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| ISU |  |

1. STANDARD OPERATING PROCEDURE

Use this form to document the Health & Safety information associated with the procedure.

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| **Procedure Title:** | Tamoxifen Injection |
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| **Dept:** |  |  | **Bldg/Rm:** |  |  | **Supervisor:** |  |

**Circumstances of Use:**

Tamoxifn is widely used for the treatment of hormone-dependent breast cancer in postmenopausal women. Tamoxifen is also approved by the FDA for the prevention of breast cancer in women who have a high risk for this disease. However, Tamoxifen is associated with an increased risk of endometrial carcinoma, and an increase of rare forms of uterine cancer, in women taking Tamoxifen for the treatment or prevention of breast cancer. The International Agency for Research on Cancer (IARC) lists Tamoxifen as a Group 1 carcinogen, carcinogenic to humans. Research also indicates that Tamoxifen may cause reproductive disorders.

**Health and safety information for materials used:** (briefly describe the hazards associated with the materials and/or equipment **OR** document your hazard assessment in Section II)

* **Acute effects:** Eye, skin, and respiratory tract irritation.
* **Chronic effects:** Carcinogen, teratogen. May affect the reproductive system.

**Hazard Control Measures:**

(Lab coat, eye and hand protection, and closed toe/heel shoes must be selected as required by Section D of the ISU Laboratory Safety Manual.)

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| **[ ]**  | **Latex gloves** | **[ ]**  | **Insulated gloves** | **[ ]**  | **Face Shield** | **[ ]**  | **Respirator** |
| **[x]**  | **Nitrile gloves** | **[x]**  | **Safety glasses** | **[x]**  | **Lab Coat** | **[x]**  | **Fume hood** |
| **[ ]**  | **Neoprene gloves** | **[ ]**  | **Vented goggles** | **[ ]**  | **Apron** | **[ ]**  | **Biosafety cabinet** |
| **[ ]**  | **Vinyl gloves** | **[ ]**  | **Splash goggles** | **[ ]**  | **Dust mask** | **[ ]**  | **Glove box** |
| **[x]**  | **Closed Toe/Closed Heel Shoes** | **[ ]**  | **Flame Resistant Lab coat** |

## Experimental Procedures (EXAMPLE):

* Once a month, dose 16 research animals with Tamoxifen. Weigh enough Tamoxifen to dose each animal into 16 separate screw-caped tubes (25 – 100 mg/kg body weight). For a 200 mg animal, therefore, Tamoxifen weights in the tubes would range from 10 to 40 mg.
* At animal facilities, add 1 ml of citrate saline to the Tamoxifen sample, weigh the animal and inject the appropriate amount of solution into the animal (0.5 ml/200 mg body weight)
* Dispose the empty, uncapped needle and syringe directly into a yellow chemotherapeutics sharps container.
* **COLLECT ALL RESIDUAL LIQUID FOR DISPOSAL AS HAZARDOUS CHEMICAL WASTE. DISPOSE THE EMPTY TUBES AND RESIDUAL MATERIAL IN YELLOW BAGS AS CHEMOTHERAPEUTIC WASTE.**
* Handle all Tamoxifen solutions over plastic backed absorbent sheets and dispose sheets in yellow chemotherapeutic waste bags when work is completed.

## Control Plan:

**General Controls:**

* Any work with Tamoxifen needs to be performed over disposable absorbent bench top spill pads.
* Any laboratory equipment or surfaces that have come into contact with Tamoxifen will be decontaminated or disposed of. This can be completed by wiping them down with soap, water and paper towels (see Waste and Recycling Guidelines for instructions on towel disposal).

<http://www.ehs.iastate.edu/sites/default/files/uploads/publications/manuals/warg.pdf>

* Non-porous materials, such as glassware, will be decontaminated by soaking in bleach for 24 hours.

**Engineering Controls:**

* To prevent inhalation, solid/crystalline forms of Tamoxifen will be handled and weighed out in a chemical fume hood or similar exhausted enclosure. (If air currents making handling difficult, a safety shield may be positioned in front of the balance to divert air around the equipment.)
* **Note:** If you do not have a fume hood, you must wear an N-95 respirator and participate in the University’s Respiratory Protection Program. <http://www.ehs.iastate.edu/occupational/respirators>
* To reduce the chance of accidental injection, syringes and IV sets with Luer-LokTM fittings will be used for preparing and administering hazardous drugs.

