UNIVERSITY OF LEICESTER

DELEGATION OF AUTHORITY and SIGNATURE LOG

Before completion read the instructions on the reverse of this document

1 Study Number UoL Ref: **2 Principal Investigator:**

3 PRINT Name	4 Role*	5 Delegated Study Task(s)	6 From (Date)	7 To (Date)	8 Initials	9 Numbers 0-9	10 Delegate Signature and Date / PI Signature and Date

***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, Other**

1 Eligibility Screening, 2 Eligibility Confirmation, 3 Informed Consent, 4 Physical Examination (Medic only), 5 Obtaining Medical History, 6 Randomisation, 7 Blood Sampling, 8 Processing Bloods, 9 Evaluation of Trial Lab Results, 10 Performing ECGs, 11 Evaluating ECGs, 12 Dispensing Study Medication, 13 Administering Study Medication, 14 Study Medication Accountability, 15 Unblinding, 16 CRF Completion, 17 Data Query Resolution, 18 Serious Adverse Event Reporting, 19 Causality/Expectedness assessment (delegated medic only), 20 eSUSAR Reporting, 21 CRF sign off, 22 Site File Maintenance, 23 EC Communication, 24 Prescribing Study Medication , Other – Specify

Any person named on this log should NOT be entered into the study.

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Delegation Log Guidance

All members of Staff MUST complete and sign and date the Delegation Log and have it countersigned and dated by the PI BEFORE they undertake any trial related procedures.

The Principal Investigator is responsible for conducting studies in accordance with the Protocol and is required to keep a log of all individuals to whom he/she has delegated a specific task within the study. Where a task is being delegated to the individual, they should be qualified by education, training and experience to perform the task. The principal investigator is responsible for ensuring all staff involved in the study have received adequate training, including any new staff who become involved after the study has begun.

All staff must have R&D Approval before they sign the Delegation Log. A signed and dated CV and copy of a current GCP certificate for each person listed on the delegation log must be filed in the Trial Master File/Investigator Site File.

The log must be reviewed for completeness and accuracy during the lifetime of the study. Final review and end dated must be added at study closure.

Completion of the Log

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

1. **Study Number: Insert UoL reference number**
2. **Principal Investigator: Insert name of Principal Investigator**
3. **Staff member must PRINT their name in this column**
4. **Staff member should enter their role in the study using the abbreviations found in the roles section at the bottom of the form. Should your role not be listed it should be added to the roles list or entered in writing in this column.**
5. **The staff member should review the list of delegated duties on the log and enter the roles that they have adequate training and experience to undertake.**
6. **Write down the start date in the format DD-MM-YYYY**
7. **This column should only be completed if a staff member leaves the study or when the study closes. Enter the date format as DD-MM-YYYY**
8. **The staff member should enter their initials in this column**
9. **The staff member should write the numbers 0,1,2,3,4,5,6,7,8,9 in this column**
10. **The staff member should sign and date the greyed delegate signature line**
    The PI should then countersign and date on the line below to document that the member has been delegated the duties listed.