

London - West London & GTAC 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.

15 October 2018

Mr Chris Graham
Director of Research and Policy
Picker Institute Europe
Buxton Court
3 West Way
Oxford
OX2 0JB

Dear Mr Graham

Study title:	Children and Young People's Inpatient and Day Case Survey 2016
REC reference:	16/LO/1939
Amendment number:	Substantial Amendment 2 02/10/20181.0
Amendment date:	21 September 2018
IRAS project ID:	216545

The above amendment was reviewed on 11 October 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.

The Sub-Committee were in agreement that the Substantial Amendment did not raise any material ethical issues

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [20180921_CYP18_Dissent Poster_V1.0_PROTECT]	1.0	21 September 2018
Letters of invitation to participant [20180921_CYP18_First Covering]	1.0	17 September 2018

Letter_V1.0_PROTECT]		
Letters of invitation to participant [20180921_CYP18_Second Covering Letter_V1.0_PROTECT]	1.0	21 September 2018
Letters of invitation to participant [20180921_CYP18_Third Covering Letter_V1.0_PROTECT]	1.0	21 September 2018
Non-validated questionnaire [20180921_CYP18_Questionnaire_0-7_V1.0_PROTECT]	1.0	21 September 2018
Non-validated questionnaire [20180921_CYP18_Questionnaire_8-11_V1.0_PROTECT]	1.0	21 September 2018
Non-validated questionnaire [20180921_CYP18_Questionnaire_12-15_V1.0_PROTECT]	1.0	21 September 2018
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 2 02/10/2018. 0	21 September 2018
Other [20180921_CYP18_Multilanguage sheet_V1.0_PROTECT]		
Other [01.8.090]		02 August 2018
Other [16CAG0041 amendment final approval letter]		02 August 2018
Other [18.CAG.0098]		31 July 2018
Other [18.CAG.0110]		28 August 2018
Other [20180921_CYP18_Section D Declaration_V1.0_PROTECT]	1.0	21 September 2018
Other [P3196_CYP18_Summary of changes_V1.0_20180921_CEG_JLM_CK_JLM_PROTECT]		21 September 2018
Participant information sheet (PIS) [20180921_CYP18_Info sheet 8-11_V1.0_PROTECT]	1.0	21 September 2018
Participant information sheet (PIS) [20180921_CYP18_Info sheet 12-15_V1.0_PROTECT]	1.0	21 September 2018
Summary CV for Chief Investigator (CI) [20180921_CYP18_CV Chief_investigator_V1.0_PROTECT]	1.0	18 September 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/>

16/LO/1939:	Please quote this number on all correspondence
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Yours sincerely

P. P. Urch

**Professor Catherine Urch
Chair**

E-mail: NRESCommittee.London-WestLondon@nhs.net

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

London - West London & GTAC Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 11 October 2018

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Cinead Eileen O'Sullivan	Legal Advisor (Solicitor)	Yes	
Professor Catherine Urch (Chair)	Consultant Palliative Medicine	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Teagan Allen	REC Assistant