

## 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. We plan to establish a National Register for those with the condition. This would enable us to clarify the number of young people in Ireland that have Down syndrome and the areas in which they live, this data would help service providers with the necessary information they need to provide the necessary services and in the planning of appropriate resources. 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 utilise the information that is collected to enable us to provide realistic data to enable planning for the future health and well being 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 what is needed and also provide more reliable information to future parents of children that will be born 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.

**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 anonymised. The data collected from this study may be utilised for further

studies by the researcher. While Down Syndrome Ireland support the study they will not have any access to your information. The study has gained ethical approval

**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 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 your child/you participating in this study.

**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.

**Where can I get more information?** You can get more information on this study by discussing it with your healthcare team or by contacting Fiona Mc Grane Research Nurse Down syndrome, Department of Paediatrics Tallaght Hospital, Dublin 24. Email: mcgranfi@tcd.ie

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

**Study Sponsor:** This research is undertaken by The Department of Paediatrics, The University of Dublin, Trinity College, Dublin by Professor Edna Roche, Prof Eleanor Molloy and Ms Fiona Mc Grane and supported by Down Syndrome Ireland

**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 Fiona Mc Grane CMN II, RCN, RNID**

**The Department of Paediatrics,**

**Trinity Centre for Health Sciences,**

**Tallaght Hospital,**

**Dublin 24. Ph 01 8963785**