**Purpose**: Establishing the safety and efficacy of an investigational product (IP) is required prior to commercialization. Clinical trials are one of the mechanisms by which this happens. Maintaining an accurate accounting of the IP is one aspect of ensuring the data collected for the clinical trial is valid and acceptable. This standard operating procedure (SOP) describes the processes for the receipt, storage, dispensing, reconciliation and return or authorized destruction of an investigational product at this investigative site.

**Scope:** This SOP applies to Investigators and clinical research team members conducting clinical research involving the use of IP.

**Definitions:**

Investigational Product (IP): a test article or pharmaceutical form of an active ingredient or placebo that is tested or used in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, used for an unapproved indication, or used to gain further information about an approved use (Segen’s Medical Dictionary, 2012)

Investigational Drug Services (IDS): UNC Healthcare System Department that provides a mechanism for the acquisition, storage, preparation, distribution, and control of clinical trials materials (CTM) for clinical trials with human subjects

Clinical Trial Material (CTM): a drug, biological, or medical supply item which may be approved or unapproved by the FDA for use under protocol for human research

Clinical Research Management System (CRMS): the electronic system which serves as a centralized resource used to manage clinical trials at UNC-CH.

**Procedures:**

**I. Investigational Drug Accountability**

1. **Prior to Study Start**
   1. Initiate a request for services with IDS in CRMS.
   2. Confirm IDS is in receipt of the investigational drugs prior to beginning the study.
2. **Investigational Drug Ordering**
   1. Only qualified investigators listed on the FDA Form 1572 or the IRB application may order investigational drug(s).
   2. Follow IDS procedures for protocol-specific ordering of the investigational drug within Epic (see UNC Health Care Investigational Drug Services policy – Policy Stat ID 4667820).
   3. Confirm the investigational drug supply is adequate and within expiration date.
3. **Investigational Drug(s) Dispensing**
   1. IDS will dispense the drug in accordance with the protocol/pharmacy manual requirements.
   2. A delegated staff member will pick-up the dispensed investigational drug from the designated IDS location and verify the information on the product provided matches the drug order placed.
   3. The delegated staff member will provide the investigational product to the study subject with the necessary instructions for using the product.
4. **Drug Return/Accountability**
   1. If applicable, collect unused study drug per protocol.
   2. If applicable, count the returned study drug to verify subject compliance.
   3. Document any discrepancies on the drug accountability log. If discrepancies exist, re-educate subjects on proper instructions for use of the investigational drug and document.
   4. Return the unused drug to IDS.
   5. Periodically during the study, expired or unused CTM will be returned to the sponsor unless authorized by the by sponsor to dispose of the CTM per institutional policy and in accordance with regulatory agencies. At the completion of the study, all CTM remaining in IDS will be returned to the sponsor unless authorized by the by sponsor to dispose of the CTM per institutional policy and in accordance with regulatory agencies.

**II. Investigational Device Accountability**

1. **Prior to study start:**
   1. A plan will be developed for the delivery (receipt), acceptance, storage, and access of the investigational device. This information will be documented and retained as part of the clinical study record
   2. Create a study specific device accountability log (see Appendix A)
2. **Device Dispensing** 
   1. The device will only be used on a subject who has signed an IRB approved informed consent document/HIPAA authorization
   2. The device accountability log will be completed with the required information at the time the device is dispensed
3. **Device Return**
   1. The device will be returned to the sponsor at the completion of the study unless the sponsor authorizes, in writing, the investigator to dispose of the device. In that instance, the device will be disposed of per institutional policy and in accordance with any regulatory agencies.
   2. The accountability log will be updated with the final disposition of the device.

**Applicable University Policies and Guidelines:**

OHRE SOP 701

OHRE SOP 1301

UNC Health Care Investigational Drug Services Policy (PHARM 0619)

**Applicable Regulations and Guidelines:**

21 CFR 312.50 General responsibilities of sponsors

21 CFR 312.56 Review of ongoing investigations

21 CFR 312.59 Disposition of unused supply of investigational drug

21 CFR 312.60 General responsibilities of investigators

21 CFR 312.61 Control of the investigational drug

21 CFR 312.62 Investigator recordkeeping and record retention

21 CFR 312.68 Inspection of investigator’s records and reports

21 CFR 312.69 Handling of controlled substances

21 CFR 812.110 Specific Responsibilities of Investigator

21 CFR 812.140 Records and Reports

ICH GCP E6 (R2) International Conference on Harmonisation: Good Clinical Practice: Consolidated Guideline

Joint Commission Medication Management Standards

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| --- | --- |
| **Revision History** | |
| Date of Revision: | Revision Description: |
|  |  |

**Appendix A - INVESTIGATIONAL DEVICE ACCOUNTABILITY / INVENTORY LOG**

**STUDY DETAILS**

|  |  |
| --- | --- |
| Sponsor Name: |  |
| Study Protocol Title: |  |
| Principal Investigator Name: |  |

**RECEIVED/RETURNED**

(**Number of devices dispensed + Number of devices returned should equal Number of devices received**)

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date Rec’d** | **Initials of Rec’vr** | **Lot #/Serial or Model #** | **Device Type/ Batch #** | **Number Rec’d** | **RET = Returned**  **DES= Destroyed**  **Rep = Repaired** | **Date** | **Initials** | **Auth #** | **# of Units** | **Comments** |
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**DISPENSED/USED**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date Used/ Dispensed** | **Rec’vd/ Dispensed by** | **Subj Initials (Device user/ recipient)** | **Subj Med Record#** | **Lot/Serial or Model #** | **Type/Batch #** | **Qty Used/ Dispensed** | **Comments** |
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