INVESTIGATOR SITE FILE INDEX

TRIAL NAME: iRehab

Section 1: Reference Information		**Principal Investigator**	**Present** Y / N / n/a
1.0	Site File Receipt: • *1.0 iRehab_eISFreceipt_v1.0_11Oct22*	Copy	
1.1	Trial contacts and coordination team details: • *1.1 Trial Contacts and Coordination Details v1.0 11Oct22*	Copy	
1.2	Trial Summary: • *1.2 iRehab Trial Summary v1.0 31Oct2022*	Copy	
Section 2: Protocol		**Principal Investigator**	**Present** Y / N / n/a
2.1	Current approved protocol: • *iRehab_Protocol_v3.0_28.09.2022*	Copy	
2.2	Previous approved versions of protocol	Copy (If relevant to site)	
2.3	Version Log/Trial History Log: • *2.3 iRehab Protocol Version Control Log v1.0 31Oct22*	Copy	
2.4	Protocol deviation/non-compliance forms	Original	
Section 3: Information for Participants		**Principal Investigator**	**Present** Y / N / n/a
3.1	1. Current approved patient information sheet: • *iRehab_PIL_V3.0_20Sep2022*	Copy	
	2. Previous approved versions of patient information sheet(s):	Copy (if relevant to site)	
3.2	1. Current approved consent form: • *iRehab_ConsentForm_V1.0_01.04.2022*	Copy	
	2. Previous approved versions of consent form(s):	Copy (if relevant to site)	
3.3	Translations of Patient Information Sheet(s) and Consent Form(s):	Copy	
3.4	Version Log: • *Participant Information Version Control Log v1.0 31Oct2022* • *PIL Version Control Log v1.0 31Oct2022*	Copy	
3.5	Advertisements for patient recruitment and any amendments: • *iRehab_PatientInvitePoster V1.0_25.03.2022*	Copy	
3.6	Letter for a patient's GP/consultant: • *iRehab Consultant_HospitalDr Letter v1.0 25.03.2022* • *iRehab GP Letter v1.0 25.03.2022*	Copy Copy	
3.7	Any other written information given to patients: • *iRehab Patient Invitation Letter from Sites_V2.0 06.05.2022*	Copy	
Section 4: Main Ethics		**Principal Investigator**	**Present** Y / N / n/a

4.1	1. HRA/REC approval for protocol and supporting documentation: • *HRA approval [310777_Letter_of_HRA_Approval_24082022]* • *REC approval [22-LO-0314 Favourable opinion on further information 18 May 2022]* • *4.1 REC Committee Composition V1.0 20Sep22*	Copy Copy	
4.2	HRA/REC approval of protocol amendments: ***SA01: Sub Folder*** • *22LO0314 Confirmation of favourable opinion for substantial amendment* • *FW IRAS 310777 notification of amendment Scotland* • *NI Gateway acknowledgement* • *SL32_Favourable_opinion_of_a_substantial_amendment_310777*	Copy (if relevant to site)	
4.3	Interim or annual reports to ethics committee	Copy	
4.4	Final report to ethics committee	Copy	
Section 5: Regulatory (if applicable)		**Principal Investigator**	**Present** Y / N / n/a
5.1	Regulatory approval letter	Copy	
5.2	Regulatory approval of protocol amendments	Copy (if relevant to site)	
5.3	Interim or Annual reports to regulatory authority	Copy	
5.4	Final report to regulatory authority	Copy	
5.5	Reports of serious breaches	Copy (if relevant to site)	
Section 6: Individual Site Information and Approvals		**Principal Investigator**	**Present** Y / N / n/a
6.1	Feasibility Questionnaire/ Pre-trial monitoring report/letter: • *6.1 iRehab_sitefeasibility_V2.0_01.08.2022*	Copy	
6.2	Principal Investigator CV (signed and dated) & GCP certificate CVs/GCP certificate for other site staff (signed and dated)	Copy Copy	
6.3	Statement of Activities (signed) NHS Trust confirmation of Capacity and Capability	Copy Copy	
6.4	Site Agreement	Copy	
6.5	Other applications/approvals ***NSA XX: Sub Folder (amend as appt):*** • *Relevant approved NSA Amendment Tool for Addition of Site* • *Relevant IRAS acknowledgement of NSA XX*	 Copy Copy	
6.6	Delegation and responsibilities signature log: • *6.6 iRehab_SiteDelegationLog_v1.0_03.10.2022*	Copy	
6.7	SIV documentation: • *6.7 iRehab_SIV_v1.0_23Sep22* • *6.7 iRehab_SIVagenda_v1.0* • *6.7iRehab_DatabaseTraining_v1.0_10Oct22* • *6.7 iRehab_SIVAttendance Log_v1.0_03Oct22*	 Original Original Original Original	

