Scotland A Research Ethics Committee

South East Scotland Research Ethics Service

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Edinburgh
EH1 3EG

Enquiries to: Sriparna Pal
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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 November 2023

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 07**
Amendment date:	**10 October 2023**
IRAS project ID:	**307862**

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

NHS
Lothian

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:

Document	*Version*	*Date*
Completed Amendment Tool [307862_Substantial Amendment 07_locked]	SA07	10 October 2023
Other [EVIS Protocol V2.1 10 Oct 2023 Schedule of Assessments]	V2.1	10 October 2023
Other [SWB EVIS Clinical Information Sheet INTERVENTION]	V1.0	10 October 2023
Other [EVIS Clinical Information Sheet USUAL CARE]	V4.0	10 October 2023
Participant consent form [EVIS PIS ICF Personal Legal Rep (England, Wales & NI) v2.1 10.10.23 CLEAN FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF Personal Legal Rep (England, Wales & NI) v2.1 10.10.23 TC FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF Prof Legal Rep (England, Wales, NI) v2.1 10.10.23 CLEAN FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF Prof Legal Rep (England, Wales, NI) v2.1 10.10.23 TC FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF Prof Legal Rep (Scotland) v2.1 10.10.23 CLEAN FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF Prof Legal Rep (Scotland) v2.1 10.10.23 TC FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF v2.1 10.10.23 CLEAN FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF v2.1 10.10.23 TC FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF WA & Guardian (Scotland) v2.1 10.10.23 CLEAN FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS ICF WA & Guardian (Scotland) v2.1 10.10.23 TC FINAL]	V2.1	10 October 2023

Participant consent form [EVIS PIS Summary v2.1 10.10.23 CLEAN FINAL]	V2.1	10 October 2023
Participant consent form [EVIS PIS Summary v2.1 10.10.23 TC FINAL]	V2.1	10 October 2023
Research protocol or project proposal [EVIS Protocol V2.1 - 10.10.2023 CLEAN FINAL]	V2.1	10 October 2023
Research protocol or project proposal [EVIS Protocol V2.1 - 10.10.2023 TC FINAL]	V2.1	10 October 2023
Summary, synopsis or diagram (flowchart) of protocol in non technical language [EVIS Summary of Protocol Changes V2.1 to V2.0 10 Oct 23]	V2.1	10 October 2023

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.

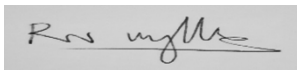
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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@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 27 October 2023

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Jessica MacLaren	Registered Nurse-Lecturer in Mental Health	Yes	
Dr Lindsay Ramage	Director of Policy, Systems & Performance, Research & Innovation Services	Yes	
Mr Robert Wyllie	Policy Adviser	Yes	

Also in attendance:

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