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

17 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**

The Proportionate Review Sub-Committee of the London - West London & GTAC Research Ethics Committee reviewed the above application on 15 June 2016.

Provisional opinion

The Sub-Committee would be content to give a favourable ethical opinion of the research, subject to clarification of the following issues and/or the following changes being made to the documentation for study participants:

1. Clarify the aim of the study.

2. Clarify the number of intended participants.

3. Explain why the hospital number in the data collection form is necessary or remove this.

4. Clarify if safety concerns could be identified during the study and if you would disseminate such information.

5. Clarify if there would be any potential conflict of interest with trainees collecting data on the practice of senior anaesthetists they are accountable to and how you might mitigate this.

6. Reassure the Sub-Committee that only fully anonymised data will be leaving the NHS Trust that treated the participant or submit consent forms for staff and patients.

7. Amend the study advert to make the logo much smaller and include more detail as to what the study is.

8. Amend the study sheet for anaesthetists as follows.
a) Correct the aims of the project.
b) Add the names and contact details of the people running the study.
c) Refer any complaints to the study co-ordinating team or chief investigator, and not the local investigator.
d) The study sheet for anaesthetists should state that outcome data for 30 days post-op is being collected.

When submitting a response to the Sub-Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

Authority to consider your response and to confirm the final opinion on behalf of the Committee has been delegated to Chair.

Please contact Tad Jones, REC Assistant, if you need any further clarification or would find it helpful to discuss the changes required with the lead reviewer.

The Committee will confirm the final ethical opinion within 7 days of receiving a full response. A response should be submitted by no later than 17 July 2016.

Summary of discussion at the meeting

- **Social or scientific value; scientific design and conduct of the study**

The Sub-Committee agreed that there appeared to be some confusion in the documentation regarding the study aim and would like this clarified.

- **Recruitment arrangements and access to health information, and fair participant selection**

The Sub-Committee noted that there was discrepancy within the IRAS form as to the number of intended participants.

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

The Sub-Committee discussed if the hospital number from the data collection form should be removed to ensure anonymity and asked for clarification on the purpose of its inclusion.

The Sub-Committee discussed if safety concerns could be identified during the study and queried if the applicants would disseminate such information. The Sub-Committee further discussed whether the trainees collecting data would be accountable to senior anaesthetists and if there might be a conflict of interest.

The Sub-Committee agreed that greater efforts could be made to inform participants of the study so they can opt out if they wish to.

- **Informed consent process and the adequacy and completeness of participant information**

The Sub-Committee discussed the lack of informed consent for the study and thought participants should be consented where possible. The Sub-Committee agreed that it may not be necessary if only anonymised data leaves the NHS Trust that treated the participant.

The Sub-Committee noted the study sheet for anaesthetists was inconsistent with the IRAS form as to the aim of the project and agreed the study sheet should be corrected if necessary.

The Sub-Committee agreed the study sheet for anaesthetists should give the names and contact details of the people running the study, and should refer any complaints to the study co-ordinating team or chief investigator, and not the local investigator.

The Sub-Committee agreed the study advert logo was much too large and there should be more detail on the advert as to what the study is.

The Sub-Committee noted the study sheet for anaesthetists should state that outcome data for 30 days post-op are being collected.

Documents reviewed

The documents reviewed were:

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

Membership of the Committee

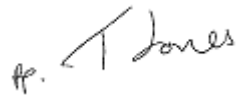
The members of the Committee who were present at the meeting are listed on the attached sheet.

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.

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

Yours sincerely



Dr Elizabeth K Lund
Chair

Email: NRESCommittee.London-WestLondon@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

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

London - West London & GTAC Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 15 June 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Elizabeth K Lund	Independent consultant	Yes	(Chair)
Mr Roy Sinclair	Pharmacist	Yes	
Miss Ravinder Summan	Research Nurse	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Tad Jones	REC Assistant