Scotland A Research Ethics Committee

South East Scotland Research Ethics Service

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

Enquiries to: Sriparna Pal
Email: Sriparna.Pal@nhs.scot

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.

15 January 2025

Dr Alasdair Corfield
NHS Greater Glasgow & Clyde
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:	**SA_09**
Amendment date:	**13 December 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.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Annex 1: Clinical Trial Application Form [EVIS_CTA_MhraProductsForm_snapshot]	12_12_24	12 December 2024
Completed Amendment Tool [307862_SA_09_13Dec2024_Locked19Dec24_141613]	V1.6	13 December 2024
Cover Letter [EVIS REC Cover Letter - SA09 - 09.12.2024]	SA09	09 December 2024
Cover Letter [EVIS MHRA Cover Letter - SA09 - 09.12.24]	SA09	09 December 2024
Interview schedules or topic guides for participants [EVIS Sub-Study Interview Guide_V2.0; 09.12.24 CLEAN FINAL]	V2.0	09 December 2024
Interview schedules or topic guides for participants [EVIS Sub-Study Interview Guide_V2.0; 09.12.24 TC FINAL]	V2.0	09 December 2024
Letter from funder [13.08.24 - HTA Contract Variation Request Outcome]	13.08.24	13 August 2024
Other [EVIS Clinical Information Sheet USUAL CARE]	V5.0	05 December 2024
Other [EVIS Clinical Information Sheet INTERVENTION]	V4.0	05 December 2024
Other [EVIS Clinical Information Sheet INTERVENTION v4.0 05.12.2024 TC]	v4.0	05 December 2024
Other [EVIS Clinical Information Sheet USUAL CARE V5.0 05.12.2024 TC]	v5.0	05 December 2024
Participant consent form [EVIS Sub-Study CF_V2.0; 09.12.24 CLEAN FINAL]	V2.0	09 December 2024
Participant consent form [EVIS Sub-Study CF_V2.0; 09.12.24 TC FINAL]	V2.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland) V4.0 - 09.12.24 TC]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (Eng, Wales & NI) V4.0 - 09.12.24 CLEAN]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (Eng, Wales & NI) V4.0 - 09.12.24 TC]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Eng, Wales, NI) V4.0 - 09.12.24 CLEAN FINAL]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Eng, Wales, NI) V4.0 - 09.12.24 TC FINAL]	V4.0	09 December 2024

Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Scotland) V4.0 - 09.12.24 CLEAN]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Eng, Wales & NI) V4.0 - 09.12.24 CLEAN]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Eng, Wales & NI) V4.0 - 09.12.24 TC]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland) V4.0 - 09.12.24 CLEAN]	V4.0	09 December 2024
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Participant information sheet (PIS) [EVIS PIS ICF V4.0 - 09.12.24 CLEAN FINAL]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF V4.0 - 09.12.24 TC FINAL]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS Summary V4.0 - 09.12.24 CLEAN FINAL]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS Summary V4.0 - 09.12.24 TC FINAL]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF WA & Guardian (Scotland) V4.0 - 09.12.24 CLEAN]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS PIS ICF WA & Guardian (Scotland) V4.0 - 09.12.24 TC]	V4.0	09 December 2024
Participant information sheet (PIS) [EVIS Sub-Study PIS_V2.0; 09.12.24 TC FINAL]	V2.0	09 December 2024
Participant information sheet (PIS) [EVIS Sub-Study PIS_V2.0; 09.12.24 CLEAN FINAL]	V2.0	09 December 2024
Research protocol or project proposal [EVIS Protocol V4.0 - 09.12.24 CLEAN FINAL]	V4.0	09 December 2024
Research protocol or project proposal [EVIS Protocol V4.0 - 09.12.24 TC FINAL]	V4.0	09 December 2024
Study Design [Justification for EVIS Change to the Primary Outcome V1.0 09.12.24]	V1.0	09 December 2024
Summary, synopsis or diagram (flowchart) of protocol in non technical language [EVIS Protocol V4.0 09 Dec 24 Schedule of Assessments]	V4.0	09 December 2024
Summary, synopsis or diagram (flowchart) of protocol in non technical language [EVIS Summary of Protocol Changes V4.0 to V3.0 09 Dec 24]	V4.0	09 December 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.

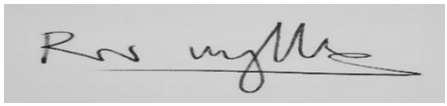
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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**

Yours sincerely,



Mr Robert Wyllie
Chair

E-mail: sriparna.pal@nhs.scot

Enclosures:	*List of names and professions of members who took part in the review*
Copy to:	*Dr Alasdair Corfield, NHS Greater Glasgow and Clyde* *Dr Pamela Sandu*

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 03 January 2025

Committee Members:

Name	*Profession*	*Present*	*Notes*
Miss Julia P. D Anderson	Medical Student (U of E Medical School)	Yes	
Miss Josephine Dewhurst	Director, Centre for Paediatric Clinical Development	Yes	
Dr Jessica MacLaren	Registered Nurse-Lecturer in Mental Health	Yes	
Dr Maria Truesdale	Senior Lecturer in Intellectual Disabilities	Yes	
Mr Robert Wyllie	Policy Adviser	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Sriparna Pal	Administrative Assistant-Scotland A REC

NHS
Lothian