



**Down Syndrome
National Register**
Uniting for your Future

Information Leaflet for Parents

National Register for Children with Down syndrome

Introduction: We would like to invite you to participate in a research study that we believe will improve the health and wellbeing of those with Down syndrome – the National Register for children with Down syndrome. This Register will enable us clarify the number of young people in Ireland that have Down syndrome and the areas in which they live, these data would give service providers the information they need to provide and plan the necessary services and the planning of appropriate resource allocation. In our work over the years with children and families with this condition we are frequently asked if certain problems and illnesses are more common for children with Down syndrome. For some conditions we clearly know the answers and for other conditions unfortunately the information is not available. However, by you agreeing to work with us by participating in the National Register and to giving us permission to contact you maybe just once a year just to check in and see how things are going, we may be able to answer more reliably these questions for families in the future.

Benefits: We plan to use the information that is collected to enable us to provide realistic data to enable planning for the future health and wellbeing of children with Down syndrome. Currently we do not know exactly the number of children born with Down syndrome every year. This vital information will greatly support the planning of appropriate services and resources. When appropriate services are provided to children and their families in relation to health and development, their quality of life is enriched. Tracking the number of annual births of children born with Down syndrome and also looking at any health issues they may face will give us a clear picture of the resources required and also provide more reliable information to future parents of children that will be born with Down syndrome.

Before you decide whether or not you wish your child to take part (Consenting for your child) when under the age of 18 years, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or Doctor. Take time to ask questions – don't feel rushed, and don't feel under pressure to make a quick decision.



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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 Consent' and this information leaflet aims to give you clear and detailed information so you can give your Informed and Explicit consent upon joining The National Register for Children with Down syndrome.

What this means for your child/you: To participate in this study is to allow your child's name to be registered as having Down syndrome. Clinical details will be recorded and include: name; address- (so we can identify geographical variations); date of birth; ethnicity; type of Down syndrome diagnosed; age of parents; your child's gender; number of brothers and sisters; the hospital where your baby was born; any medical problems; the name of the consultant responsible for your child's care; if your child required transfer to another hospital soon after birth and whether there is a family history of Down syndrome. Your doctor/midwife or nurse will ask you the specific details and record the information that you give which will then be added to the register. By agreeing to participate in this study you are giving us your permission to contact you approximately once per year to check in with you and ask you to complete a telephone interview or parental questionnaire to see how your son/daughter are getting on and their current health status. We are also asking for your permission to hold and process your child's information and your contact details (held separately) to enable the research outcomes and to anonymise these data when the research is complete.

Confidentiality: Your identity will remain confidential. Your name will not be published or disclosed to anyone. Your child's name will not be put on the register. All information on the register will be pseudo anonymised using a unique register code for your child. Your child will be asked to give their assent to being in the study from 9 years of age and will be asked to provide their own consent to remain in the study at 18 years (this process of re-consent would start between the age of 16 and 18 years due to the mobility of this age group). Your child's data will be anonymised at the end of the study. The data collected from this study may be utilised for further studies by the researcher with your consent. While Down syndrome Ireland support the study they will not have any access to your information. The study has been granted ethical approval from the Tallaght University Hospital/ St James's Hospital Joint Ethics Committee, The Coombe Women's and Infants University Hospital



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Ethics Committee, The Research Committee in The Rotunda Hospital and Children's Health Ireland, Our Lady's Children's Hospital, Crumlin.

How will the information be obtained and used? When you agree to participate the information will then be obtained from you and your child's medical chart. There will not be any additional information in the register that is not in your child's chart or offered by you, the parent(s)/guardian(s). The purpose of collecting this data is to store the information securely on the National Register within a 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 fully anonymise the participant to ensure 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 your child/you participating in this study. The risk would be of inadvertent access to your/your child's personal data which we take great care to prevent as outlined below.

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

Do I have to take part in this study? No this study is entirely voluntary and you do not have to participate at all and do not have to give us any reasons for that.

What happens if I change my mind? You can change your mind at any stage and we will not contact you any further again, you do not have to give us any reason for that.

Data Protection

1. We will be using your child's information to learn about the incidence of Down syndrome and also of any health issues your child may have.
2. The legal basis for the processing of your data is that it is done with explicit consent (Article 6) in the public interest and for scientific research which fall under Articles 6 and 9 of the General Data Protection Regulations 2016 (GDPR).
3. The research group will have access to the data. All persons carrying out the research are bound by a professional code of secrecy to ensure confidentiality.



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4. The data will be stored until completion of the project. During this time period paper data will remain stored a locked filing cabinet in a locked room whilst electronic data will be stored in an encrypted locked computer in a locked room.
5. While every effort will be made to protect your data, however if a breach of data to a third party occurred we would inform you immediately.
6. You have every right to withdraw for the research project. You can do so by contacting one of the research team.
7. You have a right to lodge a complaint with the Data Protection Commissioner. Give details of how below of how to do this
8. You have a right to request access to your data and a copy of it, unless your request would make it impossible or make it very difficult to conduct the research.
9. You have a right to restrict or object to processing, unless your request would make it impossible or make it very difficult to conduct the research e.g. you do not want your child's data shared but do not mind having it collected and stored.
10. You have a right to have any inaccurate information about you corrected or deleted, unless your request would make it impossible or make it very difficult to conduct the research.
11. You have a right to have your personal data deleted, unless your request would make it impossible or make it very difficult to conduct the research. E.g. you wanted to delete their data at the end of a research project just before it is due to be published.
12. You have a right to data portability, meaning you have a right to move their data from one controller to another in a readable format.
13. There will be no automated decision making, including profiling. Profiling is any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to the person, in particular to analyse or predict aspects of their performance at work, health or behaviour.
14. You have a right to object to automate processing including profiling if you wish.



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15. You will be informed if we intend to further process your personal data and will provide you with information on that other purpose.
16. We do not intend to transfer your data to a country outside of the EU or an international organisation, however if the occasion arose we would inform you.

Where can I get more information? You can get more information on this study by discussing it with your healthcare team or by contacting Grainne O Connor Research Nurse Down syndrome, Department of Paediatrics Tallaght Hospital, Dublin 24. Email: Grainne.OConnor@tuh.ie PH:01-4143013

Can I contact Grainne for advice if I don't want to participate in this study? Absolutely, Grainne would be delighted to talk with you further and advise you.

Principal investigator's name: Prof Edna Roche

Principal investigator's title: Professor in Paediatrics, Discipline of Paediatrics, Trinity College Dublin.

Contact details: The National Register for Children with Down syndrome, The Trinity Centre for Health Sciences, Tallaght University Hospital, Dublin 24.

Email; Grainne.OConnor@tuh.ie

Data Controller: Children's Hospital Ireland at TUH

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

Data Protection Officer's Contact Details: Email: meiread.ashe@nchg.ie

Study Sponsor: This research is undertaken by The Department of Paediatrics, The University of Dublin, Trinity College, Dublin by Professor Edna Roche, Professor Eleanor Molloy, Ms Fiona McGrane and Ms Grainne O Connor and supported by Down syndrome Ireland and the National Children's Hospital Fund.



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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 Register for children with Down syndrome

Ms Grainne O' Connor, RCN, RGN. The Department of Paediatrics

Trinity Centre for Health Sciences, Tallaght University Hospital

Dublin 24

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