TRIAL NAME: RECOVERY-RS

Section 1: Reference Information			**Principal Investigator**	**Present Y / N / n/a**
1.1	Trial Summary		Copy	
Section 2: Protocol			**Principal Investigator**	**Present Y / N / n/a**
2.1	Current approved protocol (Trial contacts and coordination team details within)		Copy	
2.2	Previous approved versions of protocol		Copy (if relevant to site)	
2.3	Protocol Version Log		Copy	
2.4	Previous protocol version log		Copy	
2.5	Protocol Non-compliance forms		Original Note to File	
Section 3: Information for Participants			**Principal Investigator**	**Present Y / N / n/a**
3.1		**Current approved versions:**		
	3.1.1	Patient Information Sheet on Commencement V2.0 29/05/2020	Copy	
	3.1.2	Short Patient Information Sheet on Commencement V2.0 29/05/2020	Copy	
	3.1.3	Patient Information Sheet V4.0 29/05/2020	Copy	
	3.1.4	Short Patient Information Sheet V4.0 29/05/2020	Copy	
	3.1.5	Consultee Cover Letter V2.0 29/05/2020	Copy	
	3.1.6	Easy Read PIS (screen) V1.0, 29/05/2020	Copy	
	3.1.7	Easy Read PIS (print) V1.0, 29/05/2020	Copy	
		Previous approved versions:		
	3.1.8	Patient Information Sheet on Commencement	Copy (if relevant to site)	
	3.1.9	Short Patient Information Sheet on Commencement	Copy (if relevant to site)	
	3.1.10	Patient Information Sheet	Copy (if relevant to site)	
	3.1.11	Short Patient Information Sheet	Copy (if relevant to site)	
	3.1.12	Consultee Cover Letter	Copy (if relevant to site)	
3.2		**Current approved versions:**		

	3.2.1	Consent Form on Commencement v1.0 20/04/2020	Copy	
	3.2.2	Consent Form Deferred Consent v2.0 20/04/2020	Copy	
	3.2.3	Consent Form Consultee V3.1, 08/06/2020	Copy	
		Previous approved versions:		
	3.2.4	Consent Form Deferred Consent	Copy (if relevant to site)	
	3.2.5	Consent Form Consultee	Copy (if relevant to site)	
3.3	**Current versions:**			
	Translations of Patient Information Sheets and Consent Forms - French - Portuguese - Polish - Bengali - Punjabi - Urdu		Copy	
3.4	Master Documents Version Log		Copy	
Section 4: Main Ethics			**Principal Investigator**	**Present Y / N / n/a**
4.1	HRA/REC approval for protocol and supporting documentation		Copy	
	REC committee composition		Copy	
4.2	HRA/REC approval of protocol amendments		Copy (if relevant to site)	
4.3	Amendment log		Copy	
4.4	Interim or annual reports to ethics committee		Note to File	
4.5	Final report to ethics committee		Note to File	
Section 5: COPI & CAG			**Principal Investigator**	**Present Y / N / n/a**
5.1	COPI regulations		Copy File note	
5.2	CAG approvals		Copy	
Section 6: Individual Site Information and Approvals			**Principal Investigator**	**Present Y / N / n/a**
6.1	Feasibility Questionnaire		Note to File	
6.2	Principal Investigator CV (signed and dated) & GCP certificate CVs/GCP certificate for other site staff (signed and dated)		Note to File	
6.3	Organisation Information Document NHS Trust confirmation of Capacity and Capability		Copy Copy	

6.4	Site Agreement	Copy	
6.5	Delegation and responsibilities signature log	Note to File	
6.6	Greenlight letter confirming PI SIV attendance/online training	Original	
6.7	Relevant communications (e.g. letters, meeting notes, notes of telephone calls)	Original	
Section 7: Monitoring			
7.1	Monitoring visit reports/letters/checklists/correspondence	Original and Note to File	
7.2	Final Trial Close-Out Monitoring Report/checklists/letters	Original	
Section 8: General Site Information		**Principal Investigator**	**Present Y / N / n/a**
8.1	List of Investigators & updates	Copy	
8.2	Study specific training documentation/certificates/ evidence	Original	
8.3	Study aids and promotional materials	Copy	
8.4	Trial Participant Checklist	Copy	
8.5	Newsletters	Note to file	
Section 9: Data Collection		**Principal Investigator**	**Present Y / N / n/a**
9.1	Signed informed consent forms	Original	
9.2	Randomisation confirmation reports/emails & CRFs	Original	
9.3	Current versions of sample Case Report Form	Copy	
9.4	Previous versions of sample Case Report Forms	Copy	
9.5	Signed, dated and completed CRFs	Note to File	
9.6	Documentation of CRF corrections/Data Clarification Forms	Note to File	
9.7	Approved list of fields where self-evident corrections are to be allowed	Note to File	
Section 10: Safety Information		**Principal Investigator**	**Present Y / N / n/a**
10.1	Serious Adverse Event forms and related correspondence	Original	
Section 11: Trial Specific Working Instructions			
11.1	CRF Completion Guidelines	Note to file	
11.2	SAE Handling Process Working Instructions	Copy	
11.3	Patient interview publicity working instruction	Copy (if relevant to site)	
11.4	Twitter guidance	Note to file	