Health Research Authority

Dr Daniel Martin
Consultant in Anaesthesia and Critical Care, Senior Lecturer,
UCL Division of Surgery and Interventional Science
Royal Free London NHS Foundation Trust
Department of Anaesthesia
Royal Free Hospital
London
NW3 2QG

Email: hra.approval@nhs.net

08 August 2016

Dear Dr Martin

Initial Assessment Letter

Study title:	**Intraoperative Hypotension in Elder Patients (IHypE): An Observational Study of Intraoperative Hypotension in patients aged over 65 in UK Hospitals**
IRAS project ID:	**186097**
Protocol number:	**15/0970**
REC reference:	**16/LO/1154**
Sponsor	**University College London**

Thank you for your application for HRA Approval for the above referenced study. You will have already received notification that your application is valid for REC and proceeding to a REC meeting.

I, (Miss Lauren Allen – hra.approval@nhs.net) have been assigned to this application and have undertaken my initial assessment, the findings of which are detailed in *Appendix B*. Please note that **this is not a letter of HRA Approval**, and the research should not begin at any participating NHS organisations in England before HRA Approval is issued.

Purpose

The purpose of this letter is to provide initial information from the HRA assessment to you, the sponsor and participating NHS organisations in England to enable the process of arranging capacity and capability to begin.

You should now provide a copy of this letter and the local document package to participating NHS organisations in England and work with them to coordinate local arrangements in preparation for HRA Approval on the basis described in this letter, even where certain arrangements detailed in *Appendix B* are still to be finalised.

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.

Notification of Outcomes

I will continue to work with you to resolve any outstanding questions whilst local arrangements are finalised prior to HRA Approval. I may contact you by phone or email to seek clarification as I complete my assessment.

You will receive written notification of HRA Approval once the assessment has been completed and subsequent to any regulatory approvals required for your study (e.g. REC Favourable Opinion, MHRA Clinical Trial Authorisation, etc.). HRA Approval will not be issued until any specific conditions on these approvals have been met.

There is no need for you to send me the REC opinion or any other regulatory approvals, as I will receive these directly, although I may contact you to confirm that any applicable conditions have been met.

Appendices

This Initial Assessment Letter contains the following appendices:

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

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.

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 186097**.** Please quote this on all correspondence.

Yours sincerely

Miss Lauren Allen

Assessor

Email: hra.approval@nhs.net

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

Confidentiality Advise Team

NIHR CRN Portfolio Applications Team

Appendix A - Documents received

The documents to be assessed as part of HRA Approval are as follows.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster]		
Covering letter on headed paper	2	30 May 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)	1	30 May 2016
IRAS Application Form [IRAS_Form_06062016]		06 June 2016
Letter from funder [AAGBI NIAA]		29 June 2016
Letter from statistician [Statistician letter]	1	01 June 2016
Letters of invitation to participant	2	30 May 2016
Other [HRA Statement of Activities]	1	30 May 2016
Other [Patient information sheet]	2.1	14 July 2016
Other [Response to REC committee]	3	14 July 2016
Other [Schedule of Events]	1.1	05 August 2016
Other [Anaesthetist Survey]		
Participant information sheet (PIS)	2.1	
Referee's report or other scientific critique report	1	30 May 2016
Research protocol or project proposal	5.3	30 May 2016
Summary CV for Chief Investigator (CI)	1	30 May 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow Sheet]	1	01 June 2016

Appendix B – Information for Sponsors and Participating NHS Organisations

The appendix below provides all parties with information that will be beneficial when discussing the arranging of capacity and capability with participating NHS organisations in England. The information in this appendix is intended to be an accurate reflection of the study at the time of issue of this letter. As part of the HRA Approval process, details may change prior to a Letter of HRA Approval being issued. NHS organisations should be assured that the HRA will continue to work with the sponsor on any HRA assessment criteria which are 'pending', and this should not impact on the arranging or capacity and capability.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study: Ms Suzanne Emerton (randd@uclh.nhs.uk, 02034477430).

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	The research will involve collection of data from anaesthetic care records only therefore there will be no direct contact with patient participants and individual consent will not be sought. Posters advertising the study will be displayed at sites and patients can request to see a more detailed study information sheet if they wish. A separate information sheet has been provided for anaesthetists at sites and consent will be implied by completion of the survey.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The Statement of Activities and Schedule of Events will act as the agreement between the sponsor and participating NHS organisations in England.
4.2	Insurance/indemnity	Yes	Where applicable, independent

Section	HRA Assessment Criteria	Compliant with Standards	Comments
	arrangements assessed		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 participating NHS organisations.
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	Pending	REC favourable opinion with additional conditions has been received. HRA Approval cannot be issued until the REC has confirmed that the additional conditions of the favourable opinion have been met.
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	Pending	An application has been made to the Confidentiality Advisory Group (CAG) for section 251 support in order to access identifiable information without consent.

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. The anaesthetic team at participating NHS organisations will be required to identify eligible participants, extract the required data from anaesthetic care records and enter anonymised data on to the study database. Clinical outcome data will also need to be collected 30 days post-surgery. Members of the anaesthetic team who have patients included in the research will be asked to complete a short survey. 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.
Participating NHS organisations in England **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's 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 local Principal Investigator will be required at participating NHS organisations. The sponsor requires all investigators to undertake NIHR CRN Good Clinical Practice Training. 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 access arrangements are expected as the study activity will be conducted by local NHS staff who have a contractual relationship with the relevant organisation.

Other Information to Aid Study Set-up

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