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 and your child spare some time to help researchers better understand how a child's immune system is working and how it affects their diabetes?

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

Control

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).

Very few people develop autoimmunity 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 children with very early-onset diabetes might help us to learn a lot about the disease, and it is very important to compare them with children that have had normal early life development of their immune system and don't have diabetes.

Why has your child been invited?

Your child has been invited into this study because they don't have diabetes and are attending hospital for elective surgery involving an anaesthetic, or a paediatric clinic involving a routine blood draw, making collection of a research blood sample possible without causing your child additional anxiety or discomfort.

What does participation involve?

We would collect the research samples with no additional needles by taking a little extra blood when your child has their anaesthetic for their surgical procedure, or when blood is collected during routine/clinical tests. Your child's hospital doctor/nurse will ask some questions about your child's health.

The blood sample will be collected from your child for our researchers to analyse their beta cell function and their immune system. The total volume of the blood sample will be between 4 mls and 30mls (approx. 2 tablespoons) according to your child's age.

We will measure immune system genes and how the immune system works, to improve our understanding of type 1 diabetes and the immune system in general, which may help to develop future treatments.

Please see the flowchart opposite for more details about the visit.

What will happen to your child's samples and data?

All samples and data will be stored under a unique study ID number. We will study immune system, genetic and insulin markers in your child's blood and combine this with their other data (height, weight, medical history). We do not plan to share diabetes related results with your child's clinician as these are expected to be normal. If, by chance, we find an abnormal result, we will feed this back to your child's paediatrician/GP. We will ask your permission to gift samples and data collected during this study to the Peninsula Research Bank for safe storage and use in future research.

How will your child's 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 child's 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 child's clinician and/or GP, as they may help with their ongoing medical management.

Separately, we will conduct novel analyses on research samples at King's College London and possibly other specialist research collaborators in the USA to study the function of their 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 child's confidentiality to prevent researchers being able to identify them.

Are there any risks or benefits in taking part?

Donation of blood samples can be uncomfortable but this procedure will be carried out during their hospital procedure by an experienced doctor/paediatric nurse to minimise any discomfort and numbing cream or spray will be offered. The project will not change your child's treatment but will help us understand more about early onset diabetes and the early life immune system and may, therefore, contribute to an improvement in healthcare in the future. However, in the unlikely event that we identify results suggestive of Type 1 diabetes or a risk of future Type 1 diabetes that could impact on your child's clinical care, we will inform your child's clinician who may then want to follow this up.

Study Visit Flowchart

What will happen during my research appointment?

VISIT	What does this involve?	Are there any risks?
Give consent to participate at your child's hospital visit **15 -20 mins**	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. During your child's pre-operation assessment appointment and/or hospital visit, a member of the study research team will discuss the study with you and answer any questions that you have. If willing for your child to take part, you will be asked to sign a consent form. You will then be asked some questions about your child's general health and medical history and their height and weight will also be recorded.	No. Participation is entirely voluntary and it is up to you whether your child joins the study and you can withdraw them at any time without giving a reason and without affecting your/their legal rights.
Blood sample **10-30 mins**	A little extra blood will be collected at the same time as your child's general anaesthetic or routine sample, using a cannula or needle and syringe. Either they will be asleep as part of the anaesthetic, or a numbing cream/ spray can be used, making collection of the research blood sample possible without causing your child additional anxiety or discomfort. The number of blood tubes will vary according to your child's age and size but it will follow WHO guidelines and will not exceed 30 millilitres (ml) (approx 2 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 doctor/nurse who will monitor your child closely throughout the whole procedure.

Does your child 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 your child taking part, we will ask you to sign a consent form like the one overleaf. You are free to withdraw your child at any point. Participation in the study will not affect your child's clinical care/treatment.

What will happen to your child's data?

Your child's research data will be protected in the same way that we protect your child's research samples by using a unique ID to safeguard their research data. Their 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, and to collect additional clinical information about your child's health. 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 their confidentiality.

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. Funding for the project has been provided by Diabetes UK and The Leona M. and Harry B. Helmsley Charitable Trust.

Will your child's participation be kept confidential?

Yes. We will follow current ethical and legal practice and all information about your child will be handled in confidence. The University of Exeter / Royal Devon University Healthcare NHS Foundation Trust (RD&E) are co-sponsors for this study based in the UK. We will use information collected from you and from your child's 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 child's information and using it properly. The University of Exeter / Royal Devon University Healthcare NHS Foundation Trust will keep identifiable information about your child indefinitely after the study ends in order to link information from their medical records to their study data, unless you/they 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 child's confidentiality and allow you choice in their participation. All information collected in this study will be kept strictly confidential and stored either on a password protected computer or in a locked cabinet at the Exeter CRF, which can only be accessed by the researcher and research team. Your child will be allocated a unique participant number, which will ensure the information from their 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 child's 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 child's 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 your child taking part or not and their 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 child's personal data. Your rights to access, change or move your child's information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. If they withdraw from the study, we will keep the information about them that we have already obtained. To safeguard their rights, we will use the minimum personally-identifiable information possible.

If you have any queries about the University's processing of your child's 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 are happy for your child 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 agree for my child to:

- attend an appointment(s) as detailed in the study flowchart.
- provide information about their health for use in this project.
- allow the research team to contact my child's clinicians/GP about their treatment and study participation now and in the future.
- provide blood samples for analysis, including genetic studies using DNA. Samples will be stored for the duration of the study.

I understand that:

- my child's participation is voluntary and that they may withdraw at any time without their clinical care being affected.
- individuals from the study team, regulatory authorities or the UK NHS Trust will have access to relevant sections of my child's 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 child's confidentiality.
- my child's 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 child's clinician and/or GP, if they might help with their ongoing medical management.

I agree for my child to take part in this research study.

Optional Consent Statements:

- I agree for my child 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 with ethical approval.
- I agree that information held by the Exeter Molecular Genetics Laboratory and in my child's medical records may be used to follow up on my child's future health status.
- I am happy to be contacted by the research team about participating in other future studies.