SPECTRUM MEDICAL, INC.
SOP 200.6.0
INVESTIGATIONAL PRODUCT/CLINICAL TRIAL MATERIAL MANAGEMENT

1. PURPOSE

To describe the requirements for managing Investigational Products/Clinical Trial Material (CTM) at the clinical site.

2. SCOPE

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

Personnel responsible: Investigator/Co-investigator(s) and, *when delegated by the investigator,* sub-investigators, clinical research coordinators, Research Director, and designated site personnel.

3. BACKGROUND

Investigational Product management includes proper handling and storage of investigational products. 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].

In accordance with:

- Title 21 CFR 312.57 - Record Keeping and Record Retention
- Title 21 CFR 312.59 - Disposition of Unused Supply of Investigational Drug
- Title 21 CFR 312.61 - Control of Investigational Drug
- Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention
- Title 21 CFR 312.69 - Handling of Controlled Substances
- Title 21 CFR 812, Subpart G - Reports and Records
- Title 21 CFR 812.5 - Labeling of Investigational Devices
- Title 21 CFR 812.140 - Records
- ICH GCP Consolidated Guideline - Part 4.6 Investigational Product(s)
- ICH GCP Consolidated Guideline - Part 4.7 Randomization Procedures and Unblinding
- Clinical Research Site SOP 200.1.0 – Documenting Delegation of Authority
- Clinical Research Site SOP 500.1.0 - IRB Approval

4. PROCEDURE

4.1. The principal investigator is responsible for Investigational Product accountability at the investigational site. The investigator may delegate some or all of the investigator's duties for investigational product accountability to qualified site personnel who is under the supervision of the investigator/research institution.

4.2. The principal investigator or designee must maintain appropriate records as follows:

4.2.1 Receipt of shipment
4.2.2 Inventory at the site
4.2.3 Dispensation/use by each subject
4.2.4 Final disposition - return of clinical supplies (or other disposal if applicable)

These records should include the following:

4.2.5. Dates
4.2.6. Quantities
4.2.7. Batch/serial numbers
4.2.8. Expiration dates (if applicable)
4.2.9. Unique code number(s) assigned to the investigational product(s)

4.3. 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 principal investigator or designee is responsible for assuring that Investigational Product is stored in a secure area with limited access in accordance with applicable regulatory requirements. Access to the storage area will be limited to essential research personnel.

4.4. Upon receipt of study drug, the shipment should be inventoried, verifying that the materials number/lot number, study medication type, and quantity on the packaging slip is the same as what is actually received. Promptly notify sponsor representative or supplier of any discrepancies.

4.5. 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 Investigational Product storage or dispensation, then sponsor should be notified and the

Form FDA 1572 or Investigator's Agreement should accordingly reflect all locations.

4.6. Only the designated site personnel shall maintain and dispense the Investigational Product. "Designated" site personnel is defined as those persons delegated the task of "drug accountability and dispensing" on the site signature log by the Principal Investigator.

4.7. The principal investigator 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 trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding of the investigational product(s).

4.8. The principal investigator or designee shall ensure that the Investigational Product is used only in accordance with the approved protocol.

4.9. The principal investigator or designee is responsible for explaining the correct use of the Investigational Product to each subject, and should check, at intervals appropriate for the trial, that each subject is properly following instructions.

4.10. Only IRB-approved patient education materials and/or Investigational product administration information will be provided to study subjects by clinical research personnel.

4.11. The principal investigator or designee shall maintain prospective records of study materials returned by each subject. The investigator or designee should review the accountability of the returned Investigational product to assess each subject's compliance. If Investigational product is lost by the subject or not returned, it should be so indicated in the source document and the Investigational product accountability log.

4.12. The principal investigator or designee should periodically review the expiration dates on Investigational Product (if applicable) and contact the sponsor regarding any articles with imminent expiration dates.

4.13. If the Investigational Product is subject to the Controlled Substance Act, the principal investigator 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 designee will comply with DEA regulations in

addition to the FDA regulations and will obtain DEA registration for the controlled substance(s) if required.

4.14 Investigational Product 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:

4.14.1 Transfer date
4.14.2 Quantity transferred
4.14.3 Means of transfer (e.g., courier, FedEx, U.S. Postal Service)
4.14.4 Name of the person to whom it was transferred

4.15. At sponsor authorized intervals throughout a study, and at the conclusion of a trial, the principal investigator or designee will arrange for return shipment of any unused Investigational Product to the sponsor. If possible, the sponsor representative(s) will conduct final accountability and reconciliation prior to Investigational Product return. If there are any discrepancies, a note to file documenting reason for discrepancy should be placed in the appropriate file. The note to file should be signed and dated by the author.

4.16. A copy of accountability logs will be maintained in the site regulatory Files and/or each subjects study file.

5. ATTACHMENTS

Protocol Drug Receipt/Dispensing/Return Record *(Optional)*

Do Not Write Between Bold Lines

Spectrum Medical, Inc.
Investigational Product Management
SOP - 200.6.0

x Original Amendment
Revision Addendum

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Approved: April Marshall, RN, Research Director CCRC Date: 02MAY2016