

2nd Floor, Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

Enquiries to: Sriparna Pal
Email: sriparna.pal@nhslothian.scot.nhs.uk

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.

23 February 2024

Dr Alasdair Corfield
Consultant in Emergency Medicine
NHS Greater Glasgow and Clyde
Royal Alexandra Hospital
Corsebar Road
Paisley
PA2 9PN

Dear Dr Corfield,

Study title:	Early vasopressors in Sepsis
REC reference:	22/SS/0009
Protocol number:	GN20AE342
EudraCT number:	2021-006886-39
Amendment number:	Substantial Amendment 08
Amendment date:	14 February 2024
IRAS project ID:	307862

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.

The Sub-Committee had no ethical concerns regarding the amendment.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [307862_Substantial Amendment 08_]	v1.6	14 February 2024
Interview schedules or topic guides for participants [EVIS Interview Guide_V1.0; 14.02.24]	V1.0	14 February 2024
Participant consent form [EVIS CF_V1.0; 14.02.24]	V1.0	14 February 2024
Participant consent form [EVIS PIS ICF Personal Legal Rep (Eng, Wales & NI) V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Personal Legal Rep (Eng, Wales & NI) V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Prof Legal Rep (Eng, Wales, NI) V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Prof Legal Rep (Eng, Wales, NI) V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Prof Legal Rep (Scotland) V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Prof Legal Rep (Scotland) V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Recovered Capacity (Eng, Wales & NI) V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Recovered Capacity (Eng, Wales & NI) V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Recovered Capacity (Scotland) V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF Recovered Capacity (Scotland) V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024

Participant consent form [EVIS PIS ICF V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF WA & Guardian (Scotland) V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024
Participant consent form [EVIS PIS ICF WA & Guardian (Scotland) V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant information sheet (PIS) [EVIS PIS Summary V3.0 - 14.02.24 CLEAN]	V3.0	14 February 2024
Participant information sheet (PIS) [EVIS PIS Summary V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Participant information sheet (PIS) [EVIS PIS_V1.0; 14.02.24]	V1.0	14 February 2024
Research protocol or project proposal [EVIS Protocol V3.0 - 14.02.24 CLEAN FINAL]	V3.0	14 February 2024
Research protocol or project proposal [EVIS Protocol V3.0 - 14.02.24 TC FINAL]	V3.0	14 February 2024
Schedule of Events or SoECAT [EVIS Protocol V3.0 14 Feb 24 Schedule of Assessments]	V3.0	14 February 2024
Summary, synopsis or diagram (flowchart) of protocol in non technical language [EVIS Summary of Protocol Changes V3.0 to V2.1 14 Feb 24]	V3.0 to V2.1	14 February 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

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

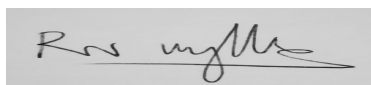
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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 - 307862:	Please quote this number on all correspondence
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Yours sincerely,

A handwritten signature in black ink, appearing to read 'Rob Wyllie', on a light grey rectangular background.

Mr Robert Wyllie
Chair

E-mail: Sriparna.Pal@nhslothian.scot.nhs.uk

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

Copy to: *Dr Pamela Sandu*

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 16 February 2024

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Jill Bradshaw	Professor of Communication in Intellectual and Developmental Disabilities/Consultant Speech & Language Therapist	Yes	
Professor Brian McKinstry	Retired GP/Director Scottish Health Research Register	Yes	
Dr Angela Ning	Retired Project Director (Clintec Ltd now IQVIA)	Yes	
Mr Robert Wyllie	Policy Adviser	Yes	In the Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Manx Neill	Scotland A/B REC Manager
Mrs Sriparna Pal	Administrative Assistant-Scotland A REC