NIDCR National Institute of Dental and Craniofacial Research National Institutes of Health

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

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Tool: Delegation of Responsibilities Log

Purpose: To record all study staff members' significant study-related duties.

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

Details: This log should provide a comprehensive list of study staff members and the duties that have been delegated to them by the Principal Investigator. It is required for both observational and interventional clinical research studies.

Best Practice Recommendations:

- List the names of study staff members and record the responsibilities that have been assigned to them using the Responsibilities Legend.
- Revise the Responsibilities Legend as needed to reflect study-specific needs, such as signing CRFs and reviewing/signing laboratory reports.
- Each study staff member listed should initial and sign to indicate understanding of the responsibilities assigned.
- The site PI should initial and date each line of the form as entries are recorded. The PI's signature at the bottom of each form is required at the conclusion of the study.
- Update the log as needed following any change in site study personnel.
- Number each page and maintain this log in the Essential Documents Binder, behind the 'Delegation of Responsibilities (DoR) 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	05Feb2010	First approved version
2.0	02Mar2010	Removed automatic page numbering
3.0	04Jan2012	Added Tool Summary Sheet; minor updates to Responsibilities Legend
4.0	14Mar2012	Updated Tool Summary Sheet; added * cross-reference and Query Management to Responsibilities Legend; added check box to footer