WARWICK
MEDICAL SCHOOL

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

Investigator Site File Index

* denotes document should be retained according to MRC-GCP guidelines

Section 1: Reference Information			
1.1	Trial contacts and coordination details	Copy	
1.2	Trial Summary	Copy	
Section 2: Protocol		**Principal Investigator**	**Present** Y / N / n/a
2.1	Current approved protocol *Version number _9.0 Date: 20 Mar 2023*	Copy*	
2.2	Previous approved versions of protocol *Version number: _8.0 Date:* 22-Sep-2022 *Version number: _7.0 Date:* 25-Nov-2021 *Version number: _6.0 Date:* 26-Apr-2021 *Version number: __5.0 Date:* 02-Feb-2021 *Version number: __4.0_Date: 09-Oct- 2020* *Version number: __3.0__ Date: 12-Feb-2019* *Version number: __ 2.0__ Date: 27-Sep- 2018* *Version number: __ 1.2__ Date: 20-Oct-2017*	Copy* (if relevant to site)	
2.3	Version Log/Trial History Log	Copy	
2.4	Protocol deviation/non-compliance forms	Original	
Section 3: Information for Participants			
3.1	Current approved patient information sheets and consent forms *Version number: __7.0_ Date: __22-Sep-2022*	Copy*	
	Previous approved versions of patient information sheets and consent forms *Version number: _____ Date: _____* *Version number: _____ Date: _____* *Version number: _____ Date: _____*	Copy* (if relevant to site)	
3.2	Current approved consultee information sheet and declaration form *Version number: _7.0_ Date: __25-Nov-2022*		

	Previous approved versions of consultee information sheet and consultee declaration form *Version number: _____ Date: _____* *Version number: _____ Date: _____*		
3.3	Translations of Patient Information Sheets and Consent Forms	Copy	
3.4	Version Log	Copy	
3.5	Advertisements for patient recruitment and any amendments	Copy*	
3.6	Letter/information for a patient's GP/consultant	Copy	
3.7	Any other written information given to patients	Copy	
Section 4: Main Ethics		**Principal Investigator**	**Present** Y / N / n/a
4.1	HRA and REC approval for protocol and supporting documentation	Copy	
	REC committee composition	Copy	
4.2	HRA approval of protocol amendments	Copy (if relevant to site)	
Section 5: Individual Site Information and Approvals		**Principal Investigator**	**Present** Y / N / n/a
5.1	Feasibility Questionnaire/ Pre-trial monitoring report/letter	Copy	
5.2	Principal Investigator CV (signed and dated) CVs for other site staff (signed and dated)	Copy* Copy	
5.3	NHS Trust confirmation of Capacity and Capability to host the study	Copy	
5.4	Site Agreement	Copy	
5.5	Delegation and responsibilities signature log	Copy*	
5.6	Trial initiation monitoring report/letter Monitoring visit reports/letters Final Trial Close-Out Monitoring Report/letters	Original* Original* Original*	
5.7	Relevant communications (e.g. letters, meeting notes, notes of telephone calls)	Original*	
Section 6: Laboratory		**Principal Investigator**	**Present** Y / N / n/a
6.1	Blood sample labels	Original*	X2
6.2	Blank Research Blood Sample Request Form	Original	X25
Section 7: General Site Information		**Principal Investigator**	**Present** Y / N / n/a
7.1	SIV attendance log/New staff training log/GCP certificates or file note to document where certificates are filed	Original	
7.2	Study aids and promotional materials	Copy	
7.3	Newsletters	Copy	
Section 8: Data Collection		**Principal Investigator**	**Present** Y / N / n/a

8.1	Subject screening log/enrolment log	Original*	
8.2	Randomisation Confirmations		
8.3	Signed informed consent forms	Original*	
8.4	Source documents	Original	
8.5	Sample Case Report Form & amendments	Copy*	
8.6	Signed, dated and completed CRFs (Inc. SAEs)	Copy*	
8.7	Documentation of CRF corrections/Data Clarification Forms	Copy*	
Section 9: Safety Information		**Principal Investigator**	**Present** Y / N / n/a
9.1	Notification by sponsor to investigators of new safety information	Copy	
Section 10: Trial Specific Working Instructions			
10.1	Copies of trial specific Working Instructions	Copy	
10.2	Copies of Emergency Sampling Backup Flowcharts	Copy	
Section 11: Co-Enrolment			
11.1	Co-Enrolment	Copy	