Parent/Legal Guardian Information Leaflet

The EpiFUN study: Correlations between phenotype, genotype and functional analysis in the (neuro)genetic disorders of childhood

- **Part 1. CINDI Registry (confirmed genetic diagnosis)**

Principal investigator's name: Dr Susan Byrne

Principal investigator's title: Consultant Neurologist

Telephone number of principal investigator: 01 428 2657

Data Controller's Identity (separate):

- CHI
- Royal College of Surgeons in Ireland (RCSI)
- University College Dublin (UCD)

CHI Data Protection Officer's Identity: Data Protection Office
CHI Data Protection Officer's Contact Details: Data Protection Officer, CHI at Crumlin, Dublin 12
Email: dpo@olchc.ie
www.olchc.ie/about-us/privacy-statement-gdpr/

RCSI Data Protection Officer's Identity: Data Protection Office
RCSI Data Protection Officer's Contact Details: Data Protection Officer, Royal College of Surgeons in Ireland, 123 St Stephen's Green, Dublin 2
Email: dataprotection@rcsi.ie
www.rcsi.com/privacy-policy

UCD Data Protection Officer's Identity: Data Protection Office
UCD Data Protection Officer's Contact Details: Data Protection Officer, UCD, Belfield Dublin 4.
Email: gdpr@ucd.ie
www.ucd.ie/gdpr/policiesprocedures/

The informed consent process

Your son or daughter is being invited to take part in a clinical research study to be carried out in CHI at Crumlin/CHI at Tallaght in collaboration with RCSI. Before you decide whether or not you wish them to take part, you should read the information provided below carefully and, discuss it with your family, friends or GP (doctor). 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 your child and family. This process is known as 'Informed Consent'.
Your child will also be given a patient information leaflet and assent form in order to make an informed choice in relation to the study. Your child does not have to take part in this study. If you decide not to take part it won't affect their future medical care. You, your child can change your mind about taking part in the study at any time. Even if the study has started, there is still the option to opt out. You don't have to give us a reason. This will not affect the quality of treatment your child gets in the future. When your child reaches the age of 18 years, and has reached the age of majority, they will be asked to re-consent to the study. If they do not wish to continue on in the study then no further information shall be collected. Information collected to date will be archived in an anonymous manner.

Why is the study being done? How will the study be done?

This study is being undertaken to help us understand more about the causes of disease in childhood, in particular genetic disorders of childhood. We have decided to approach your child for this particular study as they have a confirmed genetic diagnosis, and they are attending CHI at Crumlin/CHI at Tallaght under the neurosciences (Dr Byrne, Dr O'Regan, Professor Webb, Professor McDonald and colleagues) or genetics team (Dr Janna Kenny and colleagues), or you have been referred you to the research team for inclusion in this research registry. **There are two parts to this study. The team are asking you to be involved in part 1 of the study.**

- **Part 1: CINDI Registry**

Part 1: CINDI registry – **CINDI** stands for **C**ollaboration **I**n ge**N**omic **D**isorders in **I**reland. The team will collect clinical information including the genetic test results over time in a secure database called CINDI as part of standard clinical care. Clinical information related to your child's condition will be reviewed through their medical records and the Electronic Patient Record here at CHI, and stored in a coded format in an electronic database on CHI servers which can only be accessed by approved researchers.

Who is organising and funding this study?

This research is being conducted by a large team of doctors and scientists working together. The scientists include Prof David Henshall RCSI, Prof Gianpiero Cavalleri RCSI, Dr Katie Benson RCSI and Dr. Gary Brennan UCD. The research is funded by Science Foundation Ireland through a

number of grants including the FutureNeuro Research Centre. Investigators are not receiving any payment to recruit patients.

What will happen to my child if we agree to take part?

Part 1: CINDI Registry

1. Information such as but not limited to age, gender, diagnoses, genetic results, and medication may be stored on the CINDI registry. This is a database. Information will be stored on an application such as REDCAP within the CHI servers. Your child's identity will be protected by a code which will be kept by your medical carers, in CHI at Crumlin/RCSI. We access details of treatment and care through medical records and electronic patient record (EPR) here at CHI at Crumlin, and may contact you at intervals to update this information.
2. In order to keep our records complete and up to date, members of our team may wish to contact you via telephone/email in the future. In the consent form we will ask permission to re-contact you should a suitable treatment, trial or research study become available that may be suitable your child.

What are the benefits?

Should your child decide to participate there are no immediate benefits to them. The results of this study will not change their immediate treatment. However, by consenting to be part of this research, your child may contribute to important new information which may benefit patients in the future. We may contact you should a suitable treatment, trial or research study become available for your child.

What are the risks?

No samples will be taken. We will keep your child's information in coded format on the CINDI register. We may also request previously generated genetic information and store this on the RCSI server. It may be analysed. All information is kept securely in CHI based servers (CINDI register) and RCSI based servers. The risk of a data breach is very small, and there are many processes in place to prevent this.

