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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.**

18 January 2023

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

Dear Dr Corfield,

<b>Study title:</b>	<b>Early vasopressors in Sepsis</b>
<b>REC reference:</b>	<b>22/SS/0009</b>
<b>Protocol number:</b>	<b>GN20AE342</b>
<b>EudraCT number:</b>	<b>2021-006886-39</b>
<b>Amendment number:</b>	<b>Substantial Amendment 05</b>
<b>Amendment date:</b>	<b>20 December 2022</b>
<b>IRAS project ID:</b>	<b>307862</b>

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 amendments.

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 1: Clinical Trial Application Form [EVIS CTA MhraProductsForm_ReadyForSubmission_20_12_22]	IRAS Version 6.3.3 - 20/12/2022	20 December 2022
Completed Amendment Tool [EVIS Locked Tool 307862_Substantial Amendment 05_]	v1.6	20 December 2022
Cover Letter [EVIS REC Cover Letter - SA05 - 21.12.2022]	SA05	21 December 2022
IRAS Application Form [IRASForm_20_12_22]	20/12/2022	20 December 2022
Other [EVIS Clinical Information Sheet INTERVENTION v3.0 20.12.2022]	v3.0	20 December 2022
Other [EVIS Clinical Information Sheet USUAL CARE v3.0 20.12.2022]	V3.0	20 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (England, Wales & NI) v2.0 16 Dec 22 Clean]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (England, Wales & NI) v2.0 16 Dec 22 TC]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (England, Wales, NI) v2.0 16 Dec 22 Clean]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (England, Wales, NI) v2.0 16 Dec 22 TC]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Scotland) v2.0 16 Dec 22 Clean]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Scotland) v2.0 16 Dec 22 TC]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (England, Wales NI) v2.0 16 Dec 22 Clean]	v2.0	16 December 2022

Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (England, Wales NI) v2.0 16 Dec 22 TC]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland) v2.0 16 Dec 22 Clean]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland) v2.0 16 Dec 22 TC]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Summary v2.0 16 Dec 22 Clean]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Summary v2.0 16 Dec 22 TC]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF v2.0 16 Dec 22 Clean]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF v2.0 16 Dec 22 TC]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Welfare Attorney Welfare Guardian (Scotland) Clean]	v2.0	16 December 2022
Participant information sheet (PIS) [EVIS PIS ICF Welfare Attorney Welfare Guardian (Scotland) TC]	v2.0	16 December 2022
Research protocol or project proposal [EVIS Protocol V2.0 16 Dec 22 Final Clean]	V2.0	16 December 2022
Research protocol or project proposal [EVIS Protocol V2.0 16 Dec 22 Final TC]	v2.0	16 December 2022
Summary, synopsis or diagram (flowchart) of protocol in non technical language [EVIS Summary of Protocol Changes V1.3 to V2.0 16 Dec 22]	V1.3 to V2.0	16 December 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/>

<b>IRAS Project ID - 307862:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely,

A handwritten signature in black ink, appearing to be 'Mary-Joan Macleod', written in a cursive style.

**Dr Mary-Joan Macleod**  
**Chair**

E-mail: [Sriparna.Pal@nhslothian.scot.nhs.uk](mailto: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 13 January 2023

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Mary-Joan Macleod	Clinical Pharmacologist/Consultant Physician	Yes	
Dr Lindsay Ramage	Head Of Research Governance	Yes	
Dr Charles Wallis	Consultant in Anaesthesia & Intensive Care	Yes	

#### Also in attendance:

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