**Tamoxifen**

*Standard Operating Procedure* Rev Date: 1/12/2021

This standard operating procedure (SOP) outlines *required methods to be used by researchers during this outlined experiment or process. These practices and procedures are intended to provide a safe working environment, promote a culture of forward-thinking risk mitigation, and to promote compliance with federal, state, and local regulations.*

**APPLICABILITY**

This SOP is for processes, experiments, or manipulations that pose moderate risks and that call for protective steps beyond those dictated by accepted laboratory standards. They are intended to limit the potential for injury, equipment damage, or environmental impact. **Fill in all highlighted areas with appropriate information.**

 This SOP is not applicable to….

**RESPONSIBILITIES** (Add to list as appropriate)

PI/Supervisor:

* Implement the guidance outlined in this document within departmental/institute operations.
* Provide training to laboratory personnel regarding the specific hazards involved in working with Tamoxifen to include work area decontamination, and emergency procedures prior to conducting any work.
* Provide laboratory personnel with a copy of this SOP and a copy of the SDS provided by the manufacturer.
* Ensure that laboratory personnel have completed appropriate laboratory safety

training and/or refresher training as required.

* Ensure all personnel are trained on the proper use/operation of any equipment used during the experiment or process.
* Require the use of proper lab attire (lab coats, gloves and eye protection).

Researchers (Graduate Students/Postdocs/Research Staff)

* Implement and follow minimum working protection found in this document.
* Complete appropriate laboratory safety training.
* Wear appropriate personal protective equipment that includes but may not be limited to a lab coat, gloves and eye protection in the laboratory.
* Report all near misses, incidents, and unsafe acts or conditions to the principal investigator and [Environmental Health & Safety](https://utdirect.utexas.edu/apps/campus/safety/incident/nlogon/?_ga=2.230545435.683263765.1638826606-1985937015.1617305987).

Undergraduate Students

* Follow minimum working protection found in this document.
* Complete appropriate laboratory safety training.
* Wear appropriate personal protective equipment that includes but may not be limited to a lab coat, gloves and eye protection in the laboratory.

