Health Research Authority
London - West London & GTAC Research Ethics Committee
Nottingham REC Centre
The Old Chapel
Royal Standard Place
NG1 6FS

08 June 2016

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

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 application for ethical review, which was received on 6th June 2016. I can confirm that the application is valid and will be reviewed by the Proportionate Review Sub-Committee on 15 June 2016. To enable the Proportionate Review Sub Committee to provide you with a final opinion within 10 working days your application documentation will be sent by email to Committee members.

One of the REC members is appointed as the lead reviewer for each application reviewed by the Sub-Committee. I will let you know the name of the lead reviewer for your application as soon as this is known.

Please note that the lead reviewer may wish to contact you by phone or email between 12th and 14th of June 2016 to clarify any points that might be raised by members and assist the Sub-Committee in reaching a decision.

If you will not be available between these dates, you are welcome to nominate another key investigator or a representative of the study sponsor who would be able to respond to the lead reviewer's queries on your behalf. If this is your preferred option, please identify this person to us and ensure we have their contact details.

You are not required to attend a meeting of the Proportionate Review Sub-Committee.

Please do not send any further documentation or revised documentation prior to the review unless requested.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster]	2	01 June 2016
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
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
Participant information sheet (PIS)	1	30 May 2016
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

No changes may be made to the application before the meeting. If you envisage that changes might be required, you are advised to withdraw the application and re-submit it.

Notification of the Sub-Committee's decision

We aim to notify the outcome of the Sub-Committee review to you in writing within 10 working days from the date of receipt of a valid application.

If the Sub-Committee is unable to give an opinion because the application raises material ethical issues requiring further discussion at a full meeting of a Research Ethics Committee, your application will be referred for review to the next available meeting. We will contact you to explain the arrangements for further review and check they are convenient for you. You will be notified of the final decision within 60 days of the date on which we originally received your application. If the first available meeting date offered to you is not suitable, you may request review by another REC. In this case the 60 day clock would be stopped and restarted from the closing date for applications submitted to that REC.

Setting up sites in the NHS

All researchers and local research collaborators who intend to participate in this study at sites in the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland should work with the relevant care organisation to ensure management permission is confirmed before the study begins. Guidance on how to work with sites is provided in the IRAS help section at https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx

Final management permission will not be confirmed until after a favourable opinion has been given by this Committee, and all other relevant approvals for the research to begin are in place. Please contact the NHS R&D office at the lead site in the first instance for further guidance.

Communication with other bodies

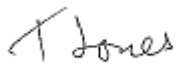
All correspondence from the REC about the application will be copied to the research sponsor and to the R&D office for University College London Hospitals NHS Trust. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

HRA Training

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

16/LO/1154	**Please quote this number on all correspondence**

Yours sincerely



Tadeusz Jones
REC Assistant

Email: NRESCommittee.London-WestLondon@nhs.net

Enclosure: *[Further information about REC membership]*

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