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Volunteer information sheet | Stage 2: Gene Recall Study

In general, South Asian people have some of the highest rates of heart disease, diabetes, and poor health in the UK. Living with a long-term illness has a major impact on a person's quality of life and on their family. Genes & Health is a medical research study set up to help fight against these and other major diseases. It is funded by the Wellcome Trust, the UK's foremost medical charity.

By involving large numbers of local Bangladeshi and Pakistani people the study hopes to find new ways of improving the health of Bangladeshi and Pakistani people in the UK and worldwide.

Some early aims of the study are:

- To study normal variation in genes in adult Bangladeshi and Pakistani people. Knowing what is normal is important when searching for genes causing inherited childhood diseases.
- To study genes in people with very high and very low cholesterol levels, to better understand why heart disease and stroke occurs.
- To study variation in genes in healthy adults whose parents are related. These studies will tell us how genes work and help develop new medicines.
- To study genes of people with diabetes, aiming to identify rarer types of diabetes for which more specific treatments can be used.

You previously volunteered for Genes & Health and completed a questionnaire and donated a saliva sample. **We would now like to invite you to donate a blood sample** for the Genes & Health research study "Gene Recall Study". Please take the time to read the following information carefully and feel free to ask if there is anything that is not clear.

By continuing to volunteer you will help researchers investigate and understand why some individuals have a disease and help suggest how new medicines and treatments might be developed.

What is the purpose of Genes & Health?

Genes & Health has established a panel of thousands of local volunteers. The volunteers were asked to donate a small saliva (spit) sample and share their GP and hospital medical records *in strict confidence* with the study team. Volunteers were asked to give their consent to be contacted again and some may be invited to participate in further medical research studies on the basis of data gathered from their samples and information.

Information and samples from the Genes & Health resource may also be made available (anonymised, so the person who gave the sample cannot be identified) to other scientists working in health care research, including universities and industry, which may be based in the UK, or worldwide. **Genes & Health is a not-for-profit project.**

Genes & Health is supporting studies looking at how genes influence disease. By looking more closely at how genes work, and how diseases develop, it will be possible to identify better treatments to cure or help prevent them.

Genes & Health will support many other medical research studies. This information sheet is about one of these further studies "Gene Recall Study".

What is the purpose of this study "Gene Recall Study"?

We are looking at how diseases may affect people according to their genetic make-up. For example, specific proteins in white blood cells function differently in people with differing genetic make-up. Because we have sequenced your genetic code, we know which naturally occurring variations you have in your genes and proteins. We are interested to find out more about how your genetic make-up may affect your health. For example, some people with certain genes are more or less likely to develop conditions such as diabetes, being overweight, heart disease or high cholesterol. By studying your genes and health in more detail, we are hoping to understand what may cause these conditions, and how to improve treatments in the future.

What are genes and proteins?

Genes are instructions to the body on how to make molecules called proteins. Proteins perform various functions in our body to keep us healthy. Genes are made of chemicals called nucleic acids, which come in units called bases and form our genetic code. Human genes vary in size from a few hundred bases to over a million bases, and every human has around 20,000 genes. Every person has two copies of each gene, one inherited from each parent. Most parts of a gene are the same, but there is some variation between people. These variations influence many factors, such as how proteins work, and contribute to each person's unique physical features.

Who can join the "Gene Recall Study"?

This study is part of Genes & Health. You have been invited because you previously joined the first stage of Genes & Health. We are only inviting previous members of Genes & Health.

If you receive an invitation, you can be assured that you have met the specific selection criteria for the study and are exactly the type of volunteer that the study team needs in order to further their research. Once you return your completed participation slip to us to confirm that you would like to participate, you will be contacted about getting involved.

Do I have to join the "Gene Recall Study"?

No. It is completely up to you to decide whether or not you wish to volunteer. If you decide not to join your decision will not affect the healthcare you receive in any way. If you do join the study, you will be free to withdraw at any time and without having to give a reason. You may continue to take part in Genes & Health but not join "Gene Recall Study". If you no longer want to be a volunteer in Genes & Health, please see the information below.

