

DIRECTORATE OF RESEARCH & DEVELOPMENT

Research & Development Office
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24th August 2012

Professor Nilesh J Samani
Professor of Cardiology
University of Leicester
Dept of Cardiovascular Science
Glenfield Hospital
Groby Road, Leicester
LE3 9PQ

Dear Professor Nilesh J Samani

Ref: UHL 107325

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

Project Status: Approved

End Date: 30/06/2017

I am pleased to confirm that with effect from the date of this letter, the above study has Trust Research & Development permission to commence at University Hospitals of Leicester NHS Trust. The research must be conducted in line with the Protocol and fulfil any contractual obligations agreed with the Sponsor. If you identify any issues during the course of your research that are likely to affect these obligations you must contact the R&D Office.

In order for the UHL Trust to comply with targets set by the Department of Health through the 'Plan for Growth', there is an expectation that the first patient will be recruited within 30 days of the date of this letter. If there is likely to be a problem achieving this target, please contact the office as soon as possible. You will be asked to provide the date of the first patient recruited in due course. In addition, the Title, REC Reference number, local target recruitment and actual recruitment for this study will be published on a quarterly basis on the UHL Trust external website.

All documents received by this office have been reviewed and form part of the approval. The documents received and approved are as follows:

Document Title	Version	Date	REC Approval
Advertisement	1	27.04.12	05.07.12
Other: Withdrawal Form	1	27.04.12	05.07.12
Participant Consent Form	2	20.06.12	05.07.12
Participant Information Sheet	2	20.06.12	05.07.12
Protocol	1.1	01.05.12	05.07.12

Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.

Undertaking research in the NHS comes with a range of regulatory responsibilities. Please ensure that you and your research team are familiar with, and understand the roles and responsibilities both collectively and individually.

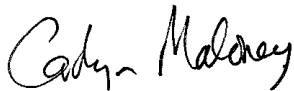
Documents listing the roles and responsibilities for all individuals involved in research can be found on the R&D pages of the Public Website. It is important that you familiarise yourself with the Standard Operating Procedures, Policies and all other relevant documents which can be located by visiting www.leicestershospitals.nhs.uk/aboutus/education-and-research

The R&D Office is keen to support and facilitate research where ever possible. If you have any questions regarding this or other research you wish to undertake in the Trust, please contact this office. Our contact details are provided on the attached sheet.

This study has been reviewed and processed by the Leicestershire, Northamptonshire & Rutland Comprehensive Local Research Network (LNR CLRN) using the Coordinated System for gaining Trust Permission (CSP). If you require any further information on the approval of this study please contact the LNR CLRN office on 0116 258 6185 making reference to the CSP number which is located at the top of this letter.

We wish you every success with your research.

Yours sincerely



Carolyn Maloney
R&D Manager

Encs: .R&D Office Contact Information

CONTACT THE RESEARCH & DEVELOPMENT OFFICE

The **R&D Office** for UHL is located at Leicester General Hospital; you are welcome to contact us for telephone advice, or to arrange an appointment. All staff contact details can be found below:

David Hetmanski	Assistant Director of R&D	0116 258 4199
Carolyn Maloney	UHL R&D Manager	0116 258 4109
Joanne Thompson	Clinical Trials Monitor/Trainer	0116 258 4140
Anne Moore	Asst. Clinical Trials Monitor/Trainer	0116 258 4140
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**Further contact details are available on the UHL Public Website
www.leicestershospitals.nhs.uk/aboutus/education-and-research/**