

SCREENING AND ENROLLMENT LOG INSTRUCTIONS

PURPOSE

This log provides a comprehensive list of all participants who were screened for eligibility and the outcome of each screening.

HOW TO USE

- Complete the form header by adding the Investigator Name and Study Title.
- The body of the form is completed as follows:
 - Complete the screening portion of the log by adding the screen date, ID#, Gender, Race/Ethnicity and Screen Failure reason for each participant screened. Be sure to use the key categories “a” and “b” at the bottom of the log to complete the Race/Ethnicity and Screen Failure reason sections of the log.
 - Complete the enrollment portion of the log by including the name of the study team member consenting the participant and the date the consent form was signed. Complete the study completion portion of the log as the participant completes or is withdrawn from the study by adding their completion date or withdrawal date. If the participant withdraws or is withdrawn from the study be sure to use the key category “c” to include a reason for the withdrawal.
 - Include comments on the log as needed.
- Number each page of the log, identifying the final page of the log at the conclusion of the study.

GOOD PRACTICE RECOMMENDATIONS

- Record participants as they are consented, to ensure completeness and accuracy of the data.
- Include all participants who were consented and screened, including screen failures.
- This log should contain no identifying information. Participants may be tracked separately on logs, such as a coded list with a key.
- File the pages of the log in reverse chronological order, with the newest pages of the log placed at the front of the section.
- Be sure to customize the template to make it study-specific.