

**West Midlands - Black Country Research Ethics Committee**

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

**Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval**

23 September 2020

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

Dear Dr Pathan

<b>Study title:</b>	<b>A pilot cluster randomised clinical trial of the use of selective gut decontamination in critically ill children</b>
<b>REC reference:</b>	<b>20/WM/0061</b>
<b>IRAS project ID:</b>	<b>239324</b>

Thank you for your correspondence. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 12 August 2020.

**Documents received**

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Resubmission Covering Letter]		
Other [PICnIC protocol clean version]	1.2	19 August 2020
Other [Study Processes]		
Other [Email confirmation]		28 August 2020
Participant consent form [PICnIC Consent Form]	3.0	19 August 2020
Participant consent form [PICnIC Consent Form]	3.0	19 August 2020
Participant information sheet (PIS) [PICnIC Pilot Trial]	1.1	10 March 2020

Parent_Guardian Information Sheet (bereaved) ]		
Participant information sheet (PIS) [PICnC Pilot Trial Parent_Guardian Information Sheet (non-bereaved)]	1.1	10 March 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Control Arm Parent Guardian Information Leaflet	1.1	10 March 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Ecology Parent Guardian Information Leaflet	1.1	10 March 2020
Research protocol or project proposal [PICnIC Protocol]	1.2	19 August 2020

## Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Ecological Poster]	1.0	10 March 2020
Covering letter on headed paper [Resubmission Covering Letter]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UofC Insurance Confirmation]	1.0	01 January 2020
IRAS Application Form [IRAS_Form_04022020]		04 February 2020
Letter from funder [Letter from Funder]	1.0	30 January 2020
Letter from sponsor [Sponsor Letter of Support]	1.0	30 January 2020
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence [Study status advice ]	1.0	
Non-validated questionnaire [PICnIC Parent Questionnaire]	1.0	30 January 2020
Non-validated questionnaire [PICnIC PICU Staff Questionnaire]	1.0	30 January 2020
Non-validated questionnaire [PICnIC Pilot Site Staff Questionnaire]	1.0	30 January 2020
Other [PICnIC protocol clean version]	1.2	19 August 2020
Other [Study Processes]		
Other [Email confirmation]		28 August 2020
Participant consent form [PICnIC Pilot Study Assent Form]	1.0	09 June 2020
Participant consent form [PICnIC Consent Form]	3.0	19 August 2020
Participant consent form [PICnIC Consent Form]	3.0	19 August 2020
Participant information sheet (PIS) [PICnIC Participant Information Sheet <8 years]	1.0	10 March 2020
Participant information sheet (PIS) [PICnIC Pilot Trial information sheet 8-10 years]	1.1	10 March 2020
Participant information sheet (PIS) [PICnIC Pilot Trial information sheet 11+years]	1.1	10 March 2020
Participant information sheet (PIS) [PICnC Pilot Trial Parent_Guardian Information Sheet (bereaved) ]	1.1	10 March 2020
Participant information sheet (PIS) [PICnC Pilot Trial Parent_Guardian Information Sheet (bereaved) ]	1.1	10 March 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Control Arm Parent Guardian Information Leaflet	1.1	10 March 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Ecology Parent Guardian Information Leaflet	1.1	10 March 2020

Research protocol or project proposal [PICnIC Protocol]	1.2	19 August 2020
Summary CV for Chief Investigator (CI) [Nazima Pathan CV]	1.0	30 January 2020

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

<b>IRAS Project ID: 239324</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Vic Strutt**  
**Approvals Officer**

E-mail: [blackcountry.rec@hra.nhs.uk](mailto:blackcountry.rec@hra.nhs.uk)

Copy to: Mr Stephen Kelleher

Lead Nation England: [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk)