



## Young Person's Information Sheet (aged 8 – 12 years)

Study title: **The EpiNet-First trials of new onset epilepsy**

Locality: **Auckland District Health Board**

Ethics committee ref.: **14/NTB/56**

Lead investigator: **Dr Peter Bergin**

Contact phone number: **09 379 7440 ext 25663**

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### What is a research study?

A research study is what doctors do when they want to learn about something or find out something new.

### Why is this research study being done?

Epilepsy is a common problem in children. We want to find out which medicine is best to treat children with epilepsy.

### Why me?

You are being asked to take part because you have epilepsy and your doctor has recommended that you start a medicine.

### What will happen to me during the study?

- Your doctor will decide if you need any tests. You will **not** need blood tests or any other samples taken for this study.
- You will receive an anti-epileptic medicine to help stop your seizures. You will receive one of the following medicines: Carbamazepine, Lamotrigine, Valproate or Levetiracetam. Neither you nor your doctor will choose which medicine you will be given, but it will be chosen at random (by a computer). However, once you have been given a medicine both you and your doctor will know which one it is.
- After you have started taking your medicine you will be seen in the hospital clinic. Your doctor will ask your mum or dad or the person who looks after you to write a diary of any seizures that you have.
- We will also ask you some questions about your epilepsy and the medicine you take to treat your epilepsy.

### Will the medicines used in this study upset me?

The medicines used in this study have been given to lots of children before. Sometimes medicines upset our body. We call this upset 'side-effects'.

Side-effects do not always happen. If they do happen, they are not usually serious and do not usually last for long. Your hospital doctor or epilepsy nurse will ask you questions in case you do get some side-effects.

*A full information sheet on the medicine will be given to you when the doctor prescribes (gives you) the medicine in clinic.*

**Are there any risks to taking part?**

There is a risk that some medicines used to treat epilepsy might have side effects. Your hospital doctor or nurse will discuss this further with you.

**Will taking part in this research study help me?**

This study might help you. The results of this study might also help us to treat other children with epilepsy.

**Do I have to take part, and can I change my mind?**

It's up to you. We only want you to take part if you want to. If you decide to take part and then change your mind, that's OK. You can stop at any time and don't have to say why you want to stop taking part in the study.

**Who can I ask about this?**

You can ask your mum or dad or the person who looks after you. The hospital doctor or epilepsy nurse who gave you this leaflet will also be able to answer your questions.

Contact:

Dr Peter Bergin, Chairman of the EpiNet study Group  
Consultant Neurologist, Neurology Department, Auckland City Hospital  
Phone: 09 379 7440 x 25663

If you require Māori cultural support, talk to your whānau or He Kamaka Waiora (Māori Health Team) on: Phone: 09 486 8324 ext 2324

or

If you have any questions or complaints about the study you may contact the Auckland and Waitemata District Health Boards Maori Research Committee or Maori Research Advisor by telephoning: 09 4868920 ext 3204

**THANK YOU FOR READING THIS INFORMATION SHEET.**



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**Assent Form for young persons (aged 8 – 12 years)**  
*(to be completed by the child and their parent/guardian/carer)*

**Centre Name:**

**Name of Investigator:**

**Trial Number:** | | | | | | | | | |

**Patient's date of birth** | | | | / | | | | / | | | | | |

**If you need an INTERPRETER, please tell us.**

**Child (or if unable, parent on their behalf)/young person to tick all they agree with:**

Have you read the information (or had read to you) about the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you been given enough time to decide whether or not to take part in the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Has someone else explained the study to you?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Do you understand what the study is about?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you asked all the questions you want?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you had all your questions answered in a way that you understand?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Do you understand that it is OK to stop taking part at any time?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are you happy to take part in this study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

If any answers are “no” or you **don't** want to take part, please **don't** sign your name.  
**If you do want to take part, please write your name and today's date:**

**Your Name** \_\_\_\_\_ **Date** \_\_\_\_\_

**Your parent or guardian or carer must write their name here too if they are happy for you to do the study:**

\_\_\_\_\_  
**Name of parent or  
guardian or carer**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date (dd-mm-yyyy)**

**The researcher who explained this study to you needs to sign too:**

\_\_\_\_\_  
**Researcher**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date (dd-mm-yyyy)**