Last updated 9/2/2015

### Institutional Animal Care and Use Committee

### Appendix G: Substance Administration



|  |
| --- |
| **Section 1: General Information** |

**Protocol Information**

|  |  |
| --- | --- |
| PI name:  |       |
| IACUC Protocol Number: |       |
| IACUC Protocol Title: |       |
| Facility name(s): |       |

**Directions:**

* Important:
* Please review [EHS Educational Information for IACUC Appendix G](https://www.ehss.vt.edu/detail_pages/document_details.php?s_document_title=Appendix+G+educational&document_id=614), [Chemicals in Animals](https://www.ehss.vt.edu/detail_pages/document_details.php?s_document_title=chemicals+in+animals&document_id=600) and current Safety Data Sheet (SDS) before completing Appendix G.
* EHS reviews this document with the primary concerns being the potential human exposure to hazardous material and appropriate disposal to protect the environment.
* 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 Environmental Health and Safety: Chemical Safety: 540-231-3427, Biological Safety: 540-231-3361, Radiation Safety: 540-231-5364.

|  |
| --- |
| **Section 2: Pharmaceutical Substances (not study related)**  |

**Complete this section if utilizing commercially available therapeutic agents per veterinary directive or manufactured label. If the substance is being used as part of the research please add to one of the following Sections 3-7.**

1. Please complete the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Agent (\*no acronyms)** | **Diluent** | **Dose (mg/kg)**  | **Volume (ml)** | **Route of Administration** | **Frequency and Duration of Administration** |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

1. Describe the PPE or appropriate precautions/disposal if applicable on manufacturer label (for each substance above:
2. Even though you are using a commercially available veterinary product, as the PI, you are still responsible for informing research staff and the animal care staff of hazards and all handling precautions associated with substances they work with or are potentially exposed to, before work begins. These hazards and handling precautions may be found on the manufacturers label, product insert, or SDS.

|  |
| --- |
| **Section 3: Non-Hazardous Substances**  |

**Complete this section if non-hazardous substances 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 (\*no acronyms)** | **Diluent** | **Dose (mg/kg)**  | **Volume (ml)** | **Route of Administration** | **Frequency and Duration of Administration** |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

|  |
| --- |
| **Section 4: Identification of Hazardous Agents**  |

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

|  |  |
| --- | --- |
| [ ]  | Chemical substances – chemicals, research 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/toxins](https://www.selectagents.gov/selectagentsandtoxinslist.html) 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.

|  |
| --- |
| **Section 5: Hazardous Chemical and Pharmaceutical Substances** |

**Complete this section if hazardous (See Section 2 of SDS) chemical and research therapeutic/pharmacologic agents will be administered to animals. Examples of agents that should be listed here includes but is not limited to chemicals, research 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 (\*no acronyms)** | **Hazard Classifications (\*Enter Hazard Code – see chart below)** | **Diluent** | **Dose (mg/kg)** | **Volume (ml)** | **Route of Administration** | **Frequency and Duration of Administration** |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |

**\*Hazard Codes** - Refer to Section 2 of each chemical’s Safety Data Sheet to select applicable Hazard Code(s)

|  |  |  |  |
| --- | --- | --- | --- |
| **Hazard Classification** | Hazard Code | **Hazard Classification** | Hazard Code |
| Health Hazard – Carcinogen | C | Health Hazard – Target Organ Toxicity (damage to organs) | TOT |
| Health Hazard – Reproductive Toxicity (damage to fertility or unborn child) | RT | Acute Toxicity – Fatal or Toxic (Oral, Dermal, or Inhalation) | T |
| Health Hazard – Germ Cell Mutagenicity (genetic effects) | M | Acute Toxicity – Respiratory Tract Irritant (Oral, Dermal, or Inhalation) | RI |
| Health Hazard – Respiratory Sensitizer | RS | Eye Damage | ED |
| Health Hazard – Aspiration Hazard | AH | Eye Irritation | EI |
| Skin Corrosion/Burns | SC | Flammable | F |
| Skin Irritation | SI |  |  |

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 –collection of waste may be required

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

[ ]  Acknowledgement

1. Describe the PPE required for animal care technicians and research staff performing standard animal care and husbandry procedures. Check all that apply. Research staff administering hazardous material must wear PPE as per lab hazard assessment.

