



Health Research Authority

South Central - Berkshire B Research Ethics Committee

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

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.

13 February 2017

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:	1.6
Amendment date:	02 February 2017
IRAS project ID:	154486

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 reviewed the following amendment:

1. Removal of a sub-study (the Quality of Recovery sub-study) from the protocol.
2. Minor changes to the dataset/questionnaires to make them more concise and more straightforward to complete.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Appendix 7 - PatientPoster v1.1 20170201 ChangesTracked.docx]	1.1	01 February 2017
Copies of advertisement materials for research participants [Appendix 7 - PatientPoster v1.1 20170201.docx]	1.1	01 February 2017
Interview schedules or topic guides for participants [Appendix 6 - QoR Telephone Interview Script v0.3 20170201 ChangesTracked.docx]	0.3	01 February 2017
Interview schedules or topic guides for participants [Appendix 6 - QoR Telephone Interview Script v0.3 20170201.docx]	0.3	01 February 2017
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission_20170203.pdf]	1.6	02 February 2017
Other [Appendix 1 - CRF main EPICCS v1.2 20170201.docx]	1.2	01 February 2017
Other [Appendix 1 - CRF main EPICCS v1.2 20170201 ChangesTracked.docx]	1.2	01 February 2017
Participant information sheet (PIS) [Appendix 2 - QoR CRF v1.0 20170201 ChangesTracked.docx]	1.0	01 February 2017
Participant information sheet (PIS) [Appendix 3 - OccupancyCRF v0.9 20170201 ChangesTracked.docx]	0.9	01 February 2017
Participant information sheet (PIS) [Appendix 2 - QoR CRF v1.0 20170201.docx]	1.0	01 February 2017
Participant information sheet (PIS) [Appendix 3 - OccupancyCRF v0.9 20170201.docx]	0.9	01 February 2017
Participant information sheet (PIS) [Appendix 4 - ClinicianPerceptionCRF v1.0 20170201 ChangesTracked.docx]	1.0	01 February 2017
Participant information sheet (PIS) [Appendix 4 - ClinicianPerceptionCRF v1.0 20170201.docx]	1.0	01 February 2017
Participant information sheet (PIS) [Appendix 5 - StudyPIS v0.7 20170201 ChangesTracked.docx]	0.7	01 February 2017
Participant information sheet (PIS) [Appendix 5 - StudyPIS v0.7 20170201.docx]	0.7	01 February 2017
Research protocol or project proposal [EPICCS Protocol v1.6 20170202 ChangesTracked.docx]	1.6	02 February 2017
Research protocol or project proposal [EPICCS Protocol v1.6 20170202.docx]	1.6	02 February 2017

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 Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

16/SC/0349:	Please quote this number on all correspondence
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Yours sincerely

PP. *L Roberts.*

Dr John Sheridan
Chair

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

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

Copy to: Ms Suzanne Emerton, University College London

South Central - Berkshire B Research Ethics Committee

Attendance at Sub-Committee of the REC meeting via correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr John Sheridan	Consultant Toxicologist and Chemist	Yes	
Miss Elena Villarreal	Clinical Trial Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Lucy Roberts	REC Manager