

Instruction for Use

INVESTIGATOR DELEGATION LOG

Template	
Purpose	To document in detail which trial-related tasks are delegated by the Principal Investigator, to whom, and over what period of time.
Use	<p>This log should provide a comprehensive list of site study staff members and the duties that have been delegated to them by the Principal Investigator.</p> <p>The delegated tasks numbered in the template are standard and should be adapted to the study and completed if necessary. The log is used to maintain signatures and initials of individuals performing study activities so that source documentation can be attributed to specific staff members; for this purpose initials should be handwritten.</p>
Details	<p>This log should provide a comprehensive list of site study staff members and the duties that have been delegated to them by the Principal Investigator.</p> <p>The delegated tasks numbered in the template are standard and should be adapted to the study and completed if necessary. The log is used to maintain signatures and initials of individuals performing study activities so that source documentation can be attributed to specific staff members; for this purpose initials should be handwritten.</p>
Best Practice Recommendations	<p>The first page is for the Principal Investigator, it is intended to enable him/her to change during the course of the study and avoid the re-signature of all already delegated site staff, as well as to document the tasks he/she is taking on.</p> <p>The following pages should include site staff who have been delegated trial-related tasks.</p> <p>In the “Delegated task(s)” column, only the figures corresponding to the tasks should be entered.</p> <p>The Principal Investigator and site research staff should record the same signature and initials on the log as when signing and initialling research source records.</p> <p>The information entered in all sections of the log should be legible.</p> <p>Initials must be unique for all clinical research site staff and other individuals (e.g., if two individuals have the initial “NM”, one staff must also use a middle initial).</p> <p>The Principal Investigator should initial and date entries on the log prior to the commencement of the assigned tasks. By initialling an entry, the Principal Investigator is acknowledging the delegation of the tasks and is confirming that the individual is qualified and trained to perform the work associated with the assigned task.</p> <p>Each study staff member listed should initial and sign to indicate understanding of the responsibilities assigned.</p> <p>The task section should be adapted to each study.</p> <p>The possible roles are given as examples.</p>



Template

The log should be updated in a timely manner as new research staff are added or removed and/or roles or tasks change.

Complete headers and number each page and maintain this log in the ISF (a copy for the TMF will be collected at the end of the trial).

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	associated with SCTO_MON_TEM-1a	Valid from: 15.09.2025	Page 2 of 2