



# 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.**

04 March 2019

Mrs Tara 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>8</b>
<b>Amendment date:</b>	<b>30 November 2018</b>
<b>IRAS project ID:</b>	<b>107325</b>

The above amendment was reviewed 04 March 2019 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.

### **Discussion**

There were no ethical issues raised.

### Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (non-CTIMP)	8	30 November 2018
Other [HRA schedule of events]		30 November 2018
Research protocol or project proposal [Clean]	1.4	30 November 2018
Research protocol or project proposal [Tracked]	1.4	

### 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.

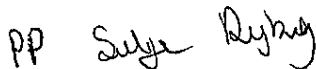
### Statement of compliance

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



**Dr John S Fenlon  
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, R+D manager*



# Health Research Authority

*Professor Nilesh J Samani, University of Leicester*  
*Diane Delahooke, University of Leicester*



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Attendance at Sub-Committee of the REC meeting on 04 March 2019

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr John S Fenlon (Chair)	Statistical Consultant	Yes	
Mrs Janet Mallett	Retired Nurse	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Silje Dybing	REC assistant (Minutes)