Protocol No.:



Date Received:

Rev. Number:

Approval Date:

|  |
| --- |
| **ANIMAL CARE AND USE PROTOCOL FORM** |

**A. PRINCIPAL INVESTIGATOR INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| PI Name |  | Office Ext |  |
| **Department** |  | Lab Ext |  |
| **Mailing Address** |  | E-mail |  |
| **Name of Designated Representative** |  | Email  **Office Ext**  **Home Phone** |  |

**B**. **PROTOCOL TITLE**

|  |
| --- |
|  |

**C. TYPE**

|  |
| --- |
| 1. ( ) **New Protocol** ( )Research or ( ) Teaching/Training |
| 2. ( ) **Three Year Resubmission** of previously approved protocol. Previous #: |

**Check the appendices that are required and completed for this research:**

( ) Appendix A. Animal Surgery Information (tail and ear snips are NOT considered surgery)

( ) Appendix B. Blood Collection and Antibody Production

( ) Appendix C. Cancer Studies and/or Tumor Development

( ) Appendix D. Explanation for USDA Classification E

( ) Appendix F. Use of Hazardous Agents

**Other Committee Review and Approvals:**

IBC Registration Number & Approval Date:

Radiation Safety Officer Approval Date:

**D. FUNDING INFORMATION**.

* + - 1. Funding Source (Check any that apply).

( ) Not funded.

( ) Internal funding: Type:

( ) Federal funding: List agency name:

( ) Subcontract. List organization name and include contact name, telephone no., and address:

2. Provide the fund number and speed type that per diems will be charged to (**Required** for all protocols unless for teaching activities):

3. If federally funded, the proposal must be provided to the IACUC Administrator for review to ensure that all proposed activities are consistent with this IACUC protocol.

Protocol has been sent to the IACUC Administrator: ( )Yes ( ) No ( ) NA

For assistance with completing this form or questions, contact the Animal Research Compliance Manager,

Office of Institutional Compliance, at 978-934-4698

**E. PERSONNEL**

Provide names, experience and applicable training for all personnel involved**. Note: Training certification is required for all PIs, students, and staff before approval is issued and must be renewed every 3 years** ([www.citiprotgram.org](http://www.citiprotgram.org)).

|  |  |  |
| --- | --- | --- |
| **Name** | **Mandatory Training Completed** | **Protocol Specific Training Completed** |
|  | ( ) CITI:  ( ) Handling/Restraint/Sexing (Rodents Only)  ( ) Euthanasia Techniques  ( ) EHS:  ( ) Occ Health Clearance: | ( ) Compound Administration Techniques  ( ) Common Blood Collection Techniques  ( ) Anesthesia/Analgesia/Aseptic Training  ( ) Surgical Techniques:  ( ) Other: |
|  | ( ) CITI:  ( ) Handling/Restraint/Sexing (Rodents Only)  ( ) Euthanasia Techniques  ( ) EHS:  ( ) Occ Health Clearance: | ( ) Compound Administration Techniques  ( ) Common Blood Collection Techniques  ( ) Anesthesia/Analgesia/Aseptic Training  ( ) Surgical Techniques:  ( ) Other: |
|  | ( ) CITI:  ( ) Handling/Restraint/Sexing (Rodents Only)  ( ) Euthanasia Techniques  ( ) EHS:  ( ) Occ Health Clearance: | ( ) Compound Administration Techniques  ( ) Common Blood Collection Techniques  ( ) Anesthesia/Analgesia/Aseptic Training  ( ) Surgical Techniques:  ( ) Other: |
|  | ( ) CITI:  ( ) Handling/Restraint/Sexing (Rodents Only)  ( ) Euthanasia Techniques  ( ) EHS:  ( ) Occ Health Clearance: | ( ) Compound Administration Techniques  ( ) Common Blood Collection Techniques  ( ) Anesthesia/Analgesia/Aseptic Training  ( ) Surgical Techniques:  ( ) Other: |
|  | ( ) CITI:  ( ) Handling/Restraint/Sexing (Rodents Only)  ( ) Euthanasia Techniques  ( ) EHS:  ( ) Occ Health Clearance: | ( ) Compound Administration Techniques  ( ) Common Blood Collection Techniques  ( ) Anesthesia/Analgesia/Aseptic Training  ( ) Surgical Techniques:  ( ) Other: |
|  | ( ) CITI:  ( ) Handling/Restraint/Sexing (Rodents Only)  ( ) Euthanasia Techniques  ( ) EHS:  ( ) Occ Health Clearance: | ( ) Compound Administration Techniques  ( ) Common Blood Collection Techniques  ( ) Anesthesia/Analgesia/Aseptic Training  ( ) Surgical Techniques:  ( ) Other: |

