

# 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 is a suggestion 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* If applicable, the log should be modified to track if consent for future use was obtained or withdrawn.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 |
| 2.0 | 30Apr2020  | Added column for subject number |

# Specimen Tracking Log

|  |  |  |
| --- | --- | --- |
| Investigator Name: | Protocol:  | Site Number: |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject Number | Visit | Specimen Name/Type | Specimen ID (Accession #) | Date Collected | Date Shipped | Tracking # | Receiving Lab | Date Received | Comments |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |
|  |   |   |   |   |   |   |   |   |   |

Check if final page of log: 