

**Janis Best-Lane**  
Senior Clinical Trial Manager  
Room 1064  
10<sup>th</sup> Floor, QEQM  
St Mary's Hospital  
1 Praed Street  
London  
W2 1NY

15<sup>th</sup> December 2025

**IRAS Reference:** 1005848

Mobile: +44 (0)7714 051680  
Email: [j.best-lane@imperial.ac.uk](mailto:j.best-lane@imperial.ac.uk)  
Email: [septic@imperial.ac.uk](mailto:septic@imperial.ac.uk)

Dear REC,

**SepTiC Trial Amendment AM011 (Substantial SA03)**

We are writing to you regarding the submission of a non-substantial amendment for the SepTiC Trial.

1. We would like to add the following new sites and Principal Investigators:-
  - Morriston Hospital – PI Dr Rowenna Morris Clarke
  - Queen Elizabeth Hospital (Woolwich) - PI Dr Nicholas Beaumont
  - University Hospital Lewisham – PI Dr Nicholas Beaumont
  - Doncaster Royal Infirmary – PI Dr Ahijit Chowdhury
  - Princess Alexandra Hospital – Dr Khalid Abdelrahman
  - West Middlesex Hospital - Dr Theodora Christodouloupoulou
2. We would like to change the following site:-
  - Change site name from Queen Elizabeth Hospital Birmingham to University Hospitals Birmingham NHS Foundation Trust (PI remains the same as Dr Dhruv Parekh)
3. We would like to change the following Principal Investigator
  - Southampton General – change of PI from Dr Cusack to Prof. Kordo Saeed
4. We would like to make a slight amendment to our patient facing consent forms (full information sheet and consent form, the information sheet summary and consent form, the full retrospective information sheet and consent form and the retrospective information sheet summary and consent form. The change is to include an option for patients to 'tick' the consent boxes, as an alternative to including initials. As our population are admitted to ICU we have received feedback that most of these patients have a rather weak hand once they regain capacity and they would find ticking boxes easier than initialling each box. The requirement to print and sign their name still remains. If a patient does not agree to a consent statements they are instructed to mark an X in the relevant box.

UK\_SepTiC\_15122025\_SA03\_PIS\_Full\_v4.0\_Tracked

UK\_SepTiC\_15122025\_SA03\_PIS\_Full\_v4.0\_Clean

UK\_SepTiC\_15122025\_SA03\_PIS\_Sum\_v3.0\_Tracked

UK\_SepTiC\_15122025\_SA03\_PIS\_Sum\_v3.0\_Clean

UK\_SepTiC\_15122025\_SA03\_Retro\_Full\_v3.0\_Tracked

UK\_SepTiC\_15122025\_SA03\_Retro\_Full\_v3.0\_Clean

UK\_SepTiC\_15122025\_SA03\_Retro\_Sum\_v3.0\_Tracked

UK\_SepTiC\_15122025\_SA03\_Retro\_Sum\_v3.0\_Clean

5. The CI would like to stipulate that ACCPs (Advanced Critical Care Practitioners) are able to assess eligibility for patients in SepTiC for the Diagnostic and Fluid part of the trial only. Medically qualified doctors will continue to be able to assess eligibility of patients in all parts of the SepTiC Trial. The ACCPs must be adequately trained in GCP and the protocol and are listed on the delegation log. ACCPs are highly experienced and educated healthcare professionals who work within a critical care team, assessing, diagnosing, and managing critically ill patients. They provide a crucial level of advanced care by performing diagnostic and therapeutic procedures, managing patient care plans, and performing invasive interventions under a consultant-led service. Therefore, ACCPs are well suited to access eligibility of these patients. Overall oversight will still be maintained by the PI and is agreed by the CI and Sponsor.

Please do not hesitate to contact is if you require any further information.

Yours sincerely

Janis

**Janis Best-Lane**

Clinical Trial Manager

Imperial College London