Last updated 9/2/2015

### Institutional Animal Care and Use Committee

### Appendix G: Substance Administration



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| **Section 1: General Information** |

**Protocol Information**

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| --- | --- |
| PI name:IACUC Protocol Number:IACUC Protocol Title:  |            |
|  |       |

Facility name:

**Directions:**

* Important: Save this form to your computer’s hard drive before completing it, or your responses may not be captured!
* This form must be completed and submitted (as a Word document) electronically. Retain a copy of your completed form for your records.
* Please respond to all applicable questions. Type responses in the designated shaded boxes or check the designated check boxes.
* **Proprietary Material:** **Provide as much detailed information as possible including whether it is chemical or biological and the base material. Include any hazards associated with the material.**
* For questions, contact the IACUC Administrative Office at IACUCadmin@vt.edu or 540/231-0931.

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| **Section 2: Non-Hazardous Substances**  |

**Complete this section if non-hazardous substances such as antibiotics, other non-hazardous pharmaceuticals such as parenteral fluids (normal saline, lactated Ringers), etc. will be administered to animals. Do not include anesthetics, analgesics, or sedatives. If this section is not applicable to your protocol, go to the next section.**

1. Please complete the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Agent** | **Diluent** | **Dose (mg/kg) and Volume (ml)** | **Route of Administration** | **Frequency and Duration of Administration** |
|       |       |       |       |       |
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| **Section 3: Identification of Hazardous Agents**  |

1. **Hazard summary:** Please check the appropriate check box below for potential hazardous agent(s) that will be administered to animals as part of this animal protocol.

|  |  |
| --- | --- |
| [ ]  | Hazardous substances – chemicals, pharmaceuticals, nanomaterials etc.  |
| [ ]  | Biological agents – infectious agents, human cell lines, microbial toxins etc. |
| [ ]  | Radioactive agents |

1. The appropriate university committees (e.g., bio-safety, radiation safety) must approve the use of these agents before you may use them. Please note the status of your protocol with the relevant university committees (e.g., approved by radiation safety on January 1, 2006).

1. Please indicate if any of the agents listed in this Appendix are on the CDC/USDA list of select agents that might be used in bioterrorism.

|  |  |
| --- | --- |
| [ ]  | No select agents will be used. |
| [ ]  | Select agents will be used in quantities that fall below the minimum amounts regulated by select agent legislation. |
| [ ]  | Select agents will be used in quantities that are regulated by select agent legislation. ***Contact the university’s biosafety officer for further instructions and approval requirements.***  |

1. Do any of the agents described in this Appendix contain recombinant/synthetic nucleic acids?

[ ]  Yes

[ ]  No

If any of the agents described in this appendix contain recombinant constructs **or involve Gene Transfer**, you must conduct the animal experiments according to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. Consult with the Institutional Biosafety Committee to make sure that you comply with these guidelines.

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| **Section 4: Hazardous Chemical and Pharmaceutical Substances** |

**Complete this section if hazardous chemical and pharmacologic agents will be administered to animals. Examples of agents that should be listed here includes but is not limited to chemicals, pharmaceuticals, nanomaterials (include parent compound), or other similar agents that are potentially hazardous to personnel coming in contact with the agents. If this section is not applicable to your protocol, go to the next section.**

1. Please complete the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Agent** | **Enter hazard, e.g. Mutagen (M) Carcinogen (C)****Teratogen (T)****Irritant (I)** **Other (Describe)**  | **Diluent** | **Dose (mg/kg) and Volume (ml)** | **Route of Administration** | **Frequency and Duration of Administration** |
|       |       |       |       |       |       |
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1. Do you have and are following an SOP(s) that describes the safe use of these agent(s) in the animal housing area?

[ ]  Yes - List title and attach in supporting document.

[ ]  No

**Substance Administration, Animal Housing and Care Information**

1. Is the hazardous agent excreted unchanged or is a hazardous metabolite excreted in urine, feces, or other bodily fluid?

[ ]  Yes - If yes, for how long after administration?

