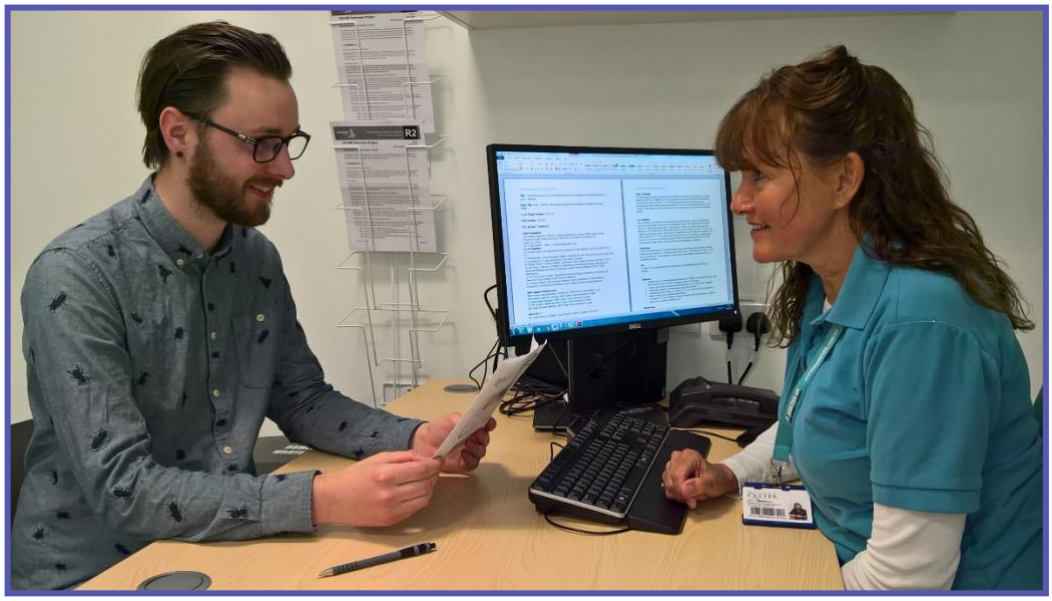
Site logo

EXE-T1D

Understanding beta-cell destruction through the study of Extremely Early-onset Type 1 diabetes

A research project helping scientists to understand why some people develop Type 1 diabetes in early life.



Could you spare some time to help researchers better understand how your immune system is working and how it affects your diabetes?

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

EXE T1D

Chief Investigator: Professor Richard Oram
[Principal Investigator: XX]

Why are we doing this research?

Type 1 diabetes (T1D) results from destruction of insulin producing beta cells by the body's own immune system (autoimmunity). We do not fully understand what causes this type of diabetes and why there is variation in age of onset and severity between people who develop the disease. The aim of this work is to study very unusual people who develop T1D and/or autoimmune diseases extremely young and compare them to people diagnosed with diabetes older or not caused by autoimmunity.

Very few people with T1D are diagnosed so early in life. We think that, for the condition to have developed that early, they must have a very unusual or extreme form of autoimmunity. Sometimes this is caused by a spelling mistake inherited in a single gene but sometimes the cause is not obvious even after genetic testing. Studying the immune system of people with very early-onset diabetes might help us to learn a lot about the disease, especially if we can compare them with children that have had normal early life development of their immune system.

Why have I been invited?

You have been invited into this study because you were diagnosed with T1D or developed autoimmunity very young and were referred to the Exeter Molecular Genetics Laboratory or to Professor Oram by your clinician or GP to investigate the cause.

What does participation involve?

We aim to collect research samples with no additional needles by taking a little extra blood when you have routine/clinical tests, or at a study visit if preferred.

Your usual doctor/clinician, diabetes nurse, or our study diabetes research nurse, will ask you questions about your autoimmunity so that we can update our records about your health.

We will collect blood and urine samples and will record your height and weight. The blood sample will be collected either as part of your usual clinic, or at a research visit at hospital / the NIHR Exeter Clinical Research Facility / King's College London. Alternatively, we may send you a home fingerprick kit. A small number of participants will be asked for a repeat sample to confirm findings.

Please see the flowchart opposite for more information about your appointment, which will take less than 1 hour.

What will happen to my samples and data?