**F. STUDY OBJECTIVES**

Provide a **brief** description of why this study is important to human or animal health, the advancement of knowledge, or the good of society and the overall goals of the research. Please write this in lay language.

Objectives:

**G. EXPERIMENTAL DESIGN**

Explain the experimental design and specify all animal procedures, including procedures that involve pain or distress. Provide enough detail to allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study.

Experimental Design:

**H. PAIN AND DISTRESS INFORMATION**

**1. Indicate here the pain or distress category for the animals (by species) to be used.**

|  |  |
| --- | --- |
| **Species** | **USDA Pain/Stress Category** |
|  | USDA Category B: Animals bred, conditioned, or held for future use. |
|  | USDA Category C: Animals to be used in procedures with minimal, momentary, or no pain or distress. |
|  | USDA Category D: Animals that will receive appropriate anesthetics, tranquilizers, or analgesics to alleviate pain and/or distress. (All animals bearing tumors or undergoing surgery or other procedures that require anesthesia or analgesia such as intracardiac or retro-orbital bleeding, injections, or radiation with intent for long-term follow-up should be placed in this section.) |
|  | USDA Category E: Animals that will experience pain and/or distress without relief**. (Appendix D must be completed for this category.)** |

**2. For Category D or E, complete sections a through g related to Pain and Distress**

a. Describe the species specific clinical signs or behavioral manifestations expected that will be used to indicate when animals are in pain or distress. (Procedures that cause pain or distress in human should be considered to cause pain or distress in animals.)

b. For each clinical sign or behavior, how do you intend to alleviate pain and/or distress?

c. Who is designated as the responsible party(s) to monitor these signs?

d. If anesthetic, analgesic, tranquilizing or other therapeutic drug (i.e. antibiotics) will be used for non- experimental purposes to treat the animals, provide the information below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | | | **Drug** | **Dose** | **Route** | **Frequency** | **Volume** |
| **A** | **B** | **C** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

e. Search Results for Painful Procedures and Alternatives

Regulations mandate that you describe **how** the lack of alternative methods was verified for each potentially painful/distressing procedure (**for Category D and/or E procedures**). The alternatives search must be in the form of a narrative description and use two databases. Alternatives that demonstrate less painful/invasive procedures should be described below.

**Note: Search terms should include the name of the painful procedure together with words such as ‘pain’ ‘distress’ and ‘ alternatives**’. Searches must be conducted within **60 days** of submission of this form.

**Databases:**

Altweb: [http://altweb.jhsph.edu/](file:///C:\Users\Amy_Finneral\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\GRJQ23S4\IACUC%20form%20Section%20H%20revision%206-7-12.docx#Check159)

AGRICOLA: [http://agricola.nal.usda.gov/](file:///C:\Users\Amy_Finneral\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\GRJQ23S4\IACUC%20form%20Section%20H%20revision%206-7-12.docx#Check155)

PubMed/Medline: [http://www.ncbi.nlm.nih.gov/pubmed/](file:///C:\Users\Amy_Finneral\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\GRJQ23S4\IACUC%20form%20Section%20H%20revision%206-7-12.docx#Check156)

