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	Protocol Non-compliance forms		Original	
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	
		Previous approved versions:		
	3.1.6	Patient Information Sheet on Commencement	Copy (if relevant to site)	
	3.1.7	Short Patient Information Sheet on Commencement	Copy (if relevant to site)	
	3.1.8	Patient Information Sheet	Copy (if relevant to site)	
	3.1.9	Short Patient Information Sheet	Copy (if relevant to site)	
	3.1.10	Consultee Cover Letter	Copy (if relevant to site)	
3.2		**Current approved versions:**		
	3.2.1	Northern Ireland Assent Form v3.0 20/04/2020	Copy (Northern Ireland only)	
	3.2.2	Consent Form on Commencement v1.0 20/04/2020	Copy	
	3.2.3	Consent Form Deferred Consent v2.0 20/04/2020	Copy	

	3.2.4	Consent Form Consultee V3.0 29/05/2020	Copy	
		Previous approved versions:		
	3.2.5	Northern Ireland Assent Form	Copy (Northern Ireland only, if relevant to site)	
	3.2.7	Consent Form on Commencement	Copy (if relevant to site)	
	3.2.8	Consent Form Deferred Consent	Copy (if relevant to site)	
	3.2.9	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	
	Previous versions:			
	Translations of Patient Information Sheets and Consent Forms		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	Interim or annual reports to ethics committee		Copy	
4.4	Final report to ethics committee		Copy	
Section 5: CAG			**Principal Investigator**	**Present Y / N / n/a**
Section 6: Individual Site Information and Approvals			**Principal Investigator**	**Present Y / N / n/a**
6.1	Feasibility Questionnaire		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	Organisation Information Document NHS Trust confirmation of Capacity and Capability		Copy Copy	
6.4	Site Agreement		Copy	
6.5	Delegation and responsibilities signature log		Copy	
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: Regulatory			
Section 8: Study Drugs and Laboratory – Not applicable			
Section 9: Monitoring			
9.1	Monitoring visit reports/letters/checklists Final Trial Close-Out Monitoring Report/letters	Original Original	
Section 10: General Site Information		**Principal Investigator**	**Present Y / N / n/a**
10.1	List of Investigators & updates	Copy	
10.2	Study specific training documentation/certificates/ evidence	Original	
10.3	Study aids and promotional materials	Copy	
10.4	Trial Participant Checklist	Copy	
10.5	Newsletters	Copy	
Section 11: Data Collection		**Principal Investigator**	**Present Y / N / n/a**
11.1	Signed informed consent forms	Original	
11.2	Randomisation confirmation reports/emails	Original	
11.3	Sample Case Report Form & amendments	Copy	
11.4	Signed, dated and completed CRFs	Copy	
11.5	Documentation of CRF corrections/Data Clarification Forms	Copy	
11.6	Approved list of fields where self-evident corrections are to be allowed	Copy	
Section 12: Safety Information		**Principal Investigator**	**Present Y / N / n/a**
12.1	Serious Adverse Event forms and related correspondence	Original	
12.2	Notification by sponsor to investigators of new safety information	Copy	
Section 13: Trial Specific Working Instructions			
13.1	CRF Completion Guidelines	Copy	
13.2	SAE Handling Process Working Instructions	Copy	