

**London - City & East Research Ethics Committee**

Research Ethics Committee Centre  
2nd Floor  
2 Redman Place  
Stratford  
London  
E20 1JQ

02 December 2024

**Study title:** Sepsis Trials in Critical Care  
**REC reference:** 23/LO/0339  
**Protocol number:** A4-1- 22SM8039  
**Amendment number:** AM005  
**Amendment date:** 05 November 2024  
**IRAS project ID:** 1005848

The above amendment was reviewed by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Amendment Summary [AmendmentSummary]		14 November 2024
Annex 2: Notification of Amendment/Amendment tool [AM005 Amendment tool]	1.6	06 December 2021
Cover Letter [AM005 Cover Letter]	1.0	05 November 2024
Participant information and informed consent form [SepTiC PerLR Sum_v2.0 22.08.2023_Tracked_Typo]	2.0	22 August 2023
Participant information and informed consent form [SepTiC PerLR Sum v2.1 21.12.2023]	2.1	21 December 2023
REC Application Form [Ethics]		14 November 2024

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

## **Working with NHS Care Organisations**

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

## **Amendments related to COVID-19**

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

## **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

## **HRA Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

<b>IRAS Project ID - 1005848:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely

PP Kevin Ahmed, Approvals Manager

**Mr Stuart Chandler**  
**Chair**

E-mail: cityandeast.rec@hra.nhs.uk

*Enclosures:                      List of names and professions of members who took part in the review*

## London - City & East Research Ethics Committee

### Attendance at Sub-Committee of the REC meeting on 19 November 2024

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Stuart Chandler	Lead Pharmacist in Clinical Trials	Yes	
Dr Panagiotis Pentaris	Academic Lead for Research, Ethics and Compliance	Yes	