**Template**

**Standard Operating Procedure**

**Management of Schedule 1 Investigational Drug**

**Topic/Activity:** *Investigational Use of Schedule 1 Drugs in Human Subject Research*

**Purpose:**  *To standardize the process for the storage, handling, dispensation and documentation of Schedule 1 Drugs*

**Policy***:* [Policy for Research Use of Controlled Substances at Emory University](http://policies.emory.edu/7.25)

**Procedure for use of \_\_\_\_\_\_\_\_\_\_\_\_\_:**

1. Investigational \_\_\_ is manufactured by \_\_\_ and distributed by \_\_\_. The Registrant, \_\_\_, will order \_\_\_ by completing and sending a DEA Form 222 to \_\_\_.
2. All investigational \_\_\_ is securely stored in ­\_\_\_ located \_\_\_ on the ­\_\_\_­ campus. Only ­\_\_\_ has/have authority to access the safe.
3. Upon receipt of investigational \_\_\_, \_\_\_working with a second study team member completes the following duties:
	1. Sign in investigational \_\_\_ on \_\_\_ (specify name of Form) to document receipt and inventory.
	2. Immediately enter the “Numbers of Packages Received” and “Date Received” in the appropriate columns on the copy of Form DEA 222 (copy 3 – purchaser’s copy)
	3. Keep a copy of Form DEA 222 in the study regulatory binder, and keep the original copy filed with \_\_\_ records.
	4. Document receipt of investigational \_\_\_ on the appropriate \_\_\_ Log
	5. Sign and date the shipping receipt, and file it in an appropriate section of study regulatory binder
4. Only the Registrant, \_\_\_, has authority to order investigational \_\_\_
5. To dispense investigational \_\_\_, the Registrant, \_\_\_ will work with a second study team member to complete the following tasks:
	1. Obtain a physician’s order from ­­­\_\_\_\_ which is required for each dispensation
	2. Confirm that order is for an eligible study subject
	3. Sign out \_\_\_\_ from the safe on \_\_\_\_\_\_\_\_\_ (Specify name of Form).

* 1. Label each bottle /kit according to State and Federal regulations and study protocol requirements
	2. Document the bottles /kits dispensed on the \_\_\_\_ Log and \_\_\_\_\_\_Logs as provided by the study sponsor
	3. File a copy of the physician’s order in the research record
1. If investigational drug will be transported from secure storage to subject dosing areas:
	1. Registrant places labeled \_\_\_\_\_ in \_\_\_\_\_, a secure transportable container and applies tamper-proof tape obtained from IDS to seal transport container.
	2. Complete relevant part of the Chain of Custody (CoC) form ([Form 12](https://rcra.emory.edu/_includes/documents/sections/oric/form12_cs_chain.docx)).
	3. Registrant transports from secure storage. On arrival, registrant and the study team member sign the CoC form for evidence of delivering investigational \_\_\_ and complete remaining part of the (CoC) form
2. Registrant physically delivers prepared investigational \_\_\_ directly to study subject verified by \_\_\_\_\_\_
	1. Registrant and the study team member sign \_\_\_\_\_\_ form for evidence of administering investigational \_\_\_
3. Unused \_\_\_ will be stored in the Study Safe until the study monitor has performed accountability and given permission for study medication return to the sponsor-designated depot
4. Perpetual inventory of investigational \_\_\_ is maintained on \_\_\_\_ (Specify Form). The Registrant conducts a physical inventory on a weekly basis.
5. Any unresolved discrepancies in investigational \_\_\_ are reported immediately to the Office of Research Integrity and Compliance.
6. Any significant loss or theft of investigational \_\_\_ will be reported by the Registrant immediately to the Emory Police Department, Environmental Emory Health and Safety, Office and Office of Research Integrity and Compliance and to the local DEA Diversion Field Office in writing within one business day of discovery and GDNA in writing within 48 hours of discovery.
7. At closure of the study, all unused and expired investigational \_\_\_ product will be sent to ­­­\_\_\_\_\_, a sponsor-designated depot using a reverse DEA Form 222
8. Handling of investigational \_\_\_ will be in compliance with State and Federal regulations and Controlled Substance Policies of Emory University, whichever is more stringent.

Registrant will maintain the following documentation:

• Log of persons with access to room where Controlled Substances are stored

• Log of persons authorized to use Controlled Substances

• Log of all orders and receipts of Controlled Substances

• Initial and biennial inventory log

• Running use and disposition log for each container of Controlled Substances

Registrant must keep all records relating to \_\_\_\_ ordering, procurement, use and inventory for three (3) years from final disposition of drug. Completed inspection forms/materials provided to the Researcher by the GDNA and/or the DEA for application approval must be perpetually retained with the respective active registration