

Instruction for Use

SCREENING, ENROLMENT & IDENTIFICATION LOG

Template	
Purpose	To record the consent, screening and identity of all participants and the outcome of each screening, including their study participation number/code (Unique Participant Number_UPN) when the Sponsor and the Investigator are the same person.
Use	<p>Study coordinator, principal investigator, other site staff, Monitor</p> <p>To be used only if the Sponsor and the Investigator are the same person, as the document contains identifying data. For participating sites consider to use logs 9a and 9b.</p>
Details	<p>This log should provide a comprehensive list of all participants who were Consented and then screened for eligibility.</p> <p>The set of columns are suggestions and can be customised to meet the needs of the study, and the drop-down menu can be adapted in the second sheet.</p>
Best Practice Recommendations	<ul style="list-style-type: none"> To be used in electronic format and printed out regularly, for example before monitoring visits Record participants as they are consented in chronological order, to ensure completeness and accuracy of the data, Include all participants who were consented and screened, including screen failures, use the drop-down menu to document screen failure reasons, This log contains also identifying information as this is a sponsor-investigator only document, Number each page and maintain this log in the ISF, in the “participants section”, Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.