Cambridge Scientific: [http://www.csa.com/factsheets/objectsclust-agr-set-c.php](file:///C:\Users\Amy_Finneral\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\GRJQ23S4\IACUC%20form%20Section%20H%20revision%206-7-12.docx#Check157)

TOXNET: [http://toxnet.nlm.nih.gov/](file:///C:\Users\Amy_Finneral\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\GRJQ23S4\IACUC%20form%20Section%20H%20revision%206-7-12.docx#Check158)

Other:

Complete the table below with the database information related to the searches completed:

|  |  |
| --- | --- |
| D**atabases** searched | 1) |
|  | 2) |
| D**ate** search was conducted |  |
| Y**ears covered** by the search |  |

Notes: Recommended Search Strategy 🡺 “*procedure*” and “*species*” and “*alternative*” = # references.

The IACUC must be able to understand the keywords and search strategy used. *Example:* For use of anesthesia in mice, search using the following terms: *[anesthesia + (species singular or plural) + (alternative or alternatives)] and report the # of references retrieved.*

f. Indicate here all the string of keywords for each search conducted and the number of references found:

For Database Search 1, describe here any alternatives, refinements, or replacements for the painful procedure that were found and your justification as to why they cannot be used in this protocol:

For Database Search 2, describe here if any alternatives, refinements, or replacements for the painful procedure were found and your justification as to why they cannot be used in this protocol:

g. Provide a narrative for each search. **The IACUC must be able to assess whether the search topics were appropriate and whether the search was sufficiently thorough.**

**Example narrative**: *On March 16, 2012 a PubMed search was performed for the indicated keywords for all the listed procedures. Many of these references have validated these procedures as safe techniques in mice. Many references were redundant or irrelevant to the procedure. Although many references were found for each search, no reasonable or obvious alternatives were found*.

Narrative for Search 1:

Narrative for Search 2:

**I.** **JUSTIFICATION FOR PROPOSED NUMBERS**

1. Explain your rationale for animal use and why in vitro methods cannot be used.

2. Use the table below to list the experimental groups, the number of animals per group, and the number of times the experiment will be repeated to calculate the total number of animals requested per year.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Experimental Group | No./Group | Number of groups/Year | Species A | Species B | Species C | Total |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**Requested Total/Yr:**

3. Please provide a power calculation or evidence to support the numbers of animals proposed for use (*For example, use data from pilot studies or similar published studies to support the numbers of animals requested and the numbers of animals per group so that you can show statistically significant differences between groups. The following link may be helpful in calculating animal numbers* [*http://www.uml.edu/ORA/institutionalcompliance/IACUC/Other\_Links.html*](#Check160)

**J. SPECIES INFORMATION**

Note: Contact the IACUC Administrator [Amy\_Finneral@uml.edu](mailto:Amy_Finneral@uml.edu) or x44698 or to order animals.

|  |  |  |  |
| --- | --- | --- | --- |
| **Category** | **Species A** | **Species B** | **Species C** |
| Strain |  |  |  |
| Sex |  |  |  |

**Note:** *If you need specific age/weight animals, provide details here:*

**K. HOUSING AND CARE**

1. Is standard food and caging being used? ( ) Yes ( ) No

2. Indicate if special conditions are required: ( ) Yes ( ) No

|  |  |
| --- | --- |
| ( ) Immunocompromised: Sterile Housing | ( ) Medications/Treatments |
| ( ) Non-Standard Light Cycle Requirements | ( ) Metabolic Cage |
| ( ) Radiation Lab | ( ) Water Restrictions |
| ( ) Special Diet or Restriction of Diet | ( ) Other, specify: |
| ( ) Non-Standard Caging (describe): |  |

3. For each special condition checked above, specify who will be responsible to oversee the treatment or condition:

4. Is off-hours access to the animal facility (other than 7am to 7pm)? ( ) Yes ( ) No

If yes, justify why:

