

West Leicestershire Clinical Commissioning Group

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East Leicestershire and Rutland Clinical Commissioning Group

Professor Mayur Lakhani Highgate Medical Centre 5 Storer Close Sileby Leicestershire LE12 7UD

26 January 2015

Dear Professor Lakhani

CSP Ref number: 107325

Study Title: The GENVASC Study: Genetics and the Vascular Health Check Programme

Sponsor's Unique Amendment Number: 2

Amendment Date: 01/10/2013

Thank you for the amendment documentation relating to the above study.

This documentation has been reviewed and I am pleased to confirm that Assurance remains in place <u>from</u> **Leicester City CCG** which provides the Primary Care R&D Service across Leicester, Leicestershire and Rutland. This assurance applies to sites in **West Leicestershire CCG**. Please note that you may only implement changes that were described in the amendment notice or letter.

The current study documents that have been reviewed as part of the assurance process are as follows:

Document Title	Version	Date	REC
			Approval
Email notification of amendment	N/A	04/10/2013	N/A
REC advice on Abbreviated PIS date error	N/A	18/11/2013	N/A
Abbreviated PIS	3.0	07/12/2012	05/11/2013
Notice of Amendment	N/A	01/10/2013	05/11/2013
PIS	4.0	12/09/2013	05/11/2013
Protocol	1.2	12/09/2013	05/11/2013
REC Letter of Favourable Opinion	N/A	05/11/2013	N/A



Chair: Prof Azhar Farooqi Co-chair: Dr Avinashi Prasad

Yours sincerely

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Deb Wall Research & Development Manager Leicester City Clinical Commissioning Group