

Scotland A REC
2nd Floor Waverley Gate
2 - 4 Waterloo Place
Edinburgh
EH1 3EG

Telephone: 0131-465-5679

19 February 2016

Professor Karim Brohi
Professor of Trauma Science
Queen Mary University of London
Blizard Institute
4 Newark Street
London
E1 2AT

Dear Professor Brohi,

Study title: Organ Dysfunction in Trauma: a national one month
point prevalence study
REC reference: 15/SS/0170
IRAS project ID: 190324

Thank you for your letter responding to the Committee's request for further information on the above research 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 opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Miss Manx Neill, manx.neill@nhslothian.scot.nhs.uk

The Committee has considered and reviewed the project as research and given the ethical opinion detailed below. However, we are of the view that the project would be more appropriately classified as audit/service evaluation rather than research. We suggest that you discuss the matter with the sponsor and lead R&D office, and following that discussion advise the REC how it is intended to manage the project. If the sponsor and R&D office advise that the project can now be considered not to be research the application should be withdrawn. If it will continue to be managed as research, the opinion given below will remain in place.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above

research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Adults with Incapacity (Scotland) Act 2000

I confirm, however, that the Committee has not approved this research project for the purposes of the Adults with Incapacity (Scotland) Act 2000. The Committee is not satisfied that the requirements of section 51 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

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

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 NHS permission for research is available in the Integrated Research Application System, 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 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.

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, 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).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering letter]		28 August 2015
Covering letter on headed paper [ORDIT study Scotland A REC response letter]	1.0	08 February 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [QM Insurance Certificate]		
Letter from sponsor [Letter from sponsor]		25 June 2015
Other [Nearest relative guardian or welfare attorney consent form]	1.3	16 September 2015
Other [Participant information sheet nearest relative, guardian or welfare attorney]	1.1	16 September 2015
Participant consent form [Participant consent form]	1.2	02 August 2015
Participant information sheet (PIS) [PIS]	1.3	29 July 2015
REC Application Form [REC_Form_07092015]		07 September 2015
Referee's report or other scientific critique report		13 February 2015
Research protocol or project proposal [ORDIT NCTIMP protocol]	1.0	01 June 2015
Research protocol or project proposal [ORDIT study protocol (Scotland)]	1.1	08 February 2016
Summary CV for Chief Investigator (CI) [CI CV]		14 June 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [ORDIT study scheme diagram]	v1.0	25 August 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study flow diagram]	1.1	09 February 2016
Validated questionnaire [EQ5D notes and questionnaire]		

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 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/>

15/SS/0170

Please quote this number on all correspondence

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

Yours sincerely



Dr Ian Zealley
Chair

Email: manx.neill@nhslothian.scot.nhs.uk

Tel: 0131-465-5680

Enclosures: "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

Copy to: Dr Sally Burtles, Queen Mary University of London/Barts Health NHS Trust