

London - Riverside Research Ethics Committee

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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 September 2018

Dr Padmanabhan Ramnarayan
Consultant in Paediatric Intensive Care & Retrieval
Great Ormond Street Hospital NHS Trust
Children's Acute Transport Service
26-27 Boswell Street
London
WC1N 3JZ

Dear Dr Ramnarayan

Study title: Critically ill children and young people: do national

Differences in access to Emergency Paediatric Intensive Care and care during Transport affect clinical outcomes

and patient experience? The DEPICT study

REC reference: 17/LO/1267
Protocol number: 15HC47
Amendment number: AM03

Amendment date: 29 August 2018

IRAS project ID: 218569

Approval was sought for the following changes:

- Changes to the IRAs;
- Changes to the Protocol; and,
- Changes to the Patient Information Sheets and Informed Consent Forms.

The above amendment was reviewed at the meeting of the Sub-Committee held on 03 September 2018 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

No Ethical Issues were raised.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper [REC COVER LETTER v4 28August2018 DEPICT [IRAS 218569]]		28 August 2018
Non-validated questionnaire [QUESTIONNAIRE Transport Questionnaire (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Non-validated questionnaire [QUESTIONNAIRE Transport Questionnaire (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] tracked]	4	28 August 2018
Notice of Substantial Amendment (non-CTIMP) [NOSA3 28 Aug2018 DEPICT Study [IRAS218569]]	AM03	29 August 2018
Other [CAGSF6-Amendment-request [IRAS218569]]		28 August 2018
Participant consent form [INTERVIEW Consent Form (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Participant consent form [INTERVIEW Consent Form (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] tracked]	4	28 August 2018
Participant consent form [INTERVIEW Consent Form (ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Participant consent form [INTERVIEW Consent Form (ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] tracked]	4	28 August 2018
Participant consent form [INTERVIEW Consent Form (Staff) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Participant consent form [INTERVIEW Consent Form (Staff) v4 28Aug2018 DEPICT [IRAS 218569] tracked]	4	28 August 2018
Participant consent form [QUESTIONNAIRE Consent Form (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Participant consent form [QUESTIONNAIRE Consent Form (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] tracked.pdf]	4	28 August 2018
Participant information sheet (PIS) [INTERVIEW PIS (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Participant information sheet (PIS) [INTERVIEW PIS (Bereaved ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] tracked]	4	28 August 2018
Participant information sheet (PIS) [INTERVIEW PIS (ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Participant information sheet (PIS) [QUESTIONNAIRE PIS (BPG) v4 28Aug2018 DEPICT [IRAS 218569] tracked]	4	28 August 2018
Participant information sheet (PIS) [INTERVIEW PIS (ParentGuardian) v4 28Aug2018 DEPICT [IRAS 218569] tracked]	4	28 August 2018
Participant information sheet (PIS) [INTERVIEW PIS (Staff) v4 28Aug2018 DEPICT [IRAS 218569] clean]	4	28 August 2018
Participant information sheet (PIS) [INTERVIEW PIS (Staff) v4	4	28 August 2018

28Aug2018 DEPICT [IRAS 218569] tracked]		
Participant information sheet (PIS) [QUESTIONNAIRE PIS (BPG) v4 28Aug2018 DEPICT [IRAS 218569] clean.pdf]	4	28 August 2018
Research protocol or project proposal [STUDY PROTOCOL v3 28Aug2018 DEPICT [IRAS 218569] tracked]	3	28 August 2018
Research protocol or project proposal [STUDY PROTOCOL v3 28Aug2018 DEPICT [IRAS 218569] clean]	3	28 August 2018

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.

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

17/LO/1267:

Please quote this number on all correspondence

Yours sincerely

PΡ

Dr Margaret Jones

Chair

E-mail: <u>nrescommittee.london-riverside@nhs.net</u>

Copy to: Ms Anika Kadchha, Joint Research and Development Office,

Division of Research and Innovation

Emma PendletonConfidentiality Advise Team

London - Riverside Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 03 September 2018

Committee Members:

Name	Profession	Present	Notes	
Dr Margaret Jones	Retired General Practitioner	Yes	Chair	
Ms Julia Williams	Senior Producer	Yes		

Also in attendance:

Name	Position (or reason for attending)	
Mr Paolo Buscemi	REC Assistant	