

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 the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

03 November 2020

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:	1
Amendment date:	08.10.20
IRAS project ID:	239324

The above amendment was reviewed 03 November 2020 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.

Discussion

There were no ethical issues raised.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [239324_Substantial Amendment 1_08Oct2020_Locked08Oct20_161955]	1.2	08 October 2020
Covering letter on headed paper [PICNIC_IRAS 239324_Substantial Amendment 1_Cover letter_08-10-20]	1	08 October 2020
Participant consent form [PICnIC Consent Form Parent or Legal Guardian (non bereaved) v3.1, 25 September 2020_clean]	3.1	25 September 2020
Participant consent form [PICnIC Consent Form Parent or Legal Guardian (non bereaved) v3.1, 25 September 2020_tracked]	3.1	25 September 2020
Participant consent form [PICnIC Consent Form Parent or Legal Guardian (bereaved) v1.0, 08 October 2020]	1.0	08 October 2020
Participant information sheet (PIS) [PICnIC Baselines Parents_Guardians PIS (bereaved) v1.0 25 September 2020]	1.0	25 September 2020
Participant information sheet (PIS) [PICnIC Baseline Parents_Guardians PIS (non bereaved) v1.0, 25 September 2020]	1.0	25 September 2020
Participant information sheet (PIS) [PICnIC Control Parent_Guardian PIS (bereaved) v2.0 25 September 2020]	2.0	25 September 2020
Participant information sheet (PIS) [PICnIC Control Parent_Guardian (non bereaved) v2.0 25 September 2020]	2.0	25 September 2020
Participant information sheet (PIS) [PICnIC Ecology Parent Guardian PIS (bereaved) v2.0, 25 September 2020]	2.0	25 September 2020
Participant information sheet (PIS) [PICnIC Ecology Parent_Guardian PIS (non bereaved) v2.0, 25 September 2020]	2.0	25 September 2020
Participant information sheet (PIS) [PICnIC Intervention Parent_Guardian PIS (bereaved) v2.0, 25 September 2020_tracked]	2.0	25 September 2020
Participant information sheet (PIS) [PICnIC Intervention Parent_Guardian PIS (bereaved) v2.0, 25 September 2020_clean]	2.0	25 September 2020
Participant information sheet (PIS) [PICnIC Intervention Parent_Guardian PIS (non bereaved) v2.0, 25 September 2020_clean]	2.0	25 September 2020
Participant information sheet (PIS) [PICnIC Intervention Parent_Guardian PIS (non bereaved) v2.0, 25 September 2020]	2.0	25 September 2020
Research protocol or project proposal [PICnIC Protocol V2.0_02 October 2020_clean]	2.0	02 October 2020
Research protocol or project proposal [PICnIC Protocol V2.0_02 October 2020_tracked changes]	2.0	02 October 2020

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.

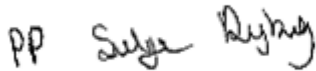
HRA Learning

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/>

IRAS Project ID - 239324:

Please quote this number on all correspondence

Yours sincerely



Dr Hilary Paniagua
Chair

E-mail: 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 22 October 2020

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>
Corcyra Burley	Approvals Administrator (Minutes)