Nova Southeastern University
Standard Operating Procedure for GCP

Title: Dispensing for Outpatient Use		Version # 1
SOP Number: OCR-AIP-003	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: Dispensing investigational products for outpatient use should be done in an accountable and safe manner.

POLICIES:

1. Investigational Products are only to be dispensed to those who have provided written Informed Consent pursuant to the requirements of the NSU IRB.
2. Investigational Product can only be dispensed under the supervision of an appropriately licensed practitioner listed on the most current version of the FDA Form 1572 for the protocol and/or only with proper delegation of authority or by Principal Investigator to do so as documented in advance in the Investigator Binder Delegation of Duties Signature Page.
3. Packaging shall be in conformance with applicable laws (e.g. to prevent accidental poisoning etc)

Procedures for Dispensing to Research Subjects for Outpatient Use

1. After a subject is enrolled in the research study, the principal investigator or his/her designee will follow the protocol-specific plan for assignment/dispensing of test article for each subject. Source documentation will include:
    a. acknowledgement that subject received/returned test article/container
    b. date test article was dispensed/returned
    c. the amount/dose/container dispensed/returned
2. Test articles will be kept in a locked cabinet/file, in a temperature controlled locked office. Only appropriate research staff will have access to this office/cabinet.

3. If test article is to be stored in a refrigerator or freezer, an investigator-designee will check and document on a regular basis the temperature of the appliance to make sure it maintains the protocol-specific temperature for storage.
4. The specific instructions on study subject numbering are to be followed exactly.
5. When discrepancies occur, explanations must be noted when appropriate, especially in the CRF and source document.