Will it cost me anything for my child to take part?

There are no costs associated with your child's participation in this study.

Is the study confidential? Yes

Will you be writing to my child's General Practitioner? We will <u>not</u> automatically tell your GP about your child's participation in this study but we can do so if you wish.

Will you be looking at my child's medical records? We will access details of your child's treatment

and care through their clinical paper record, and electronic records here at CHI at Crumlin/CHI at Tallaght. We may also wish to ask a couple of questions in relation to treatment response. In order to keep our records complete and up to date, members of our team may wish to contact you via telephone in the future.

Will the information about my child be kept confidential? All data generated from this study will be kept strictly confidential. The clinical details of your child's treatment will be studied in strictest confidence by members of the research team.

Will the information kept about my child be capable of identifying them? All research work will be coded. Dr. Susan Byrne will maintain the link between hospital number and your child's name to the sample, to allow updating of clinical information only in respect of the current research project. Your child's information may be sent to RCSI to be stored in coded format. Your child's information will not be used for identification or for any other purpose. The data and results of our study may be shared with scientific collaborators and published at a later date, your child's name or number will not appear in the publication.

A code will be assigned to your child's details, as well as to information about their Medical History. Only authorized representatives of CHI at Crumlin will have direct access to their personal medical records. This will ensure all research is performed according to the approved protocol and that data are correctly recorded.

Other investigators and industry partners who may receive information for research/clinical trial planning, will be given only the code number which will not identify them. All other parties such as personal physicians, and relatives will be refused access to the information or to the samples, unless you provide written permission, or unless we are required by law to do so. Research records may be reviewed by a funding agency. The results of these studies may be published at a later date, but individual patients will not be identified in any publication.

How long will you be keeping information about my child? Data from this specific project will be retained for a period of up to 30 years, but we would like to use information resulting from your child's participation again for other, future ethically-approved research. The information on CINDI will be retained until your child is 18 years, and then re-consent will be obtained.

The results of our study may be published/presented at a later date in a scientific or medical publication/conference, your child's name or number will not appear in the publication/presentation.

Data Protection

1. The collecting and use of personal data will be used for the purposes of reviewing clinical records and creating a unique code for each sample. Personal data will not be made

available to researchers in RCSI or UCD, only coded information will be provided (and only if necessary).

2. We wish to process your child's data under Article 6 (1) (e) public interests and article 9 (2) (j) 'for scientific research purposes' of the General Data Protection Regulation 2016 (GDPR). The legitimate interest and scientific research purpose here is to improve treatment options and care for people with neurological disorders

   Only researchers approved by Dr Byrne in CHI at Crumlin will have access to your child's medical records. The other named co-investigators will only have access to your data in a pseudonymised form, which means your child's data will be assigned a code for processing. Your child's samples and coded data will be safely stored until the study is deemed complete (and then safely destroyed).

3. Who are the recipients of the data e.g. who will have access to the research participants' information?

   A code will be assigned to your child by the team at CHI, as well as to information about their Medical History. Only authorized representatives of CHI at Crumlin will have direct access to their personal medical records. If at a later stage researchers require additional information, e.g. the type of treatment your child received, Dr Byrne (Principal Investigator) at CHI at Crumlin can make this information available to them.

4. How long will the data be stored for and, if it is not possible to say, please give the criteria which will be used to determine that period.

   The sample and the data generated will be stored within the CHI facility and secure computer servers indefinitely or until the study has been deemed complete.

5. You and your child have a right to withdraw consent from this research study

6. You and your child have a right to lodge a complaint with the Data Protection Commissioner at any time.

7. You and your child have a right to request access to their data and a copy of it, unless their request would make it impossible or make it very difficult to conduct the research.

8. You and your child have a right to restrict or object to processing of data.

9. You and your child have a right to have any inaccurate information corrected or deleted.

10. You and your child have a right to have personal data deleted, unless their request would make it impossible or make it very difficult to conduct the research. e.g. they wanted to delete their data at the end of a research project just before it is due to be published.

11. That the data subjects have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format.

12. There will be no automated decision making, including profiling, involved in this research project. 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.

13. You and your child have a right to object to automated processing including profiling if you wish.

14. We will contact you if we intend to further process your child's personal data and request your consent for that purpose.

15. Only coded information will be sent to researchers.

Where can I get further information?

If you do not understand any of the information presented to you please ask Dr Byrne or a member of his team before you agree or disagree to your child's participation in the study. If you have any further questions about the study please do not hesitate to contact us.

If you wish to withdraw from the study and/or have us destroy your child's sample you may do so (see contact details below) without justifying your decision and your child's future treatment will not be affected.

For more information on how we process your information, our lawful bases for processing and your rights, please visit each of the parties privacy notices (above on page 1). For additional information on this study now or any future time please contact:

Name: Dr Susan Byrne
Address: Consultant Paediatric Neurologist, CHI at Crumlin
Phone: 01 4282657
Note this phone number is only manned during office hours.