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Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

08 June 2016

Dear Professor Samani

<b>Confirmation of Amendment Assessment</b>
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<b>Study title:</b>	<b>The GENVASC Study: Genetics and the Vascular Health Check Programme</b>
<b>IRAS project ID:</b>	<b>107325</b>
<b>REC reference:</b>	<b>12/EM/0208</b>
<b>Amendment number:</b>	<b>Non-Substantial Amendment 4</b>
<b>Amendment date:</b>	<b>11 May 2016</b>
<b>Sponsor:</b>	<b>University of Leicester</b>

Thank you for your submission to the HRA of the above referenced amendment to a study which was processed through pre-HRA Approval systems.

The amendment has been assessed against HRA standards relating to the legal and regulatory aspects of the study and this letter confirms that these standards have been met, including that any and all applicable regulatory approvals are in place.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the categorisation email, including (where applicable), providing a copy of this letter to confirm that the amendment fulfils the relevant standards.

Please note that this was not a full assessment of the study against all HRA Approval standards but a review of the amendment only. As such, this letter **does not** confer HRA Approval to the study.

## User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at [hra.approval@nhs.net](mailto:hra.approval@nhs.net). Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

## HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>.

Your IRAS project ID is **107325**. Please quote this on all correspondence.

Yours sincerely

**Gemma Oakes**  
**HRA Assessor**

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

Copy to: *Ms Wendy Gamble, University of Leicester [Sponsor Contact]*  
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*Ms Debbie Wall, University Hospitals of Leicester [Lead NHS R&D Contact]*  
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## Appendix A - List of Documents

The document set reviewed during assessment of the amendment is below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Minor Amendment [Addition of paragraph to NHS Healthcheck invite letter]		11 May 2016
Sponsor Email confirming approval of amendment		29 April 2016
GENVASC information for addition to NHS HC invite letter.	1	21 April 2016