

**Special Animal Safety Protocol (SASP) Form**  
**Faslodex (fulvestrant)**



**POTENTIAL REPRODUCTIVE TOXIN**  
**POTENTIAL HUMAN CARCINOGEN**

<b>Investigator's Responsibility-Notification of Animal Care:</b>	Research staff will inform animal care staff ahead of time that <b>Faslodex (fulvestrant)</b> 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.
<b>All Responsible-Basic Precautions:</b>	<ul style="list-style-type: none"> <li>• Animal bedding is not to be changed for at least 3 days after the date of administration of <b>Faslodex (fulvestrant)</b>.</li> <li>• The following Personal Protective Equipment (PPE) will be worn in the laboratory during preparation: particulate mask, disposable gown and a 2<sup>nd</sup> pair of gloves (chemical resistant).</li> <li>• All individuals working with or around Faslodex (fulvestrant) should be informed of the dangers of exposure to this compound. Faslodex (fulvestrant) is a suspected carcinogen (cancer-causing agent). It <b>SHOULD NOT</b> be handled by women who are or may become pregnant, due to effects that Faslodex (fulvestrant) may have on the fetus.</li> </ul>
<b>Investigator's Responsibility-Posting Requirements:</b>	<ul style="list-style-type: none"> <li>• This SASP will be posted on the door of the room in which the animals will be housed.</li> <li>• Cages will be labeled with a red card denoting "<b>Faslodex (fulvestrant) – Do Not Change</b>" and a purple "Veterinarian Alert – Rodent Post-Procedure Monitoring" card, indicating the suspected carcinogen, dose, and date of administration.</li> </ul>
<b>Investigator's Responsibility-Administration:</b>	<ul style="list-style-type: none"> <li>• The powdered form of Faslodex (fulvestrant) is extremely hazardous and should be handled in a fume hood in the investigator's laboratory.</li> <li>• Faslodex (fulvestrant) will be administered by injection only in a fume hood or biosafety cabinet. After injections have been completed, the hood should be thoroughly cleaned by the user.</li> <li>• In addition to the standard Animal Resource Facility (ARF) PPE requirements, individuals administering the suspected carcinogen will wear a second, chemical resistant, pair of gloves.</li> </ul>
<b>Investigator's Responsibility-Cage Change:</b>	<p>The <b>first cage change</b> after each drug administration is to be done <b>no sooner than 3 days after the last administration of the drug</b>. 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 PI or an IACUC approved designee only. The bedding requires special handling in a class II type A2 biosafety cabinet.</p> <ul style="list-style-type: none"> <li>• All cage changes and bedding collection will be done in a biosafety cabinet.</li> <li>• Place an empty biohazard bag in the biosafety cabinet.</li> <li>• Transfer the animals to clean cages.</li> <li>• Placed contaminated bedding into the red biohazard bag. When change-outs are complete, tie bag closed prior to removal from biosafety cabinet.</li> <li>• Label with wide tape or other type of label marked "<b>Faslodex (fulvestrant)</b>."</li> <li>• Place in the biohazard container within the animal room. The ARF staff will transfer to the designated storage area.</li> <li>• Remove the red cage cards. Remove the sign from the door of the animal housing room once the suspected carcinogen is no longer in use.</li> <li>• All animal carcasses will be disposed of in a clearly labeled biohazard bag in the biohazard-labeled freezer located in ARF facility.</li> </ul>