**WHAT is a Drug/Device Accountability Log?**

The Drug or Device Accountability Log is a means to track and document when and how the investigational product (drug or device) has been used throughout the study.

Includes the following information

▪ Date received ▪ Return of unused drug or device

▪ Subject who received drug or device ▪ Recorder’s initials

▪ Date used or dispensed ▪ Lot number/serial number

**WHEN is a Drug/Device Accountability Log Required?**

The Principal Investigator is responsible for ensuring that all investigational product (drug or device) has been accounted for. A drug/device accountability process should be initiated for any study that uses study-supplied drug/device. A study drug/device can be an investigational product or an approved product that is being tested for a currently unapproved use.

**WHY would you need a Drug/Device Accountability Log?**

Accurate and complete drug/device accountability records demonstrate that the investigational product was dispensed and/or administered according to the protocol. The records:

* support the validity of study data and the conclusions drawn from those data
* document the handling of the investigational product from receipt to dispensing to return, disposal or destruction
* display inventory, lot numbers, dose size, quantities in stock, and expiration dates
* include shipping invoices, confirmation or receipt, condition upon receipt, and a running tally of when the drug was received, dispensed, disposed of, and returned to the sponsor
* help verify patient case histories and detect possible lot variations
* help identify patients who may have received the drug, as well as the quantities that they may still have in their possession, should recovery of any unused rug become necessary to minimize health risks

**HOW do you use it?**

The accountability log should depict a complete and accurate record of how the drug or device was received, dispensed, and disposed of, including quantities used and final disposition. The PI must ensure that the entire research team understands the procedures necessary to maintain accountability and follows the study protocol.

Dispensation of the investigational product should be recorded following each instance of dispensation (not at the end of the day, week, month, etc.) and be double-checked for accuracy and completeness. Routine internal quality assurance audits of the accountability log should be conducted to ensure accuracy and prompt resolution of any discrepancies.

**WHERE do you put it?**

The accountability log should be stored with study documents (device) or the Research Pharmacy (drug).

**Applicable References for Consideration:**

Reference: Friedman L, Managing Drug Accountability. Community Oncology 2007;4(8):487-489. <http://www.communityoncology.net/journal/articles/0408487.pdf>

CRP Research Practice Guidelines: [Guidelines for Developing Pharmacy Procedures for Clinical Trials](http://crp-apps/Intranet/Portals/1/Documents/R10%20-%20Guidelines%20for%20Developing%20Pharmacy%20Procedures%20for%20Clinical%20Trials.pdf)