1. PURPOSE

To describe the requirements for managing investigational drugs and devices, also termed investigational product (IP), at the clinical site.

2. SCOPE

Applies to all personnel involved in the implementation and coordination of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. REPONSIBILITIES

The PI is ultimately responsible for all aspects of the study that she/he directs, including the area of the management of IP.

4. BACKGROUND

IP management includes proper handling and storage of IP. Accurate records must be maintained indicating receipt, dispensation, and final disposition of investigational drugs, biologics, and devices, as required by FDA [21 CFR 312.62 and 812.140].

Only qualified Investigators will have authority to distribute investigational drugs and devices [21 CFR 312.53 (b), 312.59 and 812.140].

5. PROCEDURE

5.1. The PI is responsible for IP accountability at the investigational site. The PI may delegate some or all of their duties for IP accountability to qualified site personnel who are under the supervision of the PI/research institution.

- 5.1.1. The PI or designee must maintain appropriate records as follows:
  - 5.1.1.1. Receipt of shipment
  - 5.1.1.2. Inventory at the site
  - 5.1.1.3. Dispensation/use by each subject
  - 5.1.1.4. Final disposition - return of clinical supplies (or other disposal if applicable)
  - 5.1.1.5. These records should include the following:
    - 5.1.1.5.1. Dates
    - 5.1.1.5.2. Quantities
    - 5.1.1.5.3. Batch/serial numbers
    - 5.1.1.5.4. Expiration dates (if applicable)

5.1.1.5.5. Unique code number(s) for the IP(s), if assigned

5.2. Investigational drugs and devices need to be stored according to the sponsor's recommendations with respect to temperature, humidity, lighting, and other environmental considerations. The PI or designee is responsible for ensuring that IP is stored in a secure area with limited access, in accordance with applicable regulatory requirements. Temperature logs are to be maintained on a daily basis where study medication is stored.

5.2.1. Deviations from the storage temperature requirements for investigational drugs must be recorded and reported to the study sponsor.

5.3. Investigational drugs or devices should be dispensed to subjects only by Investigators or qualified clinical site research personnel designated by the Investigator. If more than one location will be used for IP storage or dispensation, the sponsor should be notified and the Form FDA 1572 or Investigator's Agreement should accordingly reflect all locations.

5.4. The PI is responsible for authorizing individuals who can prescribe the IP.

5.5. Only the designated site personnel shall maintain and dispense the IP.

5.6. The PI or designee shall follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the research trial is blinded, the PI should promptly document and explain to the sponsor any premature unblinding of the IP(s).

5.6.1. For third-party blinded studies, other clinical site research personnel and sponsor monitor(s) should not have access to the unblinded information.

5.7. The PI or designee shall ensure that the IP is used only in accordance with the approved protocol.

5.8. The PI or designee is responsible for explaining the correct use of the IP to each study participant (SP), and should check, at intervals appropriate for the research trial, that each SP is properly following protocol instructions.

5.9. Clinical research personnel will provide only Institutional Review Board (IRB)-approved patient education materials and/or IP administration information to SPs.

5.10. The PI or designee shall maintain prospective records of study materials returned by each SP. The PI should review the accountability of the returned IP to assess each SP's compliance. If IP is lost by the SP or not returned, it should be so indicated in the source document and the IP accountability log.

5.11. The PI or designee should periodically review the expiration dates on IP (if applicable) and contact the study sponsor regarding any IP with imminent expiration dates.

5.12. If the IP is subject to the Controlled Substance Act, the PI or designee should take adequate precautions, including storage of the investigational drug in a double-locked, well-constructed cabinet or enclosure with limited access to prevent theft or diversion of the substance into illegal channels of distribution [21 CFR 312.69]. Investigators or designees will comply with Drug Enforcement Agency (DEA) regulations in addition to the FDA regulations and will obtain DEA registration for the controlled substance(s), if required.

5.13. IP should not be transferred from one site to another unless specifically authorized by the sponsor. If the sponsor authorizes such transfer, the Investigator should record:
- 5.13.1. Transfer date
- 5.13.2. Quantity transferred
- 5.13.3. Means of transfer (e.g., courier: Federal Express, U.S. Postal Service, UPS, etc.)
- 5.13.4. Name of the person to whom it was transferred
- 5.13.5. Name of the person who authorized the transfer

5.14. At sponsor-authorized intervals throughout a study, and at the conclusion of a trial, the PI or designee will arrange for return shipment of any unused IP to the sponsor. If possible, the sponsor representative(s) will conduct final accountability and reconciliation prior to IP return.

6. TERMS & ABBREVIATIONS

CFR Code of Federal Regulations
DEA Drug Enforcement Agency
FDA Food and Drug Administration
IP Investigational Product
IRB Institutional Review Board
SP Study Participant

7. REFERENCES

7.1. Title 21 CFR 312.57 - Record Keeping and Record Retention
7.2. Title 21 CFR 312.59 - Disposition of Unused Supply of Investigational Drug
7.3. Title 21 CFR 312.61 - Control of Investigational Drug
7.4. Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention
7.5. Title 21 CFR 312.69 - Handling of Controlled Substances
7.6. Title 21 CFR 812, Subpart G - Reports and Records
7.7. Title 21 CFR 812.5 - Labeling of Investigational Devices
7.8. Title 21 CFR 812.140 - Records
7.9. ICH GCP Consolidated Guideline - Part 4.6 Investigational Product(s)
7.10. ICH GCP Consolidated Guideline - Part 4.7 Randomization Procedures and Unblinding
7.11. Clinical Research SOP 10.00 - Documenting Delegation of Authority
7.12. Clinical Research SOP 41.00 - Obtaining and Maintaining IRB approval

8. ATTACHMENTS

None