

Instruction for Use

SPONSOR DELEGATION LOG

Template	
Purpose	To document in detail which trial-related tasks are delegated by the Sponsor, to whom, and over what period of time.
Use	<p>This document must be used only at Sponsor level. Please use template 1a for tasks delegated by the Investigator.</p> <p>If there is a change in Sponsor (representative) during the course of the study, this can be documented here (no need to have another document)</p>
Details	<p>This log should provide a comprehensive list of study staff members and the roles and activities that have been assigned to them by the Sponsor.</p> <p>The activities numbered in the template are given as examples and should be adapted to the study, and completed if necessary. The log is used to maintain signatures and initials of individuals performing trial-related activities so that study 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 Sponsor, it is intended to enable Sponsor to change during the study and avoid the re-signature of all already delegated staff.</p> <p>The following pages should include staff who have been assigned trial-related roles/tasks.</p> <p>The Sponsor and research staff should record the same signature and initials on the log as is done when signing and initialing research records.</p> <p>In the “Delegated task(s)” column, only the figures corresponding to the tasks should be entered.</p> <p>The information entered in all sections of the log should be legible.</p> <p>Initials must be unique for all clinical research staff and other individuals (e.g., if two individuals have the initial “NM”, one staff must also use a middle initial).</p> <p>The Sponsor should initial and date entries on the log prior to the commencement of the assigned tasks. By initialing an entry, the Sponsor 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> <p>The log should be updated in a timely manner as new research staff are added or removed and/or roles or tasks change.</p> <p>Complete headers and number each page and maintain this log in the TMF.</p>