Voluntary participation:

Participation in the study is voluntary. You/Your child do not have to be a part of this study. If you take part you may quit at any time. It will in no way influence your clinical care if you decide not to participate. Your Doctor may stop your participation in the study at any time without your consent.

Compensation:

Your doctors are covered by standard malpractice insurance, Nothing in this document restricts or curtails your rights.

Exclusion from participation:

Those over 15 years at diagnosis or where diabetes is secondary to another condition, such as cystic fibrosis are excluded from this study.

Study sponsor:

Thanks to the National Children’s Hospital Foundation for providing financial support for this Register and to The Adelaide and Meath Hospital incorporating the National Children’s Hospital, Tallaght for hosting the Register.

This Research is undertaken by Researchers working with Trinity College Dublin and The Adelaide and Meath Hospital incorporating the National Children’s Hospital, Tallaght.

Further Information:

You can get more information or answers to your questions about the Register, your participation in the Register and your rights, from:

Irish Childhood Diabetes National Register

Care of:

• Dr. Edna Roche,
  Consultant Paediatrician/ Paediatric Endocrinologist

The Trinity Centre for Health Sciences,

The Adelaide and Meath Hospital, incorporating the National Children’s Hospital, (AMNCH) Tallaght, Dublin 24.

Phone: 085-2896164

email: diabetes.register@tcd.ie

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 or your Diabetes Nurse Specialist.
The Register;

Introduction:
The number of children and young people developing type 1 diabetes is increasing worldwide. The purpose of this study is to develop a register of children and young people developing diabetes. With the help of this register we can track if diabetes is becoming more common in Ireland.

Benefits:
The benefits of the study are that we will obtain accurate numbers of those 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 disease and improve management and quality of care.

What this means for you /your child?
To participate in this study is to allow your/your child’s name to be registered as having diabetes, as you would when applying for the long term illness card. Clinical details will be recorded and sent by post. This will include: name; address - (so we can identify geographical variations); 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. Your Doctor and Diabetes Nurse Specialist will speak with you about the Register and ask you to sign a consent form. You will receive a copy of this form.

Confidentiality:
Your/Your child’s name is required to ensure that you/your child is not counted twice. You/Your child’s identity will remain confidential. Your/Your child’s name will not be published. All data on the Register is stored anonymously with the name removed. Every effort will be made to make sure the register is accurate. It is necessary for accurate documentation to cross check names with information routinely collected for health service use but this will be done in a confidential manner by the researcher with government or healthcare officials. The information will only be used for research purposes.

Permission:
This study has received Research Ethics Committee approval.

How will the information be obtained and used?
When you agree to participate the information will then be obtained from your/your child’s medical chart in the hospital. There will not be any additional information in the Registry that is not in your/your child’s medical chart. The purpose of the Register is to store the information securely on the AMNCH hospital computer system within a central database which is similar to an electronic filing cabinet. 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 will be processed to make sure that individual patients cannot be identified.

Risks:
As there is no medication or treatment given or additional examinations, no harm or discomfort is anticipated in you/your child participating in this study.