

Policies and Procedures

SECTION: ARF	NUMBER: 7.17			
CHAPTER: Miscellaneous Experimental Animal Use Policies	ISSUED: 7/2007	REV. A: 5/12/09	REV. B: 11/2012	REV. C:
POLICY: Carcinogens: Faslodex (fulvestrant), Tamoxifen, Estrogens (Steroidal)	REV. D:	REV. E:	PAGE 1 OF 3	

Purpose

This policy is intended to provide information on appropriate procedures for the use of Carcinogens: Faslodex (fulvestrant), Tamoxifen, Estrogens (Steroidal) and to establish procedures to be followed for laboratory animal care and use. This policy is approved by the Creighton University Institutional Animal Care and Use Committee (IACUC). All investigators will follow this policy unless scientific justification is provided and approved by the IACUC.

Definition

Carcinogens are defined as any substance, radionuclide or radiation that is an agent directly involved in the promotion of cancer or increases in its propagation.

Application

Before work with carcinogens in animals may begin the IACUC requires that the Principal Investigator (PI) fulfill the following requirements:

- The animal protocol incorporating the carcinogen must be approved by the IACUC.
- Work with infectious agents, chemical hazards, and recombinant DNA must be approved by the Institutional Biosafety Committee.
- Work with radioactive materials or radiation producing equipment must be approved by the Institutional Radiation Safety Committee.
- The PI must alert the Animal Resource Facility (ARF) supervisor approximately two weeks before work with carcinogens is scheduled to begin.

Faslodex (fulvestrant), Tamoxifen, Estrogens (Steroidal)

Research staff will inform animal care staff ahead of time that Faslodex, Tamosifen, Estrogens will be used, and arrangements will be made for housing of animals. Fresh cages will be used for the animals at the time of administration.

Precautions

- Animal bedding is not to be changed for at least 3 days after the date of administration.

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- The following Personal Protective Equipment (PPE) will be worn in the laboratory during preparation: particulate mask, disposable gown and a 2nd pair of gloves (chemical resistant).
- All individuals working with or around Faslodex, Tamoxifen, or Estrogens should be informed of the dangers of exposure to these compounds. Foslodex, Tamoxifen, and Estrogens are carcinogens (cancer-causing agents). They MUST NOT be handled by women who are or may become pregnant, due to effects that carcinogens may have on the fetus.

Posting Requirements

- The Special Animal Safety Protocol (SASP) Form will be posted on the door of the room in which the animals will be housed (Attachment 1).
- Cages will be labeled with a red card denoting "*Carcinogen Name- Do Not Change*" and a purple "Veterinarian Alert- Rodent Post-Procedure Monitoring" card, indicating the carcinogen, dose and date of administration.

Administration of Carcinogen

- The powder form of Faslodex, Tamoxifen, or Estrogen is extremely hazardous and should be handled in a fume hood in the Investigator's laboratory.
- Carcinogens will be administered by injection only in a fume hood or biosafety cabinet. After injections have been completed, the hood must be thoroughly cleaned by the user.
- In addition to the standard ARF PPE requirements, individuals administering the carcinogen will wear a second, chemical resistant, pair of gloves.

Cage Change

The first cage change after each drug administration is to be done no sooner than 3 days after the last administration of the drug. The bedding is presumed hazardous for the first seven days after the end of treatment. During this time the bedding changes will be performed by the Principal Investigator or an IACUC approved designee only. The bedding requires special handling in a class II type A2 biosafety cabinet.

- All cage changes and bedding collection will be done in a biosafety cabinet;
- Place an empty biohazard bag in the biosafety cabinet;
- Transfer the animals to clean cages;

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- Placed contaminated bedding into the red biohazard bag. When change-outs are complete, tie bag closed prior to removal from biosafety cabinet;
- Label with wide tape or other type of label marked with the carcinogens name;
- Place in the biohazard container within the animal room. The ARF staff will transfer to the designated storage area;
- Remove the red cage cards. Remove the sign from the door of the animals housing room once the carcinogen is no longer in use; and
- All animal carcasses will be disposed of in a clearly labeled biohazard bag in the biohazard-labeled freezer located in the ARF.