

Information Sheet for Volunteers (People without 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.

We need to compare this information with people who do not have diabetes to identify and study possible causes of diabetes. This means collecting information to be stored on a computer database and blood samples from people like yourselves.

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. However, the genes and environmental triggers are still little understood. We hope that by studying the genetic code in people with and without diabetes we will improve our understanding of the cause of diabetes and its complications. This 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 anyone with diabetes although we do hope that in the long term all people with diabetes will benefit from the knowledge we will have obtained from this study.

Why have I been chosen?

It is because you do not have diabetes that we are keen to enroll you into the study. You may have a partner or family friend (not a blood relative) who has diabetes and has had a similar environment to yourself. In the future, we are keen to investigate these environmental factors as well as the genetic codes.

Do I have to take part?

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 will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and 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.

What will happen to me if I take part?

To take part in this research we would like to take a single blood sample from you and collect a urine sample. The blood sample would be about 30 mls which is approximately an eggcup full. These samples are taken on the basis that they constitute as 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. We would also like to take some body measurements (height, weight, waist and hips) and ask you questions about your health. This would be at a time suitable for you and could be done at the local hospital, GP surgery or elsewhere mutually convenient. We would ask that you do not eat for about 10

hours before we take your blood sample, but you may drink water and take your medications as normal. Therefore, we would normally arrange an appointment for you first thing in the morning. 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. It may be necessary to look at your health records both now and in the future but these 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.

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 nurse. 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 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 research studies related to investigate diabetes. Using the DNA, we will look for the genetic changes for diabetes in all the samples collected. All 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. We will also test your blood to check your sugar and cholesterol levels. All samples, information and data will be held in the strictest confidence.

Will I be told the results?

We will not give you, your doctor or anyone else specific results about your genetic test results. However, if any non-genetic results that may affect your health are found, we will inform you and your family doctor. 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?

In carrying out the clinical information we collect about you 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 and the GP will receive proof that you have consented to this before they release this information. It will then be uploaded onto our secure password-protected online database and used for further research.

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

If you have any questions please contact either of the following people :

Kirsty Wensley/Sarah Irvine

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