****

**PARENT – INFORMATION SHEET**

**Delphi Survey**

(Version 2, 24.04.2018)

**Project title: Core Health Outcome in Childhood Epilepsy (CHOICE)**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you with.

**Part 1** – Information about the purpose of the study and what will happen to you if you take part

**Part 2** – In-depth information about the conduct of the study

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

**PART 1**

**What is this study about?**

We are a group of researchers from King’s College London dedicated to researching childhood epilepsies. This piece of research is part of a larger project called CASTLE (Changing Agendas on Sleep Treatment and Learning in Childhood Epilepsy). We are recruiting parents from all over the UK that have children with a particular type of childhood epilepsy known as **‘rolandic epilepsy’**. Rolandic epilepsy is the most common childhood epilepsy whereby seizures start at around 5 years of age and then stop when the child reaches adolescence. Rolandic epilepsy is sometimes known as ‘epilepsy with centro-temporal spikes’. Past research investigating interventions for rolandic epilepsy have focused on stopping or reducing seizures. However, we think it is important to look at other outcomes such as a child’s learning, mental health and social support. We think it is important to include **parent’s,** children’s and professional’s opinions on what should be measured in trials. Our aim is to conduct a survey with children, parents and professionals to establish a core set of outcomes to be used in future childhood epilepsy research.

**Why only rolandic epilepsy?**

Epilepsy is an umbrella term that covers many different types of epilepsy. The focus of this research is on improving outcomes for children with common epilepsies. Rolandic epilepsy is the most common type of childhood epilepsy. This type of epilepsy isidiopathic meaning that it is unclear what causes it and it occurs spontaneously. Other types of epilepsies have different symptoms and seizures and therefore might make reaching consensus on outcomes difficult. Parents of children with very severe syndromes might have different perspectives. This is why we have decided to focus on rolandic epilepsy for this particular study. However, the findings may be generalised to other childhood epilepsies.

**What will I have to do?**

If you are a parent of a child aged 5-16 diagnosed with rolandic epilepsy, you have been invited to take part in an online survey known as a ‘**Delphi Survey’.** A Delphi survey takes part in **two** rounds and is a survey designed to help achieve consensus on a topic between different groups of people. **Each round of the survey will take approximately 15 minutes** to complete. The online link to the survey will have been provided to you in the email where you received this information sheet (please contact us on the email address at the end of the information sheet if you haven’t received it or if you would like to talk to a member of the research team about the study).

1. Round 1 - you will be presented with a list of outcomes that have been measured in previous studies of childhood epilepsy. You will be asked to rate how important you think they are on a scale of 1 (not important) to 9 (critical). There will be an option to add any outcomes you think are missing or any comments.
2. Round 2 – a couple of weeks after completing round 1, you will receive an email asking you to log-in to the survey for a second time. In round 2, you will be asked to complete the same task as before which involves rating the outcomes from 1-9. However, you will be able to see your previous answers, and the anonymous scores of all other participants.

**It is important that if you volunteer to take part that you complete both rounds of the survey so that we can gather meaningful data.**

**Can my child take part?**

Parents are eligible to take part if their child is aged **5-16 years** with rolandic epilepsy. However, if your child is aged **8-16** years of age and they have been diagnosed with rolandic epilepsy – they can take part in the survey too, as we value their opinion and contribution to this research. You will have been sent a child friendly information sheet along with this document. If you are happy for your child to take part in the survey, please show them the appropriate child friendly sheet. If your child would like to take part, you will be required to register them for the survey with a **separate email** address to the one you use for your survey responses, and ensure they tick ‘child’ to indicate the group they belong to. This can be another family members email address or your child may have their own email address. You can accompany your child when they take part in the survey to help with understanding and instructions. However, it is important that it is the child’s opinion that is reflected. Providing the child friendly information sheet to your child and signing them up to take part will be regarded as implied consent from you for your child to take part.

Implied consent is an *assumption* or indication that a person has knowingly agreed to participate in research by performing a research activity or task. In this case, completing the survey will be regarded as implicit consent.

**Do I have to take part?**

No. Your and your child’s participation is entirely voluntary. You can withdraw at any point of the study without giving a reason and it will not affect you or your child’s medical care or legal rights. Completing the survey will be regarded as your consent to take part. You can still take part in the survey if you do not wish your child to take part or your child chooses not to participate. Parents are encouraged to take part individually of each other too if they have different opinions.

