

## Generation Scotland: Donor DNA Databank Participant Information Leaflet

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You are being invited to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the project if you wish.

*Part 1* tells you the purpose of this project and what will happen to you if you take part.

*Part 2* gives you more detailed information about how the project works.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. *Thank you for considering this project.*

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### ***Part 1***

#### ***Why are we doing this project?***

Generation Scotland is a project being done by the five Scottish Medical Schools and the NHS which aims to create a new Scotland-wide approach to improving health by identifying the genetic (inherited) contribution to important diseases. We want to collect blood samples from 6,000 people throughout Scotland and information on where people and their parents and grandparents were born. The information will not include anything like name, address or date of birth so it cannot be linked back to the person that gave it. We will keep the samples and information and use them for other research studies. As part of this analysis we will look at information from people's genes (their DNA). The data collected will be used for research into the prediction, treatment and diagnosis of illness.

#### ***What would I have to do?***

If after reading this information you would like to take part, you will be asked:

- to allow a small part of your blood sample, which would otherwise be discarded, to be processed for use in future research.
- to answer a short questionnaire about your age and sex and (if you know) where you and your parents and grandparents were born.

#### ***What will you do with my blood sample?***

Your blood will be used to extract DNA and other samples ("plasma") which will be stored in a secure place for future research. We will not feed back any information as we will have no way of knowing which person donated which sample.

#### ***Would there be any disadvantages or risks to taking part?***

No, the standard technique for taking blood would be used.

#### ***Do I have to take part?***

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form.

**Will my taking part in the project be kept confidential?**

Yes. Your anonymous information and participation in this project will be strictly confidential. See Part 2.

**Contact Details:**

<b>Local Contact:</b>	Carol Garnett	0131 536 5342	Carol.Garnett@snbts.csa.scot.nhs.co.uk
<b>Chief Investigator:</b>	Dr Marc Turner	0131 242 7520	Marc.turner@snbts.csa.scot.nhs.uk
<b>Principal Investigator:</b>	Prof David Porteous	0131 651 1041	david.porteous@ed.ac.uk
<b>Project Manager:</b>	Dr Shona Kerr	0131 651 3161	shona.kerr@ed.ac.uk

For more information on this project you can visit [www.generationscotland.org](http://www.generationscotland.org) or write to:  
 Generation Scotland, The University of Edinburgh, Molecular Medicine Centre,  
 Western General Hospital, Crewe Road South, Edinburgh, EH4 2XU

***This completes Part 1. If this information has interested you and you are thinking about taking part, please read the additional information in Part 2 before making your decision.***

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## Generation Scotland: Donor DNA Databank Participant Information Leaflet Part 2

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### ***Part 2***

#### ***Can I withdraw from the project after blood has been taken?***

You can withdraw up to 28 days after having given a blood sample and leaving the SNBTS Session. After that time, the link to your donor number will be destroyed and there will be no way to tie the research samples and questionnaire data to you.

#### ***Who will do the research and where will it be done?***

Research using the anonymous samples will be done by staff in Hospitals and Universities. Samples will be initially processed in Edinburgh in the Wellcome Trust Clinical Research Facility at the Western General Hospital. Blood and DNA samples may then occasionally be distributed to laboratories in Hospitals and Universities around the UK for further research.

#### ***Will my taking part in the project be kept confidential?***

Any information we obtain from you will remain strictly confidential. To ensure confidentiality is maintained we will:

- have no personal details about you and your family
- assign a code, which cannot be linked to you, to your blood samples and questionnaire
- 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 people who take part could be identified.

#### ***Will taking part in the project affect my ability to get insurance?***

No. This project does not perform a "genetic test" as defined by insurance companies and your taking part in this project will have no effect on your eligibility for insurance.

#### ***What will happen to the samples and information?***

The anonymous samples will be stored securely in the Wellcome Trust Clinical Research Facility at the University of Edinburgh, for future research. The Generation Scotland research team will look after your samples and any material or information from them; these will be handled in complete security and with the utmost respect.

These samples will be used as a long term resource which is expected to last 50 or more years. We think that in the future researchers will be able to gain more information from these samples. Right now we don't know precisely what kind of research will be done, but any further research will be scrutinised by Generation Scotland Scientists and will have to be approved by an independent Ethics Committee first. Samples will only be used to provide information about DNA patterns in healthy people. This could be as part of studies that also collect information from ill people, to try to find out more about the relationship between DNA and health.

***Will I get any feedback on the results of genetic tests?***

No. All genetic tests will be anonymous. You can find out information on this project by visiting [www.generationscotland.org](http://www.generationscotland.org) or through the contact details in *Part 1*.

***What about commercialisation? Will industry be involved in any way?***

This project is designed first and foremost to further public good. It is funded by public money but the longer term success of the Generation Scotland project depends on attracting more funding. The main aim is to create a resource which will allow further medical research and this can be best achieved by encouraging as wide a range of research as possible. So to encourage both funding and research, Generation Scotland may allow access to the resource to private companies on a commercial basis. All access will be subject to the strictest ethical standards and keeping confidentiality. It will not be possible to give access that would lead researchers to identify any participant in the project.

Any health-related benefits of this work may take many years to develop and successful developments may give rise to intellectual property rights, such as patents. Individual contributions do not have any financial value by themselves and you will not receive any financial gain from taking part. However, some of the revenue from any successful commercial projects will be returned to support the NHS and health research.

***Who has funded this project?***

This project is funded by the Chief Scientist Office, (part of the Scottish Executive Health Department), which supports and promotes high quality research aimed at improving the services offered by NHS Scotland, and the health of the people of Scotland.

***Who has reviewed this project?***

This research project has been reviewed and obtained ethical approval from the independent Multi-centre Research Ethics Committee for Scotland A (see: [www.corec.co.uk](http://www.corec.co.uk)). Generation Scotland is subject to review by an Independent Advisory Board.

***Thank you for considering taking part in this project.***

