

South Central - Berkshire B Research Ethics Committee

Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT

Tel: 0207 104 8204

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.

16 November 2016

Dr S R Moonesinghe Anaesthetics Department, Podium 3, Maple Link Corridor University College Hospital, 235 Euston Road London NW1 2BU

Dear Dr Moonesinghe

Study title: The Second UK Sprint National Anaesthesia Project:

Epidemiology of Critical Care provision after Surgery

REC reference: 16/SC/0349

Amendment number: 1.5

Amendment date: 26 October 2016

IRAS project ID: 154486

The above amendment was reviewed at the meeting of the Sub-Committee held on 15 November 2016 via 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
Copies of advertisement materials for research participants [Appendix 7 - PatientPoster v1.0 20160928]	1.0	28 September 2016
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission]	1.5	26 October 2016
Other [Summary of amendments v.1.0 20161024]	1.0	24 October 2016
Other [Appendix 1 - CRF main EPICCS v1.0 20160916 - Tracked Changes]	1.0	16 September 2016
Research protocol or project proposal [EPICCS Protocol v1.5 20160928]	1.5	28 September 2016
Research protocol or project proposal [EPICCS Protocol v1.5 20160928 - Tracked Changes]	1.5	28 September 2016

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.

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.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/SC/0349:

Please quote this number on all correspondence

Yours sincerely

Ms Helen Sivey REC Assistant

pp. Mr Mike Arnott Chair

E-mail: nrescommittee.southcentral-berkshireb@nhs.net

South Central - Berkshire B Research Ethics Committee Attendance at Sub-Committee of the REC meeting on 15 November 2016

Committee Members:

Name	Profession	Present	Notes
Mr Mike Arnott (Chair)	Research Consultant	Yes	
Miss Elena Villarreal	Clinical Trial Manager	Yes	

Also in attendance:

Name	Position (or reason for attending)
Ms Helen Sivey	REC Assistant