



Health Research Authority

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 02071048285

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.

29 May 2020

Diane Delahooke
University of Leicester
Research and Enterprise Division, Research Governance Office
Leicester General Hospital
LE5 4PW

Dear Diane Delahooke

Study title:	The GENVASC Study: Genetics and the Vascular Health Check Programme
REC reference:	12/EM/0208
Amendment number:	SA9 18/04/2020
Amendment date:	18 April 2020
IRAS project ID:	107325

The above amendment was reviewed 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.

After several conversations, it was agreed that the amendment would be revised and restricted to the accessing of local medical records of current participants of the GENVASC study in order to determine their SARS-CoV-2 status. All other elements described in the original notice of substantial amendment were withdrawn.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Amendment (non-CTIMP) [GENVASC SA9 NoSA]	SA9 18/04/2020	18 April 2020
Research protocol or project proposal [GENVASC Protocol V2 CLEAN 26th May 2020]	2	26 May 2020
Research protocol or project proposal [GENVASC Protocol V2 TC 26th May 2020]	2	26 May 2020

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

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



Dr John Fenlon
Chair

E-mail: derby.rec@hra.nhs.uk

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

Copy to: *Professor Nilesh J Samani, University of Leicester*

East Midlands - Derby Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 01 May 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr John S Fenlon	Statistical Consultant	Yes	
Mrs Janet Mallett	Retired Nurse	Yes	Meeting Chair
Ms Margret Vince	Translator	Yes	
Mr Michael Wakeman	Consultant Pharmacist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Anna Martin	Approvals Administrator