**Carer Information Sheet**

Identifying treatment **S**ide effects in adults with an **I**ntellectual **D**isability and **E**pilepsy: Development of **P**atient-**R**eported **O**utcome Measure (PROM) for identification of Anti-Epileptic Drug (AED) side effects (**SIDE-PRO)**

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You are invited to take part in a study to develop a questionnaire that professionals can use with patients and carers to identify important side effects of anti-epileptic drugs in adults with learning disability. This information sheet is to answer some of your questions and help you decide if you want to take part.

The purpose of this study is to develop a questionnaire that professionals can use with patients and carers to identify important side effects of anti-epileptic drugs in adults with learning disability. Although similar questionnaires are available for use in the general population, it isn't clear whether these are appropriate for adults with a learning disability and it may be difficult to spot side effects of drugs because of this. We are also interested in whether side effects influence behaviour and day to day living. It is hoped results will lead to better awareness and identification of anti-epileptic drug side effects.

We would like to invite you to take part in this research study. Before you decide if you would like to take part, you need to understand what the research is about and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish, for example, members of your family or friends.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of this study?**
In this part of the research, we want to understand the side effects of anti-epileptic drugs that are most important to the individual you care for and to you as the carer, particularly those that affect quality of life.

**Why have I been chosen?**
You have been invited to take part because you are a carer of an adult who has a learning disability and is taking anti-epileptic drugs.

**Do I have to take part?**
It is up to you whether or not you take part in this study. This information sheet is yours to keep. If you agree to take part, we will ask you to sign a consent form. If you want to leave the study, you can do so at any time. You do not have to give a reason for leaving the study.

Should you decide not to join the study, or join and later leave, it will not affect the standard of care you or the individual you care for receives now or in the future.

**What will I have to do?**
The study will happen in stages including focus groups, face to face interviews with the study team (home based) and questionnaires which we will post to you at home.

You can claim back any travel or parking expenses (please keep your receipts). You will also be offered a £10 high street gift voucher as a thank you for giving up your time.

We will ask you if it would be OK to audio record the research. This will mean that we do not miss what you say. We will ask some

questions about the side effects of anti-epileptic drugs.

If you do not want to answer any individual question you do not have to do so – that is your choice.

Any audio recording will be typed up and anonymised so that we can explore what you have said in more detail and compare it to what others have said. Audio recordings will not be shared with anyone outside the research team. Recordings will be stored on secure University servers and destroyed after 15 years.
We will use anonymised quotations in the study reports and presentations. It will not be possible to identify individuals from these quotations.

**What are the possible disadvantages and risks of taking part?**
If you decide to take part, some of the side effects you talk about may be upsetting. If you participated in a focus group everybody will be asked to agree not to share anything anybody has said outside of the discussion, but there is a chance that somebody may not respect the confidentiality agreement.

**What are the possible benefits of taking part?**
We will use the answers you tell us to help us design a questionnaire that professionals can use with patients and carers to identify important side effects of anti-epileptic drugs in adults with learning disability. We hope that the research will help us to accurately measure the side effects of anti-epileptic drugs and to make sure each individual gets the best treatment for them.

**What will happen if I want to leave the study?**
You can leave at any time, without giving a reason. If you withdraw at any time, or decide not to take part, it will not affect the care you or the person you care for receives now or in the future.

**What if there is a problem?**
If you have a concern about any part of the study, you can speak to the researchers at Cardiff University who will do their best to answer your questions (contact details on the last page). If you remain unhappy and wish to complain formally, you can do this through Cardiff University by contacting:

Mr Chris Shaw,
Research Governance Officer,
Cardiff University Research & Innovation Services, 30-36 Newport Road, Cardiff, CF24 0DE
Tel: 029 2087 9140 or 029 2087 9277

**How will you protect my information?**
All information which is collected will be kept strictly confidential (not shared with anyone outside the research team). Your personal information (name, address etc.) will continue to be kept confidential. Information that we use from the study will not have your name or anything else that would identify you attached to it.

**What will happen to the results of the study?**
A report of the research results will be completed and sent to the funder who are paying for the study. Results will be published in scientific journals and presented at scientific meetings. You or the person you care for will not be identified in any report, publication or presentation. If you would like the results sent to you please contact the Chief Investigator.

**Who is organising and funding the research?**
This study is being organised by the South East Wales Trials Unit, Cardiff University. The research is being paid for by the Epilepsy Research UK.

**What will happen to my data at the end of the study?**
Once the study is complete and it is no longer necessary to keep identifiable information or contact details, we will destroy our records of this personal information. Records will be kept securely for up to 15 years in line with Cardiff University's policies.

**Who has reviewed the study?**
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Wales Research Ethics Committee 2.

**Contact for Further Information**

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**Thank you for considering taking part in this study.**