

---

## 1. PURPOSE

---

This document describes the guidelines for the use of Tamoxifen animal research.

## 2. SCOPE

---

This guideline applies to all research personnel or others at Western University and affiliated institutions, who are working with, or could potentially be exposed to Tamoxifen.

## 3. INTRODUCTION

---

Tamoxifen is a selective estrogen receptor modulator (SERM) used in the treatment of breast cancer. In animal research, Tamoxifen is administered to trigger tissue specific gene expression in genetically modified animals. The International Agency for Research on Cancer (IARC) lists Tamoxifen as a known human carcinogen. In addition, Tamoxifen can lead to the formation of DNA adducts and possible teratogenicity, genotoxicity and reproductive toxicity (See 6.3). Routes of exposure include inhalation, ingestion, accidental injection and dermal absorption (See 6.1). Tamoxifen is excreted in the feces and urine of animals after administration, consequently, these instructions **MUST** be followed when handling animals and bedding for **seven (7) days** after the final administration (See 6.4).

## 4. EXPOSURE CONTROLS

---

- 4.1. Use of Tamoxifen **MUST** be described in the Animal Use Subcommittee (AUS) approved Animal Use Protocol (AUP).
- 4.2. Laboratory workers **MUST** receive specific training regarding the proper handling of Tamoxifen, documented in their laboratory safety manual.
- 4.3. Pregnant or breastfeeding women, or either gender trying to conceive should consult institutional specific Occupational Health (See 5.6.2) prior to handling Tamoxifen or animals that have been administered Tamoxifen.
- 4.4. Any handling of Tamoxifen, including weighing, solution preparation, and drawing doses **MUST** be done in certified Chemical Fume Hood. Minimum Personal Protective Equipment (PPE) that **MUST** be worn when handling Tamoxifen:
  - 4.4.1. Double Nitrile Rubber (0.11mm) Gloves
    - 4.4.1.1. Gloves **MUST** be long enough so that there is no skin exposed between the glove and sleeve
  - 4.4.2. Canadian Standards Association (CSA) Approved Safety Glasses
  - 4.4.3. Lab Coat, Tyvek™ or Back-Closure Gown
- 4.5. Minimum PPE that **MUST** be worn when handling animals and bedding of animals that have been administered Tamoxifen:
  - 4.5.1. Double Nitrile Rubber (0.11mm) Gloves
    - 4.5.1.1. Gloves **MUST** be long enough so that there is no skin exposed between the glove and sleeve
  - 4.5.2. CSA Approved Safety Glasses
  - 4.5.3. Lab Coat, Tyvek™ or Back-Closure Gown
  - 4.5.4. Individually Fit-tested NIOSH-Approved N-95 Respirator
- 4.6. All administrations, cage manipulations, and handling of animals that have been administered Tamoxifen **MUST** be performed in a certified Biological Safety Cabinet (BSC) for **seven (7) days** after the final administration.

## 5. PROCEDURES

---

- 5.1. All procedures **MUST** be completed while wearing the appropriate PPE stated above.
- 5.2. Conducting animal work in a BSC:

- 5.2.1. A layer of towels moistened with appropriate disinfectant (See 5.3) **MUST** be placed on the work surface of the BSC prior to opening cages and handling animals that have been exposed to Tamoxifen.
- 5.2.2. The BSC **MUST** be wiped down with paper towel moistened with disinfectant (See 5.3) at the end of each use. After wiping with disinfectant, BSC **MUST** be wiped with alcohol to prevent corrosion of BSC.
- 5.3. Areas where Tamoxifen is prepared and/or administered **MUST** be cleaned and decontaminated immediately following each procedure. Spills or surfaces potentially contaminated with Tamoxifen should be routinely cleaned with the appropriate solution:
  - 5.3.1. Clidox - 1:5:1 Solution (base : water : activator) - Fume Hood or BSC
  - 5.3.2. Bleach Solution (1:10 Dilution) - Floor & Cage Dunking
- 5.4. Animal husbandry:
  - 5.4.1. Cages of animals treated with Tamoxifen **MUST** be clearly labeled with Hazardous Chemical Cage Card including:
    - 5.4.1.1. "Tamoxifen"
    - 5.4.1.2. Date of Tamoxifen administration
    - 5.4.1.3. Contact Name and Numbers (Both Laboratory & After Hours)
  - 5.4.2. Animal cages should not be changed for a minimum of **seven (7) days** after the final Tamoxifen administration.
  - 5.4.3. On the first cage change following Tamoxifen administration, the cage bedding is considered contaminated and **MUST** be changed in the following manner:
    - 5.4.3.1. Within the BSC, empty & scrape out the dirty bedding from **one cage at a time** from up to 14 cages into a garbage bag or labeled hazardous waste bag and placed in container for disposal according to institutional specific hazardous waste program (See 5.5)
    - 5.4.3.2. When finished dumping & scraping up to 14 cages seal the bag and wipe the outside of bag with the appropriate disinfectant (see 5.3).
    - 5.4.3.3. Dirty Water – dispose of directly down the sink drain. It does NOT need to be treated.
    - 5.4.3.4. Once removed from the BSC the cages, bottles, sipper tubes and other housing supplies are to be dunked in an appropriate disinfectant (see 5.3) and placed on the cart for transport to cage wash area.
    - 5.4.3.5. After this first cage change, new cages can be handled using universal laboratory precautions & PPE.
- 5.5. Laboratory Waste & Carcass Disposal:
  - 5.5.1. Items contaminated or potentially contaminated with Tamoxifen and infected carcasses **MUST** be double bagged, labeled as Hazardous Waste and placed in specified containers for removal by institutional specific hazardous waste management program. [Western's Hazardous Material Management Handbook](#), [LHSC Waste Management Program](#), [St. Joseph's Waste Management Program](#)
- 5.6. Emergency Procedures:
  - 5.6.1. In the case of an exposure to eyes or skin, flush the area for 15 to 20 minutes with running water.
  - 5.6.2. During Business Hours bring the MSDS (See 6.1) to Institutional specific Occupational Health:
    - 5.6.2.1. UWO Workplace Health UCC25 Ext. 82047
    - 5.6.2.2. Hospital Occupational Health & Safety Services; VH-Ext. 52286, UH-Ext 33201, or SJHC Ext. 64332
  - 5.6.3. After Business Hours bring the MSDS (See 6.1) to the nearest Hospital Emergency Department
  - 5.6.4. Inform supervisor, who shall complete an Accident/Incident Reporting & Investigation Form [Western's form](#), [LHSC's AEMs reports](#) (Intranet only), St. Joseph's Form (See OHSS Office for the form)

## 6. RESOURCES & RELATED DOCUMENTS

---

- 6.1. For current MSDS, search Product # T5648 on Sigma-Aldrich Website [Hyperlink](#)
- 6.2. ACVS Chemical SOP SAF-003 [Hyperlink](#)
- 6.3. Han, X. and Liehr, J.G. (1992) Induction of Covalent DNA Adducts in Rodents by Tamoxifen. *Cancer Research* (52) 1360-63.
- 6.4. Fromson, J.M. et al. (1973) The Metabolism of Tamoxifen Part I: In Laboratory Animals. *Xenobiotica* (11) 693-709.