

Patient Information Leaflet

Study title: Irish Childhood Diabetes National Register (ICDNR)

You are being invited to take part in an ongoing research study being carried out nationally by Children's Hospital Ireland (CHI) at Tallaght University Hospital (TUH) and Trinity College Dublin since 2008. The National Children's Hospital (NCH) is now part of the Children's Hospital Ireland (CHI) at Tallaght University Hospital (TUH).

Before you decide whether or not you wish your child/you to take part you should read the information provided below carefully and, if you wish, discuss it with your family, friends or Doctor/Nurse. Take time to ask questions – don't feel rushed, and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'. Changes in Irish data protection law (2018) with the introduction of GDPR, requires that you are provided with all of the detailed information you need to make your decision. This is known as 'Explicit Informed Consent' and this information leaflet aims to give you clear and detailed information so you can give your Explicit Informed Consent upon joining the ICDNR.

Why is this study being done?

The purpose of this study is to:

Develop and maintain a Register to monitor the frequency of Type 1 diabetes in Children and Young People (CYP) in Ireland, to better understand what is driving this disease (i.e. why is diabetes becoming more common) and to develop accurate data regarding where CYP with diabetes are and how old they are and so on, to support healthcare planning, service delivery, and clinical care.

The number of children and young people developing Type 1 Diabetes is increasing worldwide. With the help of this register we can track if diabetes is becoming more common in Ireland.

Who is organising and funding this study?

This Research is undertaken by Researchers and Statistical staff working with Children's Hospital Ireland (CHI) formerly The National Children's Hospital (NCH) at Tallaght University Hospital (TUH) and Trinity College Dublin. The Register (ICDNR) is funded by the National Children's Hospital Foundation and securely maintained on the Tallaght University Hospital (TUH) Server.

Why am I being asked to take part?

Your child/you are eligible to join the ICDNR if diagnosed as having Type 1 Diabetes, that is not secondary to any other condition and if your child/you are under the age of fifteen years at the time of your diagnosis.

Those over 15 years at diagnosis, or where diabetes is not Type 1, or secondary to another condition, such as cystic fibrosis are ineligible for this study.

How will the study be carried out?

Following confirmation of your child's/your diagnosis, parents and children (if old enough to understand) will be informed about the ICDNR and if agreeable for your child/you to join, parents will be asked to sign a consent form at your local hospital. Your child's/your medical team will then provide the register with basic information about your child/you as outlined below.

What will happen to me if I agree to take part?

Participation in the study is voluntary. Your child/you do not have to be a part of this study. If you take part you may opt out at any time. Rest assured that it will in no way influence your clinical care if you decide not to participate.

To participate in this study is to allow your child's/your name to be registered as having diabetes, as you would when applying for the long term illness card.

If you consent, your hospital/centre will provide the register with the following details which will include: Name, address, - (so we can identify geographical variations and ensure we don't count you twice), date of birth, date of first insulin injection, gender, number of brothers and sisters, the hospital at which the diagnosis was made, the name of the consultant responsible for your care, whether there are any other members of your immediate family who have diabetes, and blood results. Your Doctor and Diabetes Nurse Specialist will speak with you at clinic about the Register and ask both parent and child (if old enough) to sign a consent form. You will receive a copy of this form.

What are the benefits?

The benefits of the study are that we will build an accurate picture and obtain accurate numbers of those CYP with Type 1 Diabetes across Ireland and where they live and are treated. This vital information will greatly support the provision of appropriate services and resources to care for children and adolescents with Type 1 Diabetes. In Type 1 Diabetes it has been clearly shown that the outcomes in terms of health benefit relates closely to the resources and services provided to young people. This study may also in collaboration with other diabetes registries worldwide, help shed light on the cause of Type 1 Diabetes in the long term. Tracking the changes in diabetes worldwide can help us over time develop an insight into what causes this condition and improve management and quality of care.

What are the risks?

As there is no medication or treatment given or additional examinations, no harm or discomfort is anticipated in your child/you participating in this study. Consents and data forms are securely stored in the Trinity centre for Health Sciences, TUH. Our IT system is maintained on the TUH network which is secure and backed up to prevent data loss. We protect your data with the highest levels of encryption and firewalls to prevent unauthorised access.

Is the study confidential?

If you agree to participate and provide your consent the information will then be obtained from your child's/your medical chart in the Hospital your child/you attends. There will not be any additional information in the Register that is not in your child's/your medical chart. The purpose of the Register is to store the information securely on the Tallaght hospital computer system within a central database (which is similar to an electronic filing cabinet). The Database does not record your child's/your name or address, meaning your data is pseudonymised within the Register. Every participant is given a register ID or code in place of name and address which links with their hardcopy form (stored securely separately). We may be asked occasionally to contribute information to national or international studies. We will only do so where we believe the study is well-organised and the results are likely to be useful. Any information we provide or publish will be processed and **fully anonymised** to make sure that no individual patients are identified.

Your child's/your name is required to ensure that your child/you are not counted twice. Every effort will be made to make sure the register is accurate.

Your child's/your identity will remain confidential. Your child's/your name will not be published. It is necessary for accurate documentation to crosscheck names with information routinely collected for health service use but this will be done in a confidential manner by the researcher only with government or healthcare officials. The information will only be used for research purposes.

If your Doctor learns of important new information that might affect your desire to remain in the study, he or she will tell you. We hope you will join with us in trying to understand diabetes better, and improve the care offered. If you wish to discuss this further, please speak to your Consultant.

