



**Nova Southeastern University  
Standard Operating Procedure for GCP**

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| <b>Title: <u>ICH Guidelines for Drug Accountability</u></b> |                                    | <b>Version # 1</b> |
| <b>SOP Number: OCR-AIP-005</b>                              | <b>Effective Date: August 2013</b> | <b>Page 1 of 1</b> |

**Purpose:** Responsibility for Investigational product(s) rests with the Investigator

**Policies:**

1. Responsibility for Investigational product(s) accountability at the trial site(s) rests with the Investigator/Center/College
2. Where allowed/required, the Investigator/Center/College should assign some or all of the Investigator's/ Center/College duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the Investigator/Center/College.
3. The Investigator/Center/College and/or pharmacist or other appropriate individual, who is designated by the Investigator/Center/College, should maintain records of the product(s) delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration date (if applicable) and the unique code numbers assigned to the investigational product(s) and trail subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.
4. The investigational product(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s)
5. The Investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.
6. The Investigator, or a person designated by the Investigator/Center/College, should explain the correct use of the investigational product(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.