NHS
Health Research Authority

North West - Greater Manchester South Research Ethics Committee
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01 February 2016

Professor Philip A Kalra
Consultant and Honorary Professor of Nephrology
Salford Royal NHS Foundation Trust
Dept of Renal Medicine
Stott Lane
Salford
M6 8HD

Dear Professor Kalra

Study title:	**Salford Kidney Study**
REC reference:	**15/NW/0818**
IRAS project ID:	**191925**

Thank you for your email of 26 January 2016, 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 Vice-Chair and Mrs Lesley Thornton.

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, Mrs Margaret Hutchison,

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.

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 Blewet _____), 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).

Approved documents

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

Document	*Version*	*Date*
GP/consultant information sheets or letters	1	25 September 2015

GP/consultant information sheets or letters [Re-Consent]	1	25 September 2015
GP/consultant information sheets or letters [New patient]	1	25 September 2015
IRAS Checklist XML [Checklist_08102015]		08 October 2015
Other [Email confirmation of Sponsor]		08 October 2015
Other [REC favourable opinion - export of samples]	version 1	11 October 2013
Other [Amendment - export of samples]	version 1	25 September 2013
Participant consent form [Re-Consent]	1	25 September 2015
Participant consent form [Healthy heart sub-study]	version 1.1 HHSS	19 November 2015
Participant consent form [SKS Consent Form]	1.2	25 January 2016
Participant information sheet (PIS) [Re-Consent]	1	25 September 2015
Participant information sheet (PIS) [Healthy heart sub-study]	version 1.1 HHSS	19 November 2015
Participant information sheet (PIS)	1.3	19 November 2015
REC Application Form [REC_Form_29092015]		29 September 2015
Research protocol or project proposal	1	25 September 2015
Summary CV for Chief Investigator (CI)		
Validated questionnaire [EQ-5D-5L]		
Validated questionnaire [IPOS 5 - patient version]		
Validated questionnaire [IPOS Renal Patient Version]		
Validated questionnaire [MOCA]		
Validated questionnaire [Trial Making Test Parts A and B]		

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/NW/0818	**Please quote this number on all correspondence**

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

Yours sincerely

On behalf of
Professor Sobhan Vinjamuri
Chair

Email:

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Natalie Garratt,
Salford Royal NHS Foundation Trust