We will explore immune system, genetic and insulin markers in your blood and urine samples and combine this with your other data (height, weight, diabetes history). We will share anything relevant to your diabetes care with your clinician. We will ask your permission to gift samples and data collected during this study, and as part of your diabetes referral to the Exeter Molecular Genetics Laboratory / Professor Oram, to the Peninsula Research Bank for safe storage and use in future research.

How will my identity be protected?

It is NHS policy to include three forms of identification to ensure that clinical samples and results are linked to the correct person. Your samples will be sent for testing at the Exeter Clinical Laboratories at the Royal Devon & Exeter (RD&E) Hospital with three forms of identifiable information (name, DOB, NHS/CHI/hospital number) using Exeter-specific clinical analyses request forms. The samples are processed by registered healthcare scientists and are afforded the stringent information governance as given to all clinical samples. The clinical results will be made available to your clinician and/or GP, as they may help with your ongoing medical management.

Separately, we will conduct novel analyses on research samples at King's College London (KCL) and possibly other specialist research collaborators in the USA (see study website — link on pg 4) to study the function of your immune system and other factors that may play a role in the development of Type 1 diabetes. Research samples will be stored and analysed using a unique study ID — this format protects your confidentiality to prevent researchers being able to identify you.

What will happen to my data?

Your research data will be protected in the same way that we protect your research samples by using a unique ID to safeguard your research data. Your personal identifiable data will be held separately and will only be accessible to personnel with training in data protection who require this information to perform their clinical or study role. Your contact details are requested to enable the study team to communicate with you to provide you with information, to answer any queries you may have, to collect additional clinical information about your condition and to arrange your appointment. A unique Study ID will be allocated, under which all study data and samples will be link-anonymised and stored on a secure password-protected study database on an NHS server. Research data will be held separately to identifiable information and will be looked after in a secure way to protect your confidentiality.

Are there any risks or benefits in taking part?

Donation of blood samples can be uncomfortable but this procedure will be carried out by an experienced nurse / researcher to minimise any discomfort. The project may confirm that you have T1D but won't change your treatment. However, if we unexpectedly identify anything that could impact on your clinical care, we will inform your clinician/GP who may then want to follow this up with you.

Study Visit Flowchart

What will happen during my research appointment?		
VISIT	**What does this involve?**	**Are there any risks?**
Give consent to participate at at one of these locations: • Local care provider • Exeter Clinical Research Facility • King's College London **15-20 mins**	Every effort will be made to co-ordinate your visit with your routine clinic review. To minimise risk of COVID-19 infection to participants and their parents, the clinical/research teams will follow local NHS Trust policy and procedures based on the current UK government guidance. A member of the study research team will discuss the study with you and answer any questions. If you are willing to take part, you will be asked to sign a consent form. You will then be asked some questions about your general health and medical history and your height and weight will be measured.	No. Participation is entirely voluntary and it is up to you whether to join the study and you can withdraw at any time without giving a reason and without affecting your legal rights.
Urine sample (optional)	We may ask you to provide a urine sample to test how much insulin your body is able to produce. A specimen container will be provided, together with instructions about how to collect a urine sample. It is optional to provide this useful research sample and choosing not to do this will not affect inclusion into this study.	No, and this test is optional.
Blood sample **20 mins**	Where possible, the blood sample will be collected at the same time as your routine review sample, using a needle and syringe. The blood will be analysed to assess: • your immune system • your body's ability to make its own insulin. The blood sample will involve a single draw of blood and the total amount of blood we will take over the visit will follow WHO guidelines and will not exceed 60 millilitres (ml) (approx 4 tbsp).	There may be slight discomfort and bruising from the insertion of the needle into the vein. These risks will be minimised by the procedures being carried out by a qualified researcher who will monitor you closely throughout the whole procedure.
TOTAL visit time is less than 1 hour	We will ensure that you are comfortable before ending your visit.	None.
If a visit is not feasible, you can take part in most of the study via a home fingerprick sample.	We will arrange a telephone appointment with our Research Nurse to discuss the study, collect information about your health and to obtain your consent to participate. You will be sent a blood sampling kit with instructions and packaging with prepaid postage to send the sample to Exeter for analysis.	None. The fingerprick blood sample would be collected when you test your blood glucose level.

Do I have to take part in this study?

