Nova Southeastern University
Standard Operating Procedure for GCP

Title: Investigational Product/Device Accountability Log		Version # 1
SOP Number: OCR-AIP-001	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: There should be at all times a current accounting of the Investigational Product/Device inventory.

POLICIES:

1. The Center/College is to maintain adequate records of the current inventory of Investigational Product/Device including dates, quantity, use by subjects and final return/destruction.
2. Such accountability logs shall be maintained in accordance and for the duration of the record retention policy.
3. Any discrepancies are to be followed up until resolved and documented as unaccounted for.

Procedures upon Receipt of Investigational Product from Sponsor

1. Receipt of Investigational Product/Device should be documented on the Center/College or sponsor generated form that indicates:
   1.1. Date of Receipt
   1.2. The unique identifiers (including any Lot/Serial/Randomization numbers)
   1.3. Quantity Received
2. Physical examination of the packaging should search for the following:
   2.1. If research product are new drug or device, the statement "Caution: New Drug (Or Device)- Limited by U.S. Law to Investigational Use" or subsequently approved FDA statement
   2.2. An expiration date, if appropriate
3. Any discrepancies or errors should immediately be documented and reported to the sponsor.

4. A list returned to the Sponsor with comments on any missing product / device or other discrepancies. A copy of this inventory is kept in the Investigator Binder.

Procedures for Logging Administration/Dispensing of Investigational Product to Subjects

1. Throughout the trial Drug/Device Dispensing Logs are kept for each study subject including date, visit number, amount dispensed, returned, and/or lost. As each investigational product is dispensed, a recording is made in the Drug/Device Dispensing Log. At the end of each study, the list is totaled and compared with the final drug / device inventory. Any discrepancies are noted and explained.

3. The *Drug/Device Dispensing Log* is kept in the drug and supplies room or Investigator Binder, and a notation is made each time a unit is dispensed or returned and by who dispensed.

Procedures for Inventory Discrepancies

1. When a discrepancy occurs between the physical count and the logs, documentation of such will be completed in the study files.
   1.1. Date discrepancy noticed
   1.2. Narrative of attempts to reconcile
   1.3. Resolution of reconciliation
2. A Protocol Deviation should be reported internally pursuant to that policy as well as notifying any external parties as required (sponsor, IRB etc).
3. Sufficient detail of product that is unaccounted for should be logged so that there maintains an accurate inventory (example “Missing 2 bottles (V3 and V4)” instead of “missing bottles)
4. A Protocol Violation/Deviation form can be found in the Forms section of this manual.