Drug Shortage and Substitution during Research Studies

This document outlines how to address the issue of substituting another agent for a study drug due to a supply shortage during the course of a research study.

Investigator Action Steps:

1. Please submit an amendment requesting to substitute the study drug with another agent due to a supply shortage as soon as possible (*even if a formal sponsor amendment regarding the shortage/substitution is still pending*). Please include information regarding how the drug substitution will affect the study outcome (*statistical considerations, etc*). Please also note if the agent substituted for the study drug is considered standard of care or investigational, and any other relevant information.
    - If the study drug supply is expected to run out prior to the approval of the amendment, please submit a participant-specific deviation request regarding the proposed substitution including a plan for re-consenting the participant (see number 3 below).

2. Please submit a revised protocol with the amendment that provides information regarding the drug substitution (*including treatment instructions and information regarding how the drug substitution will affect the study outcome*).
    - If the protocol cannot be revised at this time, please provide a revised Alert Page with this information.

3. Please submit a revised consent form with the amendment that reflects any pertinent information related to the drug substitution (*including any updates to the risk section, etc.*).
    - Participants who are currently receiving the study treatment must be reconsented using the revised consent form.
    - If a revised consent form is not yet available (due to a formal sponsor amendment pending), please submit an information document (consent addendum) that includes language regarding the risks and any other pertinent information about the agent. This information document must also include a participant signature line and should be used along with the current consent until the revised version is available.

4. Please consider closing the study to accrual until the drug shortage issue has been resolved if there are potential implications for participant safety.