Data Protection details:

- **The purpose or reason for processing your child's/your personal data** is to monitor the incidence and prevalence of Type 1 Diabetes and the epidemiological changes in the Irish Childhood Population. It is vital to have as complete and accurate as possible information on Childhood Diabetes to both help improve Diabetes services and better service planning for children and young people. It is also important to provide further insight into Type 1 Diabetes in Childhood in Ireland and also determine how many Children in Ireland under the age of 15 years have Type 1 Diabetes in comparison to children in other European countries which may help shed further light on the cause of this important disease.
- **The legal basis under which we are processing your child's/your data** is based both on Article 6 and Article 9 of the General Data Protection Regulations (GDPR) 2018.
- **Who are the recipients of the data?** The recipients of the data are your Diabetes team at your hospital, Researchers and Statistical staff working with the ICDNR Project at CHI at TUH and Trinity College Dublin and the HSE. Sharing data is something that the ICDNR has always taken very seriously and as such has strictly restricted access to data to researchers working with the ICDNR project. Data released are always anonymised and registrants are never identified. The ICDNR collaborates with EURODIAB (A Europe wide Epidemiological study to show the variation and trends in childhood Type 1 Diabetes) but only provides anonymised data. Our work with the ICDNR has proven that Ireland is a country of high diabetes incidence within Europe and worldwide. Previously Ireland was thought to have the lowest rate of diabetes in Europe. Statistical anonymised data from the Register are published in the medical literature and presented at national and international conferences both to increase awareness about diabetes in our children and young people and enhance service planning and provision of services.
- **How long will the data be stored for?** It is envisioned that your child's/your data will be stored for the lifetime of the Irish Childhood Diabetes National Register unless you/your child decide to opt out of the study. The data of those joining the Register from 2019 will be anonymised at the age of 16 years unless the parent and child opt out of the Register before the child's 16th birthday. This anonymised Data may be used for comparison purposes. This could entail looking back over ten, twenty, or more years to see if incidence rates or other factors have changed for the under 15 year old population in Ireland. You/your child are free to decide if you want to remain on the register, restrict the data the register holds for you, or opt out entirely from the study. **You must contact us to inform us of your wishes before data is fully anonymised as we will not be able to link you with your data after the event.**

- **Risks and/or implications that might arise as a result of the data processing.** It is not anticipated that your child/you experience any adverse risks and /or implications as a result of data processing for the ICDNR. Every effort is made to store your data securely and pseudonymised* within the Database on the TUH server, (*this means your child's /your electronic data can still be linked to your child's/your hard copy data⁺ up until it is fully anonymised) and in the form of strictly anonymised statistics if shared with Health care organisations or research publications. ⁺Hardcopy data; that is your original consent and data forms are stored in separate locked units within a locked office in the Trinity centre for Health sciences, Tallaght University Hospital.
- **Your child/you have a right to withdraw consent.** Should your child/you want to opt out of the ICDNR at any time, please contact us: Irish Childhood Diabetes National Register Administrator, The Trinity Centre for Health Sciences, Tallaght University Hospital, Tallaght, Dublin 24. Phone (Landline: 01-8963769 or Mobile 085-2896164) email: diabetes.register@tcd.ie. It must be before the child reaches the age of 16 years. If this is the option you choose, you should contact the Register before January 1st of the year (you/the young person) is about to reach 16 years in the case of those registered from May 1st 2019.
- **Your child/you have a right to lodge a complaint with the Data Protection Commissioner.** We strive to manage your data appropriately, however if you wish to make a complaint please let us know. You can also make a complaint on yoursay@hse.ie. Or to the Data Protection Commissioner on info@dataprotection.ie
- **Your child/you have a right to request access to your data and a copy of it.** We can provide you with access to the data we hold about you at any time, free of charge, you just have to ask. You can request this by contacting us. If the data we hold about you is not accurate or up to date, please contact us and we will update our records. You are also able to make a standard access request (SAR) which means we must tell you all the information we store on you. Simply make a request in writing to the address below. We are obliged to respond within 30 days. **However, once the data is anonymised we will no longer be able to retrieve the data.**
- **Your child/you child have a right to restrict or object to processing**, unless your child's/your request would make it impossible or make it very difficult to conduct the research.
- **Your child/you have a right to have any inaccurate information about your child/you child corrected or deleted.**
- **Your child/you child have a right to have your child's/your personal data deleted**, unless your child's/your request would make it impossible or make it very difficult to conduct the research. e.g. requesting to delete your child's/your data at the end of a research project just before it is due to be published.
- **Your child/you have a right to data portability**, meaning your child/you have a right to move your child's/your data from one controller to another in a readable format.

- **Your child/you will be informed should the register intend to process further your child's/your personal data** and you/your child will be provided with information on that other purpose should it arise
- **Currently Register data is not transferred to a country outside of the EU or an international organisation.** Should this be the case in the future, your child's/your data will be protected and only strictly anonymised statistical data that is not in any way identifiable.

For Further Information and Contact Details:

Principal investigator's name: Professor. Edna Roche

Principal investigator's title: Consultant Paediatrician/ Paediatric Endocrinologist

Contact Details: ICDNR, The Trinity Centre for Health Sciences, Tallaght University Hospital, Dublin 24. Landline: 01-8963769, or email diabetes.register@tcd.ie

Data Controller's Identity and Contact Details:

Children's Hospital Ireland (CHI) at Tallaght University Hospital (TUH)

Data Protection Officer's Identity and Contact Details:

Ms. Meiread Ashe,
Board Secretary and Data Protection Officer,
Children's Health Ireland,
Block A, Herberton,
St. James's Walk,
Rialto, Dublin 8.

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