5. Will any marking methods be used to identify animals? ( ) Yes ( ) No

Check the methods to be used*:* ( ) Ear Punching

( ) Ear Tagging

( ) Tattooing

( ) \*Other, explain why this must be used:

6. Will procedures be conducted on animals outside of the main facility? ( ) Yes ( )No

**Note:** IACUC approval is required to house animals outside the facility.

1. Explain why animals need to be housed or taken outside of the main facility:
2. Specify how environmental conditions are provided:
3. List who will be responsible for the oversight and daily care of the animals :
4. Describe the emergency care plan:
5. Describe the plan for euthanasia at the offsite location:

**L. OTHER PROCEDURES**

1. Will there be prolonged restraint of un-anesthetized animal(s) for more than 30 min? ( ) Yes ( ) No

If yes, provide justification:

2. Is the restraint device constructed to allow for the animal’s normal postural adjustments ( ) Yes ( ) No

If No, justify:

3. Will there be any other procedures performed not covered elsewhere in the protocol?( ) Yes ( ) No

If yes, please explain:

**M. ENDPOINTS**

There are two types of endpoints that the IACUC needs to have identified for each protocol.

The scientific endpoint of a study is when the PI’s scientific aims and objectives have been reached. The protocol should clearly state what will happen to the animals once the scientific endpoints have been met.

A humane endpoint is the point at which an experimental animal's pain and/or distress is terminated, minimized or reduced. **Endpoint Criteria** describe when it is time to either:

* Euthanize an animal to prevent suffering;
* Discontinue a painful procedure; or
* Remove an animal from a study

Project personnel **must** observe for the following signs of pain or distress in all animals involved to evaluate if an animal has reached a humane endpoint:

* Changes in body weight (e.g. change in water and food intake)
* Change in physical appearance (e.g. failure to groom, hunched posture, tremors)
* Measurable clinical signs (e.g. change in heart rate, respiratory rate)
* Change in behavior (e.g. lethargic, aggressive, vocalizing, self-mutilation)
* Behavioral changes to external stimuli (e.g. excitability; righting reflex)

1. Provide scientific endpoints for this study:

2. Provide humane endpoints for this study:

3. Provide personnel responsible for monitoring the animals and frequency of observations:

**N. EUTHANASIA**

Please check the boxes that apply. If different species are undergoing different methods of euthanasia, indicates numbers in box also. Refer to the AVMA Guidelines on Euthanasia at <http://www.avma.org/issues/animal_welfare/euthanasia.pdf>

|  |  |  |  |
| --- | --- | --- | --- |
| **Method** | **Species A** | **Species B** | **Species C** |
| CO2 Inhalation |  |  |  |
| Isoflurane |  |  |  |
| Sodium Pentobarbital Overdose  **Add Route and Dose in mg/kg** |  |  |  |
| Cervical Dislocation\*  \*Requires Pre-sedation |  |  |  |
| Decapitation/Exsanguination\*  \*Requires Pre-sedation |  |  |  |
| Other: |  |  |  |

1. ( ) Animals euthanized under this protocol will be available for tissue sharing after euthanasia.

*Note: Checking this box assures that the animals were euthanized according to and in compliance with use on this protocol, that the tissues have not been exposed to infectious disease, radioactive substances, or other biological or chemical substances that would make them otherwise unsuitable for common use.*

2. Regardless of method used, indicate how death will be confirmed:

( ) Removal of vital organ (heart)

( ) Absence of cardiovascular function

( ) Use of secondary method of euthanasia:

( ) Other:

