

Generation Scotland: The Scottish Family Health Study Participant Information Leaflet

We are inviting you to take part in a research project. However, before you decide, you should understand why we are doing it and what it will involve. You should read this leaflet carefully and, if you want, discuss it with others. Part 1 of this leaflet tells you the purpose of the project and what will happen if you decide to take part. Part 2 gives you more detailed information about the running of the project. Please ask us if there is anything that is not clear or if you would like more information. Thank you for considering this invitation.

PART 1

Why is this project being done?

This project is looking at the role of genes in common illnesses and response to treatments. NHS Scotland and all Scottish university medical schools are working together on the project. We already know that many diseases (such as cancer, heart disease, mental illnesses and diabetes) run in families. Genes are therefore important, but we don't yet know which ones or how they relate to other things such as lifestyle. We want to collect and analyse blood and urine samples and health information from thousands of families in Scotland. The information collected will help future research into the prevention, treatment and diagnosis of illness. We can look at genes by studying DNA, which carries the genetic blueprint handed down through generations.

Why have I been chosen?

SFHS is approaching people through their General Practitioner or who are part of an existing research study. We got your name and address from the return slip you sent us in response to this approach, or after you or a family member contacted us. We hold no other information about you.

What would you have to do?

To help us in this research, we would need you to:

1. Ask other family members (brothers or sisters, parents or children aged 18 years or older) if they would be willing to take part. It is very important that we get families with at least one brother or sister.
2. Fill in a questionnaire about health, lifestyle and family history.
3. Bring your questionnaire to an appointment at our clinic; the appointment will last approximately 2 hours. Provide a blood sample (40mls or 8 teaspoonfuls), and urine samples, for laboratory testing and DNA and cell storage for future studies. The cells will be preserved at very low temperatures in order for the future production of cell lines. Cell lines are capable of continuously renewing themselves, providing an inexhaustible resource for future

research. If it is not possible to obtain a blood sample, you will be invited to provide a sample of saliva as an alternative.

4. Let us take physical measurements, including blood pressure, weight and height, breathing tests and a heart tracing (ECG).
5. Answer a 30-minute interview questionnaire, which includes a memory test and asks questions about possible depression. This section may be audio recorded and only used for quality control to ensure consistent delivery of the questions. Recordings will not be identified with your name, only reviewed by medically qualified staff and destroyed 1 year after recording.
6. Give us permission to follow your health through your medical records, now and in the future. Your name and address will not be attached to this part of the research.
7. Ideally, we would like to take the blood sample at a time when you have had nothing to eat for 4 hours (a "fasting sample"). If possible and you are willing, we will arrange your appointment so that this can be done. If you like, we can also arrange for you to come back for a second visit at a time when you can give us a fasting sample. This would be entirely voluntary.

Would there be any risks?

The standard technique for taking blood will be used. You may experience brief discomfort; some people experience brief dizziness and more rarely, minor bruising.

Do you have to take part?

No - it is entirely voluntary. If you decide not to take part, you do not have to tell us why, and it will not affect your future medical care.

Does your General Practitioner know about the study?

Your GP may have already written to you about this study. If so, your GP will have some information about it, in case there is anything you want to talk about. If we contacted you, we will only write to your GP with your permission.

Will you be told the results?

- We will send you the results of your blood pressure, weight, height, kidney function, blood glucose and cholesterol measurements. If these show anything that may affect your health, we may suggest that you visit your GP.
- We will also send a copy of this to your GP if you wish.
- We will not give you (or your GP) any results arising from your DNA.

What about your travel expenses?

We will refund your travel expenses in full.

Can you withdraw from the study?

Yes. You can withdraw from the study at any time without having to give a reason.

What happens if you decide to withdraw AFTER you have given information and samples?

You would simply need to tell us you want to withdraw. Your data will be deleted from the study databases and biological samples destroyed. It will not be possible to delete certain types of data such as data backups. However these data are de-identified, SFHS management systems will not allow subsequent linkage to them, and it is impossible for individuals to be identified. It will not be possible to alter published results.

If this information has interested you and you are thinking about taking part, please read the additional information in Part 2 before making any decision.

PART 2

Who will be doing the research, and where will it be done?

The research will be done by staff in Hospitals and Universities throughout the UK. Approved researchers from the UK and elsewhere may have access to the information for research, but will not be able to identify you or your family.

What about confidentiality?

Any information we obtain from you, as well as from your health records, will remain strictly confidential. To ensure confidentiality is maintained we will:

- allocate a code to your samples and records
- keep your personal details separate from samples and information but linked by that code
- make sure researchers only have access to that code, not your personal details
- hold all information in secure databases, which can only be accessed by research staff directly involved in the project.

Reports or publications of research findings will not contain information from which you can be identified. Insurance companies and employers will not have access to any information held about you. Access by the police will not be granted, other than under court order. We will make the strongest representations to resist such access.

When is this research likely to benefit patients and what about commercial interests?

- The health-related benefits of this work may take many years to develop.
- The project is publicly funded, but its long term success is dependent on the investment of additional research funding. To encourage this investment, Generation Scotland may allow access to the resource by companies on a commercial basis. Any access will be subject to the strictest ethical

scrutiny and scientific rigour, and no access will be given that could lead researchers to identify you.

- Some of the profits from such partnerships will be returned to support the NHS and research.
- Individual contributions do not have any financial value, and you will not receive any financial gain from taking part.

What will happen to the samples after the project is finished?

The samples and information will be stored indefinitely for future research. Initial studies using the information will focus on e.g. heart disease, mental illness and bone disease. All research ideas will be examined by Generation Scotland and will be approved by an independent Ethics Committee. Samples will only be used to investigate the relationships between DNA, lifestyle, health and disease. The Generation Scotland research team will act as custodians of your samples and any information from them. These will be handled in complete security and with the utmost respect.

Who should you talk to if you have any questions or concerns?

If you have any questions regarding this study, please contact:

Name of Local Project Manager

Scottish Family Health Study

Local Study Postal Address

Local Study Email Address

Local Study Telephone Number

For more information on the project you can visit the study website www.generationscotland.org or contact the study coordinator at the above address.

You want to take part so what should you do next?

Because this is a genetic study we need families where at least one brother and/or sister somewhere in the family can take part: this is extremely important.

- Talk to other members of your family to find out if they are interested in taking part in the study.
- When the study team rings you, give the contact details of all interested family members.
- Once we have at least one brother or sister agreeing to take part, we will give each family member an appointment for the research clinic.
- If there is a member of the family who would be willing to take part in the study but who lives too far away to visit one of our study clinics they could also take part by filling in a questionnaire and providing a sample of their saliva.

SFHS TB PIL v1.1 22nd Feb 2010

Finally, thank for your interest and for taking the time to consider this invitation