

26 November 2013

Professor Nilesh J Samani
University of Leicester
Dept of Cardiovascular Science
Glenfield Hospital

→ Chris Greenfield

Dear Professor Samani

Study Ref: 0330
Title: The GENVASC Study: Genetics and the Vascular Health Check Programme
Project Status: CSP Approved
End Date: 30/06/2017
Substantial Amendment 2

I am pleased to advise you that following confirmation of a Favourable Opinion from an Ethics Committee, NHS Trust R&D Approval and where relevant regulatory authority agreements have been received, the University are able to confirm the approval for above substantial Amendment.

The documents received are as follows:

Abbreviated Participant Information Sheet	V 3.0	07/12/2012
Notice of Amendment		01/10/2013
Participant Information Sheet	V 4.0	12/09/2013
Protocol	V 1.2	12/09/2013
REC Letter of Favourable Opinion		05/11/2013
R&D Approval Letter		19/11/2013

Please note, you are required to notify the Sponsor and provide copies of:

- Changes in personnel to the Study
- Changes to the end date
- All substantial amendments and provisional and favourable opinions
- All minor amendments
- All serious adverse events (SAEs) and SUSARS
- Annual progress reports
- Annual MHRA (DSUR) safety reports (if applicable)
- End of study declaration form and final report
- Notifications of significant breaches of Good Clinical Practices (GCP) or Protocol

Please copy the Sponsor into all correspondence and emails by using uolsponsor@le.ac.uk.

If you require further information or guidance please do not hesitate to contact me.

Yours sincerely

A handwritten signature in black ink, appearing to read 'W. Gamble', written in a cursive style.

Mrs Wendy Gamble
Research Governance Manager