



Tool Summary Sheet

Tool: Investigational Product Accountability Log: Subject Record

Purpose: To document all study product disposition and accountability on the subject level.

Audience/User: Study Coordinators, Principal Investigators (PIs), pharmacy staff, other site staff, clinical monitor.

Details: This tracking log should provide a comprehensive list of all study product dispositions on the subject level. It is required for interventional clinical studies using a study product for research.

The set of columns are suggestions and can be customized to meet the needs of the study.

**Best Practice
Recommendations:**

- Complete the log as study product is dispensed and/or received, to ensure completeness and accuracy of the data. A new line should be completed each time study product is dispensed and/or received.
- The “Subject Record” may be used to record dispensing and return of study product on the subject level. The associated “Stock Record” is a separate tool that may be used to record overall bulk study product supplies and accountability.
- In the "Quantity Dispensed and/or Received" column, use a “+” before the number when receiving product; use a “-” before the number when dispensing product. See the example provided within the log.
- In the “Balance Forward” column, use the diagonal line across the box to record the previous balance forward / the resulting balance (e.g., 600 / 500). See the example provided within the log.
- The log recorder should initial the line item as the information is entered.
- Create additional lines and pages as needed.
- For clinical studies that are not blinded, maintain this log in the Essential Documents Binder, behind the “Study Product Records” tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File (ISF), and Study File.)
- For blinded clinical studies, it is recommended that study product accountability records be filed in a separate location (e.g., the research pharmacy), to maintain the blind.
- Number each page and store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
- At the conclusion of the study, identify the final page of the log by checking the box in the footer.
- Remove this Tool Summary Sheet before use of the log.

Tool Revision History:

Version		
Number	Date	Summary of Revisions Made:
1.0	24Apr2013	First approved version

Investigational Product Accountability Log: Subject Record

Name of Institution:	Product Name:
Investigator Name:	Manufacturer:
Protocol No.:	Dose Form and Strength:
Protocol Title:	Dispensing Area:

Line No.	Date	Subject ID Number	Subject's Initials	Dose	Quantity Dispensed and/or Received	Balance Forward / Balance	Lot No.	Recorder's Initials
<i>Ex.</i>	<i>15Feb2012</i>	<i>12345</i>	<i>ABC</i>	<i>10 mg</i>	<i>- 100 tabs</i>	<i>600</i> <i>500</i>	<i>98765</i>	<i>JAD</i>
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								

Check if final page of log: