

NRES Committee East Midlands - Derby

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05 July 2012

Professor Nilesh J Samani
British Heart Foundation Professor of Cardiology
University of Leicester
Dept of Cardiovascular Science
Glenfield Hospital
Groby Road, Leicester
LE3 9PQ

Dear Professor Samani

Study title: The GENVASC Study: Genetics and the Vascular Health
Check Programme
REC reference: 12/EM/0208

Thank you for your letter of 25 June 2012, 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.

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.

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

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

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Advertisement	1.0	27 April 2012
Covering Letter		07 May 2012
Evidence of insurance or indemnity		18 May 2012
Investigator CV		
Other: Withdrawal Form	1.0	27 April 2012
Participant Consent Form	1.0	27 April 2012
Participant Information Sheet	2.0	20 June 2012
REC application		18 May 2012
Response to Request for Further Information		25 June 2012
Protocol	1.1	01 May 2012

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

Re-issued 17.08.12 to change document listing error

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.

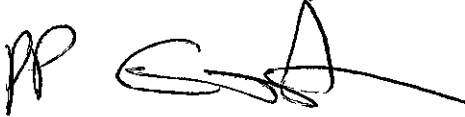
Further information is available at National Research Ethics Service website > After Review

12/EM/0208

Please quote this number on all correspondence

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

Yours sincerely

Handwritten initials 'PP' and a signature.

Mr Peter Korczak
Chair

Email: stephen.briggs@nnotts.nhs.uk

Copy to: *Sponsor - Wendy Gamble*

R & D - Ms Debbie Wall, Leicester City PCT