

London - City & East Research Ethics Committee

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

12 February 2024

Dear Professor Gordon

Study title: Sepsis Trials in Critical Care
REC reference: 23/LO/0339
Protocol number: A4-1- 22SM8039
Amendment number: AM001
Amendment date: 22 December 2023
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]		23 January 2024
Annex 2: Notification of Amendment/Amendment tool [SepTiC AM002 Amendment Tool]	1.6	22 December 2023
Cover Letter [SepTiC AM002 Cover Letter]	1.0	04 January 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/>

IRAS Project ID - 1005848:

Please quote this number on all correspondence

Yours sincerely

Dr John Keen
Chair

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

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

Copy to:

London - City & East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 13 February 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 John Keen	GP (REC Chairman)	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Chelsea Phillips	Approvals Administrator