Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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Dr Nazima Pathan
University Lecturer and Consultant in Paediatric Intensive Care
University of Cambridge
Paediatric Intensive Care, Department of Paediatrics
Level 8, Addenbrookes Hospital
Hills Road, Cambridge
CB2 0QQ

09 October 2020

Dear Dr Pathan

Initial Assessment Letter

Study title:	**A pilot cluster randomised clinical trial of the use of selective gut decontamination in critically ill children**
IRAS project ID:	**239324**
REC reference:	**20/WM/0061**
Sponsor	**Cambridge University Hospitals NHS Foundation Trust and University of Cambridge**

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.

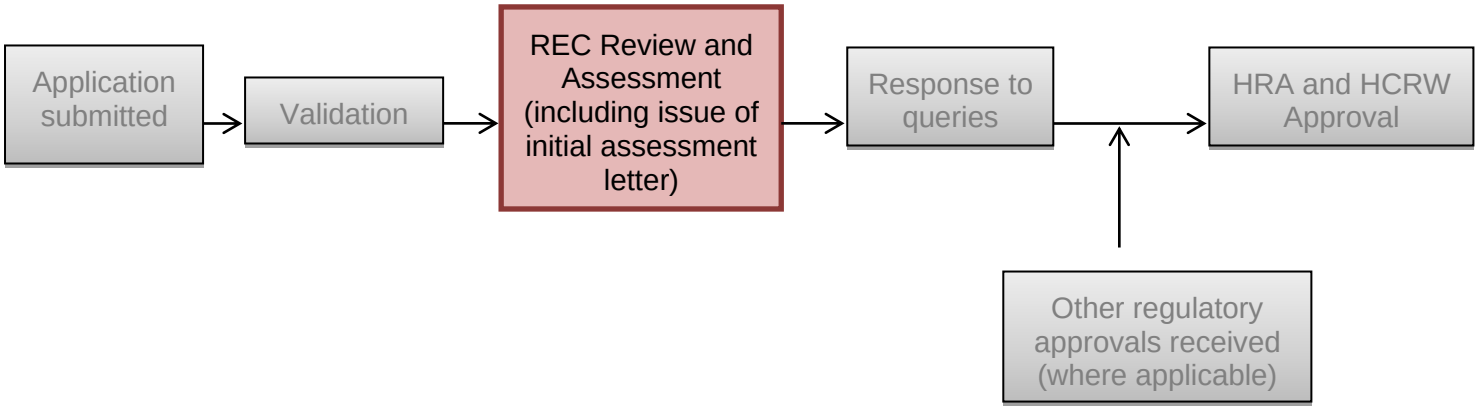
To share the Local Information Pack with participating NHS organisations in England and Wales please use the template email available on the IRAS website.

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).

IRAS project ID	239324



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 **239324.** Please quote this on all correspondence.

Yours sincerely,

Helen Penistone
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mr Stephen Kelleher*

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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
There will be one study site type in this cluster randomised clinical trial.	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.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement is unmodified.	Funding has been granted by the NIHR.	A Principal Investigator is expected at site.	Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for focus groups/ interviews), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed).

					These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only conducting focus groups/ interviews, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

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.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.