NHS
Health Research Authority
London - Brent Research Ethics Committee
80 London Road
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London
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Telephone: 020 7972 2554

08 November 2016

Professor Rupert Pearse
Professor of Intensive Care Medicine
Queen Mary University of London
Adult Critical Care Unit, Royal London Hospital
London
E1 1BB

Dear Professor Pearse

Study title:	**Optimisation of Peri-operative Cardiovascular Management to Improve Surgical Outcome II (OPTIMISE II) Trial: Open, multi-centre, randomised controlled trial of cardiac output-guided fluid therapy with low dose inotrope infusion compared to usual care in patients undergoing major elective gastrointestinal surgery.**
REC reference:	**16/LO/2067**
IRAS project ID:	**209688**

Thank you for your application for ethical review, which was received on 7th November 2016. I can confirm that the application is valid and will be reviewed by the Research Ethics Committee at the meeting on 28 November 2016.

Meeting arrangements

The meeting will be held in the Boardroom, Floor 7, Maternity Block, Northwick Park Hospital, Watford Road, Harrow, Middlesex, HA1 3UJ on 28 November 2016. The Committee would find it helpful if you could attend the meeting to respond to any questions from members. Other key investigators and a representative of the sponsor are also welcome to attend. This may avoid the need to request further information after the meeting and enable the Committee to make a decision on the application more quickly.

If you have a disability and need any practical support when attending the REC meeting you may wish to contact the REC office so appropriate arrangements can be made if necessary.

If you are unable to attend the meeting the Committee will review the application in your absence.

The review of the application has been scheduled for 17.50. Please note that it is difficult to be precise about the timing as it will depend on the progress of the meeting. We would kindly ask you to be prepared to wait beyond the allocated time if necessary.

If you cannot attend, it would be helpful if you could be available on the telephone at the time of the review.

Please let me know whether or not you would be available to attend the meeting or be available on the telephone.

Further information regarding attending a REC meeting is available on the HRA website: http://www.hra.nhs.uk/research-community/the-review-process/nhs-research-ethics-committee-rec-review/

Committee meetings are occasionally attended by observers, who will have no vested interest in the applications under review or take any part in discussion. All observers are required to sign a confidentiality agreement.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		07 November 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]		04 November 2016
GP/consultant information sheets or letters [GP letter]	1.0	03 November 2016
IRAS Application Form [IRAS_Form_07112016]		07 November 2016
IRAS Application Form XML file [IRAS_Form_07112016]		07 November 2016
IRAS Checklist XML [Checklist_07112016]		07 November 2016
Letter from sponsor [Letter from sponsor]		04 November 2016
Participant consent form [Informed consent form]	1.0	03 November 2016
Participant information sheet (PIS) [Patient information sheet]	1.0	03 November 2016
Research protocol or project proposal [Study Protocol]	1.0	02 November 2016
Summary CV for Chief Investigator (CI) [Rupert Pearse CV]		10 January 2015

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

Notification of the Committee's decision

You will receive written notification of the outcome of the review within 10 working days of the meeting. The Committee will issue a final ethical opinion on the application within a maximum of 60 days from 14 November 2016, excluding any time taken by you to respond fully to one request for further information or clarification after the meeting.

Site-specific assessments

NHS sites

Site-specific assessment (SSA) for any site within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland will form part of the nation specific local processes for that site. Guidance on how to work with sites is provided in the IRAS help section at https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx

If the REC gives a favourable opinion, this will apply to any NHS/HSC site on condition that management permission is confirmed by the host organisation prior to the research starting at the site.

There is no need to submit an SSI Form or other local information to any REC.

Non-NHS sites

SSA for any sites outside the NHS or HSC ("non-NHS sites") will be undertaken by the REC.

You should now arrange for site-specific assessment (SSA) to be carried out for all non-NHS sites at which a local Principal Investigator (PI) is to be appointed to conduct the research.

The Site-Specific Information (SSI) Form for each site should be submitted to the Research Ethics Committee together with the following:

- A CV for the local Principal Investigator
- Evidence of the Principal Investigator's professional registration
- Evidence of insurance or indemnity cover for the PI and where applicable the local host organisation *(Note: does not apply to Phase 1 clinical trials in healthy volunteers)*
- A copy of the MHRA accreditation certificate if applicable (*Note: applies only to Phase 1 clinical trials in healthy volunteers)*.

No further documents need to be submitted. The main purpose of the SSA is to assess the suitability of the local Principal Investigator, site and facilities.

Where a SSI form is submitted after the review of the application by the REC, the REC has 14 days (for a Phase 1 trial) or 25 days (for other studies) from receipt of a Site Specific Assessment application to notify the Chief Investigator of the outcome of the SSA.

When seeking permission from the host organisation, you may be required to submit localised versions of REC approved documents e.g. Participant Information Sheet, Consent Form and letter to GP (where appropriate).

Management Permission

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. 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/2067	Please quote this number on all correspondence

Yours sincerely

Julie Kidd
REC Manager

Email: nrescommittee.london-brent@nhs.net

Enclosure: List of Names and Professions of REC Members

Copy to: *Miss Ann Thomson*
Dr Sally Burtles, Queen Mary University of London

London - Brent Research Ethics Committee

The names and professions of the London - Brent Research Ethics Committee are listed in the table below. Please note, some of these members may not be present at the meeting.

Name	Profession	Capacity
Dr Daniel Bradford	Pharmacologist	Expert
Dr Anke Furck	Consultant in Paediatric Intensive Care	Expert
Dr Dusko Ilic	Reader in Stem Cell Science	Expert
Mr Adeyemi Olagbegi	Clinical Pharmacology Study Data Manager	Expert
Dr Manish Saxena	Clinical Lecturer	Expert
Dr Zdenek Slavik	Consultant Paediatric Cardiologist/Intensivist	Expert
Dr Krishna Soondrum	Consultant Paediatric Gastroenterologist	Expert
Dr Graham Davison	Pharmaceutical Consultant	Lay
Miss Ourania Xeniou	Senior Clinical Research Associate	Lay
Miss Zainab Yate	Bioethics Researcher	Lay
Mr Suresh Akula	Retired Civil Servant	Lay Plus
Mrs Sunder Chita	Manager	Lay Plus
Mrs Diana Harvey	Lawyer	Lay Plus
Mr Maurice Hoffman	Retired Teacher	Lay Plus