmental enrichment and explain why.

1. Provision of environmental enrichment (EE) is strongly recommended. Scientific justification for withholding EE must be provided. Refer to IACUC [Policy 2014-029](http://www.westernu.edu/bin/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?

 If yes, describe any special care they may need.

1. If animals will be housed outside the animal housing facility for longer than 12 hours, explain.
2. What will be the criteria used to warrant euthanasia or premature removal from the study/course?
3. Who will monitor morbidity and serve as a contact person if problems arise?
4. 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.

18. Survival Surgical Procedures Applicable?

  No, skip to 19  Yes, provide the following information:

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. If animals will be subjected to more than one survival surgery, justify.

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

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

19. Death as an Endpoint (observing or studying an animal until natural death occurs) Applicable?

  No, skip to 20  Yes, answer the following:

a. Justify using death as an endpoint and describe how these animals are expected to die.

20. Other Procedures

1. If you are performing terminal tissue harvest, state the tissues to be collected and the purpose for collecting them.
2. List all non-terminal body fluids/specimens collected indicating amounts collected each time and their frequency.

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

**(**ii) Who will collect the fluids/samplesand what are their qualifications?

**(**iii) Describe the method(s) of collection.

c. If you are conducting immunizations or producing antibodies, provide the following information:

(i) Justify why in vitro methods cannot be used.

 Ascites method: If the ascites fluid is tapped before the animals are expected to experience unalleviated pain or discomfort due to accumulation of fluid in the peritoneal cavity, the animals may be listed under Pain Category D (pain/distress relieved by use of appropriate anesthetics, analgesics, tranquilizers, or by euthanasia).  However, if significant inflammation or otherwise unrelieved pain is expected, Pain Category E (pain/distress cannot be relieved by use of anesthetics, analgesics, or tranquilizers, as the use of these agents would interfere with the experimental design) may be appropriate.

(ii) Antigens and adjuvants – Scientific justification must be given for the use of priming agents other than incomplete Freund’s adjuvant (IFA) or pristane.

 A priming dose of pristane no greater than 0.2 ml i.p. per injection must be used unless scientifically justified in the protocol. Larger doses may cause discomfort and are not more efficacious. For IFA, a dose of 0.25 ml. i.p. is appropriate.

 Ascites method: Ascites fluid must be removed before abdominal distention is such as to cause discomfort, tachypnea, or interference with normal activity. Any animal with a grossly distended abdomen, one in which the skin is drawn tight, must be tapped and/or euthanized. Animals must be tapped **before** ascites fluid volumes exceed 20% of the animal's baseline body weight prior to hybridoma cell inoculation.

 Animals must be observed **continuously** by trained personnel at least 30 minutes immediately following abdominal paracentesis for signs of hypovolemic shock and distress. If an animal appears hunched or lethargic, an equal volume of warm saline should be administered subcutaneously.

 **At a maximum, animals may be tapped twice and allowed to recover. The third tap, if one occurs, must be conducted after the animal has been euthanized.** Animals bearing ascites tumors must be euthanized promptly if they display severe signs of pain or distress or exhibit severe or persistent clinical abnormalities (ruffled coat, hunched posture, anorexia, dehydration, pallor, weight loss, inactivity, difficulty in ambulation, tachypnea, or dyspnea).

(iii) Provide the following information:

|  |  |  |  |
| --- | --- | --- | --- |
| **Site(s) of Injection** | **Route** | **Dose and Volume per Site** | **Interval Between Doses** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

d. Justify any physical restraint of conscious animals for more than 30 minutes. Include a discussion of the alternatives to physical restraint, if any, and why they cannot be used.

 **(**i) What training is provided animals to adapt them to restraint?

 (ii) 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. Contact the Attending Veterinarian, Dr. Marcelo Couto, at 310-869-7556; For emergency, call 310-869-7556 AND the Animal Facilities Manager, Ms. Victoria Hampton, (x-5610; emergency cell (909-706-8100) for instructions.

e. If you are inducing a tumor, answer the following:

(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.**

21. If work will be conducted off of Western University’s campuses, answer the following:

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:

22. Hazardous Materials

1. If you will be using infectious agents, viral vectors, human cell lines, toxins, carcinogens (suspected or known), radioactivity or other hazardous materials, 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).

1. 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.**
2. Who will care for the animals while they are considered hazardous?
3. What information will you provide the Animal Care Facility Staff to ensure they are aware of the hazards associated with handling these animals?

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

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

1. Institutional Biosafety: IBC #:  Expiration Date:

 Title:

1. Radiation Safety:
2. Environmental Health & Safety:

23. Wildlife

 a. If wildlife will be captured, 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.

24. Transferring Animals

a. If you will be transporting animals between WU facilities or between institutions, explain.

 For transfers between institutions, submit a completed Animal Transfer Form to the Office of the IACUC (**sdominguez@westernu.edu****)**. Obtain the form from the Office of the IACUC at 469-5619.

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

25. 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 encourages the use of one of the following:

 1) Pentobarbital, at least 100 mg per kg,

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

 3) Isoflurane, approximately 32%.

 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.