6.8	Relevant communications (e.g. letters, meeting notes, notes of telephone calls)	Original	
Section 7: Monitoring			
7.1	Monitoring visit reports/letters/checklists	Original	
7.2	Final Trial Close-Out Monitoring Report/letters	Original	
Section 8: General Site Information		**Principal Investigator**	**Present** Y / N / n/a
8.1	List of Investigators & updates	Cop	
8.2	Study specific training documentation/certificates/ evidence: • *8.2 iRehab Investigator Training Log _v1.0_ 03Oct22*	Original	
8.3	Study aids and promotional materials • *8.3 iRehabFAQs_v1.0_11Oct22* • *iRehab CRF Completion Guidelines V1.0 27.10.2022*	Copy Copy	
8.4	Newsletters	Copy	
Section 9: Data Collection		**Principal Investigator**	**Present** Y / N / n/a
9.1	Subject screening log/enrolment log • *iRehab Pre Screening Log V1.0 03.10.2022*	Original	
9.2	Signed informed consent forms	Original	
9.3	Randomisation confirmation reports/emails	Original	
9.4	Source documents	Original	
9.5	Sample Case Report Form & amendments • *1 iRehab Screening Form v1.0 03-Oct-2022_watermarked* • *2 iRehab Contact Details Form V1.0 31-Aug-2022_watermarked* • *3 iRehab Registration Consent Form v1.0 31-Aug-2022_watermarked* • *4 iRehab Co-morbidities Form v1.0 31-Aug-2022_watermarked* • *5 iRehab Readmission Form v1.0 31-Aug-2022_watermarked* • *6 iRehab Protocol Deviation Form v1.0 13-Sep-2022_watermarked* • *7 iRehab File Note v1.0 13-Sep-2022_watermarked* • *8 iRehab AE Form v1.0 25-Oct-2022_watermarked* • *9 iRehab Initial SAE form v1.0 25-Oct-2022* • *10 iRehab SAE Continuation Form v1.0 25-Oct-2022* • *11 iRehab Follow-up SAE form v1.0 25-Oct-2022* • *12 iRehab Discontinued Treatment Form v1.0 31-Aug-2022_watermarked* • *13 iRehab Withdrawal Form v1.0 31-Aug-2022_watermarked* • *14 iRehab Notification of Death Form v1.0 31-Aug-2022_watermarked* • *iRehab Pre Screening Log V1.0 03.10.2022* • *iRehab SAE Evaluation Form v1.0 18-Oct-2022*	Copy	
9.6	Sample of Patient Questionnaire(s) & amendments	n/a	n/a
9.7	Signed, dated and completed CRFs	Copy	
9.8	Documentation of CRF corrections/Data Clarification Forms	Copy	

9.9	Approved list of fields where self-evident corrections are to be allowed	Copy	
Section 10: Safety Information		**Principal Investigator**	**Present** Y / N / n/a
10.1	Serious Adverse Event forms and related correspondence	Copy	
10.2	Notification by sponsor to investigators of new safety information	Copy	
Section 11: Co-enrolment			
11.1	Co-enrolment document	Copy	