SPECTRUM MEDICAL, INC.
SOP 200.6.1
INVESTIGATIONAL PRODUCT DESTRUCTION

1. PURPOSE

To describe the requirements for destroying 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, 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. At sponsor authorized intervals throughout a study, and at the conclusion of a trial, the principal investigator or designee will arrange for return or destruction of any unused Investigational Product to the sponsor. Returning the Investigational Product to the sponsor if the preferred method of clearing out the inventory. In the event the Sponsor desires that the Investigational Product be disposed of on site, it shall be done in accordance with all applicable federal, state, and local laws.

4.3. All Investigational Products (used and unused) must be accounted for by the study monitor prior to destruction. Disposal must be initiated only after written/verbal instruction from the sponsor/sponsor representative have been obtained.

4.4. Once accounted for, the Investigational Product may be disposed of as biomedical waste. The procedure for destroying Investigational Product is as follows:

a. Accounted drug should be placed in red biomedical container and secured closed.
b. The biomedical container with investigational product will be stored in research department until released to the biomedical waste management \ personnel.
c. Properly document that Investigational Products were released to biomedical waste management personnel for disposal. Documentation shall include the following:
    - The quantity of the Investigational Product disposed of
    - The date and manner of disposal;
    - The staff member who conducted the disposal
d. Documentation shall be kept with Investigational Product accountability records. It is not required for Waste Management Facility to sign record of destruction as employees are not permitted to do so. Manifest documents showing box picked up are available. SCI-MED WASTE SYSTEMS 1-800-662-0088.

5. ATTACHMENTS

Drug Destruction Record *(Optional)*

Do Not Write Between Bold Lines

Spectrum Medical, Inc.
Investigational Product Destruction
SOP - 200.6.1

☐ Original ☐ Amendment
X Revision ☐ Addendum

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Research Director CCRC