Health Research Authority
NRES Committee West Midlands - Coventry & Warwickshire
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 883 9440

31 January 2014

Dr S Ramani Moonesinghe
University College London Hospitals NHS Trust
Anaesthetics Department, Podium 3, Maple Link corridor
University College Hospital
235, Euston Road, London
NW1 2BU

Dear Dr Moonesinghe,

Study title:	**A Sprint National Anaesthesia Project (SNAP) to survey patient reported outcome after anaesthesia in UK Hospitals**
REC reference:	**14/WM/0043**
IRAS project ID:	**138384**

The Proportionate Review Sub-committee of the NRES Committee West Midlands - Coventry & Warwickshire reviewed the above application on 29 January 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager, Rebecca Morledge, NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net.

Ethical opinion

- The Committee agreed the study is suitable for proportionate review

- The Committee noted this is a questionnaire based study, consisting of 2 questionnaires
  1) Bauer Patient Satisfaction – Discomfort & Satisfaction
  2) Modified Brice – Memory, awareness

- The Committee noted the 2 aims of the study
  1) A national bench mark for patient satisfaction after anaesthesia
  2) An estimate of accidental awareness under anaesthesia

- The Committee noted it had been acknowledged the study may provoke patients into making complaints

- The Committee noted the study would be carried out over 2 consecutive days

- The Committee noted all NHS hospitals in the UK with anaesthetic departments will be invited to participate

- The Committee agreed a consent form is not required as the prospective patients would be shown the Participant Information Sheet, and completion of the questionnaire would show consent

- The Committee noted the data would entered onto a database locally, and no patient identifiable data would be transferred outside the hospital site

- The Committee were concerned that this study should be reviewed by an appropriately experienced statistician, as this could be very important data.

- The Committee noted funding for the study is from RCAnaesth and UCL/UCLH NIHR BiomedicalRes Centre

- The Committee felt it may be helpful to record the number of non-respondents and if possible the demographics of this group.

The sub-committee confirmed that this study has no material ethical issues.

On behalf of the Committee, the sub-committee 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.

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" below).

Conditions of the favourable opinion

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

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System 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 approvals 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 within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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 contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

a. A PALS contact number needs to be included on the Participant Information Sheet

b. The date on the questionnaire should be left blank for the participant to fill in on the day it is completed rather than having to circle a date

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made 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.

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).

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Investigator CV		
Participant Information Sheet	1.2	27 November 2013
Protocol	1.3	27 November 2013
Questionnaire: Modified Brice	1	20 January 2014
Questionnaire: Bauer Patient Satisfaction	1	20 January 2014
REC application	138384/552668/1/398	17 December 2013

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review 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.

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 NRES 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 website.
Information is available at National Research Ethics Service website > After Review

14/WM/0043	Please quote this number on all correspondence

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/

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

Yours sincerely,

Dr Helen Brittain
Chair

Email: NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

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

"After ethical review – guidance for researchers"

Copy to: *Miss Alka Mistry, Joint Research Office, UCL*

NRES Committee West Midlands - Coventry & Warwickshire

Attendance at PRS Sub-Committee of the REC meeting on 29 January 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Helen Brittain	Clinical Psychologist Retired	Yes	
Dr John S Fenlon	Statistical Consultant	Yes	
Reverend Keith Lackenby	Lay member	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Victoria Strutt	REC Assistant