

South Central - Oxford C Research Ethics Committee

Health Research Authority (Bristol)
Ground Floor, Temple Quay House, 2 The Square
BS1 6PN

17 January 2022

Prof Gavin Perkins
Professor in Critical Care Medicine
University of Warwick
Gibbet Hill Road
Coventry
CV4 7AL

Dear Prof Perkins

Study title: Pre-hospital RANdomised trial of MEDICATION route in out-of-hospital cardiac arrest (PARAMEDIC3)
REC reference: 21/SC/0178
Protocol number: SOC.20/20-21
Amendment number: Substantial Amendment One
Amendment date: 29 November 2021
IRAS project ID: 298182

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [298182 Substantial Amendment One Amendment Tool]	V1.0	29 November 2021
Covering letter on headed paper [PARAMEDIC3_REC Letter_19Nov21]	V1.0	19 November 2021
Other [Letter to relatives of enrolled nonsurvivors_v1.0_22 Oct 2021]	V1.0	22 October 2021
Research protocol or project proposal [Paramedic3 Protocol TC]	3.0	23 November 2021
Research protocol or project proposal [PARAMEDIC3 Protocol V3.0 23Nov21]	V3.0	23 November 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/>

IRAS Project ID - 298182:

Please quote this number on all correspondence

Yours sincerely



**Dr Linda Cartwright
Vice Chair**

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

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

Copy to: Mrs Carole Harris Confidentiality Advise Team

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Attendance at Sub-Committee of the REC meeting on 24 December 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Linda Cartwright	Retired Consultant Epidemiologist	Yes	Vice Chair
Dr Pamela Ross	GP Principal	Yes	
Dr David Scott	Lecturer	Yes	
Mr Ioan Wigley	Regulatory Affairs Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Simon Fisher	Approvals Administrator