



Health Research Authority

London - West London & GTAC Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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

20 July 2016

Dr Daniel Martin
Consultant in Anaesthesia and Critical Care, Senior Lecturer, UCL Division of Surgery and Interventional Science
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Royal Free Hospital
London
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Dear Dr Martin

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

Thank you for your letter of 15th July 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

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 favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Tad Jones, NRESCCommittee.London-WestLondon@nhs.net. Under very

limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The 'What if I decide I don't want to be a part of this study?' section in the participant information sheet should state that once data has been anonymised and sent to the researchers it will not be possible to identify a specific record to withdraw a participant.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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 Approval (England)/ NHS permission for research is available in the Integrated Research Application System, 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 Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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

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” above).

Approved documents

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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
IRAS Application Form XML file [IRAS_Form_06062016]		06 June 2016
IRAS Checklist XML [Checklist_06062016]		06 June 2016
IRAS Checklist XML [Checklist_15072016]		15 July 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 [HRA Schedule of events]	1	30 May 2016
Other [Patient information sheet]	2.1	14 July 2016
Other [Response to REC committee]	3	14 July 2016
Participant information sheet (PIS)		
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

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.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service 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>


We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

16/LO/1154

Please quote this number on all correspondence

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

Yours sincerely



Dr Catherine Urch
Chair

Email: NRESCommittee.London-WestLondon@nhs.net

Enclosures: *"After ethical review – guidance for researchers"* [\[SL-AR2\]](#)

Copy to: *Ms Suzanne Emerton*
Ms Suzanne Emerton, University College London