

Improving Clinical Care in Diabetes

Can you help by sharing information about your diabetes?

The world-leading diabetes research team in Exeter, led by diabetes consultant Professor Andrew Hattersley, have already helped to improve the diagnosis and treatment of diabetes but there are still important questions that remain unanswered: Why does diabetes, and its associated complications, progress quickly in some patients and much slower in others? The Improving Clinical Care in Diabetes (ICCD) study aims to determine the predictors of those differences in progression which will help us to understand the reasons for the variation, develop better treatments and identify those patients who may benefit from closer monitoring & treatment that may slow progression.

For more information about the Exeter team, please visit our website:
www.diabetesgenes.org/current-research



Would you allow blood and urine leftover from your routine clinical tests to be used for research?

When you provide a sample for your doctor/nurse it will be analysed at your local hospital. We are asking your permission for any leftover samples to be used for research tests to help us better understand diabetes. DNA (genetic material) from your blood will be extracted. Your DNA, research samples and data will be stored securely and provided anonymously to members of the research study team. You may be given the option to provide an additional research blood sample. This option will be clearly stated on the consent form.



Would you give permission for the NHS to share relevant information from your medical records with researchers?

We are asking your permission for information from your GP and hospital notes, related to your diabetes, to be provided to the ICCD research team so that they can undertake research into the causes, diagnosis and treatment of diabetes and related conditions. Medical records will be accessed on a regular basis, now and in the future, to ensure we have up-to-date information about your diabetes and its progression. With your optional consent, we will also register your involvement with NHS Digital in order to follow up your health status in the future.



Would you like to get involved in other research?

You will be given the option to decide whether you wish to be contacted about future research taking place locally in the NHS and the University of Exeter. You will also be given the option to gift your research samples and data to the Peninsula Research Bank (PRB) at the RD&E Hospital to be used in other future research. These options will be clearly indicated on the study consent form.

What do I need to do?

All you need to do is complete a consent form and answer some questions about your diabetes. You can take part remotely (via email or online) or at a face to face appointment.



Can I change my mind?

Yes, you can withdraw your consent at anytime and without giving a reason.



Frequently Asked Questions (FAQs)

About my samples

What are leftover clinical samples? When you have a blood test as part of your routine care, a small volume of blood is taken and sent to your local hospital. After clinical tests have been carried out, any blood remaining is usually thrown away as waste. With your permission, these samples can be kept and used for research.

How will this study access my clinical samples? Once you have consented to take part in this study, we will inform the hospital laboratory that carries out routine tests. Your record will be flagged on their database to enable your leftover clinical samples to be saved for research rather than thrown away.

Do I have to provide any additional blood samples? You may be given the opportunity to provide an optional research blood sample. This option will be clearly stated on the consent form.

How will my research samples and data be stored? All samples and research data will be stored securely using unique study codes. Researchers analysing the data and samples will not have access to your personal identifiable data (e.g. name, address, NHS number). All data will be stored on password-protected databases or on RedCap database hosted on a secure NHS-server.

What will my research samples be used for? Samples including your DNA could be used in research now and in the future to investigate the progression of diabetes and related conditions. Your coded DNA could be used in to identify genes (the inherited code which may be passed down through generations) associated with diabetes. By joining this study you will be helping doctors and scientists better understand diabetes and its complications and this may help to improve diagnosis and treatment in the future.

If I withdraw my consent, what will happen to my research samples? Some of your samples may have already been used in research but we will destroy all unused samples and we will write to you with confirmation when this has been done.

About my health records

How will information held by the NHS and in my health records be accessed?

With your permission health information related to your diabetes will be collected from GP and hospital records on a regular basis using secure NHS networks. Your NHS number will be used to identify these records. With your consent, we will also register your involvement in this study with the Data Access Request Service (DARS) which is part of NHS Digital in order to follow up your health status.

What is NHS Digital?

NHS Digital provides information from the Personal Demographics Service (PDS) and the Office for National Statistics (ONS) to help keep our research data up to date. Further information about NHS Digital is available at <https://digital.nhs.uk>. This is optional and so the research team will only share your information with NHS Digital if you have given specific consent for us to do so.

Why does ICCD need my personal details?

We will store your identifiable information for the duration of the study, to enable us to contact you about anything related to your participation in this study and to access your health records (see above).

Who will have access to my health information?

NHS-based research staff will be able to look at your medical records now and in the future in order to update the information held about your medical history. We will ensure that information about you is handled in the strictest confidence, in accordance with NHS information governance and data protection.

About future research

How will I be contacted about other research studies?

If you agree to be contacted about future research studies we will contact you according to your preferences (phone, email or letter). It will be your choice whether you take part in any further studies.

What happens when I gift my samples to the Peninsula Research Bank?

The Peninsula Research Bank is an ethically approved facility at the Royal Devon & Exeter Hospital, that manages data, contact details and samples for use in future research. All research is approved by a steering committee and samples will not be used for any of the following: sold for profit; used in animal research; used in research into the termination of pregnancy or reproductive cloning; screened for markers predictive of disease (e.g. Huntington's). Non-identifiable samples may be provided to researchers from the UK and abroad including academic organisations and commercial companies.

About my information

How will we use information about you?

We will need to use information from you and from your GP and hospital records for this research project. This information will include your **NHS number, your name, date of birth and your contact details**. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records and NHS Digital if you have given specific consent for us to do so. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Please read the 'About future research' section of this leaflet.

Where can you find out more about how your information is used?

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to rduh.dpo@nhs.net.

Thank you for reading this information. If you would like to take part, you will be asked to agree to the following consent statements below. You will have the opportunity to ask questions and discuss the study before giving consent

I agree to:

- allow samples leftover from my routine clinical care to be used for research and DNA to be extracted from my blood.
- allow the research team to access relevant sections of my health records and to contact my clinical care team about my research participation.

I understand that:

- individuals from regulatory authorities, or the Royal Devon University Healthcare NHS Foundation Trust will have access to data collected during the study, and relevant sections of my medical notes, for monitoring and audit purposes.

Optional Statements:

- I agree to complete the optional study questionnaires
- I agree to donate research blood samples by venepuncture and/or finger-prick (relevant to face to face visits only)
- I understand and agree that personal details will be shared with NHS Digital to obtain information held by them and the Office for National Statistics in order to follow up on my future health status (see FAQs for more details).
- I agree that the research team may contact me about future research.
- I agree to transfer my research samples and non-identifiable data collected during this study to the Peninsula Research Bank (PRB). Please refer to FAQ's for details about the PRB.

Who else could I talk to about taking part in research?

Before you make a decision about participating in this study, you may want to discuss the project with your GP or family members. The Patient Advice & Liaison Service 01392 402093 can provide independent advice on participating in research and can help if you have any queries or complaints about your research experience.

Contact details:

If you have any questions about the study, please contact the local research team:

Telephone: **01392 408181**

Email: **rde-tr.ResearchReferrals@nhs.net**

Website: **www.diabetesgenes.org/current-research**

This research study has been reviewed by the Leicester Central Research Ethics Committee