**SOLVe TRIAL**

**Sampling of the Lateral Ventricle**

**Understanding the impact of Intraventricular Haemorrhage on Brain Development in the Premature Neonate**

**Parent / Guardian Information Sheet**

**Version 1.0**

**21st May 2018**

We would like to invite your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you and your child. One of our team will go through this information sheet with you and answer any questions you may have.

**PART 1**

**Why is this study needed?**

Babies born prematurely are prone to bleeding within the brain; this can unfortunately have a devastating impact on their brain development and is a significant cause of neurodisability in childhood. The aim of this research project is to develop new therapies aimed at improving outcome following brain bleeds in premature babies.

**Why has my child been chosen?**

Your child has been asked to take part in this trial, as they are due to undergo surgery for medically intractable Epilepsy.

**Do we have to take part?**

If you do not wish your child to take part in the study you do not need to give a reason. Your decision whether to participate, or not, will not in any way impact on the standard of care that your child will receive.

You may stop participating in the research at any time that you wish. If you decide to withdraw your child from the study all samples will be destroyed and no more information will be collected about him/her. All information collected up to the time of withdrawal will be included in the study analysis unless you request that it is removed.

**What will happen to my child if we join the study?**

The standard surgical technique, used for disconnection surgery for medically intractable epilepsy, involves exposing the wall of the lateral ventricle and cutting a trench through it to disconnect the epileptic focus from the rest of the brain. This is done to prevent propagation of the epileptic discharge throughout the brain and is the gold standard surgical method. Under normal circumstances the tissue that is removed to cut the trench is discarded, if you agree for your child to participate in the SOLVe trial then instead of discarding the tissue it will be saved and used for research purposes.

A single sample of Cerebrospinal fluid (CSF) around 10ml and a single sample of Blood, around 2ml, will also be taken at the time of surgery and used for the research study. CSF is routinely drained during the operation, as such repurposing a sample for research rather than discarding it will not pose any extra risk to your child, similarly blood samples are routinely taken during the operation to monitor the progress of the anaesthetic as such taking a sample of blood for research will not pose any extra risk to your child.

The tissue, CSF and blood samples will be stored in research laboratories at Great Ormond Street Hospital or in the Institute of Child Health. They will be stored for around 15 years after which time any remaining samples will be destroyed.

Basic clinical information will also be recorded for each patient in the study; this data will be stored on computers at GOSH on secure servers and will only be available to members of the research team.

**What if I change my mind**

If at any time you choose to withdraw from the study just let a member of the medical team know and your child will be removed from the study and all samples will be destroyed. Any information obtained up to that point will be used but no further data will be collected.**PART 2**

**Consent**

If you are happy for your child to take part, and are happy with the explanations given to you by the research team, you will be asked to sign a consent form on behalf of your child before their surgery. You will get a copy of the signed consent form and information sheet to keep.

**What are the risks to my child if they join the study?**

Taking part in this research study does not expose your child to any increased risk. In essence we are seeking your permission to take tissue which would normally be discarded during the normal course of the operation and repurpose this tissue for use in research.

If you suffer an injury and you suspect that itis the result of the Sponsor’s (Great Ormond Street Hospital) negligence then you may be able to claim compensation, please discuss this further with the research team. Cover for negligent harm will be provided by the Great Ormond Street Hospital for Children NHS Foundation Trust through the Clinical Negligent Scheme for Trusts (CNST).

**What are the benefits to my child if they join the study?**

There are no potential benefits to your child if they join this research study.

**What if there is a problem?**

If you have any concerns about any aspect of this study you should speak with the neurosurgical team who can do their best to answer your questions. If you remain unhappy and wish to complain formally, the normal National Health Service complaints mechanisms are also available to you. Details can be obtained from the hospital or the Patient Advisory Liaison Service (PALS), contactable on 020 7829 7862.

If your child suffers an injury and you suspect that itis the result of the Sponsor’s (Great Ormond Street Hospital) negligence then you may be able to claim compensation, please discuss this further with the research team. Cover for negligent harm will be provided by the Great Ormond Street Hospital for Children NHS Foundation Trust through the Clinical Negligent Scheme for Trusts (CNST).

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

Yes. Only people working on the study or working to ensure the study is run correctly will have access to the data. All information collected about your child during the study will be confidential and will be handled, stored, and destroyed in accordance with the Data Protection Act 1998.

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

We aim to publish the results of this study in medical literature. Your child’s confidentiality will be maintained at all times and you will not be identified in any publication.

**Who is doing this study?**

This study is funded by Great Ormond Street Hospital with support from the Royal College of Surgeons. It is being run by the Neurosurgical team at Great Ormond Street Hospital for Children.

**What will happen to the data collected in this study?**

Great Ormond Street Hospital is the sponsor for this study based in the United Kingdom. We will be using information from your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your child’s information and using it properly. Great Ormond Street Hospital will keep identifiable information about your child for approximately 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at URL www.Prembrain.com and or by contacting the research team on the details given below.

The SOLVe research team will keep your child’s name, NHS number and contact details confidential and will not pass this information to other organisations. The SOLVe research team will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your child’s care, and to oversee the quality of the study.

Certain individuals from Great Ormond Street Hospital and regulatory organisations may look at your child’s medical and research records to check the accuracy of the research study. The regulatory authorities will only receive information without any identifying information. The people who analyse the information will not be able to identify your child and will not be able to find out your child’s name, NHS number or contact details.

The SOLVe research team will keep identifiable information about your child from this study for approximately 15 years after the research project has ended.

***Please ask us if there is anything that is not clear or if you would like more information***

**Please contact: Mr Martin Tisdall**

 **Department of Neurosurgery – Great Ormond Street Hospital**

 **0204 059200 Martin.Tisdall@GOSH.nhs.uk**

**Or contact:** **Mr Zubair Tahir**

 **Department of Neurosurgery – Great Ormond Street Hospital**

 **0204 059200** **Zubair.Tahir@GOSH.nhs.uk**