iRehab Site Signature & Delegation Log

Trust Name: _____ **Study Sponsor: _____**

Principal Investigator: _____ **IRAS ID:_____**

Sites within the trust for which this log applies: ***(a delegation log can only be used for multiple sites if the sites are within the same trust and the PI is the same at all)***

Site 1: _____	**Site 2:** *(Delete if not applicable)* _____	**Site 3:** *(Delete if not applicable)* _____
General Site address:	*General Site address:*	*General Site address:*

Please find the link to the research collaborators privacy notice. It contains important information on who we are, how and why we collect, store, use and share personal data, your rights in relation to your personal data and on how to contact us and supervisory authorities in the event that you have a query or complaint.

https://warwick.ac.uk/fac/sci/med/research/ctu/privacy/

Trust/site name:_____

Instructions:

Please use the 'Trial Responsibilities Key' below to indicate which responsibilities have been agreed locally. Only suitably qualified members of the research team are permitted to undertake the trial responsibilities.

Should any member of the research team who has been delegated responsibilities below either **join** or **leave** post, an updated Site Signature and Delegation Log must be sent to the iRehab Trial Office immediately, to indicate who the responsibility has now been transferred to or to inform the trial office about associated start and end dates.

Trial Responsibility Codes:

A = Overall responsibility for trial at site *(PI only)*
B = Subject screening and selection
C = Obtaining Informed consent
D = Assisting in informed consent process
E = Review eligibility and sign patient eligibility form
F = CRF/eCRF completion, correction and return
G = Data query resolution and return
H = SAE attribution assessment and sign off SAE form
I = SAE reporting
J = Investigator Site File maintenance
K = Remote Data Entry

Each responsibility is explained in further detail in the table below, however, if you are unclear as to what each responsibility involves please contact the iRehab Trial Office.

Code	Responsibility	Applicable restrictions	Descriptions
A	Overall responsibility for trial at site	PI only (this task cannot be delegated)	All trial responsibilities.
B	Subject screening and selection	Suitably trained personnel	Presenting patient with the patient information sheet and discuss trial with patient. Complete the online screening form.
C	Obtaining Informed consent	Delegated member of the research team	Countersign patient's consent form to confirm that the trial has been discussed with patient and patient has had the opportunity to ask any questions.
D	Assisting in informed consent process	Suitably trained personnel	Discuss trial with patient and assist clinician with consent procedures.
E	Review and confirm eligibility	Suitably trained member of the hospital research team listed on the trial delegation log	Ensure patient is eligible for trial.
F	CRF/eCRF completion, correction and return	Suitably trained personnel	Complete, modify, and sign CRF in accordance with ICH GCP. Access online portal to complete, submit and amend eCRF
G	Data query resolution and return	Suitably trained personnel	Respond to data queries from trial office in accordance with ICH GCP
H	SAE attribution assessment and sign off SAE form	Registered trial investigator only	Ensure information provided on SAE form is accurate, complete causality assessment, and sign completed form

Trust/site name:_____

I	SAE reporting	Suitably trained personnel	Fill in SAE form and report SAEs to Warwick Clinical Trials Unit, in accordance with the protocol, ICH GCP and notify other bodies in accordance with local NHS/R&D policy.
J	Investigator Site File maintenance	Suitably trained personnel	Keep Investigator Site File documentation up to date, including maintenance of Site Signature & Delegation Log, filing completed consent forms, case report forms (CRF), correspondence from Sponsor, Trust, etc. Perform stock-take of trial materials and request further supplies when required.
K	Remote Data Entry	Suitably trained personnel	Entry of trial data directly onto the trial database.
L	Site Research Champion	Suitably trained personnel	To complete the roles and responsibilities of the iRehab champion as per the protocol.

Please make all entries in ink. Cross out errors with a single pen stroke and initial and date. Send the original to the iRehab office and retain a copy in the Investigator Site File.

*****A current CV and GCP certificate for the PI should be sent to the central trial office as evidence of appropriate training. CVs and GCP certificates for all other members of staff should be collected and retained at site and be available on request*****

iRehab site signature & Delegation Log

Trust/site name:_____

By signing each member of staff off on this log, the PI is confirming that the personnel listed are authorised to perform trial responsibilities on their behalf as indicated, within the dates indicated. It also confirms that the staff members agree to take on these responsibilities and that they are qualified and appropriately informed about the trial. **A current CV and GCP certificate for the PI should be sent to the central trial office as evidence of appropriate training. CVs and GCP certificates for all other members of staff should be collected and retained at site and be available on request**

Name:	Title:	Trial role:	Trial responsibility codes:	Signature:	Initials:	Date start in trial:	Date stop in trial:

Job title:	Department/room name:	Telephone No. (inc ext):	Fax No.:	Email: \	
					CV sent to WCTU? ☐ GCP certificate sent to CTU? ☐ Main contact for data queries? ☐ Main contact for ISF updates? ☐ Main RN contact? ☐

Main site located at for contact purposes:	PI Signature:	Date of PI approval:

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