PURPOSE

No investigational product will be released until the FDA and the site's IRB/HIC have approved the clinical study. Once released to the sites, all investigational product inventories will be monitored and accounted for throughout the course of the study. The investigational product must be accounted for at all times and handled according to applicable regulations, the BRCC funding agency requirements and institutional policies. Neither the BRCC, nor any participating investigator will represent the investigational product as safe or effective for the purposes for which it is under clinical study or to otherwise promote the product.

Investigational products are stored in a secure environment. Access is limited to key study personnel, according to the storage requirements detailed in the protocol or other instructions supplied by its provider. Only individuals authorized by institutional guidelines and state law are permitted to dispense investigational products to study subjects. Procedures for destruction of any investigational products must comply with institutional requirements and applicable Occupational Safety and Health Administration (OSHA) and biohazard materials policies if appropriate and with the express written authorization of the BRCC or other supplier.

SCOPE

These policies and procedures apply to the BRCC and its employees.

RESPONSIBILITY

The monitor is responsible for ensuring all necessary study approvals have been obtained prior to investigational product being transferred to investigators.

The monitor is responsible for ensuring investigator requests for investigational product are processed expeditiously to ensure sites have adequate supplies on-hand at all times.

The investigators are responsible for tracking the disposition of all investigational products during the course of the study from the time of receipt to the time of final disposition (return to the BRCC, on-site destruction, etc.).

The BRCC monitoring staff are responsible for evaluating the adequacy of investigational product accountability during routine monitoring visits.

PROCEDURE

Labeling and Release of Investigational Product:

1. Confirm products are packaged properly, labels/labeling provide required information, and the FDA required statement is present: CAUTION: New Drug - Limited by US law to investigational use. (These SOPs do not address GMP regulations and compliance.)

2. Authorize shipping of product to study site(s) when training is complete and applicable regulatory requirements have been
3. Prior to the release of product to the site(s), complete the Investigational Product Release Form.

4. All investigational products must be released in a manner which allows for adequate stock control throughout the duration of the study.

5. Copies of the shipping form (the original unsigned version and the signed, completed and returned version) and any other commercial shipping records are maintained in the Regulatory Master File (RMF).

Investigational Product Receipt, Storage and Issue:

1. Instruct the site investigator or designee to perform an inventory upon receiving products. This inventory should include verifying lot numbers, subject numbers and the contents of each kit, against the information provided on the Investigational Product Release Form, labels and labeling.

2. Instruct the investigator or designee to sign the form and return it to the BRCC with notes on any missing investigational product or other discrepancies.

3. If there is an urgent need to replace any missing or otherwise discrepant shipment contents, instruct the investigator to contact the BRCC.

4. A copy of the form is kept in each site’s study file and is subject to review by the monitor during routine monitoring visits.

5. Verify site’s proper use (including distribution by protocol-specified randomization schema) of investigational products during study.

6. Verify investigational products are stored in a secure location at the site, with access restricted to authorized personnel and with appropriate monitoring equipment.

7. Verify investigational product is dispensed or otherwise provided only to subjects enrolled in the clinical study.

8. Verify the use of the investigational product occurs under the direct supervision of the investigator or other approved designee(s).

9. Verify the product blind is not broken except in the case of an emergency or a protocol-defined situation.

10. If the blind is broken, verify BRCC was notified, the exact manner in which the code was broken, and the justification is noted in the site’s files.

11. Verify each site has accurate and complete records showing
receipt and disposition of all investigational products.

12. Verify records are maintained in the appropriate subject or study files during periodic monitoring visits.

13. Document inadequate recordkeeping practices, discuss them with the investigator and report them to the sponsor of the trial.

14. A pattern of inadequate inventory management and documentation is considered grounds for terminating the site’s participation in the study.

Investigational Product Accountability:

1. At study conclusion or termination, account for all supplies of investigational product, cross-referencing all forms, including those returned to BRCC or destroyed on site. The investigative site must have written authority from BRCC to destroy the investigational product on site.

2. Verify the site has documented and explained any discrepancies in the beginning and ending inventory.

3. Collect all investigational product inventory documentation, make copies to leave at the site and return the original forms to <<Sponsor Designee>>, where they will be reconciled with BRCC's internal records.

4. Keep copies of the forms in the site’s study files.

5. Instruct sites to keep investigational product accountability records for two (2) years after a marketing application is approved for the product, or if the application is not approved, until two (2) years after shipment and delivery of the product for investigational use is discontinued.

ASSOCIATED POLICIES

702 Documentation and Records Retention
703 Clinical Protocol Development
705 Initiation Visit and Site Training
706 Routine Monitoring Visits
707 Study Closeout Visit

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.6 Labeling of an Investigational New Drug
21 CFR 312.7 Promotion and Charging for Investigational Drugs
21 CFR 312.40 General Requirements for Use of an Investigational New Drug in a Clinical Investigation
21 CFR 312.59 Control of the Investigational Drug
21 CFR 312.69 Handling of Controlled Substances
21 CFR 312.110 Import and Export Requirements
21 CFR 312.160 Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests
ICH E6, 2.12 The Principles of ICH GCP
ICH E6, 4.6 Investigational Product
ICH E6, 4.7 Randomization Procedures and Unblinding
ICH E6, 5.13 Manufacturing, Packaging, Labeling and Coding
ICH E6, 5.14 Supplying and Handling Investigational Product(s)

☑ Original  □ Revision or Review

Research Institute Compliance Committee Review Date: __________________________

Corporate Administration Approval: __________________________ Date: __________
  V.P. Research or Chief Medical Officer

Research Institute Board Approval: __________________________ Date: __________

Research Administration Approval: __________________________ Date: __________
  Administrative Director