**Will the data be confidential?**

Yes. Only the researchers will have access to the data. Any identifying information for you or your child will be removed before it is used in research publications. All personal information will be kept in a secure unit at King’s College London.

**What are the risks & benefits?**

The survey is very low risk. There are no direct benefits to taking part, but your opinions on the survey could help future research into childhood epilepsy.

**What happens next?**

The link to the online Delphi Survey has been provided to you in the email that contained this information sheet. If you have not received this link, please contact us on the email address below. To take part, please press the link and fill in the registration questions. This will then provide you with a unique log-in I.D. Please then fill out the first round of the survey and submit your responses. You will be sent an email reminder when part 2 is ready to start. You will need the unique I.D to log back in, so please keep it safe. If you lose your log-in details, please contact the email address below.

If your child would like to take part separately to you please provide them with a different email address so that they can also have their own individual log-in for each round of the survey. It’s important that your log-in I.D and your child’s log-in I.D are kept separate so that we receive the correct information for each person. Please feel free to share information about the study to any other parents of children with rolandic epilepsy that you know. If they would like to take part they will need to go to our website and register in the same way as you did to receive the information about the study. Please do not give them your survey link.

**What happens after the survey?**

We will be conducting a face-to-face consensus meeting after the final round of the survey. This consensus meeting will last around half a day and will take place within a month of the final round of the survey. The meeting is to help decide on any outcomes that did not reach consensus in the survey. We would like parents, children and professionals to take part. If you take part in both rounds of the survey you may be eligible to take part in the meeting. We expect to invite 10-20 participants and there will be financial acknowledgement for your participation. More information about the meeting will be sent you after round 2 of the survey.

**Questions?**

If you have any further questions about the survey or consensus meeting, please do not hesitate to contact one of our research team.

**Contact details:**

* **Holly Crudgington**

Study Coordinator (CHOICE)

castle-study@kcl.ac.uk

* **Professor Deb Pal**

(Paediatric Neurologist, Chief Investigator)

deb.pal@kcl.ac.uk

**Our address:**

King’s College London

Maurice Wohl Clinical Neuroscience Institute

Department of Basic & Clinical Neuroscience

Denmark Hill LONDON SE5 8AF

Telephone: 020 7848 5162

**This completes Part 1 of the Information Sheet.**

**If the information in Part 1 has interested you and you are considering participation please continue to read the additional information in Part 2 before making any decision.**

**PART 2**

**What happens if I don’t want to carry on with the study?**

You (and your child) can withdraw from the study at any time, even if you have registered for the first round of the survey. If you withdraw from the study, we would still like to use any information we might have already collected. However, if you want us to destroy the information we have collected from you, we will.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (020 7848 5162). If you would like independent and unbiased advice about this study, then please contact:

PALS (Patient Advice and Liaison Service) at Kings College Hospital

King's College Hospital NHS Foundation Trust

Denmark Hill

London SE5 9RS

Telephone: 020 3299 3601

**Will my taking part in this study be kept confidential?**

Yes. We will collect information about you which could identify you personally (for example, because the information includes your name or email address). The information will be stored on computers owned by King’s College London university. These computers will be securely controlled by the research team, under the direct responsibility of Professor Deb Pal. We will use the information we collect from the survey to questions relevant to this project. The university and the hospital has a duty to ensure research conducted here is of the highest standard and auditors from the hospital may need to review any information we hold about you. The auditors will maintain the highest standard of confidentiality. Procedures for handling, processing, storage and destruction of your data are compliant with the Data Protection Act 1998.

**What will happen to the results of this study?**

The results of this research study will be published in scientific journals and may be discussed at scientific meetings. The outcomes from the survey will be used to inform a later clinical trial called CASTLE (changing agendas on sleep treatment and learning in childhood epilepsy) www.castlestudy.org.uk You will not be personally identified in any way.

**Who is funding the research?**

This study is funded by the National Institute of Health Research (NIHR) Programme Grants for Applied Research RP-PG-0615-20007. Neither the views and opinions expressed in this brochure are those of the NHS, NIHR or the Department of Health. King’s College London are the sponsor for the study.

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the Proportionate Review Sub-Committee of the North Eat – Newcastle & North Tyneside 1 Research Ethics Committee.

**Thank you for considering to take part in this research project, and taking the time to read the information sheets.**