

Dr Sudhin Thayyil
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West of Scotland REC 5

West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
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Date 24 August 2018

Direct line 0141 232 1804
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Dear Dr Thayyil

Study title: Optimal duration of Cooling therapy in Mild Encephalopathy (COMET 1)
REC reference: 18/WS/0087
Amendment number: 2
Amendment date: 06 August 2018
IRAS project ID: 241031

Summary of Amendment: The amount of blood to be collected at 6 and 80 hours after randomization is increased to 1 ml from 0.5 ml. The protocol, information sheet, and consent forms have been updated to reflect this change.

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>
Notice of Substantial Amendment (non-CTIMP)	2	06 August 2018
Participant consent form [Clean]	1.3	06 August 2018
Participant consent form [Tracked]	1.3	06 August 2018
Participant consent form [Telephone Clean]	1.3	06 August 2018
Participant consent form [Telephone Tracked]	1.3	06 August 2018
Participant information sheet (PIS) [Clean]	1.3	06 August 2018
Participant information sheet (PIS) [Tracked]	1.3	06 August 2018
Participant information sheet (PIS) [Short Clean]	1.3	06 August 2018

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant information sheet (PIS) [Short Tracked]	1.3	06 August 2018
Research protocol or project proposal [Clean]	1.3	06 August 2018
Research protocol or project proposal [Tracked]	1.3	06 August 2018

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/>

18/WS/0087:	Please quote this number on all correspondence
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Yours sincerely

R Golbcher

On behalf of
Mrs Naomi Campbell
Alternate Vice Chair

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

Copy to: *Mrs Becky Ward, Imperial College London*

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Attendance at Sub-Committee In Correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Naomi Hickey	Research Nurse (Alternate Vice-Chair)	Yes	
Dr Chikkanayakanahalli (Manju) Manjunatha	Consultant Neonatologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Rose Gallacher	Assistant Co-ordinator