



## Tool Summary Sheet

**Tool:** Specimen Tracking Log

**Purpose:** To record all specimens collected and specimen shipment information

**Audience/User:** Study coordinators, principal investigators, other site staff, clinical monitor

**Details:** This tracking log should provide a comprehensive list of all specimens collected and the shipment information for each specimen. It is required for both observational and interventional clinical studies collecting clinical samples.

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

**Best Practice  
Recommendations:**

- To ensure completeness and accuracy of the data, record specimens in the tracking log as they are collected, and update shipment information as specimens are shipped or received.
- If applicable, the log should be modified to track if consent for future use was obtained or withdrawn.
- Number each page and maintain this log in the Essential Documents Binder, behind the Specimen Tracking Log tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File [ISF], and Study File.)
- 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