[ ]  No

[ ]  Unknown

1. Animal room doors will have signage stating “Hazardous Chemical In Use” and the hazard warning (e.g., toxic, mutagenic, carcinogenic, etc.). Cage cards will be labeled with “Hazardous Chemical” and the name of the chemical:

[ ]  Acknowledgement -

1. Describe the PPE required for safe handling of the agent during administration or in case of accidental release during administration, and by animal care technicians performing standard animal care and husbandry procedures. Check all that apply.

[ ]  Standard animal facility PPE (disposable gown or lab coat, gloves, hair bonnet, shoe covers)

[ ]  Double gloves

[ ]  Double gown

[ ]  Safety glasses or goggles

[ ]  Respiratory Protection

[ ]  Surgical Mask for Splash Protection

[ ]  Other -

1. Describe safety equipment required for cage changing or other manipulation of cages or animals:

[ ]  Standard animal transfer station

[ ]  Chemical fume hood

[ ]  Class II, Biosafety Cabinet

1. Where will the agent be administered?

|  |  |
| --- | --- |
| [ ]  | Animal housing room |
| [ ]  | Animal facility procedure room – Enter room number:       |

1. Please indicate if animals will be anesthetized or sedated when the agents are administered.

|  |  |
| --- | --- |
| [ ]  | Animals will not be anesthetized or sedated.  |
| [ ]  | Animals will be anesthetized or sedated when the agents are administered. *Complete Section 10 question 2 (in the protocol if this is a protocol) or Appendix F (if this is an amendment) then go to section 3.* |

1. Describe the procedures to be followed and emergency contacts in the event of a spill, or release of the agent. PI is responsible for providing appropriate spill cleanup materials and procedures to all personnel involved.

1. Provide any special requirements or emergency procedures (e.g., antidote) for an overt exposure to the agent.

**Disposal of Waste and Cleaning of Cages and Equipment**

1. Will the bedding, caging, food, water, or any other materials have the potential to be contaminated with the hazardous substance?

[ ]  Yes or unknown - Describe any special handling requirements (e.g., inactivation of chemicals, collection of water, etc.) and/or PPE:

[ ]  No

1. All animal bedding and carcasses must be disposed of as “Regulated Medical Waste for Incineration”. Describe any additional special waste handling requirements.

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| **Section 5: Biological Agents (infectious or non-infectious) or Materials** |

**Complete this section if bacteria (including rickettsia), viruses, fungi, protozoa, prions, viral vectors, or other biologic agents will be used; include serum, cell lines, tissue, nucleic acid, microbial toxins. If this section is not applicable to your protocol, go to the next section.**

1. Please complete the following table.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  **Biological Agent (add R if recombinant)** | **Diluent** | **Source****(e.g., vendor)** | **Biosafety Level of Agent (BSL 1, 2, 3, or 4)** | **Dose (e.g., CFU, PFU) and Volume (ml)** | **Route of Administration** | **Frequency of Administration** |
|       |       |       |       |       |       |       |
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1. Describe all potential health risks for humans who may be exposed to the agents.

1. For infectious agents, has an antibiogram, anti-viral drug sensitivity screen, or other appropriate drug sensitivity panel been determined for the agent(s) listed to assist physicians in selecting proper therapy if an inadvertent human infection occurs?

|  |  |
| --- | --- |
| [ ]  | Yes |
| [ ]  | No |

1. For the use of cell lines or tissues, have the materials been screened to make sure that it does not harbor infectious agents that could infect other laboratory animals?

[ ]  Yes – Describe method and attach results to protocol

[ ]  No – See [Policy on Testing Biological Materials used in Rodents](https://www.researchcompliance.vt.edu/iacuc/sites/researchcompliance.vt.edu.iacuc/files/policy_cell_line_testing_policy.pdf) …. You must coordinate testing with OUV.

1. Is the biologic agent being shed in urine, feces, or other bodily fluid?

[ ]  Yes - If yes, for how long after administration?

[ ]  No

[ ]  Unknown – the animals must remain housed in the same ABSL level throughout the experiment.

1. Animal room doors will have University Biohazard signage posted. Cage cards will be labeled with a “Biohazard” sticker and the name of the infectious agent:

[ ]  Acknowledgement -

1. Describe the PPE required for safe handling of the agent during administration or in case of accidental release during administration, and by animal care technicians performing standard animal care and husbandry procedures. Check all that apply.

[ ]  Standard animal facility PPE (disposable gown or lab coat, gloves, hair bonnet, shoe covers)

[ ]  Double gloves

[ ]  Double gown

[ ]  Safety glasses or goggles

[ ]  Respiratory Protection

[ ]  Surgical Mask for Splash Protection

[ ]  Other -

1. Describe safety equipment required for cage changing or other manipulation of cages or animals:

[ ]  Standard animal transfer station

[ ]  Class II, Biosafety Cabinet

1. Where will the agent be administered?

|  |  |
| --- | --- |
| [ ]  | Animal housing room |
| [ ]  | Animal facility procedure room – Enter room number:       |

1. Please indicate if animals will be anesthetized or sedated when the agents are administered.

|  |  |
| --- | --- |
| [ ]  | Animals will not be anesthetized or sedated.  |
| [ ]  | Animals will be anesthetized or sedated when the agents are administered. *Complete Section 10 question 2 (in the protocol if this is a protocol) or Appendix F (if this is an amendment) then go to section 3.* |

1. Describe the procedures to be followed and emergency contacts in the event of a spill, or release of the agent. PI is responsible for providing appropriate spill cleanup materials and procedures to all personnel involved.

1. Provide any special requirements or emergency procedures (e.g., antidote) for an overt exposure to the agent.

**Disposal of Waste and Cleaning of Cages and Equipment**

1. For agents handled as BSL2 or BSL3 all bedding, caging, water, or any other equipment or materials in contact with the animals must be autoclaved prior to being taken to the cage wash. Describe any other special waste handling requirements.

1. All animal bedding and carcasses will be disposed of as “Regulated Medical Waste for Incineration”. Describe any additional special waste handling requirements.

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| **Section 6: Radioactive Agents** |

**Complete this section if radioactive compounds or agents will be used. If this section is not applicable to your protocol, go to the next section.**

1. Please complete the following table.

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| --- | --- | --- | --- | --- | --- |
| **Radioactive Agent****(Include Isotope)** | **Diluent** | **Dose (mg/kg) and Volume (ml)** | **Route of Administration** | **Activity (e.g., mCi/kg)** | **Frequency and Duration of Administration** |
|       |       |       |       |       |       |
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1. Describe the reason for administering the agent(s) and the expected effects of the agent(s).

1. Please list the name(s) of the personnel who have been given permission by the Virginia Tech Radiation Safety Committee to use the radioactive agent(s) listed in question 1.

1. Who will be handling the radioactive material and the animals following administration of the material?

1. Please indicate if animals will be anesthetized or sedated when the agents are administered.

|  |  |
| --- | --- |
| [ ]  | Animals will not be anesthetized or sedated.  |
| [ ]  | Animals will be anesthetized or sedated when the agents are administered. *Complete Section 10 question 2 (in the protocol if this is a protocol) or Appendix F (if this is an amendment) then go to section 6.*  |

1. Where will the agent be administered?

|  |  |
| --- | --- |
| [ ]  | Animal housing room – Enter room number:       |
| [ ]  | Animal facility procedure room – Enter room number:       |

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| **Section 7: PI Assurance** |

**tress**

1. The principal investigator is responsible for ensuring that all personnel who may come in contact with the hazardous agents listed in the appendix are trained to work safely. By checking the boxes below, you confirm that you will fulfill the following responsibilities prior to initiation of this project by checking the box next to each statement.

|  |  |
| --- | --- |
| [ ]  | Before any animal procedures involving the agents listed in this appendix are performed, appropriate safety precautions and any applicable Standard Operating Procedures to protect all animal facility staff and non-study animals will be approved by the appropriate university safety committee and uploaded in supporting documents of the protocol. |
| [ ]  | Prior to beginning the project, all animal care staff and scientific staff that may be exposed to the agents listed in this appendix will be informed of possible risks and will be properly trained to follow the appropriate safety precautions and any applicable Standard Operating Procedures to minimize the risk of exposure and work safely with the agent(s).  |

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