Nova Southeastern University
Standard Operating Procedure for GCP

Title: Return-To-Sponsor or Destruction of Investigational Product		Version # 1
SOP Number: OCR-AIP-004	**Effective Date: August 2013**	**Page 1 of 2**

Purpose: Investigational Products should not be maintained in inventory when their use is not anticipated. This procedure describes the methods to be used for return to the Sponsor or destruction of clinical study product used in clinical trials. This procedure is intended to meet Food and Drug Administration (FDA} federal regulations and Good Clinical Practice Guidelines (GCP) for the handling of clinical study supplies at the Investigator Site.

Policies:

1. When it no longer becomes necessary for the Center/College to keep an inventory of the Investigational Product, it shall be returned to the sponsor or destroyed. Examples of such times would include:
   1.1. The Study is completed or discontinued.
   1.2. The Investigational Product has expired.
   1.3. The Investigational Product is damaged, returned by a subject or otherwise unfit for use.
2. Returning the Investigational Product to the sponsor shall be the preferred method of clearing out the inventory as opposed to alternative methods of disposal.
3. In the event the Sponsor desires that the Investigational Product be disposed of by the Center/College as opposed to being returned, it shall be done according to the Sponsor's request provided it comply with all applicable federal, state, local laws and other relevant Center/College policies.

Procedure for the Return of Unused Investigational Product

1. After the study has been completed, a comprehensive inventory of the product / devices is completed before returning them to the Sponsor.

(ONLY at the instruction of the Sponsor should any study product / device be destroyed). Any discrepancies in the beginning and ending inventory are noted and explained. A copy of the post-study inventory and all study subject dispensing logs will be kept in the study files at the Center/College, and a copy is placed in the box of study product / device being returned to the Sponsor.

2. The manner of shipment of used or unused investigational product must be defined by the Sponsor and followed by site personnel. Returned investigational product must be packed and shipped with the documentation provided by Sponsor. The manner of shipment must have mechanism of being traced.

Procedure for Destruction of Used Investigational Drugs

1. All investigational products used and unused must be accounted for by the Study Monitor. Disposal of used or unused investigational products must be initiated only after the written instruction from the Sponsor/Study Monitor had been obtained.

2. Once accounted for, if the sponsor does not request that drugs need to be returned, then the products may be disposed of. The procedure for destroying used study drugs is as follows:

a. Safety and Regulatory Compliance Administrator must be contacted (phone. #954-262-8816) to arrange for pick up of used or unused investigational product for disposal as biomedical waste.

b. Prepare accounted drug and place them in a biohazard bag. Secure and tape the bag closed.

c. Keep bag with investigational product locked at site until it may be released to biomedical waste management personnel.

d. Document that drugs were disposed of according to policy.

Documentation shall be maintained concerning the disposal of the Investigational Product which shall contain:

- The quantity of the Investigational Product disposed of;
- The date and manner of disposal;
- The staff member who conducted the disposal;

A copy of this documentation shall be sent to the sponsor and kept with the research records.