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

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

26 July 2019

Dear Dr Ramnarayan

HRA and Health and Care Research Wales (HCRW) Approval Letter

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**
IRAS project ID:	**260536**
REC reference:	**19/EE/0185**
Sponsor	**Great Ormond Street Hospital for Children NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **260536**. Please quote this on all correspondence.

Yours Sincerely

Beverley Mashegede

Email: hra.approval@nhs.net

Copy to: Dr Jenny Rivers, Sponsor Contact

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Ethics re-submission cover letter]		24 June 2019
HRA Statement of Activities	1	03 May 2019
IRAS Application Form [IRAS_Form_26062019]		26 June 2019
IRAS Application Form XML file [IRAS_Form_26062019]		26 June 2019
IRAS Checklist XML [Checklist_26062019]		26 June 2019
Letter from funder [Grant Award Letter]		14 August 2018
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 [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 [Bereaved-Consent Form]	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) [Participant Information Sheet (age 11+ years)]	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 (Parents or Guardian)]	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
Schedule of Events or SoECAT [SoECAT - validated by Lead CRN]	1.0	07 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 [PedsQLâ„¢ Infant Scales 13-24 months]		
Validated questionnaire [Child Health Utility - 9D]	1.0	24 June 2019

IRAS project ID	260536

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Multicentre study.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	Funded by National Institutes for Health Research (NIHR). Funds will be provided to the participating organisations to support this study.	A PI is expected at each participating organisation.	All study activities will be undertaken by local staff employed by the NHS organisation. Therefore, no honorary research contracts or letters of access are expected for this study.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.