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
W1W 7TS

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

04 September 2019

Dear Prof Moonesinghe

HRA and Health and Care Research Wales (HCRW) Approval Letter

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

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **234524**. Please quote this on all correspondence.

Yours sincerely,

Rekha Keshvara

Approvals Manager

Email: **INSERT for nation of sender** hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

Copy to: *Ms Suzanne Emerton*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template		
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
HRA Schedule of Events	1	09 May 2019
HRA Statement of Activities	1	05 February 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

IRAS project ID	234524

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
There is one type of participating NHS organisation; activities will be the same at all organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	Statement of Activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used. NB: the information included in the statement of activities should now be transposed to Organisation Information Document.	As per the statement of activities, there are no funds being provided to the sites by the sponsor.	A Principal Investigator is expected to be in place at the participating NHS sites.	Use of identifiable patient records held by an NHS organisation to identify potential participants should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation. A Letter of Access (or equivalent) would be expected for any external NHS/research staff undertaking all of the other activities for the study once consent from the participant is in place. The pre-engagement checks should include a standard DBS check and Occupational Health Clearance

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.