

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.

23 December 2016

Miss Tara Sadler
LCBRU Research Governance Officer
Department of Cardiovascular Sciences
Clinical Sciences Wing
Glenfield Hospital
Grobby Road
Leicester
LE3 9QP

Dear Tara Sadler

Study title:	The GENVASC Study: Genetics and the Vascular Health Check Programme
REC reference:	12/EM/0208
Amendment number:	6
Amendment date:	24 October 2016
IRAS project ID:	107325

The above amendment was reviewed on 21 December 2016 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.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Poster]	2.0	21 August 2012
GP/consultant information sheets or letters	1.0	28 April 2014

Notice of Substantial Amendment (non-CTIMP)	6	24 October 2016
Other [Withdrawal form]	1.0	27 April 2012
Other [CV - Azhar]		19 January 2015
Other [CV - Heer]		19 October 2016
Other [Information for addition to NHS HC invite letters]	1	21 April 2016
Participant consent form [Un-witnessed]	1.1	12 September 2013
Participant consent form	4.2	12 September 2013
Participant information sheet (PIS) [abbreviated]	3.0	12 September 2013
Participant information sheet (PIS)	4.0	12 September 2013
Research protocol or project proposal	1.3	22 September 2016

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.

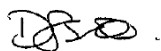
Statement of compliance

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/>

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



PP
Mr Peter Korczak (Chair)
Chair

E-mail: NRESCommittee.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
Professor Nilesh J Samani, University of Leicester
Mrs Wendy Gamble*

East Midlands - Derby Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 21 December 2016

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