Health Research Authority
South Central - Berkshire B Research Ethics Committee
Whitefriars
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Lewins Mead
Bristol
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Telephone: 0207 104 8037

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

15 July 2016

Dr S R Moonesinghe
Anaesthetics Department, Podium 3, Maple Link Corridor
University College Hospital, 235 Euston Road
London
NW1 2BU

Dear Dr Moonesinghe

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

The Research Ethics Committee reviewed the above application at the meeting held on 12 July 2016. Thank you for attending with Dr Wong to discuss the application.

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, Tina Cavaliere, nrescommittee.southcentral-berkshireb@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.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

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

The Committee gave a favourable opinion of the application (with additional conditions):

1. Please include the following to the Participant Information Sheets (PIS):

a. Please add to **all the information sheets:**

i. A short introduction explaining that the study is a follow on from SNAP I.

ii. Please explain explicitly in all information sheets that the data will be kept for 10 years.

b. Explain in the **Main study PIS**:

i. That patients, clinicians and others involved in the operation and post-operative care will also be taking part.

ii. Please expand the section "Why haven't I been asked for permission to use my information", you may wish to use the wording "For the majority of studies informed consent is required before collecting information; in this case due to the nature of the study, we have been given exemption from Section 251 of the Health and Social Care Act 2001…"

iii. Under the title "Why haven't I been asked for permission to use my information?" change "Some patients are very sick before…" to "Some patients are very unwell before…".

c. Add in the **Clinical Perceptions Participant Information Sheet:**

i. That the questionnaire has been previously used and is validated for the study being currently undertaken.

ii. Under "What are the possible disadvantages and risks of taking part?" specifically highlight that participants would not be identified "All data will be anonymised so there is no risk of you being identified".

d. In the **Charge Nurse Information Sheet:**

i. Add in the first paragraph "most hospitals across the country and your hospital is taking part".

ii. Add: "Patients, clinicians and other members of staff are being given questionnaires to fill in".

iii. Add the phrase "Information will be anonymised and you will not be able to be identified from it".

e. In the **Quality of Recovery Information Sheet**:

i. In page 2 under "What are the possible benefits of taking part?" change the sentence "We cannot promise the study will help you directly…" to "The study will not help you directly…".

2. Please add to the Protocol that the charge nurse would be informed when a participant is given the questionnaire.

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, at 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

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study 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" below).

Summary of discussion at the meeting

Ethical issues raised by the Committee in private discussion, together with responses given by the researcher when invited into the meeting

The Chair welcomed you and Dr Wong (Key Investigator) and introduced the Committee.

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

The Committee queried how the pilot sub-study was included within the main study.

Dr Wong replied that the pilot would be conducted only in 2 hospitals in the London and South East area to iron out any problems and check the feasibility of data collection.

The Committee asked whether the 8177 proposed patient sample would be able to be recruited from the 7 sites listed on the application.

You replied that there would be up to 230 hospitals taking part in the study but as advised by the HRA Approvals Team a sample of 7 sites was listed on the IRAS form.

The Committee thanked you and Dr Wong for this information. It was content with the clarification.

The Committee noted that the cover letter stated that the study would "estimate whether planned critical care admission reduces post-operative complications".

You thanked the Committee for highlighting this and explained that using matched scoring you hoped to find whether there was a relationship between planned critical care admissions and post-operative complications.

The Committee reflected that as an observational study it would be more accurate to note that an "indication" may be found but did not raise this as an ethical issue.

The Committee commented that transcribing and data entry could be very onerous and asked whether it may be a challenge to ask staff to complete the study when they were already very busy.

Dr Wong replied that as the study was over a very short period of time that it should not take up too much time. Dr Wong stated that there were also Research Co-ordinators in approximately 95% of the hospitals who would be able to facilitate the transcribing. Dr Wong also explained that the computer systems used were very intuitive and therefore would highlight any incorrectly-completed or missing fields.

The Committee was content with the explanation given.

The Committee noted that some participants may need support when filling out the questionnaires. The Committee requested that the charge nurse would be informed when a participant had been approached.

You and Dr Wong confirmed that this would be possible.

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

The Committee commented that data may be collected for up to 10 years but this was not stated in the Participant Information Sheet (PIS).

The Committee asked whether you felt it was sufficient to use the completion of the questionnaires as implied consent.

Dr Wong responded that they had used SNAP I as a foundation for the design of SNAP II. He explained that asking patients to fill out the questionnaires had worked well in the previous study and the team had not had any major problems.

The Committee was content with the response given.

The Committee explained that there would be
a few minor changes in the participant-facing documents which would require amending but that this would be outlined in the REC Opinion Letter.

You and Dr Wong left the room and the Committee discussed the application further.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		20 May 2016
IRAS Application Form [IRAS_Form_08062016]		08 June 2016
IRAS Application Form XML file [IRAS_Form_08062016]		08 June 2016
IRAS Checklist XML [Checklist_30062016]		30 June 2016
Other [Appendix 3: Occupancy questionnaire]	0.6	20 April 2016
Other [Appendix 4: Clinician Perception Case Report Form]	0.7	19 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
Participant information sheet (PIS) [Appendix 5: Main Study Participant Information Sheet]	0.4	21 March 2016
Research protocol or project proposal [EPICCS Protocol]	1.3	29 June 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]	0.8	

Membership of the Committee

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

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.

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 use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

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/SC/0349	**Please quote this number on all correspondence**

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

Yours sincerely

Pp Dr John Sheridan
Chair

E-mail: nrescommittee.southcentral-berkshireb@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Ms Suzanne Emerton, University College London*
Confidentiality Advise Team

South Central - Berkshire B Research Ethics Committee

Attendance at Committee meeting on 12 July 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Nicola Adey	Regulatory Officer	No	
Mr Mike Arnott	Research Consultant	Yes	
Dr Alan Clark	Pharmacist	Yes	
Dr Mike Proven	Coordinator for QAR (UREC Secretary)	Yes	
Mrs Sue Harrison	Retired Managing Director of a Trade Association	Yes	
Mr John Inman (Alternate Vice Chair)	Retired Pharmacist	Yes	
Dr Joanne Milton	Project Manager	No	
Dr John Sheridan (Chair and Meeting Chair)	Consultant Toxicologist and Chemist	Yes	
Mrs Mary Sneade	Clinical Trial Manager	Yes	
Mr Paul Soper	Research Manager	Yes	
Miss Elena Villarreal	Assistant Clinical Research Coordinator	Yes	
Dr Thomas Edward Woodcock	Consultant - Intensive Care Unit (Retired)	Yes	
Mr Stuart Young	Director	No	

Also in attendance:

Name	*Profession (or reason for attending)*
Miss Sadie McKeown-Keegan	REC Assistant (Minutes)