NHS
Health Research Authority

Dr S R Moonesinghe
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University College Hospital
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London NW1 2BU

Email: hra.approval@nhs.net

20 September 2016

Dear Dr Moonesinghe,

Letter of HRA Approval

Study title:	**The Second UK Sprint National Anaesthesia Project: Epidemiology of Critical Care provision after Surgery**
IRAS project ID:	**154486**
REC reference:	**16/SC/0349**
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 **154486**. Please quote this on all correspondence.

Yours sincerely,

Emma Stoica
Senior Assessor

Email: hra.approval@nhs.net

Copy to:

Ms Suzanne Emerton, University College London
Confidentiality Advisory Team
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 [CAG application approval]		16 September 2016
Covering letter on headed paper [Cover letter]		
Covering letter on headed paper [Cover letter]		20 May 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Confirmation Letter]		10 May 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [insurance policy]	2016-17	11 July 2016
IRAS Application Form [IRAS_Form_08062016]		08 June 2016
Letter from funder [Royal College of Anaesthetists]		23 February 2016
Letter from funder [AAGBI Foundation]		15 December 2014
Other [HRA schedule of events]	0.4	27 April 2016
Other [Statement of Activities]		11 April 2016
Other [Appendix 1: Case Report Form]	0.9	03 June 2016
Other [Appendix 6: Quality of Recovery Telephone Interview Script]	0.2	30 June 2016
Other [Appendix 3: Occupancy questionnaire]	0.7	20 July 2016
Other [Appendix 4: Clinician Perception Case Report Form]	0.8	20 July 2016
Other [Cover Letter - Response to REC]	1	26 July 2016
Other [List of proposed sites and investigators]		
Other [List of QuARCs]		
Participant information sheet (PIS) [Appendix 5: Main Study Participant Information Sheet]	0.6	25 July 2016
Research protocol or project proposal [EPICCS Protocol]	1.4	20 July 2016
Summary CV for Chief Investigator (CI) [CI CV]		
Summary CV for student [CV for Dr Danny Wong]		30 June 2016
Validated questionnaire [Appendix 2: Quality of Recovery questionnaire]	0.9	20 July 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:

Ms Suzanne Emerton, email: randd@uclh.nhs.uk; Telephone: 02034477430.

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	The lead site is located in England and all NHS hospitals in the UK which undertake inpatient surgery will be eligible to take part. Therefore Part C of the IRAS form is not listing all sites. The applicant explained that the sites listed, apart from the lead site, were randomly selected among those agreeing in principle to participate. A separate list with NHS organisations which will be invited to participate has been provided.
2.1	Participant information/consent documents and consent process	Yes	Approval under Section 251 of the Health and Social Care Act 2001 has been sought to recruit patients without consent in the main part of the study.
3.1	Protocol assessment	Yes	No comments.
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor confirmed that a Statement of Activities will act as agreement of an NHS organisation in

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			England to participate. The sponsor is not requesting and does not expect any other site agreement.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) 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 funding will be provided to NHS organisations in England by the sponsor, as specified in 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	No comments
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	Yes	The Health Research Authority, having considered the advice from the Confidentiality Advisory Group, has approved the application submitted for approval under Regulation 5 of the Health Service (Control of Patient

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			Information) Regulations 2002 to process patient identifiable information without consent for the main part of the research study.

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.
There is one site type participating in this study. The applicant confirmed that all NHS organisations will be undertaking the same activities, as detailed in the Schedule of Events. All NHS hospitals in the UK which undertake inpatient surgery will be invited to take part. Because of the number of eligible NHS organisations, Part C of the IRAS form is not listing all sites. Hospitals will be recruited using the National Institute for Academic Anaesthesia Health Services Research Centre (NIAA HSRC's) Quality Audit and Research Coordinator (QuARC) network. A very similar study was undertaken recently by the same research group (SNAP-1 study); the researchers will be approaching the PIs who participated, with the assumption that the majority will also be participating in this study. A list of SNAP-1 PIs, as well as a list of QuARCs, has been provided. 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.
All participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**. The Statement of Activities details the capabilities and capacity required locally in order to undertake the study.

- 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).

The HRA determined that Principal Investigators will be required at each NHS organisation, as indicated by the sponsor in the Statement of Activities. A list of PIs who participated in a previous, similar study (SNAP-1), the majority of whom are assumed to also participate in this study, has been provided, as well as a list of QuARCs, many of whom were also PIs in SNAP-1, and whom will also be approached to be PIs for this study.

The sponsor will not have to provide training for local staff. The Royal College of Anaesthetists' National Institute of Academic Anaesthesia Health Services Research Centre will conduct any required training for data collection and entry into the web-based CRF database remotely.

The sponsor expects that Principal Investigators at each participating site are familiar with and act in full compliance with Good Clinical Practice, the Data Protection Act 1998 and the Research Governance Framework for Health and Social Care (2005).

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

No additional HR arrangements will be necessary. All research activities are undertaken by staff members who have contractual relationship with the participating NHS organisations.

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 intend to apply for inclusion on the NIHR CRN Portfolio.