

**STUDY TITLE:** Engaging Parents of Children with Sickle Cell Disease and their Providers in Shared-Decision Making for Hydroxyurea (ENGAGE HU)

**STUDY NUMBER:** 2017-6612

**FUNDING ORGANIZATION:** Patient Centered Outcomes Research Institute (PCORI)

**<Insert Site Principal Investigator Name and Title>**

Name of Principal Investigator

**<Insert Site PI Phone Number>**

Telephone Number

## **INTRODUCTION**

We are asking for your permission for you and your child to be in a research study so that we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of him/her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and you/your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to allow you/your child to be in the study. You can ask questions at any time.

## **WHY ARE WE DOING THIS RESEARCH?**

In this research study, we want to learn more about the best ways to help clinicians have a shared decision with parents about starting their child diagnosed with sickle cell disease (SCD) on hydroxyurea.

We are asking your child and other children with sickle cell disease, age birth to 5 years to be a part of this research study, because we want to understand what helps parents feel less uncertain and more involved in decision making for hydroxyurea.

## **WHO IS IN CHARGE OF THE RESEARCH?**

**<Insert Site PI Name>** is the researcher at **<Insert Site Name>** that is in charge of this study.

Dr. Lori Crosby at Cincinnati Children's Hospital Medical Center is the lead researcher and oversees study activities at all of the study sites.

PCORI is funding this study.

## WHO SHOULD NOT BE IN THE STUDY

Your child cannot be in this study if he/she:

- Does not have sickle cell disease
- Is not eligible for hydroxyurea
- Is age 6 or older

## WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you and may give you a handout that explains each visit in more detail. You will be able to ask questions to make sure that you understand what will happen to your child.

If your child qualifies, and you decide you want your child to be in the study, your child will come to **<Insert Site Name>** 2 times over the next 6 months.

These are the things that will happen to you/your child while in the study:

**Baseline Visit:** You (parent/caregiver) will complete surveys about your family, general health knowledge, SCD treatment knowledge, decision making, and your child's health status and developmental level. This may take 15-30 minutes. You will also have a discussion with your provider about hydroxyurea that may be audio-recorded (i.e. voice only). You may also be asked to review educational materials (e.g. brochure, video, and booklet).

**Refill Updates:** You (parent/caregiver) may be asked to text or email pictures/information about medication refills. You may do this 1 time or up to 5 times.

**Final Visit:** You (parent/caregiver) will complete surveys about your child's health status, development level, and any recent events that have affected child's health. This may take 10-20 minutes.

**Medical Record Review:** Research staff will review your child's medical record for information about your child's health status including but not limited to lab values, sick visits, emergency room visits, hospitalizations, etc.

Your child will be in one of 2 study groups based on when you join the study (month and year): group H or group U.

## WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this study may not help your child right now but you may learn more about hydroxyurea. When we finish the study, we hope that we will know more about how parents make decision about starting treatments like hydroxyurea. This may help other children with sickle cell disease later on.

## WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

You (parent/caregiver) may be asked questions that make you uncomfortable or upset. You do not need to answer any questions that you do not wish to and can stop completing surveys at any time. If you become very upset, we will end the visit. We will also offer to have you speak to someone about what you are feeling. We will also tell you about any problems.

There may be other risks that we do not know about yet.

### **WHAT OTHER CHOICES ARE THERE?**

Instead of being in this study, you can choose not to have your child be in it.

### **HOW WILL INFORMATION ABOUT YOUR CHILD BE KEPT PRIVATE?**

Making sure that information about you/your child remains private is important to us. To protect your privacy in this research study we will:

1. Your child will be assigned a study number. This number will be used on all surveys and forms. All surveys/forms will be kept in a locked in a locked cabinet that only ENGAGE HU study staff can open.
2. Audiotapes: We will use audiotapes to check that the clinician used a shared decision making approach with you (parent/caregiver). Nothing else will be done with the tapes and you will not be identified by name in any written reports. The tapes will not be used for any purpose other than for the study. The tapes will be destroyed at the end of the study.
3. Text messages/emails: we will write down information about your medication refills on a form with your child's study number (not name). We will destroy the texts or emails at the end of the study.
4. Researchers will probably publish the results of this study in places such as medical journals. They may also include a summary of the findings in grants to the PCORI and other agencies. No one will be able to tie this information to you or your child.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you/your child. At most, the website will include a summary of the study results. You can search this website at any time.

### **WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?**

The study doctor will tell you if they find out about new information from this or other studies that may affect your child's health, safety or your willingness for your child to stay in this study.

### **WILL IT COST YOU ANYTHING EXTRA FOR YOUR CHILD TO BE IN THE RESEARCH STUDY?**

There are no costs to participate in this study. Your child's insurance should not be billed for anything related to the study.

### **WILL YOU/YOUR CHILD BE PAID TO BE IN THIS RESEARCH STUDY?**

You (your child) will be reimbursed for your time and effort while you are in this research study. You (your child) will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you (your child) a handout that will explain how to use the card. Because you (your child) are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your (your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

You (your child) will be paid \$40 for each study visit as reimbursement for your time and effort. This may be split into 2 \$20 payments if you complete some surveys before your first study visit.

You will be paid \$5 for each text message/email.

### **WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?**

If you believe that you have been injured because of this research you should contact the [<Make specific for each site>](#) as soon as possible to discuss the concerns. Treatment for injuries is available at [<Make specific for each site>](#). If you go to the Emergency Room or to another hospital or doctor, it is important that you tell him or her that you are in a research study. If possible, you should give them a copy of this consent form.

[<Insert site / hospital policy for making decisions about compensation>](#)

### **WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff, or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

### **AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH**

[<Insert site-specific language below. If you don't have site specific language you may use the following>](#)

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

### **What protected health information will be used and shared during this study?**

CCHMC will need to use and share your child's PHI as part of this study. This PHI will come from:

- Your child's [name of site] medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

#### **Who will share, receive and/or use your child's protected health information in this study?**

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

#### **How will you know that your child's PHI is not misused?**

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

#### **Can you change your mind?**

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

#### **Will this permission expire?**

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

#### **Will your child's other medical care be impacted?**

By signing this document, you agree for child to participate in this research study and give permission to CCHMC and <name of site> to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document, your child will not be able to participate in the study. However, your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits would not be affected.



**SIGNATURES**

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

\_\_\_\_\_  
Printed Name of Research Participant

\_\_\_\_\_  
Signature of Research Participant  
Indicating Consent or Assent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent or Legally Authorized  
Representative\*

\_\_\_\_\_  
Date

\_\_\_\_\_  
\* If signed by a legally authorized representative, a description of such representative's authority must be provided

\_\_\_\_\_  
Signature of Individual Obtaining Consent

\_\_\_\_\_  
Date