Health Research Authority
South Central - Berkshire B Research Ethics Committee
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12 August 2016

Dr S Ramani Moonesinghe
Royal College of Anaesthetists
NIAA Health Services Research Centre
Royal College of Anaesthetists
35 Red Lion Square, London
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Dear Dr Moonesinghe

Title of the Research Database:	**Perioperative Quality Improvement Programme (PQIP)**
REC reference:	**16/SC/0374**
IRAS project ID:	**211179**

Thank you for your letter of 08 August 2016, responding to the Committee's request for further information on the above research database and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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, Miss 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

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation as revised.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter and provided that you comply with the standard conditions of ethical approval for Research Databases set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research database.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper		
Covering letter on headed paper		08 August 2016
IRAS Checklist XML [Checklist_08082016]		08 August 2016
Other [Chief Investigator CV]		
Other [List of eligible procedures]		
Other [Data Sharing Agreement]	1.0	26 July 2016
Other [PQIP Patient information on website]	1.0	26 July 2016
Other [PQIP Patient information on website]	1.0	26 July 2016
Other [PQIP Database protocol WITH TRACKED CHANGES]	1.1	26 July 2016
Other [PQIP Patient information Sheet, Consent form and questionnaires WITH CHANGES HIGHLIGHTED]	0.5	20 July 2016
Participant information sheet (PIS) [PIS, Consent form and patient reported outcome questionnaires CLEAN]	0.5	20 July 2016
Protocol for management of the database [PQIP database protocol]	1.1	26 July 2016
REC Application Form [RD_Form_08082016]		08 August 2016

Research governance

Under the Research Governance Framework (RGF), there is no requirement for NHS research permission for the establishment of research databases in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the RGF.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the database has ethical approval.

Site-specific assessment (SSA) is not a requirement for ethical review of research databases.

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 standard conditions give detailed guidance on reporting requirements for research databases with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

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/0374	**Please quote this number on all correspondence**

Yours sincerely

Ms Helen Sivey
REC Assistant

pp. Dr John Sheridan
Chair
E-mail: nrescommittee.southcentral-berkshireb@nhs.net