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31 May 2019

Dear Dr Ramnarayan

Initial Assessment 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

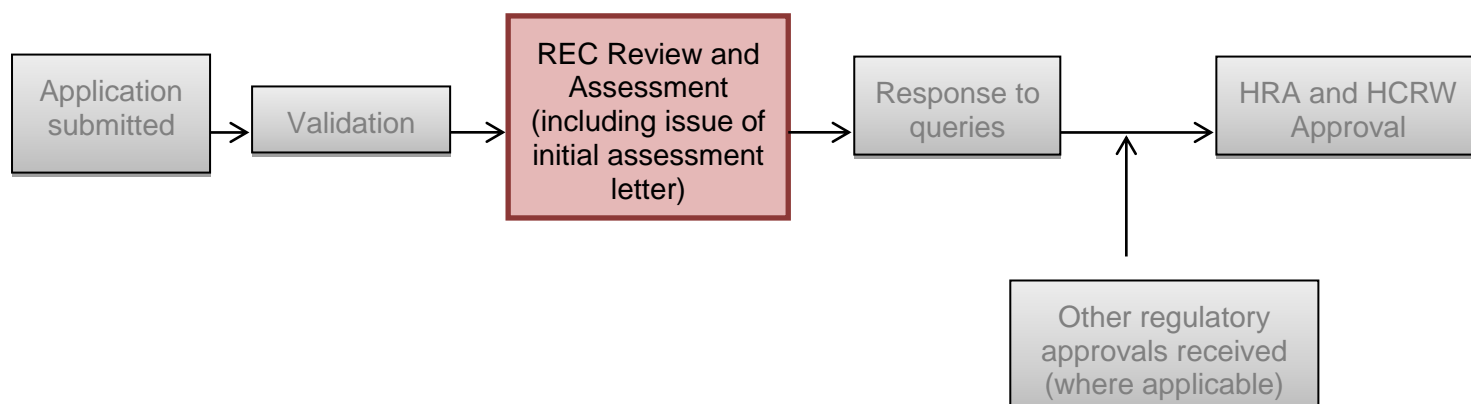
Thank you for your application for [HRA and Health and Care Research Wales \(HCRW\) Approval](#). I am writing to confirm that you are now able to share the Local Information Pack with participating NHS organisations in England and Wales in order to invite them to arrange of capacity and capability to deliver your study. Please note that **the research should not begin** at any participating NHS organisations in England or Wales until HRA and HCRW Approval is issued.

To share the Local Information Pack with participating NHS organisations in England and Wales please use the template email available on the [IRAS website](#).

Once the Local Information Pack has been shared, please work with participating NHS organisations to arrange capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

What happens next with my application for HRA and HCRW Approval?

Your application is progressing. Please find below an indication of where you are in the process (indicated by the red box).



I am undertaking the assessment of the application and you will receive any queries following the REC meeting.

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 in Northern Ireland and Scotland.

If you indicated in your IRAS form that you have participating organisations in Northern Ireland and/or Scotland, the national coordinating function of each participating nation has been informed and provided with the initial document set. The relevant national coordinating function/s will contact you as appropriate. We will provide them the final document set and study wide governance report when available.

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.

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

Information to support study set up

The below provides all parties with information to support the arranging 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. As part of the application process, details may change prior to a Letter of HRA and HCRW Approval being issued.

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.