Chemical Standard Operating Procedure for *in vivo* studies with chemotherapeutic drugs

This document is intended for the use of chemotherapeutic drugs administered to animals. All experiments performed must have an SOP outlining the steps and risks and mitigations of the experimental process. **This SOP should have an accompanying Chemical SOP for laboratory procedures and practices.** This SOP must be attached to the IACUC protocol and made available to Animal Care Services staff upon request.

The Investigator and Laboratory Staff are required to notify Animal Care Services **2 business days prior to the start** of any experiments involving toxic, hazardous, or potentially hazardous chemical in animals.

<table>
<thead>
<tr>
<th>Agent Name(s)</th>
<th>Chemotherapeutic/ antineoplastic agents (e.x. Doxorubicin, cyclophosphamide, Bleomycin, Taxol, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IACUC Number(s)</td>
<td></td>
</tr>
<tr>
<td>Investigator Name(s)</td>
<td></td>
</tr>
<tr>
<td>Procedure Author</td>
<td></td>
</tr>
<tr>
<td>Creation Date</td>
<td>Review Date(s)</td>
</tr>
<tr>
<td>Name of Responsible person</td>
<td></td>
</tr>
<tr>
<td>Location to be performed</td>
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</tr>
</tbody>
</table>

1. **THIS STANDARD OPERATING PROCEDURE (SOP) IS FOR ANIMAL WORK INVOLVING:**

   - ☒ Chemicals used in animals
     - Examples: Perusions, toxic or hazardous drugs, pesticides, reproductive toxins.
   - ☐ Investigational and/or Novel Compounds with limited, or no toxicity data available
     - Examples: Pharmacokinetic studies
   - ☐ Nanoparticles
     - Examples: Iron oxide nanoparticles, etc.

2. **RISK IDENTIFICATION: Identify potential safety hazards.**

   - ☒ Carcinogen
   - ☐ Sensitizer
   - ☐ Irritant
   - ☐ Acute Toxicity – Harmful
   - ☐ Acute Toxicity – Fatal Single Dose
   - ☒ Germ Cell Mutagen
   - ☒ Reproductive Toxicity
   - ☐ Target Organ Systemic Toxicity: Single Exposure
   - ☒ Target Organ Systemic Toxicity: Repeated Exposure
Other: pregnant women, lactating women or women who are attempting to conceive are advised not to handle Chemotherapeutics or contaminated cages.

Exposure Limit: Click or tap here to enter text.

Duration of Administration: Click or tap here to enter text.

3. **EH&S Training Requirements**
   
   List the general and laboratory-specific training required.

   - User Laboratory Training
   - Hazardous Waste Management Training
   - Other

4. **Procedures for Handling and Disposing Equipment and Animals Administered a Chemical Hazard**

   Outline the process for transporting toxic, or hazardous, chemicals/drugs to Animal Care Services (ACS) Rooms, include the packaging information. Highlight the steps with the highest hazards:

   - Containers and bottles must be labeled.
   - Transport chemicals in a non-breakable, hard sided container within a secondary container lined with absorbent material.
   - Container must be labeled with the PI’s name and contact information.
   - Every effort should be made to transport only the amount of chemical needed away from the lab. For example, syringes are prefilled in a certified chemical fume hood in the lab, and only the amount needed for the day’s injections will be transported to ACS spaces.

5. **Transportation of Animals Exposed to Chemicals**

   If applicable, outline the steps to transport animals administered chemicals to and from locations. Include the packaging and location information. Enter the information below the line.

   Transportation of animals should be limited between administration and the first cage change after the “clear date”. If they must be moved before the clear date has past and a cage change has occurred, they must be transported in their home cage, within a secondary container (e.g. sterilite bin) that contains small airholes, and placed on a cart.

6. **What Engineering Controls Will Be Used to Minimize Exposures to These Hazards in Animal Care Service Rooms?** See [Rodent Housing Procedures & Practices](#)

   - Biosafety Cabinet
   - Animal Transfer Station
   - Static caging
   - Negative pressure ventilated caging
   - Positive pressure ventilated caging
7. **WHAT PERSONAL PROTECTIVE EQUIPMENT IS REQUIRED DURING CAGE CHECKS AND HANDLING OF ANIMALS AFTER ADMINISTRATION?**  See [Rodent Housing Procedures & Practices](#).

