Patient Information Leaflet

Study title: *Development and Establishment of a Register of Patients with Epilepsy caused by Genetic Mutations – The Epilepsy Associated Gene Ready Register (EAGER).*

Principal investigator's name:	**Professor Norman Delanty**
Principal investigator's title:	**Consultant Neurologist, Beaumont Hospital / RCSI**
Telephone number of principal investigator:	**(01) 809 2210**
Data Controller's Identity:	**Royal College of Surgeons Ireland (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**

You are being invited to take part in a clinical research study to be carried out as part of the FutureNeuro Research Centre, RCSI. FutureNeuro Research Centre is a Science Foundation Ireland funded national research centre aimed at advancing knowledge in rare and chronic neurological disease. Its aim is to change the patient journey through research informed by the needs of both patients and neurologists. This includes developing rapid and accurate tools for diagnosis, the development of therapies to modify brain networks, and technologies to enable patients to monitor their own health and well-being. FutureNeuro is multi-disciplinary, inter-institutional and works with patient organisations, the health service and industry to transform the lives of patients in Ireland and worldwide. One of our key focus is on epilepsy, a chronic brain disease-affecting people of all ages,

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions. Do not feel rushed or 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'.

You do not have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it will not affect the quality of treatment you get in the future.

Why is this study being done?

The aim of this study is to set up an Irish register of patients with epilepsy due to known genetic mutations (changes in DNA structure that lead to or predispose to human disease).

This will allow us to identify you as a patient who may be suitable for new treatments developed in the future to target particular types of genetic epilepsies (this is known as precision or targeted medicine).

You will only ever be contacted by the research nurse in relation to this register, you will never be contacted by a third party. This research nurse has been employed by the Royal College of Surgeons in Ireland to manage this register.

Who is organising and funding this study?

This research is being conducted by Professor Norman Delanty of Beaumont Hospital and RCSI. This study is funded by RCSI and FutureNeuro Research Centre.

Why am I being asked to take part?

We have decided to approach you for this particular study as you are a patient being treated for epilepsy at Beaumont Hospital, and the cause of your epilepsy is due to a known genetic mutation in one of your genes. We are asking you for your permission to store your basic clinical information and specific relevant genetic information about your epilepsy to create a register of patients with genetic epilepsies in Ireland.

How will the study be carried out?

The study will take place between Beaumont Hospital, Dublin and the Royal College of Surgeons in Ireland. If you agree to participate, you will be asked to consent and your name will go on a register.

Basic clinical information related to your epilepsy will be reviewed through your medical records and the Epilepsy Electronic Patient Record (EPR) system at the hospital. Your

information will be identifiable and will only be accessed by the research nurse and consultant assigned to this register as we require:

1. Your name, age and contact details.
2. Your epilepsy type and associated relevant conditions
3. Your specific genetic information related to your epilepsy.

This study will be ongoing. We hope to continue to enrol people in the study in order to create a relevant register of patients.

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

If you decide to participate, we will:

1) As a patient of the EAGER Register, we will access details of your genetic results related to your epilepsy through your medical records and electronic patient record (EPR) at Beaumont Hospital.

2) Should precision therapies or clinical trials become available in the future, you will be contacted and provided with information if these are relevant to you.

Note that should you decide to participate in this study, your treatment will not be changed in any way as a result of participation.

As a participant, you have the right should you wish, to withdraw your name from the register.

What are the benefits?

Should you decide to participate in the research, there are no immediate benefits to you directly. However, we hope this register may be useful in the future for contacting you and other patients should new precision medicine treatments become available that you may wish to consider and learn more about.

What are the risks?

We believe that they are no risks to you if your data is entered into the register

Will it cost me anything to take part?

No costs will be incurred by you as a study participant.

Processing and sharing of your data

Will you be contacting my General Practitioner?

Yes, we will inform your GP about your participation in this study.

Will you be looking at my medical records?

Yes, the research nurse and consultant assigned to this register will look at your medical record.

Will the information about me be kept private and confidential?

All data generated from this study is used and stored confidentially. The clinical details of your treatment will be treated in the strictest confidence by the research nurse and consultant assigned to this register.

Will information kept be capable of identifying me?

Yes. Your name, age, contact details, epilepsy type, and genetic information related to your epilepsy are required to accurately record the number of patients per type of gene mutation. However, only the research nurse and consultant assigned to this register will be capable of identifying you.

Where will you be sending information about me?

Your clinical and epilepsy genetic information will be sent to a research nurse Sarah-Jane Byrne and Professor Norman Delanty, and under the terms of the consent you have provided will be entered onto the EAGER register.

Will I get any results from this research study?

This study is not diagnostic, and is for future potential research purposes. The Register may identify that your specific genetic cause of your epilepsy may may be amenable to a targeted precision treatment. You are given the option as whether you would want to receive notification that clinical trials examining target/precision therapies are available.

In this context, you have a choice to

A. Consent to being contacted by the research nurse only to find out information about trials on precision/target therapies as they become available.

Or

B. Consent to being on the register but not to receiving further communication from the research nurse if precision/target therapies become available.

If you choose to receive results (i.e. option A), then you have the choice of receiving information regarding trials on new precision therapies that may become available in the future.

Data Protection

1. We will be using your personal information to compile a register of patients with epilepsy caused by genetic changes (mutations).

2. We wish to process your data under Article 6 (91) (f) 'Legitimate 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 create a register of epilepsy patients with genetic mutations.

3. Your data will only be accessed by the consultant and research nurse assigned to the Register.

4. Your data will be stored long-term as this will be an ongoing study.

5. You have the right to withdraw consent should you change your mind about having your data included as part of the Register.

6. You have the right to lodge a complaint with the Data Protection Commissioner, 21 Fitzwilliam Square South, Dublin 2, D02RD28, Ireland. www.dataprotection.ie should you be unhappy about how your data has been processed.

7. You have the right to a copy of your genetic data.

8. You have the right to have any inaccurate information corrected or deleted.

9. You have the right to have your personal data deleted.

10. This study will not include 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. .

Consent to Future Uses

In the future, clinical trials on precision targeted therapies may become available. You have the option to consent to being contacted by the research nurse only in relation to this or not. You will not be contacted by a third party directly. If you wish to withdraw from the study and/or have us destroy your information you may do so (see contact details below) without justifying your decision and your future treatment will not be affected.

Where can I get further information?

If you do not understand any of the information presented to you please ask Professor Delanty or the research nurse assigned to this register before you agree or disagree to participation in the study. If you have any further questions about the study please do not hesitate to contact us.

For additional information now or at any future time, please contact:

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Name: Professor Norman Delanty
Address: Consultant Neurologist, Beaumont Hospital, Dublin 9, Ireland
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Note: This phone number is only manned during office hours.