Health Research Authority

West Midlands - Black Country Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

12 August 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 correspondence, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

- Please confirm that you will only be using the newly submitted Ecological Poster and this replaces the Family Room Poster.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

[Omit this sub-section if no NHS sites will be taking part in the study, e.g. Phase 1 trials in healthy volunteers]

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Ecological Poster]	1.0	10 March 2020
Covering letter on headed paper [Resubmission Covering Letter]	1.0	23 June 2020
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
Participant consent form [PICnIC Qualitative Consent Form]	2.0	19 June 2020
Participant consent form [PICnIC Pilot Study Assent Form]	1.0	09 June 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 (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
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
Research protocol or project proposal [PICnIC Protocol]	1.1	10 March 2020
Summary CV for Chief Investigator (CI) [Nazima Pathan CV]	1.0	30 January 2020

Membership of the Committee [This section only to be inserted in cases where any declarations of interests were raised at the initial full REC meeting by any members – User to manually insert any material declarations of interest]:example as follows;

A member declared an interest in the study.[Omit this section if not applicable]

Statement of compliance

[If CTIMP]:

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

[All studies]:

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

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/

IRAS project ID: 239324 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Hilary Paniagua
Chair

Email:blackcountry.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: Mr Stephen Kelleher