

Sponsor Reference Number	IRAS number	Short Title/Acronym	Principal Investigator	Location

Research Location Delegation of Activities

All members of staff must personally complete the DoA Log by hand and have it countersigned and dated by the PI (^this will also act as the start date – no research-related activities should be undertaken prior to this date). All relevant Protocol and role-specific training must be completed **before** an individual undertakes any activities. The original copy of this log must be retained in the Investigator Site File (ISF; copy in the TMF).

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

Tables 1 and 2 should be completed once and they apply to all pages of the DoA.

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

PI = Principal Investigator	SI = Sub Investigator	RN = Research Nurse	RF = Research Fellow
CRA = Clinical Research Associate	P = Pharmacist	T/SA = Trial Administrator	HCA = Health Care Assistant
RA = Research Assistant			

Table 2 Delegated activities*: Additional activities can be added to the empty boxes.

1 Eligibility Screening	2 Eligibility Confirmation	3 Obtaining Informed Consent	4 Physical Examination (Medic only)	5 Obtaining Medical History	6 Randomisation
7 Perform trial visit assessments	8 Sample handling (e.g., processing, storage, transfer)	9 Prescribing Trial Medication	10 Dispensing Trial Medication	11 Administering Trial Medication	12 Accountability of Trial Medication
13 Unblinding (PI/sub-I only)	14 Safety Reporting (e.g., SAEs)	15 AE/SAE/SAR Causality/Expectedness assessment (Medic only)	16 SUSAR Reporting	17 CRF Completion	18 CRF sign-off (PI/sub-I only)
19 Data entry	20 Data Query Resolution	21 Recruitment uploads (e.g., EDGE/CPMS etc)	22 Coordinate approval communications/submissions (e.g., R&I)	23 Site File Maintenance	24
25	26	27	28	29	30
31	32	33	34	35	36

SOP Reference	S-1010 Appendix 2
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Delegated Individual					PI Authorisation		Role Finished
PRINT Name	Role*	Delegated Activities(s)#	Initials	Signature	PI Signature	Date^	End Date

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