

London - City & East Research Ethics Committee

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

**Please note: This is the
favourable opinion of the REC
only and does not allow the
amendment to be implemented
at NHS sites in England until
the outcome of the HRA
assessment has been
confirmed.**

02 February 2026

Professor Anthony Gordon
Imperial College
St Mary's Hospital, Praed Street
London
W2 1NY

Dear Professor Gordon,

Study title:	Sepsis Trials in Critical Care
REC reference:	23/LO/0339
Protocol number:	A4-1- 22SM8039
Amendment number:	AM011
Amendment date:	15 December 2025
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]		20 January 2026
Annex 2: Notification of Amendment/Amendment tool [SepTiC Amendment Tool AM011]	1.8	30 April 2025
Cover Letter [SepTiC AM011 Cover Letter]	1.0	15 December 2025
Participant information and informed consent form [SepTiC Retro Sum v3.0 15.12.2025_Tracked]	3.0	15 December 2025
Participant information and informed consent form [SepTiC Retro Sum v3.0 15.12.2025_Clean]	3.0	15 December 2025
Participant information and informed consent form [SepTiC Retro Full v3.0 15.12.2025_Tracked]	3.0	15 December 2025
Participant information and informed consent form [SepTiC Retro Full v3.0 15.12.2025_Clean]	3.0	15 December 2025
Participant information and informed consent form [SepTiC PIS Sum v3.0 15.12.2025_Tracked]	3.0	15 December 2025
Participant information and informed consent form [SepTiC PIS Sum v3.0 15.12.2025_Clean]	3.0	15 December 2025
Participant information and informed consent form [SepTiC PIS Full v4.0 15.12.2025_Tracked]	4.0	15 December 2025
Participant information and informed consent form [SepTiC PIS Full v4.0 15.12.2025_Clean]	4.0	15 December 2025
Project Information - PDF [ProjectStudyInformation]		20 January 2026
REC Application Form [Ethics]		20 January 2026

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,

PP Mrs Safia Awais, Approvals Administrator

**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

Copy to: *Rinat Ezra, Imperial College London*

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Attendance at Sub-Committee of the REC meeting on 02 February 2026

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	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Safia Awais	Approvals Administrator