UNIVERSITY OF Southampton

Southampton NHS
University Hospitals NHS Trust

Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Parent/Guardian Information Sheet – Children with history of neonatal HIE

Study Title: **Neurodevelopmental trajectories and neural correlates in children with Neonatal Hypoxic-Ischaemic Encephalopathy (HIE) - NENAH**

You and your child are being invited to take part in a research study. Before you decide to take part in the study it is important to understand why the research is being done and what it will involve for you and your child. Please take time to read the following information and don't hesitate to ask us if there is anything you are unsure of or would like more information about.

What is the purpose of the study?
We want to investigate the long term outcome of children who received "brain cooling" (hypothermia treatment) after being starved of oxygen around the time of birth.

Babies who are born under such difficult conditions are at high risk for brain injury and long term problems. Brain cooling" has been shown to reduce severe disability at toddler age but there is very little information on how the affected children do at school age. We want to examine whether "brain cooled" children differ from children who were not starved of oxygen as a baby and did not need "brain cooling" in measures of general health, thinking and behaviour, all of which are important for school success and relationship with peers.

Why has my child been chosen?

Your child underwent brain cooling as a baby at Princess Anne Hospital in Southampton and is now 6 to 8 years old.

What will happen to my child if they take part?
If you decide to take part, we will invite you and your child to attend 2 sessions at Southampton General Hospital (SGH). During the first session your child's ability will be assessed on a range of measures including their general intellectual ability, academic performance (reading, language and mathematics ability), problem solving, and motor skills. This session will be held at the Wellcome Research Centre Facilities at SGH. However, if you prefer or if travelling to SGH is difficult for you, this can also be arranged either at your child's school or your home.

These assessments will take about four hours in total, but they can be split in two or three sessions if you prefer, and your child can take regular breaks. We may ask you if we can video record some of the

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assessments with your child, so another researcher can make sure the assessments were carried out and scored correctly. We need to do this for about 10% of the children that participate in our study and we will randomly select children from those that agreed to be filmed. Of course, you can let us know if you are not happy for your child's assessment to be recorded and we will then not record the assessment. If you agree for the assessment to be videotaped, we will store the video in a folder protected by a secure password on the University of Southampton password protected server. The video will only be accessed and watched by the research team for scoring purposes. Nobody else has access to the video. The video will be deleted immediately when the study is finished (end of February 2022).

We will also invite you and your child to a second session at SGH. At this session, we would like to look at how your child's brain has developed since birth. The way we will do this is by using a Magnetic Resonance Imaging (MRI) camera to do a MRI brain scan. The MRI will be done in a playful setting and we will invite you and your child for a visit to get familiar with the MRI camera and ask any questions you or your child may have, before we arrange for the visit to do the MRI. The MRI will be completed while your child is awake. Your child will be able to listen to music or watch a movie during the scan.

When you attend a session at Southampton General Hospital, we will reimburse any travel expenses you may encounter, and we will provide a lunch voucher to use in the hospital restaurant.

To compensate for your and your child's time we will offer a £10 voucher at the end of both sessions.

We would like your permission to use some of the findings from the routine 2-year neurodevelopmental assessment as well as findings from brain imaging from the time when your child was on the neonatal unit so that we can relate this information to the findings at 6 - 8 years of age.

We would like your permission for students of the University of Southampton to participate in the study as part of the research team and for them to use some of the research data for their educational projects. They will always work under supervision of one of the senior researchers and will only have access to the research data under supervision of one of the senior researchers.

Do I have to take part?

It is up to you to decide whether or not you want to include your child in this study. Involving your child in this research study is entirely voluntary, and you and your child are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your child receives.

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What do I have to do?
If you decide to take part, you will be asked to sign a consent form (a copy of which you will keep). We will arrange a date for you and your child to come to the hospital and take part in the research study.

We will ask you to fill in some questionnaires about your child's behaviour and whether their health has impacted your or your family's life since they were discharged. You will be able to complete these questionnaires while your child is taking part in the study assessments.
With your permission, we will ask your child's teacher to fill in some of these questionnaires too.

What are the possible benefits of taking part?
There is no direct benefit to your child from taking part in this study. However, the study will provide essential information about any difficulties in thinking and problem solving that children who received 'brain cooling' might experience when they are at school. We hope that this research will eventually improve information and support for parents and also alert teachers to potential difficulties that these children may experience at school.

What will happen after the assessments and brain scan have been completed?
Once all assessments have been completed, we will also ask you if you would like a report about your child's performance. We will not send you a report if you don't want it; however, If any specific problems are detected for your child as part of this study, this will be first discussed with you, and then a referrals to any relevant specialists will be made by the research team within 2 weeks from the completion of the assessments.

What if something goes wrong?
Although we think it is very unlikely that anything will go wrong, if your child is harmed by taking part in this research study, there are no special compensation arrangements. If your child is harmed through someone's negligence, then you will have grounds for legal action, but you may have to pay for it.
Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or your child treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you (Patient Advice and Liaison Service).

PALS
C Level Centre Block **Email:** PALS@suht.swest.nhs.uk

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Will my taking part in this study be kept confidential?
All information collected about you and your child during the course of the research will be kept strictly confidential. Any study information about your child which leaves the hospital will have their name and address removed so they cannot be recognised from it.

With your consent, your GP will be notified of your child's participation in the study and any relevant medical information obtained about your child as part of the study. We will also ask the GP surgery if they could advertise our study by displaying a study information poster in the surgery so we can recruit children who did not have cooling treatment as a baby to act as control.

What will happen to the results of the research study?
The results of the study, once analysed, will be published in appropriate professional journals, shared with medical and nursing professionals locally, nationally and internationally in reports, at conferences and through network groups.

Also, at the end of the study, we will organise an event for families of children who have been treated at Princess Anne Hospital and non-medical professionals who work with the children (e.g. teachers, educational psychologists, community paediatricians), at which we will feed back the study findings. All data will be anonymous -neither you or your child will not be identifiable.

A summary of the research findings can be sent to you, upon your request.

Who is organising and funding the research?
This study is funded by Action Medical Research. It has been approved by the <xxx> Research Ethics Committee and the local research governance committee.
If you would like more information on the study you can check out this link:
https://action.org.uk/research/birth-asphyxia-predicting-long-term-effects

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University Hospital of Southampton (UHS) is the sponsor for this study based in the United Kingdom. We will be using information from from your child and/or your child's medical records 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 information and using it properly. University Hospital of Southampton will keep identifiable information about you for 30 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 https://www.hra.nhs.uk/information-about-patients/.

The research team will collect information from your child's medical records for this research study in accordance with our instructions.

The research team will keep your and your child's name your child's NHS number and contact details confidential.. The 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 care, and to oversee the quality of the study. Certain individuals from UHS and regulatory organisations may look at your medical and research records to check the accuracy of the research study. UHS will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out you and your child's name, NHS number or contact details.

The research team will keep identifiable information about you from this study for 30 years after the study has finished.

When you agree to take part in a research study, the information about your child's health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your child's information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

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This information will not identify you or your child's and will not be combined with other information in a way that could identify you or your child. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care or that of your child. It will not be used to make decisions about future services available to your child, such as insurance.

Contact for further information

- Study email address - HTstudy@soton.ac.uk

- Dr Brigitte Vollmer – Principal Investigator
- Dr Rina Cianfaglione– Psychology Research Fellow

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