

DIABETES RESEARCH ON PATIENT STRATIFICATION

- The DIRECT study

Updated Data Protection: Information Sheet

Introduction

This information sheet gives you new information that you have a right to receive under changes in the law made by the General Data Protection Regulation ('GDPR'). It follows on from the Participation Information Sheet (PIS) you were given when you signed up for the study. You can find a copy of the PIS online at www.direct-diabetes.org/information/, or if you need an additional hard copy, please contact us using the details provided below. We will continue to use your information in the ways described in the PIS, but under the new law we must explain this in more detail.

As you may recall, you kindly agreed to participate in DIRECT: a clinical study designed to investigate type 2 diabetes: why it develops differently in different people and which treatments are best for particular groups. The University of Dundee and NHS Tayside are co-sponsors for this study based in the United Kingdom.

We will use information collected from you and from your medical records to undertake this study and will act as the 'data controllers' for this study. This means that we are responsible for looking after your information and using it properly. The University of Dundee and NHS Tayside will keep identifiable information about you for up to 10 years after the study ends in order to link information from your medical records to your study data, unless you ask for this information to be deleted before that time

Your Rights

You have rights to delete, access, restrict, change or move your information, or to object to the way it is used. These rights may be limited because we need to make sure the research is reliable and accurate. If you withdraw from the study, we will keep the results of any analysis which has already been completed using your health information. To protect your rights, we will only keep the minimum amount of information needed to identify you. You can ask for your rights unless your request would seriously affect the study.

You can ask to use your GDPR rights by contacting Research Governance, Tayside Medical Science Centre (TASC) on 01382 383900, or tascgovernance@dundee.ac.uk. If you wish to complain about the use of your information please email dataprotection@dundee.ac.uk

How we use your information

The University of Dundee and NHS Tayside have collected information about you for this research study from your study visits and from your medical records. This includes your name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information to analyse changes in your blood sugar readings and medication. This helps researchers identify differences in the development of type 2 diabetes among different individuals and what are the best treatments for different groups of people.

The Clinical Research Centre at Ninewells Hospital will use your name, NHS number and contact details:

- to contact you about the research study,
- to make sure that relevant information about the study is recorded for your care, and
- to oversee the quality of the study.

Overseeing the study means that individuals from the University of Dundee/NHS Tayside and regulatory organisations may look at your medical and research records to check the accuracy of the research. The Clinical Research Centre may need to pass details to the University of Dundee/NHS Tayside along with the information collected from you and your medical records.

The only people in the University of Dundee/NHS Tayside who will have access to information that identifies you will be people who need to contact you to invite you for visits, or who send information (such as newsletters) about the study, or who audit the data collection process. The people who analyse your health information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Any study data we share with other researchers as part of DIRECT will be 'anonymised'. This means it will be coded and not contain personal information such as your name, NHS number or contact details. Researchers across Europe, including some in countries outside the EU such as Switzerland, will not have access to your personal information, but only to the health information using a study code. This anonymised information will be kept for 10 years after the study ends and used for approved scientific research. Some anonymised information may be shared with a repository such as the European Genome-Phenome Archive. Please see the PIS for further details (available at www.direct-diabetes.org/information/).

The 'legal basis' on which we process your data—this means the reason for using the information under the GDPR—is that the research is “a task in the public interest”.

You can find out more about how we use your information at:

*<http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information>
<https://www.dundee.ac.uk/information-governance/dataprotection/>
http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm*