

East of England - Cambridge South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

27 February 2020

Dear Dr Ramnarayan

Study title: FIRST-line support for Assistance in Breathing in Children (FIRST-ABC): A master protocol of two randomised trials to evaluate the non-inferiority of high flow nasal cannula (HFNC) versus continuous positive airway pressure (CPAP) for non-invasive respiratory support in paediatric critical care

REC reference: 19/EE/0185

Protocol number: 1.0

Amendment number: 1

Amendment date: 06 February 2020

IRAS project ID: 260536

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>
Covering letter on headed paper		31 January 2020
Non-validated questionnaire [Health services questionnaire]	2	21 January 2020
Non-validated questionnaire [PedsQL 2-4 years]	1	16 December 2019
Non-validated questionnaire [PedsQL 5-7 years]	1	16 December 2019
Non-validated questionnaire [PedsQL 8-12 years]	1	16 December 2019
Non-validated questionnaire [PedsQL 13-18 years]	1	16 December 2019
Notice of Substantial Amendment (non-CTIMP)	1	06 February 2020
Research protocol or project proposal [Master Protocol]	1.2	23 January 2020

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.

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/>

19/EE/0185: Please quote this number on all correspondence

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: Dr Padmanabhan Ramnarayan, Children's Acute Transport Service
Dr Jenny Rivers*

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Attendance at Sub-Committee of the REC meeting on 24 February 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Leslie Gelling	Principal Academic in Adult Nursing	Yes	
Mrs Alison Hall	Programme Lead - Humanities	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Chelsea Phillips	Approvals Administrator