

Tool Summary Sheet

Tool: Site Screening and Enrollment Log

Purpose: To record the consent and screening of all subjects and the outcome of each screening.

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

Details: This log should provide a comprehensive list of all subjects who were screened for eligibility if the information is not maintained electronically. It is required for both observational and interventional clinical research studies.

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

- Best Practice Recommendations:**
- Record subjects as they are consented, to ensure completeness and accuracy of the data.
 - Include all subjects who were consented and screened, including screen failures.
 - This log should contain no identifying information. Subjects may be tracked separately on logs, such as a coded list with a key.
 - Number each page and maintain this log in the Essential Documents Binder, behind the 'Screening/Enrollment 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 | 22Feb2010 | First approved version |
| 2.0 | 02Mar2010 | Removed automatic page numbering |
| 3.0 | 04Jan2012 | Added Tool Summary Sheet; no revisions to the log |
| 4.0 | 14Mar2012 | Revised Tool Summary Sheet and added check box to footer |

Site Screening and Enrollment Log

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| Investigator Name: | Protocol: | Site Number: |
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| Subject ID | Date of Consent | Version of Consent | Date Screened | Eligible for Enrollment? | Ineligibility Reason (if applicable) |
|------------|-----------------|--------------------|---------------|--------------------------|--------------------------------------|
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