

# Instruction for Use

## SCREENING & ENROLMENT LOG

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Template	
<b>Purpose</b>	To record the consent and screening of all participants and the outcome of each screening. This log is intended to be used when it's to be passed on to the sponsor (e.g. for statistical purposes), as it is anonymous.
<b>Use</b>	<p>Study coordinator, Principal investigator, other site staff, Monitor, Sponsor.</p> <p>In case the Sponsor and the Investigator is the same person, the combined log 9 may be used instead of 9a and 9b.</p>
<b>Details</b>	<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>
<b>Best Practice Recommendations</b>	<ul style="list-style-type: none"> <li>To be used in electronic format and printed out regularly, for example before monitoring visits</li> <li>In the upper part of the page identifying the study, delete (Local) if the study is monocentric, and ( ) if the study is multicentric,</li> <li>Record participants as they are consented in chronological order, to ensure completeness and accuracy of the data,</li> <li>Include all participants who were consented and screened, including screen failures, use the drop-down menu to document screen failure reasons,</li> <li>This log does not contain any identifying information. Participants identity can be tracked on logs 9b or 9,</li> <li>Number each page and maintain this log in the TMF/ISF binder, in the "participants section",</li> <li>Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.</li> </ul>