

Information Sheet for People with Diabetes

You are being invited to take part in a research study. 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Introduction

In order to understand the cause of diabetes and its complications such as heart disease, diabetic eye disease and diabetes kidney disease, and to improve treatment and prevention of these important illnesses, we need to find both the genes (the inherited code which may be passed down through generations) and also non-inherited factors that make some people more likely to get diabetes and the medical problems related to diabetes. In addition to this, we sometimes need to carry out clinical research with new drugs or agents to see if they can improve upon existing treatments.

To do this we need to compile a database of people with diabetes in the SW Peninsula region and collect updated standard clinical information on their diabetes. We will also require a blood sample from people in the study to allow DNA (the material from which genes are made) to be isolated and analysed by researchers. By developing a large community database and combining it with information from molecular and genetic tests, it will be possible to study both inherited and non-inherited factors. This study, which started in the SW of England, has now become adopted by the National Diabetes Research Network.

What is the purpose of the study?

Diabetes often runs in families; you may have relatives with diabetes yourself or know somebody with diabetes. However, the genes involved are still poorly understood. We hope that by studying the genetic code in people with diabetes we will understand the cause of diabetes and its complications better. Improved knowledge should help us in the treatment and prevention of diabetes. We do not think it is likely in the immediate future, that taking part in this study will directly benefit you although we do hope that in the long term all patients with diabetes will benefit from the knowledge obtained.

Why have I been chosen?

You have been chosen because you have diabetes and are in the SW Peninsula area. We hope to contact all people with diabetes in your region and ask them to help. Our search to find differences between those with and those without diabetes means we are also keen to involve people who have not been diagnosed with diabetes. It is likely therefore, that we may ask your husband, wife or partner or a family friend who is not "blood related" to join you in our research.

Do I have to take part?

You do not have to take part; it is entirely up to you to decide whether or not you do so. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Even if you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part in this or future studies will not affect the standard of care you receive in any way.

What will happen to me if I take part?

We will be asking you to consider three separate things; firstly, to give us your permission to collect updated clinical information and non-invasive samples (i.e. urine) that you would normally give as part of

your standard care, and collect information from your notes about your diabetes and to store it on our clinical database; secondly, to allow us to contact you in the future to see if you would be interested in taking part in further research projects; thirdly, to allow us to take a blood sample. This would be about 20 mls, which is approximately a tablespoon. The DNA samples are taken on the basis that they constitute a “gift” from you to the Royal Devon & Exeter NHS Foundation Trust & SW Peninsula Diabetes Research Network. This means that by volunteering to take part in this study, you are acknowledging that you are not expecting to derive any financial benefit from your participation. Similar to other consultations you might have had we would also take some body measurements (height, weight, hips and waist) and ask you questions about your health. This would be arranged at a time convenient for you and could be done at the local hospital, GP surgery or elsewhere mutually convenient. You may eat, drink and take your medications as normal. It may be necessary to look at your medical notes for details of your diabetes but these notes will not be removed from the premises where they are stored. By using your personal details and NHS number, your clinical details will be updated on the study database using information from your NHS records. This will include your general practice & hospital medical records, and information maintained by the NHS Information Centre and NHS Central Register. The risk of taking part in this research is minimal and is the same as any normal clinical appointment where blood is taken by trained professionals.

What happens to the information and samples that I give?

Your clinical data will be entered directly onto the database using secured web-based portals by your local research team. This is completely confidential and only the research team will have access to your identifiable information. The paper copy will be kept in a locked research facility with limited access to ensure they are kept safe. Your blood samples will be processed by a dedicated technical staff in order to extract the serum and genetic materials (DNA) for storage for future research projects. Anonymised clinical information about you will also follow your samples, this is so that researchers within other Trusts and universities can carry out the highest quality research around the causes and complications of diabetes.

What will be done with the blood?

To search for diabetes related genes we will treat the white cells from your blood sample. This will allow us to extract DNA (this is the material from which genes are made) and will leave us with the blood serum and plasma which will also be used for important research studies. We will look for the genetic changes for diabetes in all the samples collected also using your clinical information. Your samples will be stored for an indefinite period until the study, including all molecular and genetic analysis, is finished. Your DNA will only be supplied to researchers in an anonymous coded form and will only be used in analysis of diabetes or diabetes-related disorders. All anonymised samples along with your information and data will be held on a password protected database and we will make sure only researchers authorised by the research team will have access.

Will I be told the results?

We will not give you, your doctor or anyone else specific results of your genetic test results, however, please feel free to contact us about the overall progress of the study if you wish.

How will my clinical information be kept up to date?

The clinical information we collect about you and your condition is very important but will of course change over time. We would like to keep informed about you through either consulting your medical records or by receiving updated clinical information from your GP. Update information will be received every 6 -12 months after the GP has seen proof that you have consented to this. It will then be uploaded onto our secure password-protected online database and used for further diabetes research.

Who can I contact to find out more about this study?

If you have any questions please contact one of the following people –

Kirsty Wensley / Sarah Irvine
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