The University of Nottingham	**Record Form** **RF2 TA008** **Version 1.0**
Title:	**SITE RESPONSIBILITY (DELEGATION) LOG**
Reference SOP:	TA008

Title of Protocol: CerebroVascular Disease – Cognition Trial

Study Site:

Study Acronym / Reference: CVD-Cog

Principal Investigator Name:

Individual					**PI Authorisation**		**Role Finished**	
Name	Responsibilities in Study, (job title and coded roles* or list)	Signature	Initial	Date	Signature of PI	Date	Initial (PI)	Date

* codes for specific trial tasks are listed in appendix A.

Appendix A **Delegated Trial Related Duties**

The following trial related duties may be delegated and authorised as such by the Principal Investigator. Overall responsibility remains that of the PI and shall not be delegated but day-to-day practice, documentation and administration of the activity may be delegated to suitably qualified trial staffs.

A. Overall responsibility for study at Site and responsible for local financial management where appropriate B. Medical care and supervision of trial patients C. Obtain local ethics committee and R&D approvals and communication of subsequent amendments D. Ensuring all staff delegated to work on the trial are adequately informed as to the protocol requirements and trained in study procedures E. Delegation and authorisation of study related duties F. Act as document controller for trial related documents G. Set up and maintenance of Site File H. Implementation of subject recruitment strategy and obtaining informed consent I. Screening of potential subjects J. Obtaining consent and signing of consent forms (as appropriate to local policy & practice) K. Randomisation (allocation of trial intervention)	L. Completion and return of CRFs, including electronic entries M. Authorisation of CRFs N. Respond to data queries O. Prescription of and administration of IMP P. Be familiar with IMP safety data and disseminate to staff Q. Ensure IMP accountability R. Documentation of adverse events and timely SAE reporting S. Adhere to CI recommendations in response to SAEs T. Collection of trial related biological samples U. Initiation (training) of new trial personnel V. Prepare and be available for audit and inspections W. Archiving of trial data X. Responsibility for data monitoring. Y. Unblinding Others as locally applicable or trial specific (list): Z.