

ROCSS-EX SITE SIGNATURE AND DELEGATION LOG

Site Name:

Principal Investigator:

Duties: For each individual listed in the "Name" column, enter the letter(s) from the list below that correspond to their duties in the "Tasks Delegated by PI" column.

A	Obtain local approval for trial	D	Completion of electronic CRFs/data entry including data query resolution (required to be provided with logins/access to database)	F	Data sign off data/SDV (PI only)
B	Inform patient of trial (includes posting letters and PIS)			G	Other (specify) _____
C	Confirm continuing consent/agreement to participate	E	Investigator Site File (ISF) maintenance	H	Other (specify) _____

Name (please print)	Trial Role (PI, Trainee, RN)	Tasks Delegated by PI (see legend above)	Staff Initials	Staff Signature	Date of signature	Date of duties (dd-mm-yyyy) *	PI Signature	Date of PI Signature
						FROM: _____ TO: _____		
						FROM: _____ TO: _____		
						FROM: _____ TO: _____		
						FROM: _____ TO: _____		
						FROM: _____ TO: _____		
						FROM: _____ TO: _____		

PI Signature: By signing an entry, I confirm that the person listed is authorised to perform the study procedures in the tasks section and that the person is qualified to undertake these tasks. I also confirm that the person is appropriately informed about the study protocol and relevant study procedures.

This log must include the principal investigator, sub investigators, nurses and any staff who have specific data collection/interpretation duties. Add new or replacement staff as appropriate and send an updated copy of the log to the ROCSS-EX Trial Office.

* 'From' date should be on or after latest signature date for

CVs (MUST be signed & dated) and GCP certificates should be provided for staff listed on the log. A "work" email address (e.g. nhs.net, nhs.uk, doctors.org or .ac.uk) should be included in the CV or provided separately.

The PI should sign below during Site Close-Out: I have reviewed the information on this log and have found it to be accurate. All delegated duties were performed with my authorisation.

PI Signature: _____ Name (please print): _____ Date: ____ / ____ / _____