Michigan State University investigators are responsible for assuring the institution / Institutional Review Board (IRB) that there are appropriate plans in place for the inventory control, storage, monitoring, and dispensing of test articles (investigational drugs, biologicals, devices or in vitro diagnostics). The following guidance and sample inventory log is provided for investigators and IRB members. This guidance should be used in conjunction with any policies and procedures from the sponsor, if applicable, and at the research site concerning the storage and handling of investigational drugs and devices.

Accountability plan elements:

- Maintenance of records of test article delivery to the institution
  - Records with dates, quantities delivered, serial/batch numbers, expiration dates. Retention of shipping inventory/packing slips in the records.

- Maintenance of inventory of the test article at the study site
  - Inventory records updated and signed.

- Documentation of use of the test article by each subject
  - Identify the test device, date the subject received the test device, quantity/dosage dispensed, and signature of the dispenser on accountability logs.

- Return or disposal of the test article as specified by the sponsor
  - Maintenance of records of return or disposal of test articles, performed in accordance with any written authorization from the sponsor and/or applicable federal or state regulatory requirements.

- Secure storage of the test article
  - Store test articles separately from standard clinical inventory
  - Lock/secure the storage area. Limit access to the study staff.
  - Store non-dispensed test articles separately from returned dispensed test articles
  - Provide environmental controls (ambient / controlled room temperature, refrigeration, freezer) appropriate for storage of the test article.
  - Controlled substances must be stored in a locked location with storage and usage in compliance with federal and state regulations. For requirements on controlled substances, see MSU Environmental Health and Safety web site.
- Assurance that test articles are used only in accordance with approved protocols
  - Reconcile the medication administration records in the subject's medical chart with the documentation of use of the test article by each subject.

**SAMPLE LOG**

<table>
<thead>
<tr>
<th>Drug Accountability Log</th>
<th>Investigator/Investigator #</th>
<th>Investigational Product Name#</th>
<th>Lot #</th>
<th>Expiry Date</th>
<th>Verification of Accountability</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Number of Bottles Dispensed</th>
<th>Dispenser's Initials</th>
<th>Date Dispensed</th>
<th>Number Returned</th>
<th>Receiver's Initials</th>
<th>Date Returned</th>
</tr>
</thead>
</table>

I certify that the returned drug and containers have been destroyed according to local regulations.

Investigator Signature and Date