3. If animals are NOT going to be euthanized, indicate their final disposition will be at the end of the study:

|  |  |  |  |
| --- | --- | --- | --- |
| **Disposition** | **Species A** | **Species B** | **Species C** |
| Transferred live to another Protocol | ( ) Yes Protocol No.: | ( ) Yes Protocol No.: | ( ) Yes Protocol No.: |
| Transferred live to another institution or vendor (insert name) |  |  |  |
| Other: |  |  |  |

|  |
| --- |
| **O. PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE PAGE**  (Each box must be checked and an original signature provided below):  ( )I certify that all animal species, numbers, and procedures proposed in this project have been completely described on this application. I, the undersigned, accept responsibility for assuring that all personnel involved in this study have met training requirements, are aware of and will not deviate from approved procedures outlined on this form, and are in accordance with the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals, and applicable Federal and State Laws and regulations and policies of the University of Massachusetts Lowell with regard to the humane care and use of animals involved in this study.  ( ) These activities do not unnecessarily duplicate previous experiments.  ( ) I understand that if I (or my designated representative) cannot respond within 24 hours and animals on this project show evidence of illness or pain, emergency care, including euthanasia, may be administered by the ORS Manager after consultation and approval from the AV or the IACUC Chair. (Note: indicate here if there are any drugs that should NOT be used because they might interfere with your study data if the AV has to recommend treatment during the study and you are unavailable:(       )  ( ) I have received and reviewed the UMass Lowell IACUC Policies and Procedures and the Office of Research Services Facility Policies and Procedures.  ( ) I understand that research may not begin until I have received the official notice of approval from the IACUC and that my signature has been received by the IACUC Administrator. |

|  |  |
| --- | --- |
| **PRINCIPAL INVESTIGATOR SIGNATURE:** | |
| PI Signature: | Date: |
| Print name: | Protocol No. and Title: |

Fax or send this page by intercampus mail, with the original signature, to:

Animal Research Compliance Manager

Office of Institutional Compliance

198 Riverside Street, Olsen Hall Room 618

Fax: 978-934-3029

**APPENDIX A: ANIMAL SURGERY INFORMATION** ( )N/A

*All personnel new to performing surgery are* ***required*** *to watch* [*Principles of Rodent Surgery for the New Surgeon*](http://r20.rs6.net/tn.jsp?llr=y7g6zqcab&et=1104524340723&s=122777&e=001_5ifJLf7HTP-I9dNCvC_1bQQgml4Xq7qK86QUnzz2LTMTIupPJfRIjmuMioAKFyy18FfaP5qZCotiRjMpOjSQ_R_yuAHuP7r84n7YFRgRPCg5u9_NvWJORE8kmAw5q2V-ezHkzW_2gI=) *to understand essential principles and practices involved in aseptic surgery in rodents. Click on the following link to access the video:* [*http://www.jove.com/details.php?id=2586*](http://www.jove.com/details.php?id=2586)

**Surgery Information (Provide a detailed description for each surgical procedure proposed.)**

***Please Note****: Lubricating ophthalmic ointment* ***must*** *be used on all animals undergoing surgery*

1. Surgical procedures are intended to be **survival** ( ) Yes ( )No

(*Aseptic/sterile surgical techniques must be used for all species)*

2. Will multiple surgeries be performed on the same animal? ( ) Yes ( )No

*If YES, please justify*.

3. Where will surgery be performed? ( ) Olsen 618 OR Other (Building and room no.):

4. Name of Surgeon(s):

5. Individual(s) responsible for postoperative care (including weekend and Holiday care), include contact information:

6. Please list all drugs or compounds that will be administrated:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | **Species** | | | | **A** | **B** | **C** | | ( ) | ( ) | ( ) | | ( ) | ( ) | ( ) | | ( ) | ( ) | ( ) | | ( ) | ( ) | ( ) | | |  |  |  | | --- | --- | --- | | **Type** | Name | **Dose/Route/**  **Frequency/Volume** | | Pre-anesthetic(s): |  |  | | Anesthetic(s): |  |  | | Analgesic(s): |  |  | | Other |  |  | |

***Note:*** *The use of pharmaceutical grade chemicals and other substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. Pharmaceutical grade chemicals should be used, when available, for all animal-related procedures*

