



Health Research
Authority

West Midlands - Black Country Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0207 104 8010

05 February 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

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

Thank you for your application for ethical review, which was received on 04 February 2020. I can confirm that the application is valid and will be reviewed by the Committee at the meeting on 24 February 2020.

Meeting arrangements

The meeting will be held in the Village Urban Resort Dudley, 2Castlegate Park, Birmingham Road, Dudley, West Midlands, DY1 4TB on 24 February 2020. The Committee would find it helpful if you could attend the meeting to respond to any questions from members. Other key investigators and a representative of the sponsor are also welcome to attend. This may avoid the need to request further information after the meeting and enable the Committee to make a decision on the application more quickly.

If you have a disability and need any practical support when attending the REC meeting you may wish to contact us so appropriate arrangements can be made if necessary.

If you are unable to attend the meeting the Committee will review the application in your absence.

The review of the application has been scheduled for 12.50 pm. Please note that it is difficult to be precise about the timing as it will depend on the progress of the meeting. We would kindly ask you to be prepared to wait beyond the allocated time if necessary.

If you cannot attend, it would be helpful if you could be available on the telephone at the time of the review.

Please let me know whether or not you would be available to attend the meeting or be available on the telephone.

Further information regarding attending a REC meeting is available on the HRA website:
<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/attending-rec-meeting/>

Committee meetings are occasionally attended by observers, who will have no vested interest in the applications under review or take any part in discussion. All observers are required to sign a confidentiality agreement.

Documents received

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [PICnIC Pilot Family Room Poster]	1.0	30 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
Participant consent form [PICnIC Qualitative Consent Form]	1.0	30 January 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Parent_Guardian Information Sheet (bereaved)]	1.0	30 January 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Parent_Guardian Information Sheet (non-bereaved)]	1.0	30 January 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Control Arm Parent Guardian Information Leaflet]	1.0	30 January 2020
Participant information sheet (PIS) [PICnIC Pilot Trial Ecology Parent Guardian Information Leaflet]	1.0	30 January 2020
Participant information sheet (PIS) [PICnIC Pilot Trial information sheet 8-10 years]	1.0	30 January 2020
Participant information sheet (PIS) [PICnIC Pilot Trial information sheet 11+years]	1.0	30 January 2020
Research protocol or project proposal [PICnIC Protocol]	1.0	21 November 2019
Summary CV for Chief Investigator (CI) [Nazima Pathan CV]	1.0	30 January 2020

No changes may be made to the application before the meeting. If you envisage that changes might be required, we would advise you to withdraw the application and re-submit it.

Notification of the Committee's decision

You will receive written notification of the outcome as soon as possible after the meeting.

The Committee will issue a final ethical opinion on the application within a maximum of 60 days from 10 February 2020, excluding any time taken by you to respond fully to one request for further information or clarification after the meeting.

Assessment of site suitability

For CTIMPs and Clinical Investigations of Medical Devices only, the suitability of any non-NHS/HSC sites will be checked as part of the REC review.

NHS Site Set up

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) will not be confirmed until after a favourable opinion has been given by this Committee, and all other relevant approvals for the research to begin are in place. Please contact the NHS R&D office at the lead site in the first instance for further guidance.

Communication with other bodies

All correspondence from the REC about the application will be copied to the research sponsor. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

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/>

20/WM/0061

Please quote this number on all correspondence

Yours sincerely



Helen Penistone
Approvals Specialist

Email: nrescommittee.westmidlands-blackcountry@nhs.net

Enclosure: List of Names and Professions of REC Members

Copy to: Stephen Kelleher

West Midlands - Black Country Research Ethics Committee

The names and professions of the West Midlands - Black Country Research Ethics Committee are listed in the table below. Please note, some of these members may not be present at the meeting.

Name	Profession	Capacity
Dr Joseph Arumainayagam	Consultant and Honorary Senior Clinical Lecturer in HIV and GUM	Expert
Dr Nicola Erb	Consultant Rheumatologist	Expert
Mrs Helen Moore	Trust Lead Research Nurse & Clinical Trials Manager	Expert
Dr Hilary Paniagua	Senior Lecturer	Expert
Dr Giridharan Rajaratnam	Deputy Regional Director	Expert
Mr Nanak Singh Sarhadi	Consultant Plastic Surgeon	Expert
Dr Tony Zalin	Expert Member	Expert
Mrs Lynne Gray	Retired Senior Biomedical Scientist	Lay
Dr David Vallance	Consultant Biochemist	Lay
Mrs Jennifer Walton	Retired Research Nurse	Lay
Miss Nicola Brooks	Solicitor	Lay Plus