**PROCEDURE**

**Fill in all highlighted areas with appropriate information**

|  |
| --- |
| **INSERT TITLE OF EXPERIMENT OR PROCESS** |
| This is where you can type out a description of the experiment or process you will perform. Just give an overall view. You will be walking through the experiment or process step by step below.  |
| **Preparer:** Insert Name | **Location:** AAA 000.0 |
| **Authorized Personnel with Contact Information** |
| **Position** | **Name** | **Number/Email** |
| Principle Investigator/Supervisor | Insert Name | 555-5555 |
| Student/Technician/Operator | Insert Name | 555-5555 |
| Others to be notified (e.g., other workers in the same laboratory, or other members of the research group) | Insert Name | 555-5555 |
| **HAZARDS, CONTROLS, CONDITIONS, & REQUIREMENTS** |
| **Potential Hazards** |
|  |
| **Planned Chemicals Involved** | **Hazards** |
| Tamoxifen | Carcinogen, Reproductive toxicity, Aquatic Hazard |
| **Planned Equipment Involved** | **Hazards** |
| Insert equipment name | List relevant hazards for equipment. (Examples in attachment 1) |
| **Hazard Controls** |
| **Engineering** | **Work Practice** |
|  * Fume hood (chemical work)
* Biosafety cabinet (animal work)
* Enclosed scale
* Bench paper, pads, plastic-backed paper
* Appropriate waste containers
* Safe sharp devices
* Additional Engineering controls (e.g. glovebox, special ventilation, guards, temperature control etc.)
 | * Double glove
* Designated areas for work
* Procedures for requesting emergency assistance (including after-hours)
* Emergency phone numbers
* Locations of fire alarms, fire extinguishers, fire blankets, eye washes, showers, etc.
* Training on all experimental techniques and experiments
* Housekeeping
* Additional work practices (e.g. Preventive maintenance, mask, etc.)
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| **Required PPE** |
|  |
| **Experiment Operational Ranges and Conditions** |
| **Pressure:** | Insert info | **Temperature:** | Insert info | **Volume:** | Insert info |
| **Physical State:** | Insert info | **Odor:** | Insert info |
| **Flammability Range:** | Insert info | **Other:** | Insert info |
| **Volatility:** | Insert info |
| **Routes of Exposure:** | Insert info |
| **Special Handling & Storage Requirements** |
| Cleanup Procedures: All surfaces/containers exposed to Tamoxifen will be cleaned with 70% ethanol.Chemical Preparation:Preparation of Tamoxifen including reconstitution, weighing, and diluting must be done in a fume hood to minimize any aerosol risks. Once mixed into an aqueous solution, tamoxifen should then be transferred into a sealed bottle.This will prevent volatilization, spillage, and accidental contamination of the environment.Use the smallest practical quantities for the experiment being performed. Transport tamoxifen-containing solutions in secondary containment.Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: 2 - 8 °C Light sensitive. |
| **Spill & Incident Procedure**  |
| **If exposed:****General advice****List information here.****If inhaled****List information here.****In case of skin contact****List information here.****In case of eye contact****List information here.****If swallowed****List information here.****Spill Response****Spill – General Instructions:****List spill procedure response.****Minor Spills – Liquid:****List spill procedure response.****Minor Spills – Solid:****List spill procedure response.****Major Spills – Liquid and Solid****List spill procedure response.** |
| **Waste Handling & Disposal** |
| Most spent, unused, and expired chemicals/materials are considered hazardous wastes, they must be properly disposed of. **Do not dispose of chemical wastes by pouring them down a sink or drain, or discarding in the regular trash containers.** Cage Changing: 72 h after the final administration of Tamoxifen, cages will be changed under a Class II Biosafety Cabinet or cage changing station. When cages are changed, dirty bedding will be placed in biohazard bags, and [specify animal/species] move to clean cages and returned to their regular racks.All potentially contaminated bedding, carcasses, and other non-sharps materials will be disposed of as Regulated Medical Waste. All contaminated sharps waste must be placed in proper sharps container and disposed as Regulated Medical Waste. Any waste tamoxifen must be placed in a labeled and sealed waste container, for pick-up by EHS. **Contact EHS-HMM at** EHS-HazardousMaterials@austin.utexas.edu **or call (512) 471-3511** for waste supplies and for any questions regarding proper waste disposal. Also, refer to the EHS [Hazardous Waste](https://ehs.utexas.edu/environment-waste/waste-management) Web page for more information. |
|  |
| **Training Requirements**  |
| * Complete EHS online Laboratory Safety training available through UT Learn. (<https://ehs.utexas.edu/training/lab-training-requirements>).
* Review SOP with knowledgeable person.
* Complete training on operation of specialized equipment prior to use (e.g., ultracentrifuge, hydrogenation apparatus).
* Other EHS training requirements (e.g., Biosafety, Radiation Safety, Hazardous Waste Management) as appropriate.
 |
|  **PROCEDURE** |
| **Steps** | **Directions** |
| **Process/Use** | Before injecting Tamoxifen, you must be trained by xxxxx.  |
| 1 | Please list your actual procedural SOP here.  |
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| **NOTE** | Tamoxifen and its active metabolites are excreted in the feces, and to a much lesser extent in urine, for 3 days post injection. Therefore, precautions must be taken so that [specify animal/species] users are not unknowingly exposed to excreted Tamoxifen. Tamoxifen-injected animals will be placed in separate cage and segregated to a designated rack or a specific location on their regular rack. The cage will be labeled with a "Chemical Hazard -- Tamoxifen" cage card and the information regarding the dates of administration. [specify animal/species] will be placed in a clean cage immediate after injection, so cage changing can be minimized during the period in which the drug and its metabolites are excreted. 72 h after the final administration of Tamoxifen, cages will be changed under a Class II Biosafety Cabinet or cage changing station. When cages are changed, dirty bedding will be placed in biohazard bags, and [specify animal/species] move to clean cages and returned to their regular racks. |
| **Use in Animals** | Work should be conducted in appropriate facility in a BSC or cage changing station and all animal carcasses are picked up and disposal is handled through EHS. Tamoxifen is administered to [specify animal/species] in via xxx. Before injecting Tamoxifen, you must be trained by xxxxx.  |
| 1 | Insert procedural steps for experiment or process. Add to table as needed. |
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| **NOTE** | Tamoxifen and its active metabolites are excreted in the feces, and to a much lesser extent in urine, for 3 days post injection. Therefore, precautions must be taken so that [specify animal/species] users are not unknowingly exposed to excreted Tamoxifen. Tamoxifen-injected animals will be placed in separate cage and segregated to a designated rack or a specific location on their regular rack. The cage will be labeled with a "Chemical Hazard -- Tamoxifen" cage card and the information regarding the dates of administration. [specify animal/species] will be placed in a clean cage immediate after injection, so cage changing can be minimized during the period in which the drug and its metabolites are excreted.  |
| **VERIFICATION & REVIEW** |
| **Current Date**  | **Date of SOP Expiration** |
| 00/00/0000 | 00/00/0000 |
| **PI Name** | **PI Signature** |
| Insert Name |  |
| **Safety Reviewer Name** | **Safety Reviewer Signature** |
| Insert Name |  |
| **LIST OF REFERENCES** |
| Include Safety Data Sheets, Globally Harmonized System, any outside personnel consulted in preparation of document, peer reviewers, etc. |

# SOP Training Certification

I have read and understand the above SOP. I have taken all appropriate EHS training. I have received prior approval from my supervisor to perform this procedure. I agree to contact my supervisor if I plan to modify this procedure.

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| Principal Investigator | Revision Date |

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| **PROCEDURE MODIFICATIONS/REVISIONS** |
| **Current Date** | **Modifications or Revisions** | **Name** |
| 00/00/0000 | Insert summary of changes made | Insert name of person making and/or approving changes |
| 12/9/2021 | Original document | Suzanne Kilpatrick |
| 12/9/2021 | Updates to responsibility, waste, training requirements sections and addition of SOP training certification section.  | Rudy Guerrero, Andrea McNair (Reviewers: Suzanne Kilpatrick) |
| 1/12/2021 | Updated for Tamoxifen use. | Rudy Guerrero (Reviewer: Chris Singh and Eric Wilson) |
| 2/1/2024 | Reviewed and Updated | Josh Hart  |
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