Delegation of Authority and Signature Log

Delegation Log Guidance

The PI is responsible for ensuring this study is conducted in accordance with the approved Protocol, GCP and all relevant regulations. The Delegation of Authority Log (DoA Log) is evidence that the PI has confirmed that the individuals performing study-related tasks/procedures are appropriately trained, experienced and authorised to do so. The PI is responsible for ensuring all staff involved in the study have received adequate and ongoing training, including any new staff who become involved after the study has begun.

The DoA should initially be completed as close to the Site Initiation Visit/Sponsor Green Light as possible and preferably at or after the Site Initiation Visit/ Protocol Training has taken place. 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 before they undertake any trial related procedures. The original copy of this log must be retained within the Investigator Site File (ISF)/Trial Master File (TMF) as appropriate.

All staff must have R&D Approval to work within the Trust (e.g., letter of access/honorary contract as required) before they sign the DoA. Copies of CV's, GCP's and evidence of study training spanning the duration of study involvement must be available for each person listed on the DoA Log and must be filed in the ISF/TMF as appropriate.

The log must be maintained prospectively and should be reviewed for completeness and accuracy during the lifetime of the study. Final review and end dates must be added as individuals leave the study and at study closure.

Completion of the Log

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

1. Sponsor number: Insert 4-digit UoL reference number
2. IRAS number: Insert the studies 6-digit IRAS number
3. Study Acronym: Insert the studies short title or acronym
4. Principal Investigator: Insert the name of the Principal Investigator
5. Site: Insert the name of the site the DoA relates to
6. Print name: Staff member to print their name in this column
7. Role: Staff member to enter their role in the study using the abbreviations found in Table 1. Should a role not be listed, it should be added to Table 1.
8. Delegated study tasks: The staff member should review the list of delegated study tasks (Table 2) and enter the roles that they have adequate training and experience to undertake
9. Initials: The staff member should enter their initials in this column
10. Signature: The staff member should sign in this column
11. Date: The staff member should date in this column (format DD-MM-YYYY)
12. Signature: The PI should countersign in this column to document that the member has been delegated the duties listed
13. Date: The PI should date next to their signature (format DD-MM-YYYY). This will also act as the start date – no activities should be undertaken prior to this date.
14. End date: This column should only be completed if a staff member leaves the study, 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. Study 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 Study 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 Obtain informed Consent	4 Physical Examination (Medic only)	5 Obtaining Medical History	6 Randomisation
7 Blood Sampling	8 Processing Bloods	9 Evaluation of study Lab Results	10 Performing ECGs	11 Evaluating ECGs	12 Ordering Study Medication
13 Prescribing Study Medication	14 Preparing/Dispensing Study Medication	15 Administering Study Medication	16 Study Medication Accountability	17 Unblinding	18 Serious Adverse Event Reporting
19 AE/SAE Causality/Expectedness assessment (delegated medic only)	20 ICSR Reporting (CTIMPS only)	21 CRF development	22 CRF Completion	23 CRF sign off	24 Database development
25 Data Query Resolution	26 Data Analysis	27 Trial Master File/Site File Maintenance	28 Ethics Committee Communication	29 Recruitment uploads (e.g. EDGE/CPMS)	30 Annual report preparation and/or submission
31	32	33	34	35	36