**PURPOSE:** The purpose of this SOP is to ensure that records of product delivery, inventory, subject use and return of drug and drug products to sponsors are maintained for clinical trials conducted at Kent State University.

**SCOPE:** This SOP applies to all clinical trials conducted at Kent State that involves study drug intervention.

**RESPONSIBILITIES:**

**Principal Investigator (PI):**

* Accountable for receipt, storage, and dispensing of study drug
* Ensures that drug is used in accordance with protocol

**Research Coordinator:**

* Maintains all documentation related to study drug accountability including all shipping receipts/invoicing as part of the study file
* Initiates the Master Drug Accountability Log
* Dispenses study drug (is this allowable?)
* Monitors temperature for drug supply storage
* Orders drug supply for investigator initiated studies
* Instructs subjects on proper use and handling of drug

**DEFINITIONS:**

**Investigational Product Accountability:** Includesdocumentation of the following on an ongoing basis:

* When drug supplies arrive
* When a drug is dispensed
* When a drug is returned by a subject
* When a drug is returned to supplier or is destroyed
* A pill count on the drug accountability record (if applicable)

**Investigational New Drug Application (IND):** Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. As the sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

**Investigational Brochure (IB)**: The IB is a comprehensive document summarizing the body of information about an investigational product ("IP" or "study drug"). The purpose of the IB is to compile data relevant to studies of the IP in human subjects gathered during preclinical and other clinical trials.

**Investigational Product (IP):** A [pharmaceutical](http://en.wikipedia.org/wiki/Pharmaceutical) form of an active ingredient or [placebo](http://en.wikipedia.org/wiki/Placebo) being tested or used as a reference in a [clinical trial](http://en.wikipedia.org/wiki/Clinical_trial). May also be referred to as a test article.

**PROCEDURE:**

1. The Investigator and study coordinator/research personnel will be knowledgeable of the Investigator’s Brochure (IB) and protocol that provide information about the study test article, its proper use, and required storage conditions during the clinical study.
2. Receipt of Investigational Product:
   1. When drug is received by the study coordinator, the box is immediately opened and counted to ensure that the study drug is packaged and labeled with the following information:

* Study name and number
* Study drug name
* Study drug dose and formulation
* Statement: “CAUTION: New investigational Test Article-Limited by U.S. law to investigational use.”
* Study subject numbers and/or visit numbers
* Special instructions regarding dosage or storage
* Expiration date
* Quantity in container
  1. For Investigator-initiated studies, the study coordinator orders drug supply from the supplier and documents receipt as above.
  2. Upon receipt of investigational study drug, an inventory is performed by the research coordinator and a list returned to the sponsor with comments on any missing test article or discrepancies.

Inventory includes:

* A check on lot numbers
* Study subject numbers
* Number of elements in each kit
* A retained copy of inventory in regulatory documentation file

1. Storage of Investigational Product:
   1. Study drugs are stored in a secure area with restricted access, and under conditions appropriate for the material as specified in the protocol.
   2. The required storage temperature range is recorded on the drug accountability logs.
   3. The temperature of the drug storage area is monitored per schedule detailed in protocol.
   4. The temperature record contains the acceptable temperature range for that storage area.
   5. If temperature is found to be outside of required range, drug is moved to another temperature monitored environment until temperature range can be restored.
   6. Sponsor is notified if drug is stored outside required range.

5. Dispensing of Investigational Product**:**

5.1 Drug/test article is prepared by research coordinator or PI for dispensing no more than 72 hours prior to the time it is needed.

5.2If the study design has a requirement to blind the supplies, the Sponsor provides the test article randomization code and blinding supplies. The research coordinator or PI ensures that the supplies are packaged and blinded properly.

5.3If the study test article is blinded, the blind is not to be broken except in the case of an emergency or a protocol-defined situation. If the blind is broken, the Sponsor is notified and the exact manner in which the code was broken and the rationale are noted in writing as a note to file in the regulatory binder.

5.4Study drug is labeled per protocol but must include at a minimum:

* Subject number
* Subject initials
* Study number
* Protocol number
* Name of investigator
* Expiration Date
* Directions for use
* Includes the statement “for investigational use only”

5.5 The individual removing the medication from the drug storage area signs for the drug on the Drug Accountability Log which is kept in the same location as the study drug.

5.6 Investigational Product accountability records must include, as applicable:

* Name of the institution
* Name of investigational product, dose form and strength
* Protocol title and number
* Name of PI
* Name of manufacturer or product source
* Lot number or other control/identification number
* Study subject initials/unique identification number
* Dose received/dispensed
* Quantity received/dispensed
* Date received/dispensed
* Remaining balance
* Initials of recorder

6. Disposal and Destruction of Investigational Product:

6.1 At the conclusion of the study, a final drug accountability check is performed to ensure that all study drugs are accounted for.

6.2 Discrepancies should be documented with an explanation in the beginning and ending inventory.

6.3 A copy of the post- study inventory, and all study subject administration logs are kept in the study files at the site and a copy is returned to the Sponsor.

6.4 If requested by the Sponsor, the study monitor and study coordinator package drug for return together.

6.5 Return receipt of drug is requested from the sponsor.

6.6 For investigator initiated studies, drug is destroyed in accordance with protocol guidelines.

6.7 If the Sponsor provides written instructions to destroy unused study drug, destruction will take place in accordance with KSU Health Environmental Health and Safety Universal Waste Program.

6.8 Documentation of the destruction process is to be stored as a note to file in the regulatory binder.

6.9 Records of IP accountability are kept as long as required by Sponsor.

|  |  |
| --- | --- |
| **REFERENCES:** | 1. CFR 312.57- Record Keeping and Record Retention 2. CFR 312.59- Disposition of Unused Supply of Investigational Drug   21 CFR 312.61- Control of Investigational Drug  21 CFR 312.69 Handling Controlled Substances  ICH GCP Consolidated Guideline—Part 4.6 Investigational Product(s)  NIH Tool Summary Sheet – Investigational Product Accountability Log: Subject Record |
|  |  |
| **RELATED POLICIES:** |  |
|  |  |
| **APPENDICES:** | Appendix U: Investigational Product (IP) Accountability Log |
|  |  |
| **REVISION HISTORY:** Keep a running history of all revision dates.   |  |  |  | | --- | --- | --- | | **Approval Date** | **Effective Date** | **Review/Revision Dates** | |  | **01/29/2017** |  | |  |  |  | | |
|  | |

**Investigational Product Accountability Log: Subject Record**

|  |  |
| --- | --- |
| **Name of Institution: Kent State University** | **Product Name:** |
| **Investigator Name:** | **Manufacturer:** |
| **Protocol No.:** | **Dose Form and Strength:** |
| **Protocol Title:** | **Dispensing Area:** |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Line No.** | **Date** | **Subject ID Number** | **Subject’s Initials** | **Dose** | **Quantity Dispensed and/or Received** | **Balance Forward / Balance** | **Lot No.** | **Recorder’s Initials** |
| *Ex.* | *15Feb2017* | *12345* | *ABC* | *10 mg* | *- 100 tabs* | *600*  *500* | *98765* | *JAR* |
| 1. |  |  |  |  |  |  |  |  |
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| 3. |  |  |  |  |  |  |  |  |
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| 8. |  |  |  |  |  |  |  |  |
| 9. |  |  |  |  |  |  |  |  |
| 10. |  |  |  |  |  |  |  |  |

Check if final page of log: Checkbox.