Novel Compounds are any chemical entities that 1) have never been tested in animals; or 2) are in preliminary stages of animal testing. Due to their nature, novel compounds present a unique set of hazards for staff (laboratory and animal care). There is limited information on how these compounds will be excreted and if the bedding and waste present a hazard to staff. Information on the parent compound can help guide you in the appropriate safety measures to incorporate if available.

This document is intended for the administration of novel compounds to rodents. This SOP template provides general guidance on the minimum expectations for laboratories when working with novel compounds. It is the responsibility of the PI to provide training and guidance on the lab-specific requirements for their experiments. **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.

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| Agent Name (s) | Novel Compounds and Investigational Drugs with limited safety data available. |
| IACUC Number(s) |  |
| Investigator Name(s) |  |
| Procedure Author |  |
| Creation Date |  | Review Date(s) |  | Revision Date(s) |  |
| Name of Responsible person |  |
|  | **This standard operating procedure (SOP) is for animal work involving:** |
| [ ] Chemicals used in animals* Examples: Perfusions, toxic or hazardous drugs, pesticides, reproductive toxins.

[x] Investigational and/or Novel Compounds with limited, or no toxicity data available* Examples: Pharmacokinetic studies

[ ] Nanoparticles* Examples: Iron oxide nanoparticles, etc.
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|  | **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[x] Other: Unknown**Exposure Limit**: Unknown |
|  | **Parent Compounds/Closely Related Compounds**: (*please provide the name of any closely related compounds to help in the risk assessment process*) |
|  | **Mode of Action:** |
|  | **Source** (*please provide information on where you will obtain the novel compound. For example, will it be created in your laboratory, provided by a company, etc.)* |
|  | **EH&S Training Requirements**List the general and laboratory-specific training required. |
|  | [x] Laboratory Specific Training (provided lab manager or PI)[x] Hazardous Waste Management Training[ ] Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Procedures for Handling and Disposing Equipment and Animals Administered a Chemical Hazard** |

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|  | Outline the process for transporting toxic, or hazardous, chemicals/drugs to Animal Care Services (ACS) Rooms, include the packaging information. Add any additional, laboratory specific steps below.1. Containers and bottles must be labeled.
2. Transport chemicals in a non-breakable, hard sided container within a secondary container lined with absorbent material.
3. Container must be labeled with the PI’s name and contact information.
4. 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.
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|  | Transportation of Animals exposed to ChemicalsIf applicable, outline the steps to transport animals administered chemicals to and from locations. If animals are not being transported, delete the information below.Transportation of animals should be limited between administration and the first cage change after the “clear time”.  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.  |
|  | Are hazardous materials excreted by animals? [ ] Yes[ ] No[x] Unknown If yes, in:[ ] Urine[ ] Feces[ ] Other: Click or tap here to enter text.Clear Time (if applicable): Click or tap here to enter text. |
|  | **What Engineering Controls will be used to minimize exposures to these hazards in Animal Care Service Rooms?** [x] Biosafety Cabinet[ ] Animal Transfer Station[ ] Static caging[ ] Negative pressure ventilated caging[x] Positive pressure ventilated caging[x] Other: Chemical fume hood if administration is occurring in the laboratory |
|  | **What Personal Protective Equipment is required during handling of animals during and after administration? (Only complete if hazardous materials are being excreted by animals. If not being excreted, standard ACS specified PPE is required.)**Supplied by ACS: *select all that apply*[x] Gown[ ] Boufant Cap[x] Face shield/ Safety goggles/ Safety glasses[ ] Goggles (not supplied by ACS)[x] Surgical mask[x] Gloves[ ] Double gloves[ ] N-95 respirator (not supplied by ACS)[ ] Other: Click or tap here to enter text. |
|  | If hazardous materials are excreted, how will the bedding and waste be labeled prior to disposal?[ ] 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. |
|  | How animal carcasses are be disposed of? [x] Incineration[ ] Other: Click or tap here to enter text. |
|  | **Spill Cleanup (Small Spills)** (*Check all that apply*)[x] Plastic backed absorbent pad will be used to line the work surface during administration. In the event of a spill, the chemical should have spilled onto the liner, which can then be folded-inwards containing any spilled material. [x] Follow with soap and water. *For spills that are NOT on the liner:*[ ] **Powders:** place paper towels (wet with water) over the spilled material to avoid aerosolization and to wipe up powder. Wipe down surfaces with soap and water.[ ] **Liquids:** Wipe down surfaces with soap and water. |

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| **Approval***Standard Operating procedures must be approved by the Principle Investigator*. |
| *PI (name, signature, date)* |
| Comments |  |