Epilepsy in Infancy

INFORMATION SHEET FOR PARENTS/GUARDIANS

Your child has recently been diagnosed with epilepsy. You and your child are invited to participate in a study that is being carried out by UCL–Institute of Child Health in collaboration with Young Epilepsy and Great Ormond Street Hospital for Children. Before you decide on participating, 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 and ask questions if anything is not clear, or if you would like further information.

PART 1

What is the purpose of this study?
A large number of children who develop epilepsy under the age of twelve months unfortunately do not get a clear diagnosis. There is also lack of information about the best treatments to use in this age group. The aim of this study is to determine the causes of epilepsy within this group of very young children (including new causes) and ultimately to get more information on which treatments work best for the different types of epilepsy in this age group. To achieve this, we wish to review children at diagnosis and follow them over a period of time. We also wish to establish a centralised registry to be used by local paediatricians, who will record and map management of children from point of diagnosis. This will encompass information on clinical, neurodevelopmental, behavioural, and sleep assessments, as well as EEG, MRI and other investigations. This will then be analysed by a central research team. We hope that this will provide more comprehensive information, and lead to improved understanding and outcomes for children with epilepsy in relation to their overall health and neurodevelopment, thus improving their quality of life and life opportunities.

Why have we been invited?
Your child has been invited to the study as he/she is between >four weeks and </= twelve months of age, and has recently been diagnosed with epilepsy.

Do we have to take part?
You and your child do not have to take part in the study if you do not wish to. The decision about whether to take part or not will not affect your child's care and management in any way. If you decide to take part you will be given a copy of this information sheet to keep and be asked to sign a consent form, a copy of which you will also be given to keep. If you decide to take part you are free to withdraw your child's data at any time without having to give a reason.

What will happen to my child if we take part?
If you decide to take part in this study, your child will have a full clinical evaluation at your local hospital by a trained clinical research fellow. Tests such as EEG (brain wave test) and MRI (brain imaging) will have been organised by your local doctor as part of standard care. Detailed neurodevelopmental evaluation will be undertaken by a neuropsychologist from the research team. Also, we will ask you to use an actigraph for a week, which is a wrist-watch device measuring your baby's movements and giving us an idea of her/his sleep patterns. Other preliminary tests (blood, urine, CSF or other) may have been performed as part of standard care. If these are found to be normal, a further blood test will need to be taken. This is to look at the DNA, to allow advanced genetic analysis to be performed as part of the study. It would be of additional benefit to obtain a further sample from parents and unaffected siblings. This would better help provide a specific diagnosis. Your consultant will be informed of any abnormal results from these tests.

As part of the research, anonymised details of your child's clinical presentation and investigations will be entered on a centralised database. Your paediatrician will update details about the epilepsy each time they review your child. We will contact you again in the future about further assessments at age 12m and 24m.

What happens to the DNA (blood test) samples?
With your consent the samples will be stored for twenty five years allowing future ethically approved research in this field, with the potential for advances in the treatment of childhood epilepsy.

What are the possible disadvantages and risks of taking part?
Taking part in this research will not affect the management of your child's epilepsy. You may ask for all information collected for this study to stop at any time. All information regarding your child's medical records will be treated as strictly confidential and will only be used for medical and research purposes. Your child's medical records may be inspected by the regulatory authorities and properly authorised persons, but if any information is released this will be done so in a coded form so that confidentiality is strictly maintained.

What are the possible benefits of taking part?
The results of this research may help your child specifically by determining an underlying diagnosis. This may lead to changes in treatment. In the long term, it may influence treatment choices in individuals with similar epilepsy.

What if there is a problem?
Any complaint about the way your child has been dealt with during the study or any possible harm he or she might suffer will be addressed. The detailed information concerning this is given in Part 2 of this information sheet.

Will our taking part in the study be kept confidential?
All information we gather for the study will be kept strictly confidential; we will follow ethical and legal practice. Only Professor Cross and the research team undertaking this study will have access to any identifiable information. The information you give will only be used for medical research and will be stored and disposed of securely. The details are included in part 2.

PART 2 – INFORMATION YOU NEED TO KNOW IF YOU WANT TO TAKE PART

What will happen if we don't want to carry on with the study?
If you wish to withdraw your child from the study at any time, we will destroy all identifiable samples.

What if there is a problem?
Every care will be taken in the course of this study. However, in the unlikely event that your child is injured by taking part, compensation may be available.

If you suspect that the injury is the result of the sponsor's (Great Ormond Street Hospital) negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Helen Cross, who is the Chief Investigator for the research and is based at the Neurosciences Unit, UCL Institute of Child Health, 30 Guilford Street, London WC1N1EH; telephone number: 0207905 2981;; email address: h.cross@ucl.ac.uk. The Chief Investigator will then pass the claim to the sponsor's insurers, via the sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your child's participation in the research, the normal National Health Service complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. Details can also be obtained from the Department of Health website: http://www.dh.gov.uk or by contacting the NHS Patient Advice and Liaison Service, known as PALS. Luke Murphy is the contact for the PALS Office at Great Ormond Street Hospital for Children and can be reached on 0207 8297862.

Will our taking part in this study be kept confidential?
This information will be held on a database, with a unique identification number allocated. The database will be developed and hosted by Young Epilepsy, and only Professor Cross and the research team undertaking this study will have access to it.

All information regarding your child's medical records will be treated as strictly confidential and will only be used for medical and research purposes. All results will be anonymised and there is no way anybody will be able to identify your child from the study.

Involvement of the General Practitioner
Your GP will be informed of your child's participation in the study. No information will be released without your consent.

What will happen to any samples from my child?
Your child's DNA sample will be analysed by the genetic technician on the research team. All information collected including EEG, MRI and neurodevelopmental evaluation will be held on a computer server at Young Epilepsy and only Professor Cross and the research team undertaking this study will have access to it. At the end of the study the samples will be stored for 25 years maintaining confidentiality to uphold good research practice. The samples will only be used for this medical research and will be stored and disposed of securely.

What will happen to the results of the research study?
The overall results at the end of the study will be made available to all participants. Results will be published in medical journals. No patient will be identified in any report or publication unless consent has been obtained.

Who is organising and funding the research?
The research is being organised through UCL-Institute of Child Health in collaboration with Young Epilepsy and Great Ormond Street Hospital for Children NHS Trust. It is being funded by the Charles Wolfson Foundation.

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 you and your child's interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee.

Further information and contact details

1. For general information about research please review the UKCRN website: www.UKCRN.org.uk
2. If you require specific information about this research project, or are unhappy with the study, please contact Professor Helen Cross, Neurosciences Unit, UCL Institute of Child Health, 30 Guilford Street, London WC1N1EH; telephone number: 0207905 2981;; email address: h.cross@ucl.ac.uk.
3. For advice about whether to participate please consult with your consultant.