Delegation of Authority and Signature Log

Delegation Log Guidance

All members of staff must personally complete the DoA Log by hand, sign and date and have it countersigned and dated by the PI. This must occur **after** all relevant Protocol and training has been completed and **before** they undertake any duties. The original copy of this log must be retained within the Investigator Site File (ISF)/Trial Master File (TMF), as appropriate.

The log must be maintained prospectively and should be reviewed regularly for completeness and accuracy. End dates must be added as individuals cease working on the research and/or once the research has ended.

Completion of the Log

If more than one page is required, the pages must be marked accordingly (e.g., Page 1 of 2)

Field	Column Details	Completed by	Additional Completion Guidance
1	Sponsor number	Administrator/site contact	Insert 4-digit UoL reference number.
2	IRAS/Combined Review Number	Administrator/site contact	Insert the IRAS/Combined Review number.
3	Short title/Acronym	Administrator/site contact	Insert the short title or acronym.
4	Principal Investigator (PI)	Administrator/site contact	Insert the name of the Principal Investigator.
5	Site	Administrator/site contact	Insert the name of the site the DoA relates to.
6	Print Name	Research Staff Member	Print name (i.e., in capitals).
7	Role	Research Staff Member	Enter role using the abbreviations found in Table 1. Should a role not be listed, it should be added to Table 1.
8	Delegated Tasks	Research Staff Member	Review the list of tasks in Table 2 and enter the tasks that have been delegated (adequate training and experience is required for all tasks).
9	Initials	Research Staff Member	Enter initials.
10	Signature	Research Staff Member	Add signature.
11	Date	Research Staff Member	Insert date of completion (format DD-MM-YYYY).
12	Principal Investigator (PI) Signature	Principal Investigator	PI must countersign to document that the member has been delegated the duties listed.
13	Date	Principal Investigator	Insert date of completion (format DD-MM-YYYY) – *this will also act as the start date – no research-related activities/duties should be undertaken prior to this date.*
14	End Date	Research Staff Member/Administrator/site contact	This column should only be completed if a staff member leaves/stops working on the study and/or will not be working on the study for a prolonged period (e.g. maternity leave) OR when the study closes (format DD-MM-YYYY).

UNIVERSITY OF LEICESTER

1. Sponsor number	2. IRAS number	3. Short Title/Acronym	4. Principal Investigator	5. Site

Delegation of Authority and Signature Log

Delegated Individual						PI Authorisation		Role Finished
6 PRINT Name	**7 Role***	**8 Delegated Task(s)#**	**9 Initials**	**10 Signature**	**11 Date**	**12 PI Signature**	**13 Date**	**14 End Date**

Any person named on this log (or immediate family member) must not be entered into this study

***Table 1 Roles: Additional roles and their abbreviation should be added to the empty boxes.**

CI = Chief Investigator	**PI** = Principal Investigator	**SI** = Sub Investigator	**RF** = Research Fellow	**RN** = Research Nurse
CRA = Clinical Research Associate	**P** = Pharmacist	**RA** = Research Administrator	**HCA** = Health Care Assistant	**S** = Statistician

#Table 2 Delegated study tasks: Additional tasks can be added to the empty boxes.

1 Eligibility Screening	2 Eligibility Confirmation	3 Obtaining Informed Consent	4 Physical Examination (delegated Medic only)	5 Obtaining Medical History	6 Randomisation
7 Perform study visit assessments	8. Order Study Medication	9. Prescribing Study Medication	10. Preparing/Dispensing Study Medication	11. Administering Study Medication	12 Study Medication Accountability
13 Unblinding	14 Safety Reporting (e.g. SAEs/SUSAR)	15 AE/SAE/SAR Causality/Expectedness assessment (delegated Medic only)	16 SUSAR Reporting	17 CRF development	18 CRF Completion
19 CRF sign-off (PI/delegated sub-PI only)	20 Data entry	21 Data Query Resolution	22 Data Analysis	23 Trial Master File/Site File Maintenance	24 Regulatory Communication (e.g REC/HRA/MHRA)
25 Recruitment uploads (e.g., EDGE/CPMS etc)	26 Annual report preparation and/or submission	27	28	29	30
31	32	33	34	35	36