Supplied by ACS: *select all that apply*

- ☒ Gown
- ☐ Boufant Cap
- ☒ Face shield
- ☐ Goggles (not supplied by ACS)
- ☒ Surgical mask
- ☐ Gloves
- ☒ Double gloves
- ☐ N-95 respirator (not supplied by ACS)
- ☐ Other: Click or tap here to enter text.

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8. **WHAT PERSONAL PROTECTIVE EQUIPMENT IS REQUIRED DURING CAGE CHANGES AND CAGE DUMPING AFTER ADMINISTRATION?**  See [Rodent Housing Procedures & Practices](#).

Supplied by ACS: *select all that apply*

- ☒ Gown
- ☐ Boufant Cap
- ☒ Face shield
- ☐ Goggles (not supplied by ACS)
- ☒ Surgical mask
- ☐ Gloves
- ☒ Double gloves
- ☒ N-95 respirator – for cage dumping (not supplied by ACS; see [Steps for Respirator Use](#))
- ☐ Other: Click or tap here to enter text.

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9. Are hazardous materials excreted by animals?

- ☒ Yes
- ☐ No
- ☐ Unknown

If yes, in:

- ☒ Urine
- ☒ Feces
- ☐ Other: Click or tap here to enter text.

Clear Date (if applicable): Examples of Drug specific clear dates include: Doxorubicin= 48 hours; Cyclophosphamide= 48 hours; Bleomycin= 72 hours; Taxol= 48 hours
10. If hazardous materials are excreted by animals, explain how animals and cages are handled
   - [ ] Contaminated cages changed by laboratory staff
   - [ ] Contaminated cages changed by ACS

11. If hazardous materials are excreted, how will the bedding and waste be labeled prior to disposal? See Rodent Housing Procedures & Practices
   - [ ] Not Applicable
   - [x] Chemical; Non-Regulated Waste for incineration
   - [ ] Chemical; Regulated Waste for disposal through EH&S Hazardous Waste
   - [ ] Nanoparticle; Non-Regulated Waste for incineration
   - [ ] Nanoparticle; Regulated Waste for disposal through EH&S Hazardous Waste
   - [ ] Other: Click or tap here to enter text.

12. How animal carcasses are be disposed of?
   - [x] Incineration
   - [ ] Other: Click or tap here to enter text.

**APPROVAL**

Standard Operating procedures must be approved by the Principle Investigator.

*PI (name, signature, date)*

Comments
Please complete the following section as part of the SOP preparation procedure.

The following completed label must be printed and used to identify cages and racks holding animals exposed to chemical agents. The procedures described in this SOP must be discussed with the facility manager prior to administration of chemicals to animals:

Label to be placed on rack holding the cages housing animals exposed to chemical agents

<table>
<thead>
<tr>
<th>***** Chemical Hazard in use *****</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: ______________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agent:</th>
<th>Disinfectant:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Chemical</td>
<td>☐ Virkon-S 1%</td>
</tr>
<tr>
<td>☐ Novel agent</td>
<td>☐ Bleach</td>
</tr>
<tr>
<td>☐ Nanoparticle</td>
<td>☐ Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of administration:</th>
<th>Housing:</th>
</tr>
</thead>
<tbody>
<tr>
<td>________________________</td>
<td>☑ positive ventilation</td>
</tr>
<tr>
<td>Clear Date (if applicable):</td>
<td>☐ static</td>
</tr>
<tr>
<td>________________________</td>
<td>☐ Negative ventilation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cage card #’s:</th>
<th>Carcass disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ Incineration</td>
</tr>
<tr>
<td></td>
<td>☐ Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Must handle in Biosafety Cabinet?</th>
<th>Additional information/Requirements: (e.g. safety sharps recommended, may return to ABSL-1 housing, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Yes</td>
<td>☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who will change cages?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Lab staff</td>
<td>☐ ACS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required PPE:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Yellow gown</td>
<td>☐ N-95 respirator</td>
</tr>
<tr>
<td>☐ Bouffant</td>
<td>☑ Surgical mask</td>
</tr>
<tr>
<td>☑ Face shield</td>
<td>☐ Gloves</td>
</tr>
<tr>
<td>☐ Goggles</td>
<td>☑ Double gloves</td>
</tr>
<tr>
<td>☐ Other:</td>
<td></td>
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</tbody>
</table>

Facility manager verified (initial):