

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.

Enquiries to: Ruth Fraser
Email: ruth.fraser4@nhslothian.scot.nhs.uk

11 May 2022

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: AM01 (your Substantial Amendment 01)
Amendment date: 26 April 2022
IRAS project ID: 307862

The above amendment was reviewed 04 May 2022 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
Completed Amendment Tool [EVIS SA01 Amendment Tool]	1.0	26 April 2022
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [MHRA Approval]	1.0	31 March 2022
Confirmation of Clinical Trial Authorisation from MHRA and relevant correspondence [CTA Notice of non acceptance]	1.0	02 March 2022
Cover Letter [EVIS Cover letter]	1.0	26 April 2022
GP/consultant information sheets or letters [EVIS Clinical Information sheet Intervention]	1.0	26 April 2022
GP/consultant information sheets or letters [EVIS Clinical Information Sheet Usual Care]	1.0	26 April 2022

Other [EVIS Sponsor Confirmation]	1.0	26 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (England Wales NI)]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (England Wales NI) TC]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (England, Wales NI)]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Scotland) TC]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Scotland)]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (England, Wales NI)]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (England, Wales NI) TC]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland) TC]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (England, Wales NI)]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Summary TC]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Summary]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland)]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF TC]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS ICF]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS Welfare Attorney/Welfare Guardian/Nearest Relative (Scotland) TC]	1.2	25 April 2022
Participant information sheet (PIS) [EVIS PIS Welfare Attorney/Welfare Guardian/Nearest Relative (Scotland)]	1.2	25 April 2022
Research protocol or project proposal [EVIS Protocol TC]	1.2	15 March 2022
Research protocol or project proposal [EVIS Protocol]	1.2	15 March 2022
Research protocol or project proposal [EVIS Summary of Protocol Changes]	1.1	15 March 2022

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

A handwritten signature in black ink, appearing to read 'Mary-Joan Macleod', with a long horizontal flourish extending to the right.

Dr Mary-Joan Macleod
Chair

E-mail: ruth.fraser4@nhslothian.scot.nhs.uk

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

Copy to: *Pamela Sandu*

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 04 May 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Mary-Joan Macleod	Clinical Pharmacologist/Consultant Physician	Yes	
Dr Anthony Pottage	Retired Physician/Clinical Pharmacologist	Yes	
Dr Charles Wallis	Consultant in Anaesthesia & Intensive Care	Yes	

Also in attendance:

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