

City Headquarters

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17 June 2014

Dr Leslie Borrill
Latham House Medical Practice
Sage Cross Street
Melton Mowbray
Leicestershire
LE13 1NX

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

Dear Dr Borrill,

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 Clinical Research Network: East Midlands. 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 Clinical Research Network: East Midlands 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 **East Leicestershire & Rutland 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 Clinical Research Network: East Midlands.

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 Clinical Research Network: East Midlands 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
REC Substantial Amendment	2	05/11/13	N/A
Withdrawal Form	1	27/04/13	05/07/12
Protocol	1.2	12/09/12	05/11/13
GP/Consultant Information Sheets	1	31/10/12	21/12/12
Participant Consent Form: Un-witnessed ICF	1.1	12/09/13	NSA 03/01/13
Participant Consent Form	4.2	12/09/13	NSA 03/01/13
Participant Information Sheet	4	12/09/13	05/11/13
Participant Information Sheet – Short Information Sheet	3.0	07/12/12	05/11/13
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 Clinical Research Network: East Midlands Primary Care research office. I wish you every success with the research.

Yours sincerely



Deb Wall
R&D Manager
Leicester City CCG

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CC: Chris Greengrass - BRU GENVASC/BRICCS project manager
Janice Strand – Locality Hub Manager
Roz Sorrie – Lead RM&G Manager CRN: East Midlands
CRN: East Midlands CSP Generic Inbox