Health Research Authority

East of England - Cambridge South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

26 July 2019

Dr Padmanabhan Ramnarayan
Consultant in Paediatric Intensive Care & Retrieval
Great Ormond Street Hospital for Children NHS Foundation Trust
Children's Acute Transport Service
26-27 Boswell Street
London
WC1N 3JZ

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**
IRAS project ID:	**260536**

Thank you for your letter of 26 June 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and another member of the Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

- The Committee commented that they had some concerns about the proposed approach to recruitment but as the applicants were trying to minimise the possibility of causing additional upset to parents it was agreed that the application should be offered a favourable opinion. The Committee hoped the applicants would maintain careful oversight of the process and would inform the Committee if any issues arose.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that all clinical trials are registered on a publicly accessible database. For this purpose, clinical trials are defined as the first four project categories in IRAS project filter question 2. For clinical trials of investigational medicinal products (CTIMPs), other than adult phase I trials, registration is a legal requirement.

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Ethics re-submission cover letter]		24 June 2019
IRAS Application Form [IRAS_Form_26062019]		26 June 2019
IRAS Checklist XML [Checklist_03052019]		03 May 2019
Letter from funder [Letter from funder]		18 December 2018
Letters of invitation to participant [Enrolment Covering Letter (1)]	1.0	22 March 2019
Letters of invitation to participant [Enrolment Follow-up Covering Letter (2)]	1.0	22 March 2019
Letters of invitation to participant [Bereaved-Enrolment Covering Letter (1)]	1.0	22 March 2019
Letters of invitation to participant [Bereaved-Enrolment Follow-Up Covering Letter (2)]	1.0	22 March 2019
Non-validated questionnaire [Health Services Questionnaire (HSQ)]	1.0	22 March 2019

Other [Assent Form]	1.0	22 March 2019
Other [Newsletter]	1.0	22 March 2019
Other [Family Room Poster]	1.0	22 March 2019
Other [Follow-Up Email]	1.0	22 March 2019
Other [Follow-up Letter]	1.0	22 March 2019
Other [Participant Information Leaflet (Parents or Guardians)]	1.1	18 June 2019
Other [FIRST-ABC Master Protocol tracked]	1.1	24 June 2019
Other [Participant Information Leaflet (Parents or Guardians) tracked]	1.1	18 June 2019
Other [Harron 2015]		
Other [O'Hara 2017]		
Other [Peters 2019]		
Participant consent form [Consent Form (Parent or Guardian)]	1.1	18 June 2019
Participant consent form [Consent form (Parent or Guardian) tracked]	1.1	18 June 2019
Participant consent form [Bereaved-Consent Form]	1.1	18 June 2019
Participant consent form [Bereaved-Consent Form (Parents or Guardians) tracked]	1.1	18 June 2019
Participant consent form [Postal Consent Form]	1.0	18 June 2019
Participant information sheet (PIS) [Bereaved-Participant Information Sheet (Parents or Guardians)]	1.1	18 June 2019
Participant information sheet (PIS) [Bereaved-Participant Information sheet (parents or Guardians) tracked]	1.1	18 June 2019
Participant information sheet (PIS) [Participant Information Sheet (age 11+ years)]	1.1	18 June 2019
Participant information sheet (PIS) [Participant Information sheet (age 11+ years) tracked]	1.1	18 June 2019
Participant information sheet (PIS) [Participant Information Sheet (ages 8-10 years)]	1.1	18 June 2019
Participant information sheet (PIS) [Participant Information Sheet (ages 8-10 years) tracked]	1.1	18 June 2019
Participant information sheet (PIS) [Participant Information Sheet (Parents or Guardian)]	1.1	18 June 2019
Participant information sheet (PIS) [Participant Information sheet (Parent or Guardian) tracked]	1.1	18 June 2019
Referee's report or other scientific critique report [Response to NIHR Funding Board]		
Research protocol or project proposal [FIRST-ABC Master Protocol]	1.1	24 June 2019
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator]		26 April 2019
Validated questionnaire [Health Utilities Index Mark 2 (HUI2)]		
Validated questionnaire [Parental Stressor Scale]	1.1	18 June 2019
Validated questionnaire [Parental Stressor Scale tracked]	1.1	18 June 2019
Validated questionnaire [PedsQLв„ў Infant Scales 13-24 months]		
Validated questionnaire [Child Health Utility - 9D]	1.0	24 June 2019

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

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**

With the Committee's best wishes for the success of this project.

Yours sincerely,

Dr Leslie Gelling
Chair

Email:nrescommittee.eastofengland-cambridgesouth@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Jenny Rivers