Animal Care Staff

[ ]  Standard animal facility PPE

[ ]  Double gloves

[ ]  Double gown

[ ]  Safety glasses or goggles

[ ]  Respiratory Protection

[ ]  Surgical Mask for Splash Protection

[ ]  Other -

Research Staff

|  |  |
| --- | --- |
| [ ]  Standard animal facility PPE  | [ ]  Safety glasses or goggles |
| [ ]  Gloves | [ ]  Face shield |
| [ ]  Double gloves | [ ]  Respiratory Protection |
| [ ]  Gown | [ ]  Surgical Mask for Splash Protection |
| [ ]  Double gown | [ ]  Boots |
| [ ]  Coveralls | [ ]  Apron |
| [ ]  Other -       |  |

1. Describe any safety equipment required for procedures, handling and other manipulation of cages or animals:

[ ]  Standard animal transfer station

[ ]  Chemical fume hood

[ ]  Class II, Biosafety Cabinet

[ ]  Other -

1. Where will the agent be administered?

|  |  |
| --- | --- |
| [ ]  | Animal housing room |
| [ ]  | Lab/procedure room – Enter room number:       |
| [ ]  | Other -       |

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).* |

1. Procedures to be followed and emergency contacts in the event of a spill, or release of the agent are available in the location where animals are housed. PI is responsible for providing appropriate spill cleanup materials and procedures to all personnel involved.

 [ ]  Acknowledgement

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 or metabolite?

[ ]  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.

|  |
| --- |
| **Section 6: 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 (\*no acronyms, add R if recombinant)** | **Diluent** | **Source****(e.g., vendor)** | **Biosafety Level of Agent (BSL 1, 2, 3, or 4)** | **Dose (e.g., CFU, PFU)**  | **Volume (ml)** | **Route of Administration** | **Frequency of Administration** |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |

1. Describe all potential health risks for humans who may be exposed to the agents.

1. For the use of cell lines or tissues, have the materials been screened to make sure that they do 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://internal.research.vt.edu/system/files/policy_-_testing_biological_materials_used_in_rodents.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, stalls, and/or pens (if applicable) will have University Biohazard signage posted. Cage cards (if applicable) will be labeled with a “Biohazard” sticker and the name of the infectious agent:

[ ]  Acknowledgement

1. Describe the PPE required for animal care technicians and research staff performing standard animal care and husbandry procedures. Check all that apply. Research staff administering hazardous material must wear PPE as per lab hazard assessment.

Animal Care Staff

[ ]  Standard animal facility PPE

[ ]  Double gloves

[ ]  Double gown

[ ]  Safety glasses or goggles

[ ]  Respiratory Protection

[ ]  Surgical Mask for Splash Protection

[ ]  Other -

Research Staff

|  |  |
| --- | --- |
| [ ]  Standard animal facility PPE  | [ ]  Safety glasses or goggles |
| [ ]  Gloves | [ ]  Face shield |
| [ ]  Double gloves | [ ]  Respiratory Protection |
| [ ]  Gown | [ ]  Surgical Mask for Splash Protection |
| [ ]  Double gown | [ ]  Boots |
| [ ]  Coveralls | [ ]  Apron |
| [ ]  Other -       |  |

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

[ ]  Standard animal transfer station

[ ]  Class II, Biosafety Cabinet

[ ]  Chemical Fume Hood

[ ]  Other -

1. Where will the agent be administered?

|  |  |
| --- | --- |
| [ ]  | Animal housing room |
| [ ]  | Lab/procedure room – Enter room number:       |
| [ ]  | Other -       |

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).* |

1. Procedures to be followed and emergency contacts in the event of a spill, or release of the agent are available in the location where animals are housed. PI is responsible for providing appropriate spill cleanup materials and procedures to all personnel involved.

 [ ]  Acknowledgement

1. Provide any special requirements (e.g., specific disinfectant if standard animal facility disinfectant is not effective against the agent you are using) 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 sanitization. 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.

|  |
| --- |
| **Section 7: 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.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Radioactive Agent****(\*no acronyms, Include Isotope)** | **Diluent** | **Dose (mg/kg)**  | **Volume (ml)** | **Route of Administration** | **Activity (e.g., mCi/kg)** | **Frequency and Duration of Administration** |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |

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).*  |

1. Where will the agent be administered?

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

|  |
| --- |
| **Section 8: PI Assurance** |

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 hazardous 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).  |

|  |  |
| --- | --- |
|  |  |