Reissue to remove statement on HRA approval as study is service evaluation.

Health Research Authority
London - West London & GTAC Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

19 October 2016

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**
IRAS project ID:	**216545**

The Proportionate Review Sub-committee of the London - West London & GTAC Research Ethics Committee reviewed the above application on 19 October 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant, Tad Jones, NRESCommittee.London-WestLondon@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, 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.

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1. The 1st reminder letter should be amended to make it clear that it is the first of two reminders.

2. The 2nd reminder letter should be amended to make it clear that no further contact will be made even if no form is returned.

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.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission 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 Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

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be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

  The Sub-Committee agreed that the 1st reminder letter should be clear that it is the first of two reminders and the 2nd reminder letter should state that no further contact will be made even if no form is returned.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [CYP16_ Ethics Covering Letter]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity Cover certificate v1]		
IRAS Application Form [IRAS_Form_10102016]		10 October 2016
IRAS Application Form XML file [IRAS_Form_10102016]		10 October 2016
IRAS Checklist XML [Checklist_10102016]		10 October 2016
IRAS Checklist XML [Checklist_11102016]		11 October 2016
Letters of invitation to participant [CYP16_First mailing letter v1]		
Letters of invitation to participant [CYP16_First reminder letter v1]		
Letters of invitation to participant [CYP16_Second reminder letter v1]		
Other [CYP16_Multilanguage_Sheet_v1]		
Other [CYP16_Summary of Changes v1]		
Other [15CAG0209 final approval outcome]		
Other [CYP16_Childrens Information Leaflet v1]		
Other [CYP16 Dissent Poster v1]		
Research protocol or project proposal [CYP16 Research Protocol V1]		
Summary CV for Chief Investigator (CI)		
Validated questionnaire [CYP16_Questionnaire 0-7 years v1]		
Validated questionnaire [CYP16_Questionnaire 8-11 years v1]		

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Validated questionnaire [CYP16_Questionnaire 12-15 years v1]		

Membership of the Proportionate Review Sub-Committee

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

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.

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

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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 Training

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

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

16/LO/1939	**Please quote this number on all correspondence**

Yours sincerely

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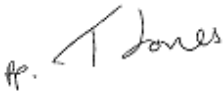

Dr Elizabeth Lund
Chair

Email: NRESCommittee.London-WestLondon@nhs.net

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

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

Copy to: *Ms Tamatha Webster*

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Attendance at PRS Sub-Committee of the REC meeting on 19 October 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Ted Barker	Reader in Developmental Psychopathology	Yes	
Miss Gayle D'Souza	Senior Trials Coordinator	Yes	
Dr Elizabeth Lund	Independent Consultant, Nutrition and Gastrointestinal Health	Yes	(Chair)

Also in attendance:

Name	*Position (or reason for attending)*
Mr Tad Jones	REC Assistant