7. Are any of the above Non-pharmaceutical grade Agents? ( ) Yes ( ) No

*If Yes*: Please justify and describe how the drug will be prepared to assure sterility:

8. Describe methods used to sterilized instruments prior to surgery and between animals if multiple animals are to be used:

9. Describe preparation of surgical site:

10. Describe the surgical procedure(s) to be performed:

11. Describe method of wound closure:

12. State the anticipated duration of the procedure:

13. When will analgesics be administered?

( ) Pre-operative ( ) Intraoperative ( ) Immediately Post-operative

( ) Long term: If yes, state frequency:

**Animal Monitoring Plan**

**a. Intra-operative plan:**

1. What type of heat source will be used to keep the animal warm during surgery (e.g. recirculating water heating pad):

2. Explain frequency and criteria that will be used to monitor anesthesia throughout the procedure:

3. In the instance of an adverse event during surgery, describe the process to determine when and how the animal will be euthanized:

**b.** **Immediate post-op care:**       **OR**  ( ) NA

*Note: please provide easy access to food and water post-surgery if required*

1. Please indicate where the animals will recovery after surgery (*Note:* animal **must** be fully recovered from anesthesia and has regained head control): ( ) Cage ( ) Incubator/heating unit ( ) Other:

2. Describe location, environment and frequency at which animals are observed o determine recovery from anesthesia is complete:

**c.** **Long term post-operative care plan:**        **OR** ( )NA

*Note: provide easy access to food and water if required*

1. Describe how frequently animals will be observed after surgery:

2. Describe what you are going to monitor for the specific surgical procedure proposed:

The following are examples of physiological and behavioral parameters that may be used to monitor animal’s health post- operatively:

* Changes in body weight (e.g. change in water and food intake)
* Change in physical appearance (e.g. failure to groom, hunched posture, tremors)
* Measurable clinical signs (e.g. change in heart rate, respiratory rate)
* Change in behavior (e.g. lethargic, aggressive, vocalizing, self-mutilation)
* Behavioral changes to external stimuli (e.g. excitability; righting reflex)
* Incision site changes including redness, swelling, discharge and dehiscence (suture line failure)

4. Describe your plan if any of the above symptoms occur:

5. Describe how and at what point post-op you will be removing the wound closure material:

6. Will analgesia be required long term: ( ) Yes ( ) NO *If yes, name and frequency of administration:*

**APPENDIX B: BLOOD COLLECTION INFORMATION ( )** N/A

***Note****: Each animal should be weighed before blood collection to determine maximum sample amounts according to the Guidelines*

1.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Anatomical Site** | **Volume to be collected** | **Bleeding frequency** | **Method of restraint** |
| ( ) Mouse  ( ) Rat  ( ) Hamster  ( ) Gerbil  ( ) Other: | ( ) Retro-orbital\*  ( ) Cardiac \*  ( ) Submandibular facial vein  **( ) Saphenous Vein**  ( ) Tail Vein  ( ) Jugular Vein (Rat)  ( ) Other: |  |  |  |

\*\***Retro-orbital/Cardiac Puncture**: *The UML Institutional Animal Care & Use Committee has determined that retro-orbital eye bleeding and cardiac puncture be performed only on animals under deep anesthesia and will require specific training.*

