



# Leicester City Clinical Commissioning Group

  
**West Leicestershire  
Clinical Commissioning Group**

  
**East Leicestershire and Rutland  
Clinical Commissioning Group**

## City Headquarters

St John's House  
30 East Street  
Leicester  
LE1 6NB

Tel: 0116 295 1478  
[www.leicestercityccg.nhs.uk](http://www.leicestercityccg.nhs.uk)

1 November 2013

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

CSP Ref: 107325  
REC Ref: 12/EM/0208  
Portfolio Ref: 12698  
End Date: 30/06/2017  
Project Status: Research Site Assured

Dear Prof Mayur Lakhani

### Re: **The GENVASC Study: Genetics and the Vascular Health Check Programme**

I am pleased to confirm that **Leicester City Clinical Commissioning Group** which provides the Primary Care R&D Service across Leicester, Leicestershire and Rutland, has received a review of this research study via the Coordinated System for gaining NHS Permission (CSP) from the LNR CLRN. This review confirms that the appropriate study-wide and local research governance checks have been undertaken and that this study complies with the requirements of the Research Governance Framework and national legislation. In conjunction with the local discussions the CLRN have had with you regarding participating as a site for this study, I am now happy to formally provide assurance for this study to proceed within **West Leicestershire CCG**. Your research has been entered onto our primary care research database.

This assurance is provided with the following conditions: that no additional costs are incurred at the site (s) as a result of this study being undertaken and unmet service support costs will be provided by the LNR CLRN.

**Please reply to this letter confirming the expected start date and duration of the study.** As part of the Research Governance Framework it is important that the Leicester City CCG R&D office is notified as to the outcome of your research. As such the CLRN will request feedback once the research has finished along with details of dissemination of your findings. We may also request brief updates of your progress from time to time, dependent on duration of the study. Similarly, if at anytime details relating to the research project or research team change, the Leicester City CCG R&D office must be informed.



The documents reviewed for assurance are as follows:

Document Title	Version	Date	REC Approval
REC Favourable Opinion Letter-re-issued	N/A	05/07/12	N/A
REC Substantial Amendment	1	21/12/12	N/A
Withdrawal Form	1	27/04/13	05/07/12
Protocol	1.1	01/05/12	05/07/12
GP/Consultant Information Sheets	1	31/10/12	21/12/12
Participant Consent Form: Un-witnessed ICF	1	31/10/12	21/12/12
Participant Consent Form	4.1	14/01/13	NSA
Participant Information Sheet	3	21/08/12	NSA
Advertisement Text	2	21/08/12	NSA

If you have any further questions regarding this or other primary care research you may wish to undertake in the Leicester, Leicestershire and Rutland area, please feel free to contact me again, or the LNR CLRN Primary Care research office. I wish you every success with the research.

Yours sincerely



Deb Wall  
R&D Manager  
Leicester City CCG

Tel: 0116 295 1520

Email: [debbie.wall@leicestercityccg.nhs.uk](mailto:debbie.wall@leicestercityccg.nhs.uk)

CC: Roz Sorrie, Lead RM&G Manager, LNR CLRN  
Di Baldwin, PA, R&D, Leicester City CCG  
Janice Strand, Locality Hub Manager, EMSY PCRN