



# Health Research Authority

## East Midlands - Derby Research Ethics Committee

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

**Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

10 August 2017

Mrs T Maitland  
Research Governance Officer  
NIHR Leicester Biomedical Research Centre – Cardiovascular Theme  
Department of Cardiovascular Sciences  
Clinical Sciences Wing  
Glenfield Hospital  
Groby Road  
Leicester  
LE3 9QP

Dear Mrs Maitland,

<b>Study title:</b>	<b>The GENVASC Study: Genetics and the Vascular Health Check Programme</b>
<b>REC reference:</b>	<b>12/EM/0208</b>
<b>Amendment number:</b>	<b>7</b>
<b>Amendment date:</b>	<b>10 July 2017</b>
<b>IRAS project ID:</b>	<b>107325</b>

The above amendment was reviewed on 03 August 2017 by the Sub-Committee in correspondence.

### **Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Decision: No ethical issues.

### **Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters [SystemOneGENVASC GP Invitation Letter near side test draft.docx]	1	29 June 2017

GP/consultant information sheets or letters [GP practice invitation letter near side test draft. v1 0 280414.doc]	1	29 June 2017
Notice of Substantial Amendment (non-CTIMP) [SA 7 AmendmentForm_ReadyForSubmission.pdf]	7	10 July 2017
Other [Paragraph to be added to the NHS Health Check invite letter near side testing draft.docx]	1	29 June 2017

### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

### Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

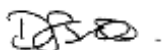
### Statement of compliance

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>12/EM/0208:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



PP  
**Mr Peter Korczak (Chair)**  
**Chair**

E-mail: NRESCCommittee.EastMidlands-Derby@nhs.net

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Ms Deb Wall  
Professor Nilesh J Samani  
Mrs Wendy Gamble*

**East Midlands - Derby Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 03 August 2017**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr John S Fenlon	Statistical Consultant	Yes	
Mr Peter Korczak (Chair)	Consultant Maxillofacial Surgeon	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Daniella Sarno	REC Assistant