2. Will blood collection be in accordance with the Blood Collection Guide below? ( ) Yes ( ) No

|  |  |  |  |
| --- | --- | --- | --- |
| **Body weight (g)** | **CBV\*(ml)** | **1% (ml)** | **10% (ml)** |
| 20 | 1.10 - 1.40 | .011 - .014 | .11 - .14 |
| 25 | 1.37 - 1.75 | .014 - .018 | .14 - .18 |
| 30 | 1.65 - 2.10 | .017 - .021 | .17 - .21 |
| 35 | 1.93 - 2.45 | .019 - .025 | .19 - .25 |
| 40 | 2.20 - 2.80 | .022 - .028 | .22 - .28 |
| 125 | ﻿6.88 - 8.75 | .069 - .088 | .69 - .88 |
| 150 | ﻿8.25 - 10.50 | .082 - .105 | .82 - 1.0 |
| 200 | ﻿11.00 - 14.00 | .11 - .14 | 1.1 - 1.4 |
| 250 | ﻿13.75 - 17.50 | .14 - .18 | 1.4 - 1.8 |
| 300 | ﻿16.50 - 21.00 | .17 - .21 | 1.7 - 2.1 |
| 350 | ﻿19.25 - 24.50 | .19 - .25 | 1.9 - 2.5 |

**\*Note:** Of the circulating blood volume, approximately 10% of the total volume can be safely removed every 2 to 4 weeks and 1% every 24 hours.

3. State frequency of blood collection:

*Please provide justification if proposed total blood volume exceeds recommendations and outline the process for fluid replacement:*

Drugs to be administered for blood collection:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Drugs Administered** | | | **Species** | | |
| **Type** | Name | **Dose/Route/Frequency/Volume** | **A** | **B** | **C** |
| Pre-anesthetic(s): |  |  | ( ) | ( ) | ( ) |
| Anesthetic(s): |  |  | ( ) | ( ) | ( ) |
| Analgesic(s): |  |  | ( ) | ( ) | ( ) |
| Other |  |  | ( ) | ( ) | ( ) |

**APPENDIX C: CANCER STUDIES AND/OR TUMOR DEVELOPMENT** ( )N/A

***Note****: all outside materials used for tumor production etc.* ***must*** *be screened for rodent viruses and mycoplasmas. If human cell lines are to be used an application* ***must*** *be filed with the IBC. All other cell lines will be treated as though they carry infectious diseases or blood borne pathogens.*

**A. Study Information:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Carcinogen** | **Route** | **Tumor Type** | **Site of Development** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Have all personnel Completed CITI training for cancer research studies? ( ) Yes ( ) No

2. Individual(s) responsible for animal health monitoring (including weekend and Holiday care), include contact information:

**Please Note:** An Observation Checklist **must** be used for cancer research studies to assess physical condition and tumor growth/metastasis. This checklist should be available to the Attending Veterinarian and/or IACUC upon request.

3. State the body system and/or organ system most likely affected by the tumor type:

4. Explain how body weight will be monitored and documented:

5. Describe the monitoring system and how frequently monitoring will be performed:

**Note:** Tumor size guidelines

* Must **not** exceed 20mm at the largest diameter in an adult mouse, 40mm in adult rats
* A maximum tumor size **must not** exceed 10% of body weight at day of injection
* Baseline body weights **must** be recorded at the start of the study, and periodically through the completion of the study

Some recommended endpoints are:

* the tumor mass should not proceed to the point where it significantly interferes with normal bodily functions, or causes pain or distress due to its location (solid tumors)
* weight loss exceeding 20% of the body weight of a similar normal animal (taking into account the tumor mass)
* ulceration/infection of the tumor site
* palpation of tumor elicits` a pain response
* animal appears weak with “hunched posture”, unresponsive or moribund
* respiratory distress
* persistent self-induced trauma

8. Will there be carcinogens, toxins or other hazardous material used in live animals? ( ) Yes ( ) No

*If YES*, also complete Appendix F.

