PURPOSE & Description

The purpose of this SOP is to delineate the minimum standards for the use of tamoxifen when administered to rodents by injection. Tamoxifen is a synthetic estrogen receptor modulator which is commonly used to treat breast cancer in women. In animal research, tamoxifen is used to trigger tissue-specific gene expression in genetically modified animals. Tamoxifen is a known human carcinogen, teratogen, and mutagen; it must be handled carefully. It causes eye and skin irritation; may cause respiratory and digestive tract irritation if swallowed causing reproductive and fetal effect.

Scope

This SOP applies to the Principal Investigator (PI) and their laboratory staff.

Responsibilities

PIs are responsible for training of their laboratory staff and continued participation in following safety guidelines.

PI and laboratory staff are responsible for following the [Policy on Handling Animals Exposed to Hazardous Chemicals](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Hazardous-Chemicals.pdf).

Definitions

* **Clear time** – The period of time required to allow for excretion of a hazardous chemical before standard handling practices can be used.
* **Safety-engineered sharps** –a non-needle sharp or needle device with a built-in safety feature or mechanisms that effectively reduces the risk of an exposure incident. More information on safety engineered sharps can be found here: [[UF EHS Safety-Engineered Sharps Fact Sheet](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D)](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D).

Hazard Identification & Control Measures

**Potential Hazards**

* **Physical Hazards**
  + Needlestick
* **Chemical Hazards**
  + Carcinogenicity (Category 1A), H350
  + Reproductive toxicity (Category 1B), H360
  + Short-term (acute) aquatic hazard (Category 1), H400
  + Long-term (chronic) aquatic hazard (Category 1), H410

**Engineering Controls / Administrative Controls**

* Use of an Animal Transfer Station (ATS) or higher engineering control such as a Biosafety Cabinet (BSC) or Chemical Fume Hood (CFH) is required for agent administration.
* Syringes used for injection should comply with the details outlined in [UF EHS Safety-Engineered Sharps Fact Sheet](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D).
* Rodents should be appropriately restrained prior to administration, as described in the approved Animal Use Protocol (AUP).
* Gloves should be changed frequently, at a minimum when contaminated with tamoxifen or torn, and before handling animals in other experimental groups.
* Hands and arms should be washed with soap and water upon completion of procedure.

**Personal Protective Equipment (PPE)**

* Appropriate lab attire including skin protection, closed shoes, and eye protection.
* Long-sleeve gown or long-sleeve dedicated lab coat
* Gloves
  + Single gloves if using chemo-rated nitrile gloves (ASTM D6978 standard).
  + Double gloves if not using chemo-rated nitrile gloves (ASTM D6978 standard).

Procedure

* Prior to working with chemical hazards in rodents, all work must be described in an approved AUP.
* Contact the ACS facility manager where the rodents are housed at least 48 hours prior to use of the chemical hazard.

Special Handling and Storage Requirements

* The tamoxifen clear time is 72 hours after the last administration. Tamoxifen is excreted in the feces and urine of animals after administration, consequently, the procedures inthis SOP must be followed when handling animals and bedding for 72 hours after the final tamoxifen administration.
* Women who are pregnant, expecting to become pregnant, or nursing should not handle or be exposed to tamoxifen or feces/urine of animals treated with tamoxifen prior to the clear time.
* Tamoxifen storage and transport containers should be shatter-resistant, rigid, shock-resistant, leak-proof, and made of a non-reactive material which can be easily cleaned and decontaminated in the event of a leak.
* Personal protective equipment as described above must be worn when handling tamoxifen, in addition to any PPE requirements of the animal room. Hands and arms should be washed with soap and water after removing PPE.
* Needles and sharps used with tamoxifen must be disposed of immediately in a sharps container. Do not reuse, bend, or recap needles. Safety-engineered sharps should be used whenever possible. More information on safety engineered sharps can be found here: [[UF EHS Safety-Engineered Sharps Fact Sheet](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D)](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D).
* An approved solution must be used for decontamination of equipment and areas exposed to tamoxifen (e.g. Peroxigard).

Waste Disposal Procedures

* Contaminated and/or potentially contaminated laboratory PPE and laboratory consumables are disposed of as Non-Regulated Hazardous Waste.
* Contaminated and/or potentially contaminated bedding and PPE originating within the animal facility are disposed of as Non-Regulated Waste for Incineration according to the [Policy on Handling Animals Exposed to Hazardous Chemicals](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Hazardous-Chemicals.pdf).
* Rodents euthanized or found dead prior to the clear time are identified, labeled, and disposed of according to the [Policy on Handling Animals Exposed to Hazardous Chemicals](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Hazardous-Chemicals.pdf).

Emergency Response (Spill & Accident Procedures)

**Spills**

* If a small spill occurs, clean up with an approved solution (e.g. Peroxigard). Collect spilled material and clean up material into appropriately labeled, nonmetallic waste container.
* For large spills, call EH&S Chemical and Radioactive Waste Disposal group at 352-392-8400 for clean-up assistance.
* See [UF EHS Spill Response](https://www.ehs.ufl.edu/departments/research-safety-services/hazardous-waste-management/spill-response/#:~:text=Call%20EH&S%20Chemical%20and%20Radioactive%20Waste) for additional information.

**Needlesticks**

* Allow to bleed freely. If necessary, control bleeding by applying direct pressure with a sterile gauze or bandage.
* Immediately wash with copious quantities of soap and water.
  + If eyes or mucous membranes are exposed, irrigate the area for at least 15 minutes with water.
* Seek medical treatment.
* Report the incident to the PI/supervisor and Environmental Health and Safety (352) 392-1591 and submit an online Injury /Incident Report (<https://apps.ehs.ufl.edu/incidents/>).

**If an emergency occurs outside of normal work hours, contact the University Police Department at 352-392-1111 or call 911.**

**Emergency Contact Numbers:**

* Principal Investigator: xxx-xxx-xxxx
* Lab Manager: xxx-xxx-xxxx
* Poison Control Center: 800-222-1222
* Emergency: 911
* EH&S: 352-392-1591

**Physical Address on Campus:**

[Add your lab’s address here.]

References

* [Policy on Handling Animals Exposed to Hazardous Chemicals](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Hazardous-Chemicals.pdf)
* [[UF EHS Safety-Engineered Sharps Fact Sheet](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D)](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D)
* [UF EHS Spill Response](https://www.ehs.ufl.edu/departments/research-safety-services/hazardous-waste-management/spill-response/#:~:text=Call%20EH&S%20Chemical%20and%20Radioactive%20Waste)

Documents and attachments

List applicable forms and attachments here.