NHS
Health Research Authority

London - Queen Square Research Ethics Committee
HRA NRES Centre Manchester
Barlow House
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Manchester
M1 3DZ

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

12 June 2019 (Revised: 16 July 2019)

Prof S. Ramani Moonesinghe
Professor and Head of Centre for Perioperative Medicine, UCL; Honorary Consultant in Anaesthesia, UCLH; Director NIAA Health Services Research Centre
University College London
Division of Surgery, University College London
Charles Bell House
43-45 Foley Street
London W1W 7TS

Dear Prof Moonesinghe

Study title:	**Children's Acute Surgical Abdomen Programme: CASAP**
REC reference:	**19/LO/0267**
IRAS project ID:	**234524**

Thank you for your letter of 01 February 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

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 opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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, subject to the conditions specified below.

Conditions of the favourable opinion

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 Trial

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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

NHS 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" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [CASAP Patient Study Poster]	1.0	16 January 2019
Covering letter on headed paper [Covering Letter]		28 May 2019
IRAS Application Form [IRAS_Form_28052019]		28 May 2019
Letter from funder [CASAP Funding Confirmation Email and Peer Review]		29 June 2017
Letter from sponsor [Confirmation of Sponsorship from UCL]		18 January 2019
Other [UCL Information Security Policy]	.	05 September 2016
Other [UCL Insurance Certificate]		21 January 2019
Other [CASAP PIS 10 - 15 years old]	1.0	15 May 2019
Other [CASAP CRF]	1.0	28 May 2019
Other [CASAP CRF Appendix 1]	1.0	28 May 2019
Participant consent form [CASAP Consent Form]	1.0	23 May 2019
Participant information sheet (PIS) [CASAP Patient Study PIL 6-9 yrs old]	1.0	16 January 2019
Participant information sheet (PIS) [CASAP PIS for Parents]	1.0	09 May 2019
Referee's report or other scientific critique report [CASAP Funding Letter and Peer Review]		29 June 2017
Referee's report or other scientific critique report [YPAG Feedback Covering Letter]		12 April 2017
Referee's report or other scientific critique report [Patient Group feedback]		
Research protocol or project proposal [CASAP Study Protocol]	1.1	21 May 2019
Response to Request for Further Information [Application clarification]		01 February 2019
Summary CV for Chief Investigator (CI) [SRM CV]		21 January 2019
Summary, synopsis or diagram (flowchart) of protocol in non technical language [CASAP Data Flow Diagram]		16 January 2019

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/

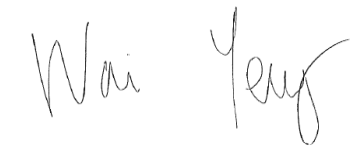
HRA Learning

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/

19/LO/0267	**Please quote this number on all correspondence**

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

Yours sincerely



PP - Dr Eamonn Walsh
Chair

Email:nrescommittee.london-queensquare@nhs.net

Enclosures:	*List of names and professions of members who were present at the meeting and those who submitted written comments* "After ethical review – guidance for researchers"
Copy to:	*Ms Suzanne Emerton*

London - Queen Square Research Ethics Committee

Attendance at Sub-Committee of the REC meeting

Committee Members:

Name	*Profession*	*Present*	*Notes*	
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Yes		
Dr Eamonn Walsh	Senior Lecturer and Programme Lead for MSc Neuroscience	Yes		
Ms Danielle Wilson	Clinical Research Operational Manager	Yes		

Also in attendance:

Name	*Position (or reason for attending)*	
Mr Wai Yeung	Approvals Administrator	