**APPENDIX D: EXPLANATION FOR USDA CLASSIFICATION E** ( )N/A

*Note: This page is required with USDA Form 7023 for any USDA Classification E Listings.*

1. Name of investigator:

2. Animal Study Proposal Title:

3. Species and number of animals listed in Classification E for each year:   
 a. Species:      

b. Number of animals:

Year One -

Year Two-

Year Three-

Total:

4. Description of project including reason(s) for species selection:

5. Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives, or tranquilizers during and/or following painful or distressing procedures is contraindicated:

**Signatures:**

**Investigator:**        **Date:**      

**IACUC Chair**:       **Date:**      

**APPENDIX F: USE OF HAZARDOUS AGENTS ( ) N/A**

*Note: Contact EHS at x42778 or x42746 for**questions about use of any hazardous agents.*

**1. Biological –**A“yes” answer to these questions indicate that an IBC Registration also needs to be submitted to [biosafetyofficer@uml.edu](mailto:biosafetyofficer@uml.edu) before final IACUC approval is granted.

a. Will biological materials, biotoxins, human or mammalian cells, tissues or body fluids be used in live animals (e.g. transfection via viral vectors)? ( )Yes ( ) No

*Note: All biological materials should be tested for pathogenic organisms/agents for the species intended to receive such materials (e.g. MAP and RAP test).*

If yes, list:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name Material(s) / Tissue Type(s)** | **Species** | | |
| **A** | **B** | **C** |
|  | ( ) | ( ) | ( ) |
| **Describe Route and Dose and DNA Source (if applicable)** | | | |
|  | ( ) | ( ) | ( ) |

b. If biological materials are from an external source, provide the source and intended use of the materials:

c. Will infectious agents be used in live animals?( )Yes ( ) No

If yes,list:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name Infectious Agent** | **Species** | | |
| **A** | **B** | **C** |
|  | ( ) | ( ) | ( ) |
| **Describe Route and Dose** | | | |
|  | ( ) | ( ) | ( ) |

**Note: A*ll animal cages should be labeled to indicate that bedding is contaminated.***

d. Please state if special handling instructions of cages are needed:

e. A registration form has been filed with the IBC. ( ) Yes ( ) No

IBC Registration No. and Date of Approval:

**2. Radiological**- Individuals handling radioactive isotopes, animals injected with or containing radioactive isotopes, or persons using an irradiator must also receive Radiation Safety Committee review and approval. Contactthe Radiation Safety Office at x43372 or x43373 for more information. IACUC approval is contingent upon Radiation Safety approval.

***Note:*** *Irradiation with the intent for long-term survival usually is USDA Pain/Stress Category D and should be noted in Section H.*

* 1. Will radioisotopes be used in live animals? ( ) Yes ( ) No

If yes,list:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name Isotope** | **Species** | | |
| **A** | **B** | **C** |
|  | ( ) | ( ) | ( ) |
| **Describe Amount per Animal and Route** | | | |
|  | ( ) | ( ) | ( ) |

b. Will live animals be exposed to an external radioactive field? ( ) Yes ( ) No

c. Will animals be radioactive after exposure? ( ) Yes ( ) No

If yes, indicate the approximate time before it is considered safe to handle them:

If yes,list:

|  |  |  |  |
| --- | --- | --- | --- |
| **Dose** | **Species** | | |
| **A** | **B** | **C** |
| ( ) Straight Dose:      rads | ( ) | ( ) | ( ) |
| ( ) Split Dose: 1st      rads ; 2nd      rads | ( ) | ( ) | ( ) |

c. I have contacted the radiation safety office for assistance. ( ) Yes ( ) No

Additional:

**3. Chemical** –For questions about the use of specific chemicals, contactthe EHS at x 42618.

a. Will any compounds, toxins, or other potentially hazardous material be used in live animals that are not described in **Appendix C** (do not include anesthetics and analgesics described in Appendix A or B)? ( ) Yes ( ) No

If yes, list*:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name Agent:** | **Species** | | |
| **A** | **B** | **C** |
|  | ( ) | ( ) | ( ) |
| **Describe Route and Dose:** | | | |

* 1. Will any other substances be administered that are not listed above or in Appendix C and that may have unknown properties? ( ) Yes ( ) No

If yes, list:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name Agent:** | **Species** | | |
| **A** | **B** | **C** |
|  | ( ) | ( ) | ( ) |
| **Describe Route and Dose:** | | | |