West Midlands - Coventry & Warwickshire 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 you to start your study at NHS sites in England until you receive HRA Approval

31 January 2019

Dr Mark Edwards
Consultant in Anaesthesia and Perioperative Medicine
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

Dear Dr Edwards

Study title:	**PErioperAtive CHildhood obesitY (PEACHY): A prospective observational cohort study investigating the proportion of overweight and obese children presenting for a procedure under general anaesthesia in the UK and the incidence of preoperative adverse outcomes in this patient group**
REC reference:	**18/WM/0394**
IRAS project ID:	**248493**

Thank you for your letter of 28/01/2019, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

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 please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

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 and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at 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

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" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Local info poster]	v1	03 October 2018
GP/consultant information sheets or letters [Study summary]	v1	07 October 2018
HRA Schedule of Events [SOE]	v1	18 October 2018
HRA Statement of Activities [SOA]	v1	17 October 2018
IRAS Application Form [IRAS_Form_29112018]		29 November 2018
IRAS Application Form XML file [IRAS_Form_29112018]		29 November 2018
IRAS Checklist XML [Checklist_29112018]		29 November 2018
Letter from funder [APA confirmation of funding]		25 May 2018
Non-validated questionnaire [Appendix 4 - Case Record Form]	v1	02 October 2018
Referee's report or other scientific critique report [APA scientific review 1]		31 July 2018
Referee's report or other scientific critique report [APA scientific review 2]		23 July 2018
Research protocol or project proposal [PEACHY protocol]	Final v1	03 October 2018
Response to Request for Further Information [Response to provisional opinion]		
Summary CV for Chief Investigator (CI) [Mark Edwards CV]		12 April 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Local investigators invitation to participate]	v1	03 October 2018

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

<u>Reporting requirements</u>

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.

Feedback

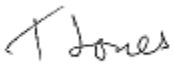
You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

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

18/WM/0394	**Please quote this number on all correspondence**

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

Yours sincerely



Ronald Jubb
Vice Chair

Email: NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

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

Copy to: *Mrs Viki Rumble*

Dr Mikayala King, University Hospital Southampton NHS Foundation Trust

Lead Nation
England: HRA.Approval@nhs.net