Volunteer information sheet | Stage 1

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 England 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.

We would like to invite you to join Genes & Health as a volunteer. Please take the time to read the following information carefully and feel free to ask if there is anything that is not clear.

By joining 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 is establishing a panel of thousands of local volunteers. The volunteers will be asked to donate a small saliva (spit) sample and share their GP and hospital medical records *in strict confidence* with the study team. Volunteers will be 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. Some are shown above. A full list will be on our website (https://www.genesandhealth.org/).

What are genes?

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 Genes & Health?

Genes & Health is recruiting adult volunteers (age 16 and over), with and without health problems, from across England, and who regard themselves as of Bangladeshi, British-Bangladeshi, Pakistani or British-Pakistani origin.

Do I have to join Genes & Health?

No. It is completely up to you to decide whether or not you wish to become a 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.

What will happen if I agree to join Genes & Health?

If you agree to become a volunteer, you will be asked to sign a consent form and provide a small sample of your saliva (spit).

You will be asked to provide your contact details (including email and mobile phone if available) and answer a one page questionnaire about your health and lifestyle. With your permission information about your health and prescribed medicines will be retrieved (electronically or on paper) from your health-related records held in NHS General Practices and Hospitals; other healthcare organisations and providers; and registers and records held by the NHS including NHS Central Register, NHS England, NHS Personal Demographics Service, Department of Health, and Office for National Statistics for the duration of the study.

What will happen to the samples I give?
We will look after your saliva 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.

Samples collected as part of the present research project may be stored and used by Queen Mary University of London and approved research within a hospital, university, non-profit institution or a company laboratory within and/or outside the EU.

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 databases at Queen Mary University of London, or for NHS patient data in a ISO27001 Certified Trusted Research Environment at either SAIL/UKSeRP or Queen Mary University of London controlled Cloud, for use in medical research.

It is possible that this information may help some future research studies without any need for further involvement from yourself.

There may be other research studies you could take part in that do need your further involvement. In that case we will contact you to invite you to take part in these separate studies. We call this Stage 2 of Genes & Health. You may be asked to participate in studies on the basis of genetic results obtained from your sample as described above and other information given to us or obtained from your medical records. You will be provided with full information regarding each of these studies and you will be free to decide whether or not to take part in each study. Only some selected volunteers will be invited to Stage 2, and the maximum number of invitations to studies will be 4 per year.

What are the risks and disadvantages of joining Genes & Health?
Volunteering in Genes & Health will involve you donating a small sample of your saliva (spit). This can be done in your home or elsewhere. There is no risk in doing this.

What are the benefits of joining Genes & Health?
There will be no direct benefit to you by joining (at Stage 1) but you will be making a contribution to science and future improvements in NHS care. The information we will gain from studies using Genes & Health will help lead to a better understanding of the links between genes and environmental factors in causing disease and will contribute to improving healthcare and the long term prevention and treatment of a number of common diseases.

The benefits to the Bangladeshi and Pakistani communities will include better understanding and treatments for disease, for example diabetes and heart disease. We will also understand more about how genes work, which will help the development of new treatments. We will understand better the normal variation in Bangladeshi and Pakistani genomes, which will help the diagnosis of inherited rare diseases.

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. However 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.

If you are invited for further medical studies, then you may ask to know (or alternatively, ask not to be told) why you were invited. This will usually 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 and share your samples and data in anonymous format with others in the public (e.g. Universities) and the private sector (e.g. pharmaceutical or biotechnology industry, who may be UK based or overseas) 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 Medical Research Council and Wellcome. It is supported by NHS Trusts, and NHS GP Practices. A complete up to date list is on our website https://www.genesandhealth.org/research/scientific-publications-authorship-and-acknowledgments

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 http://www.jrmo.org.uk/

Genes & Health has been reviewed and approved by London South East National Research Ethics Service Committee (16/09/2014).

How will we use information about you?

We will need to use information from you, from your medical records and NHS health records for this research project.

This information will include your name, NHS and contact details. The Chief Investigator and core Genes & Health team will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead (‘pseudonymised’). Scientific researchers will view your code numbered data within a ISO27001 Certified Trusted Research Environment, and not be able to export individual level data.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- ☐ at www.hra.nhs.uk/information-about-patients/
- ☐ by asking one of the research team
- ☐ by sending an email to elgh@qmul.ac.uk
- ☐ by emailing our Sponsor: data-protection@qmul.ac.uk
- ☐ On our website: https://www.genesandhealth.org/about-study/privacy-and-data-processing-statement

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 via email (elgh@qmul.ac.uk; locally: XXX or phone number of local team). The study website **www.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).

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 in Genes & Health.

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