Remember, you are under no obligation to take part in any study. We closely monitor how many times we invite you to studies and volunteers participate in a maximum of four studies a year.

Please remember you are always in control and when you receive an invitation to join a study you decide if you want to participate or not.

What will happen if I agree to join the "Gene Recall Study"?

We will contact you to arrange to take a blood sample (up to 50ml, about 4 tablespoons) and/or a urine sample. This would usually be in the hospital or clinical research facility but can sometimes be arranged in your home. We would also like to perform a standard medical assessment (history-taking and brief examination).

I have been asked to fast before my blood test. What does this mean?

We may ask you to fast for up to 8 hours before your blood test. Please do not fast before your blood test unless we have asked you to do so. If we ask you to fast, then we would like you to have nothing to eat or drink apart from water for 8 hours before your blood test. We will offer you an appointment at the start of the morning so that you can fast overnight. If your appointment is at 8am, please don't eat or drink (apart from water) from midnight the night before. A member of the research team will contact you by telephone before your appointment to discuss whether you should take your medications whilst fasting.

If you have fasted, then we may also ask you to have a glucose/meal tolerance test. If you agree, then we will put a small plastic tube (a cannula) in your arm. We will take a blood test from this cannula and then ask you to drink a sugary liquid or supplement drink and/or a small snack. We will then take small blood samples (still less than 50ml in total, where possible through the cannula) half an hour apart. This test takes 2-4 hours and helps us understand how your body responds to nutrients and sugars.

What are the risks and disadvantages of joining "Gene Recall Study"?

There are no major risks. Sometimes there is a small bruise in the arm where the blood is taken. Occasionally some people feel or do faint. Around 100,000 blood tests are performed in the UK each week.

A visit usually lasts less than one hour but may rarely take up to six hours. We will warn you if we expect your visit to take a long time. We'll ask you routine questions about your health and medical history and, with your agreement we may perform a short examination (e.g., listen to your heart and lungs with a stethoscope and using a measuring tape around your waist). We will ensure that your privacy and dignity are maintained.

What will happen to the samples I give?
We will look after your blood sample and store it safely. We want to know how genes influence disease and may use some of your sample to understand (sequence) your genetic code. We may use some to analyse other nucleic acids (RNA) and to analyse proteins.

We may want to send some of the blood you donate to a specialist laboratory, where scientists will turn cells from your blood into a special type of cell called an 'induced stem cell'. These induced stem cells can then be made to grow into lots of types of cells in the body, like heart muscle cells or nerve cells, to help researchers understand how your genes affect different parts of your body. The induced stem cells can grow in a lab and will grow and divide forever. Cells may be sent to other scientists doing research about health, but those scientists won't know the name of the person who donated the cells.

If we would like to make these types of cells using your sample, and if you agree, we will ask you to tick the relevant part of the consent form. You may still volunteer for the rest of the study if you do not agree to this part, and we will not use your samples for these purposes. The induced stem cells would be stored at Queen Mary University of London or a partner organisation like a University, or at a tissue bank like ECACC.

Samples collected as part of the present research project may be stored and used by Queen Mary University of London and by external organisations, like universities, hospitals, charities and companies, that may be based in the UK, EU, USA or worldwide. All requests for samples held by QMUL are reviewed by a committee. Where the research is about a sensitive topic, we also ask our community advisory group (made up of community leaders and community members) to review the application.

What will happen next?
All the information provided by you or retrieved from your medical notes or other health records and the results of tests performed with your samples will be held on a confidential research database at Queen Mary University of London for use in medical research.

We will compensate you for your travel expenses and time (£25 per hour in vouchers for a choice of shops), up to a maximum of £150 per half-day.

As part of Genes & Health, we may invite you up to 4 times per year to take part in further research studies. This study "Gene Recall Study" is one of these invites.

