Health Research Authority

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Email: hra.approval@nhs.net

27 October 2016

Dear Dr Moonesinghe

Letter of HRA Approval

Study title:	**Improving perioperative care through the use of quality data: Patient Study of the Perioperative Quality Improvement Programme**
IRAS project ID:	**215928**
Protocol number:	**16/0577**
REC reference:	**16/LO/1827**
Sponsor	**University College London**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

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.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

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 email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

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

Your IRAS project ID is **215928**. Please quote this on all correspondence.

Yours sincerely

Thomas Fairman
HRA Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Suzanne Emerton, University College London Hospitals NHS Foundation Trust, (Sponsor Contact and Lead NHS R&D Contact)*

NIHR CRN Portfolio Applications Team

Appendix A - List of Documents

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

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. NIGB) and all correspondence [PQIP Database Protocol]	1.0	06 June 2016
Confirmation of any other Regulatory Approvals (e.g. NIGB) and all correspondence [PQIP Database IRAS form]	1.0	06 June 2016
Confirmation of any other Regulatory Approvals (e.g. NIGB) and all correspondence [PQIP Database REC opinion letter]	Final decision	12 August 2016
Copies of advertisement materials for research participants [Participant Information Poster]	1.0	22 September 2016
IRAS Application Form [IRAS_Form_26092016]		26 September 2016
IRAS Application Form XML file [IRAS_Form_26092016]		26 September 2016
IRAS Checklist XML [Checklist_23092016]		23 September 2016
IRAS Checklist XML [Checklist_26092016]		26 September 2016
Non-validated questionnaire [PQIP Patient Study Questionnaires Booklet]	v0.8a	19 October 2016
Notice of Substantial Amendment (non-CTIMP)	1.0 12/10/16	21 October 2016
Other [Schedule of Events]	1.1	21 September 2016
Other [Statement of Activitieshttps://www.harp.org.uk/Member/Applications/Edit/343047#Overview]	1.1	21 September 2016
Other [PQIP Eligible Procedures]	1.0	19 September 2016
Other [Insurance confirmation letter]		23 September 2016
Other [UCL Insurance Policy]		11 July 2016
Other [HSRC confirmation of statistician funding draft 22 02 16]		23 February 2016
Other [PQIP confirmation of funding draft 22 02 16]		22 February 2016
Other [Ramani Moonesinghe & UCLH (7386) Impsci award agreement - all signed]		
Other [Fwd 16 LO 1827 - IRAS 215928 Confirmation of non-substantial amendment]		27 October 2016
Participant consent form	0.8	12 October 2016
Participant information sheet (PIS) [PQIP Patient Study PIS]	v0.7c	12 October 2016
Research protocol or project proposal [Protocol]	1.4	21 September 2016
Summary CV for Chief Investigator (CI) [CV Ramani Moonesinghe]	1.0	29 June 2016

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Ms Suzanne Emerton

Tel: 02034475274

Email: randd@uclh.nhs.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites in England. The sponsor is not requesting, and does not require any additional contracts with study sites.
4.2	Insurance/indemnity	Yes	Where applicable, independent contractors (e.g. General Practitioners)

Section	HRA Assessment Criteria	Compliant with Standards	Comments
	arrangements assessed		should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for external funding has been made. External study funding has been secured from The Health Foundation and Royal College of Anesthetists. No study funding will be provided to sites, as detailed at Schedule 1 of the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable Opinion was issued by the South East Coast Surrey Research Ethics Committee on the 30 September 2016 Amended documents were submitted on by the researchers to comply with HRA Approval standards. The changes to the PIS and non-validated questionnaire were classified by the sponsor as a substantial amendment. This was given a Favourable Onion by the REC on the 26th October 2016. Other amended and new documents, including the consent form, v0.8 and letters confirming funding were

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			categorised as a non-substantial amendment.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

All participating NHS organisations will undertake the same study activities. There is therefore only one study site 'type' involved in the research.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

NHS organisations in England that are participating in the study **will be expected to formally confirm their capacity and capability** to host this research.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) section of this appendix.

- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator should be appointed at study sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
The sponsor has confirmed that all study activities will be undertaken by local staff who have a contractual relationship with the relevant organisation. Therefore no honorary research contracts or letters of access are expected for this study.

Other Information to Aid Study Set-up

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