



# Health Research Authority

## West Midlands - Black Country Research Ethics Committee

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0207 104 8141

**Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

10 August 2021

Mr Stephen Kelleher  
R+D Manager Cambridge University Hospitals  
Addenbrooke's Hospital  
Cambridge  
Hills Road  
Cambridge  
CB2 0QQ

Dear Mr Kelleher

**Study title:** A pilot cluster randomised clinical trial of the use of selective gut decontamination in critically ill children  
**REC reference:** 20/WM/0061  
**Amendment number:** Substantial amendment 2  
**Amendment date:** 30 July 2021  
**IRAS project ID:** 239324

The above amendment was reviewed by the Sub-Committee in correspondence.

### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Completed Amendment Tool [239324_Substantial amendment 2_]	1.5	30 July 2021
Research protocol or project proposal [PICnIC Protocol _V3.0_05 July 2021]	3.0	05 July 2021
Research protocol or project proposal [PICnIC Protocol _V3.0_05 July 2021_tracked changes]	3.0	05 July 2021

## Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

## Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

## Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

## Statement of compliance

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.

## 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/>

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



**Dr Hilary Paniagua**  
**Chair**

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

*Enclosures:*                      *List of names and professions of members who took part in the review*

*Copy to:*                          *Dr Nazima Pathan, University of Cambridge*

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

**Attendance at Sub-Committee of the REC meeting on 10 August 2021 via correspondence**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Joseph Arumainayagam	Consultant and Honorary Senior Clinical Lecturer in HIV and GUM	Yes	
Dr Hilary Paniagua (Chair)	Principle Lecturer & Head of Doctoral Studies	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Mia Crispin	Approvals Administrator