No. Participation is entirely voluntary. It is up to you to decide to join the study. If you agree to take part, we will ask you to sign a consent form like the one overleaf. You are free to withdraw at any point. Participation in the study will not affect your routine care.

Who is organising and funding this research?

The research will be managed through the NIHR Exeter Clinical Research Facility (Exeter CRF), which is funded by the National Institute for Health and Care Research, a part of the NHS, and a collaboration with the University of Exeter. Additional funding for the project has been provided by Diabetes UK and The Leona M. and Harry B. Helmsley Charitable Trust.

Will my participation be kept confidential?

Yes. We will follow current ethical and legal practice and all information about you will be handled in confidence. The University of Exeter / Royal Devon University Healthcare NHS Foundation Trust are co-sponsors for this study based in the UK. We will use information collected from you and from your medical records to undertake this research 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 Exeter / Royal Devon University Healthcare NHS Foundation Trust will keep identifiable information about you indefinitely 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. Research data will be held separately to identifiable information. For the purposes of this study we will use consent to protect your confidentiality and allow you choice in your participation. All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer or in a locked cabinet at the Exeter CRF, which can only be accessed by the researcher and research team. You will be allocated a unique participant number, which will ensure the information from your samples and tests cannot be identified by anyone else.

Where can I find out more?

For further information about the project, please contact [XX / a member of our study team] on:
[XX]

Additional information can be found on the study website:

https://www.diabetesgenes.org/current-research/exe-t1d/

Who has reviewed this study?

This project has been reviewed and approved by the NRES East Midlands — Derby Research Ethics Committee and the Health Research Authority (HRA).

What if there is a problem?

The research team will be happy to discuss any problems you may have. However, if you have concerns or complaints arising from your experience of participating in this study which you do not wish to discuss with the research team directly, the RD&E Patient Engagement/Patient Advice & Liaison Service (PALS) team (01392 402093) will provide independent advice.

General Data Protection Regulation ('GDPR') and your rights

This information sheet gives you new information that you have a right to receive under changes in the law. In 2018, regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies. We have provided you with as much information as possible to help you to make an informed decision about taking part or not and your right to withdraw. The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest' and continue to be transparent about the processing of your personal data. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer at: https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/ . If you have any concerns about how the data is controlled and managed for this study then you can also contact the Sponsor Representative, Dr Antony Walsh, Head of Research Governance, Ethics and Compliance, University of Exeter, Research Ethics and Governance Office Tel: 01392 726621 or Email: res-sponsor@exeter.ac.uk.

Thank you for reading this leaflet, which is yours to keep.

If you wish to participate in this study, you will be asked **to sign a consent form in the presence of a member of your usual clinical team/the research team,** a copy of which you will be given to keep.

The consent form will include the following statements:

CONSENT STATEMENTS

I have been given the study information leaflet. I have had the opportunity to ask questions and have had these answered satisfactorily.

I agree to:

- have an appointment(s), as detailed in the study flow chart in the information leaflet.
- provide information about my health for use in this project.
- allow the research team to contact my clinicians/GP about my treatment and study participation now and in the future, and to provide them with clinical results relevant to my care.
- provide blood and/or urine samples for analysis, including genetic studies using DNA. Samples will be stored for the duration of the study.

I understand that:

- my participation is voluntary and that I may withdraw at any time without my clinical care being affected.
- individuals from the study team, regulatory authorities or the UK NHS Trust will have access to relevant sections of my medical notes and data collected during the study for research, monitoring and audit purposes.
- the research data and samples will be stored separately and securely from any identifiable data, by using an ID format to protect my confidentiality.
- my clinical samples will be sent for testing at the Exeter Clinical Laboratories, together with three forms of identifiable information (name, DOB, NHS/CHI/hospital number) in accordance with the NHS requirements for clinical sample analysis. The clinical results will be made available to my clinician and/or GP, as they may help with my ongoing medical management.

I agree to take part in this study.

Optional Consent Statements:

- I agree to gift samples and data from the project to the Peninsula Research Bank, managed by the NIHR Exeter Clinical Research Facility, to be used for future research.
- I agree that information held by the Exeter Molecular Genetics Laboratory and in my medical records may be used to follow up on my future health status.
- I am happy to be contacted by the research team about participating in other future studies.