Health Research Authority

East of England - Cambridge South Research Ethics Committee

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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.

09 November 2021

Dr David Inwald
Consultant in Paediatric Intensive Care
Cambridge University Hospitals NHS Trust
PICU
Addenbrooke's Hospital
Cambridge
CB2 0QQ

Dear Dr Inwald

Study title:	**PRESSURE: PRotocolised Evaluation of permiSSive blood pressure targets versus Usual caRE. Evaluating the clinical and cost effectiveness of using a permissive blood pressure target to guide titration of vasoactive drugs in critically ill children with hypotension.**
REC reference:	**21/EE/0084**
Protocol number:	**A095842**
Amendment number:	**Substantial Amendment 1**
Amendment date:	**30 September 2021**
IRAS project ID:	**289545**

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*
Completed Amendment Tool [PRESSURE 289545_Substantial Amendment 1]	1.5	30 September 2021
Research protocol or project proposal [PRESSURE Protocol V3.1_28 October 2021_tracked changes]	V3.1	28 October 2021
Research protocol or project proposal [PRESSURE Protocol V3.1_28 October 2021]	V3.1	28 October 2021

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

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/

Yours sincerely

Dr Leslie Gelling
Chair

E-mail: cambridgesouth.rec@hra.nhs.uk

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

Copy to: *Ms Alanna Brown, ICNARC*

East of England - Cambridge South Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 25 October 2021

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Emma Louise Cannon	Pharmacist	Yes	
Dr Leslie Gelling	Principal Academic in Adult Nursing	Yes	Chair

Also, in attendance:

Name	*Position (or reason for attending)*
Miss Aoife Harrington	Approvals Administrator
Sarah Ferry	Approvals Administrator