Will my details be kept confidential?
Yes. Best ethical and legal practice will be followed to ensure that all information collected about you will be handled in confidence. Your samples will be labelled with a unique sample study number (not your name) before being stored. Information from genetic and other tests and from your health records will be linked to this unique number but stored separately from your personal details (surname, first name, contact details).

Information from these tests will not be used or made available for any purpose other than for research and improvements in health care. You will not be identified personally in any report or publication, including information about Genes & Health studies or the data they have gathered, which will be released on the Internet, scientific journals or other media.

Can I know the results obtained from my study samples?
We will not provide genetic or other laboratory results obtained from your sample. In the unlikely event that a result obtained from your sample indicates that you require immediate medical treatment, we would contact you and your GP.

You may ask to know (or alternatively, ask not to be told) why you were invited to "Gene Recall Study". This will usually be because of some specific information in your genetic code (of interest to a researcher, but of unknown health significance) and/or in your medical records.

What happens if a discovery is made using the donated sample?
The samples donated to Genes & Health are given as an "absolute and non-returnable gift". For example, if results from the research undertaken

with the donated samples are used to develop a new test to improve diagnosis or better medicines for treatment, then you will not receive any compensation, nor will funds be forthcoming to you.

Genes & Health will work in partnership with others in the public (e.g., Universities) and the private sector (e.g., pharmaceutical or biotechnology industry, who may be UK or overseas based) to develop any discoveries for the benefit of patients.

What will happen to the results of the research study?

To speed up developments of new diagnostic tests and better treatments, results of the studies will be made available to the public through scientific publications, including placing information on the internet, in press articles and project leaflets. This information may include part or your entire genetic code or the results of other tests performed with your samples and other relevant non-identifying information from the research database, e.g., your age in years, your gender etc. Under no circumstances would your name (or identity) be disclosed in any publication, although Genes & Health will be identified as the source of the material.

What if I no longer want to be a volunteer in Genes & Health?

You are free to withdraw from Genes & Health at any time without giving a reason. If you choose to withdraw, then you will not be contacted again, and stocks of the linked samples held at Genes & Health will be destroyed. It will not be possible to destroy samples already prepared for testing or to withdraw samples that have been distributed to other laboratories with whom Genes & Health collaborates. It will not be possible to delete information obtained from your samples or medical records from the research databases or laboratory notebooks. However, no new data will be added to the research databases or notebooks from the moment the Genes & Health team has confirmed your withdrawal. Your personal details will not be held in the research database or laboratory notebooks at any time.

Who funds and sponsors Genes & Health?

Genes & Health is funded by the Wellcome Trust and Barts Charity. It is supported by multiple NHS Trusts such as Barts Health NHS Trust, Bradford Teaching Hospitals NHS Foundation Trust, and Manchester University NHS Foundation Trust. It is also supported by multiple Clinical Commissioning Groups from the local areas of East London, Bradford and Manchester GP Practices.
Queen Mary University of London is the sponsor for this study based in the United Kingdom.

We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen Mary University of London will keep identifiable information about you for 10 years after the study has finished.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at qmul.ac.uk/privacy/ and genesandhealth.org/about-study/

Genes & Health has been reviewed and approved by London - South East National Research Ethics Service Committee (14/LO/1240).

Further information

If you want more information before deciding or have any questions about anything concerning Genes & Health, please feel free to contact the study team: elgh@qmul.ac.uk. The study website genesandhealth.org contains an up-to-date list of frequently asked questions. The procedure for any complaint about the study is to contact the Chief Investigator (02078822385 or email d.vanheel@qmul.ac.uk). Independent advice about taking part in medical research is available from INVOLVE (02380651088 or email admin@invo.org.uk).

Further learning materials about genes and human genetics are available at our science education facility in Whitechapel, Centre of The Cell (www.centreofthecell.org)

Thank you for considering volunteering for the Genes & Health study “Gene Recall Study”