If you are asked by an insurance company whether you have had genetic testing, you should inform them that you have voluntarily provided samples for research purposes include genetic research, but do not have any information on the results.

**Risk** of harm by the project

The project does not involve any treatments, special investigations, or changes in the clinical care you receive. Therefore participation in the project is unlikely to result in any harm. The additional blood sample you have taken may cause transient discomfort and a small bruise.

In the unforeseen circumstance that you believe that you have been harmed, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanism is available to you. This project has been reviewed by a Research Ethics Committee to ensure that your rights and wellbeing are protected.

Problems, complaints and withdrawing from the project

If you have any concerns you can contact the study team on 0116 258 3385, or for independent advice you can contact University Hospitals of Leicester Patient Information and Liaison Service on 08081 788337.

You are free to withdraw from the research project at any time without any prejudice to the care you receive or your legal rights, by informing the NIHR Leicester Cardiovascular Biomedical Research Unit administrator at the address shown on the back of this leaflet or by returning the withdrawal form that you were given. You can ask for the samples and data you have provided to be destroyed or allow the samples and data you have already donated to continue to be used but not to have any further involvement.

**Organisation and funding of the project**

This project is managed by the NIHR Leicester Cardiovascular Biomedical Research Unit, which is funded by the National Institute for Health Research which is part of the Department of Health. The Unit is a partnership of the University Hospitals of Leicester and the University of Leicester.

The East Midlands – Leicester Research Ethics Committee has reviewed this project and given a favourable opinion of it. Research Ethics Committees are independent bodies which review all NHS research projects to ensure that your rights and wellbeing are upheld and risks are managed properly.

Funding for this project has been provided by the British Heart Foundation and the National Institute for Health Research.
The GENVASC Study: Genetics and the NHS Health Check Programme

You are being invited to participate in a research project called GENVASC that is being run by the NIHR Leicester Cardiovascular Biomedical Research Unit, based at Glenfield Hospital. This brochure provides details of the project. We would like you to understand why we are doing the project, and what participating in it would involve for you. Please ask us if anything is not clear from this leaflet.

Purpose of the project
You are having a health check to assess your risk of developing cardiovascular disease, so that if you are deemed at high risk preventative measures can be initiated. The risk is calculated by combining information on things that we know influence the chance of getting cardiovascular disease such as age, sex, blood pressure and cholesterol levels and whether you smoke and/or have diabetes. While this assessment is valuable in targeting prevention, we know that it is not perfect and some people who are deemed to be at low to medium risk still develop the disease. This is because there are other things that also affect risk of cardiovascular disease. We know that many cardiovascular diseases occur more frequently in some families, and that inheritance is also an important risk factor. For example, recent scientific advances have identified several common genetic variants that affect risk of coronary heart disease and heart attacks. Individually, the effect of each variant is small, but if some people carry many of them, this may have a substantial effect on their coronary heart disease risk. In this project, we want to test whether adding genetic information can improve prediction of cardiovascular diseases, such as coronary heart disease. By collecting appropriate blood samples and data on a large group of people attending for a health check and seeing who develops coronary heart disease and other cardiovascular diseases with time, we can retrospectively determine whether adding genetic information, or other information we can gain from the blood samples you donate, would have better identified such people compared to the current methods. If this proves to be the case, then including such information could, in the future, be of enormous individual and public benefit.

Participation
If you agree to participate the following things will happen.
• You will be asked to sign a consent form.
• A blood sample of up to 20 mls (4 teaspoons) will be taken for research. In most cases this will be done at the same time as the blood tests for your health check. We also ask for permission to save any blood left over from your health check sample.
• We will take some information from your medical records now.
• In the future we may access your medical records again for scientific information. We do this by tracking you with your NHS number.
• Subject to your specific consent, we may contact you again in the future, by post or email, to invite you to participate in other research. You are under no obligation to agree to do so.

Please note that participation in this project is entirely voluntary. It is up to you to decide if you want to take part. Your decision will not affect the care, investigations or treatment that you receive in any way. Also, to allow you more time to consider your participation, we will not undertake any tests on the samples you have provided for 30 days. If during this period (or subsequently) you wish to withdraw from the study you can do so by returning the withdrawal form you have been given.

Confidentiality and use of samples and data
Your participation in this project will remain confidential. You will be assigned a unique study number, which will be used to label your data and samples. When any researcher uses your information or your samples they will only know your study number. This will protect your identity.

Your data will be stored in a purpose built secure research database in the NIHR Leicester Cardiovascular Biomedical Research Unit. Your samples will be stored in secure facilities in the Biomedical Research Unit. They will be used for future cardiovascular research. We will extract your DNA from part of the blood you provide for genetic analysis. You can be reassured that no confidential health information on you will be released, published or presented in a manner that can identify you.

The staff managing the project will use your NHS number to source data from your medical records (now and in the future) and to invite you to take part in future research projects (if you have consented to be contacted). The research may be inspected or audited by the Research Sponsor or the UK Authorities to ensure that it is being conducted properly. The inspectors or auditors may access your records where it is relevant to the conduct of the study.

Benefits of the research
The purpose of the research is to improve the prediction of cardiovascular diseases. We will not provide individuals with results of the research findings on a routine basis. This is because the clinical relevance of some of the research findings may take several years to realise and require further validation. If our research does change clinical practice, then any tests or treatments should become available through the NHS after appropriate evaluation.

You are therefore unlikely to personally and directly benefit from taking part in the project but the information we get from this project will help in the future to improve healthcare of people at risk of cardiovascular diseases.