**Required PPE:**

* To prevent skin exposure, appropriate personal protective equipment (PPE) will be worn when handling any amount of Tamoxifen. Wear a lab coat, disposable gown, or coveralls. Ensure that all exposed skin is covered. Shorts and sandals are not allowed in the lab!
* Use two pairs of powder-free, disposable chemotherapy gloves, with the outer one covering the gown cuff whenever there is risk of exposure to hazardous drugs.
* Wear ANSI Z-87 approved safety glasses.
* Wear goggles and a face shield when splashes to the eyes, nose, or mouth may occur

**Control Procedures for animal care:**

* PI or Supervisor will be informed of the intent to use Tamoxifen two weeks prior to use
* Cages of animals injected with Tamoxifen will be clearly labeled as such
* All bedding changed during chemical administration and for 72 hours beyond final administration must be collected in yellow bags for disposal

Follow PPE and handling requirements specified in the Standard Animal Husbandry

**Waste Disposal Procedures:**

* **Excess Tamoxifen solids and solutions**: Dispose as hazardous chemical waste, following procedures detailed in the University’s Waste and Recycling Guidelines.

<http://www.ehs.iastate.edu/sites/default/files/uploads/publications/manuals/warg.pdf>

* **Disposable lab supplies** (e.g., gowns, gloves, bench top pads, etc.,): Collect in yellow bags for incineration.
* **Needles and sharps**: Must be disposed of in separate sharps container that is labeled “Tamoxifen Sharps”, sealed and placed in a yellow bag for incineration.
* **Spill cleanup materials**: Place in leak proof container and box for disposal as hazardous waste following procedures detailed in the University’s Waste and Recycling Guidelines.

Contact EH&S Environmental Programs at 4-5359 to arrange for additional guidance on disposal.

**Accidental Exposures:**

* Wash exposed skin with soap & water, flush eyes for 15 min.
* Call **911** or seek medical attention.
* **All accidents and injuries occurring at work or in the course of employment must be reported to the employee's supervisor as soon as possible (even if no medical attention is required).**

<http://www.ehs.iastate.edu/occupational/accidents-injuries>

**Spill/Release Containment, Decontamination, and Clean Up Procedures:**

* **Solid:** If source container drops and breaks (1-100 grams maximum), avoid raising dust – do not sweep up dry material. Evacuate spill area, restrict others from entering the area and from a safe spot, call EH&S (4-5359) or 911 (after hours).

If a small amount (<250 mg) spills outside of spill containment, ensure PPE is appropriate (an N-95 respirator if outside of the hood, double-nitrile gloves, goggles, and a lab coat), cover material with paper towels, spray lightly with bleach water solution (10% bleach) and carefully scoop material and paper towels into container for appropriate disposal (see Waste and Recycling Guidelines) For other amounts, use prudent judgment to decide whether to attempt cleanup, or call for spill response.

* **Solution:** IfTamoxifen solution should spill, prevent liquid from entering drains. Apply absorbent pads or absorbent material from the spill kit for larger amounts of liquid and, using appropriate PPE (double-nitrile gloves, goggles, and a lab coat), carefully scoop wetted absorbent material into container for appropriate disposal (see Waste and Recycling Guidelines).

Contact EH&S Environmental Programs at 4-5359 to arrange for additional guidance on disposal.

**Using Substances Requiring Special Procedures?** No [ ]  Yes [x]

(If Yes; identify authorized personnel, designate a use area and specify specialized safety precautions here. Refer to Section B in the ISU Laboratory Safety Manual for details.)

Use of Tamoxifen requires site specific training and the approval from the professor in charge.

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| **Written By:** |  |  | **Date:** |  |
|  |  |  |  |  |
| **Approved By:** |  |  | **Date:** |  |

 (PI or Lab Supervisor)

1. **HAZARD ASSESSMENT**

Use the hierarchy of controls to document the hazards and the

corresponding control measure(s) involved in each step of the procedure.

Consider *elimination or substitution* of hazards, if possible.

*Engineering Control(s):* items used to isolate the hazard from the user (i.e. fume hood, biosafety cabinet).

*Administrative Control(s):* policies/programs to limit the exposure to the hazard (i.e. authorizations, designated areas, time restrictions, training).

*Required PPE*: indicate PPE including specific material requirements if applicable (i.e. flame resistant lab coat, type of respirator or cartridge).

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| **Hazard** | **Engineering Control(s)** | **Administrative Control(s)** | **Required PPE**  |
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1. **Training Record**

Use the following table to record the training associated with this Standard Operating Procedure.

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| **Print Name** | **Signature** | **Date** |
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**Note: Attach to or file with written materials and methods**