

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.

04 March 2025

Dr Alasdair Corfield
NHS Greater Glasgow & Clyde
Corsebar Road
Paisley
PA2 9PN

Dear Dr Corfield,

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|--------------------------|-------------------------------------|
| Study title: | Early vasopressors in Sepsis |
| REC reference: | 22/SS/0009 |
| Protocol number: | GN20AE342 |
| EudraCT number: | 2021-006886-39 |
| Amendment number: | SA_10 |
| Amendment date: | 13 February 2025 |
| IRAS project ID: | 307862 |

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

Ethical opinion

The Sub-Committee reviewed the amendment and raised concerns regarding the GP letter's lack of REC approval details, uncertainty over audio recording retention, missing independent contact on the Evis Sub Study PIS, and a minor grammatical issue on page 4 of the Evis PIS WA & Guardian Document.

Headquarters
Waverley Gate
2-4 Waterloo Place
Edinburgh EH1 3EG

Chair Professor John Connaghan CBE
Chief Executive Professor Caroline Hiscox
Lothian NHS Board is the common name of Lothian Health Board

The applicant addressed the concerns by explaining that the specific REC reference was removed from the GP letter as it is already included in the PIS. Regarding audio recording retention, NHS GG&C Governance confirmed it must be kept alongside transcriptions for audit purposes in case of MHRA inspection, which was previously approved in the EVIS PIS and protocol submitted in SA09.

The independent contact name has also been included in the Sub-Study PIS.

The applicant requested that the minor grammatical issues be corrected and submitted in the next substantial amendment.

The Sub-Committee was satisfied with the response.

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 further 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_SA_10_13Feb2025_Locked14Feb25] | SA10 | 13 February 2025 |
| Cover Letter [EVIS REC Cover Letter - SA10 - 13.02.2025] | SA10 | 13 February 2025 |
| GP/consultant information sheets or letters [EVIS GP Letter V2.0 03.02.25 CLEAN FINAL] | V2.0 | 03 February 2025 |
| GP/consultant information sheets or letters [EVIS GP Letter V2.0 03.02.25 TC FINAL] | V2.0 | 03 February 2025 |
| Participant consent form [EVIS Sub-Study CF_V4.0; 03.03.25 TC FINAL] | V4.0 | 03 March 2025 |
| Participant consent form [EVIS Sub-Study CF_V4.0; 03.03.25 CLEAN FINAL] | V4.0 | 03 March 2025 |
| Participant information sheet (PIS) [EVIS PIS ICF WA & Guardian (Scotland) V5.0 - 09.01.25 CLEAN] | V5.0 | 09 January 2025 |
| Participant information sheet (PIS) [EVIS PIS ICF WA & Guardian (Scotland) V5.0 - 09.01.25 TC] | V5.0 | 09 January 2025 |
| Participant information sheet (PIS) [EVIS PIS Summary V5.0 - 09.01.25 TC FINAL] | V5.0 | 09 January 2025 |

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| Participant information sheet (PIS) [EVIS PIS ICF V5.0 - 09.01.25 CLEAN FINAL] | V5.0 | 09 January 2025 |
| Participant information sheet (PIS) [EVIS PIS ICF Personal Legal Rep (Eng, Wales & NI) V5.0 - 09.01.25 TC] | V5.0 | 09 January 2025 |
| Participant information sheet (PIS) [EVIS PIS ICF Prof Legal Rep (Eng, Wales, NI) V5.0 - 09.01.25 CLEAN] | V5.0 | 09 January 2025 |
| Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland) V5.0 - 09.01.25 TC] | V5.0 | 09 January 2025 |
| Participant information sheet (PIS) [EVIS PIS ICF Recovered Capacity (Scotland) V5.0 - 09.01.25 CLEAN] | V5.0 | 09 January 2025 |
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| Participant information sheet (PIS) [EVIS Sub-Study PIS_V4.0; 03.03.25 TC FINAL] | V4.0 | 03 March 2025 |
| Participant information sheet (PIS) [EVIS Sub-Study PIS_V4.0; 03.03.25 CLEAN FINAL] | V4.0 | 03 March 2025 |
| Research protocol or project proposal [EVIS Protocol V5.0 13 Feb 25 Schedule of Assessments] | V5.0 | 13 February 2025 |
| Research protocol or project proposal [EVIS Protocol V5.0 - 13.02.25 CLEAN FINAL] | V5.0 | 13 February 2025 |
| Research protocol or project proposal [EVIS Protocol V5.0 - 13.02.25 TC FINAL] | V5.0 | 13 February 2025 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [EVIS Summary of Protocol Changes V5.0 to V4.0 13 Feb 25] | V5.0 | 13 February 2025 |

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/>

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| IRAS Project ID - 307862: | Please quote this number on all correspondence |
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Yours sincerely,



Professor Jill Bradshaw
Chair

E-mail: Sriparna.Pal@nhs.scot

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

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 20 February 2025

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|-------------------------|---|----------------|--------------|
| Professor Jill Bradshaw | Professor of Communication, Health and Social Care/Consultant Speech and Language Therapist | Yes | |
| Mrs Anne Forster | Retired Product Development Manager (Standard Life) | Yes | |
| Mr Robert Wyllie | Policy Adviser | Yes | |

Also in attendance:

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

