Site Signature and Delegation Log

Site Name: _____ **Location:** _____

Please use the 'Trial Responsibilities Key' below to indicate which responsibilities have been agreed locally. Only members of the research team who are authorised by the Principal Investigator 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 ADAPT-Sepsis Trial Office immediately, to indicate who the responsibility has now been transferred to.

Trial Responsibility Key:

1	Overall responsibility for the trial at the site [a]	9	SAE attribution assessment and sign off SAE form [b]
2	Subject screening and selection	10	SAE reporting
3	Obtaining informed consent	11	Perform randomisation
4	Assisting in informed consent process	12	Sample collection, preparation and dispatch
5	Review eligibility and sign patient eligibility form	13	Receipt and dissemination of protocol advice
6	Medical care of patient	14	Investigator site file maintenance
7	CRF/eCRF completion, correction and return	15	Laboratory site file maintenance
8	Data query resolution and return	16	Laboratory lead*

Key: *a* = P.I. only
b = Medical doctor only

* The Laboratory lead is the member of the laboratory team who has taken on the role of oversight of the lab team involved in the ADAPT-Sepsis trial, tasks include nominating members of the team who will be working on the ADAPT-Sepsis trial and ensuring the members of the team have read & acknowledged the Lab Manual.

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://www.manchester.ac.uk/discover/privacy-information/data-protection/privacy-notices/

Site Signature and Delegation Log

Site Name: _____ **Location:** _____

Name	Trial role	Trial responsibilities	Signature	Initials	Date start in trial	Date stop in trial	PI signature & date #

Please make all entries in ink. Cross out errors with a single pen stroke and initial and date. Send original to the ADAPT-Sepsis office. File a copy in the Trial Site File.

 # PI declaration - I confirm that I take overall responsibility for the conduct of this study at the above site, and that the trial personnel listed above are authorised to perform trial responsibilities on my behalf as indicated, within the dates indicated. I confirm that they agree to take on these responsibilities and are qualified and appropriately informed about the trial.

Trial Responsibility Key:

Site Signature and Delegation Log

Site Name: _____ **Location:** _____

1	Overall responsibility for the trial at the site [a]	9	SAE attribution assessment and sign off SAE form [b]
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Key: *a* = P.I. only *b* = Medical doctor only

Site Signature and Delegation Log

Site Name: ____________________ **Location:** ____________________

Name:	**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 Research Nurse contact? ☐
Name:	**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? ☐
Name:	**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? ☐
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