ADULT CONSENT /PARENTAL PERMISSION FORM PHASE II

TITLE: Enhancing Use of Hydroxyurea in Sickle Cell Disease Using Patient Navigators

VCU IRB NO.: HM14641

SPONSOR: National Institute of Health

This consent form may contain words that you/your child do not understand. Please ask the study staff to explain any words that you/your child do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. If you are approached about this research study in a public place, you will be given a private place to ask your questions about the study and to decide whether or not you want to be in this study.

In this consent form, "you" always refers to the research participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

PURPOSE OF THE STUDY

A navigator is a member of the community who is trained to help patients move through the health care system and get the care they need. They can assist with appointments, educate patients about their illness, and assist patients with taking medicines.

Hydroxyurea (HU) is the only FDA-approved drug to treat patients with sickle cell disease. It can help patients stay healthier. HU is not an experimental drug. It was approved in 1994. But some people who could take HU decide not to. And some patients who only take it sometimes need to take it more.

So, we are especially interested in whether a navigator can help patients understand and decide whether to take HU. We are also interested in whether they can help patients take HU at the right dose.

You/your child are being asked to participate in this study because you have been diagnosed with sickle cell disease and are eligible to take HU. You may or may not be taking it already. We understand that is your decision.

DESCRIPTION OF THE STUDY AND YOU OR YOUR CHILD'S INVOLVEMENT

If you decide to be in this research study, you will be followed in the study for up to 18 months. You may or may not be assigned a patient navigator for 12 months. If you are NOT assigned a patient navigator, you will be assigned to the Passenger group. If you are assigned a patient navigator, you will be assigned to the Patient Navigator group. What

group you are assigned to will depend on chance, just like the flip of a coin. You have a 50/50 chance of being assigned a patient navigator.

No matter what group you are in, you do not have to take HU. It will still be your decision to start or stop HU. Whether or not you decide to take HU, you will still stay in the same group. You will still see your sickle cell provider in the clinic just like you always have. They will also talk to you about HU.

If you agree to be in the study, you will be asked to sign this consent form. If you are a parent/legal guardian of a minor child, signing this form means you are agreeing to your child's participation in this study. Signing this form also means you have had all your questions answered and understand what will happen to you /your child if your child gives us assent.

Approximately 200 individuals will participate in this study.

If you agree to be in the study, you will be asked to complete three official "study visits" at (Baseline, 6 months, and 1 year). Each visit will be approximately 2-3 hours long and will take place in your sickle cell clinic. A baseline assessment will be conducted at your initial visit. Throughout the study, if you are taking HU study staff may ask you to bring in or make available your prescription bottle. We will record prescription information and pill counts from your prescription bottle. Study staff will ask you to count your remaining pills in front of them. They may also ask to read or have you to read the instructions on your bottle. Also, if you sign a release of information as part of this study, we will call your usual pharmacies to get dates and amounts of your HU prescriptions, we will ask you about names and phone numbers of all the pharmacies where you have received prescriptions in the last six months so we can call them. Also at the same time, you will be asked to fill out some questions on the computer and give blood to the laboratory. We will need about 2 teaspoons of blood each time you visit your doctor during your time in the study. You can make your 6-month and one-year "study visits" at the same time you come to see your provider in the clinic. If you give us permission by signing below, we may call you later to participate in other studies like this.

In the future, if you are assigned to the patient navigator arm, the navigator may ask if you are okay with him/her talking with your doctor once your time in the study is over. You will have the chance to choose if you do or do not want the navigator to talk with your doctor. Your choice will not affect the quality of your medical care.

If you relocate during the study, you may be asked to have about 2 teaspoons of your blood drawn at a doctor near you at 6 months and/or 12 months after you enter the study. We will ask the doctor to ship your blood to the doctor you visited for the study. The study will pay your local doctor for shipping your blood. At 6 months and/or 12 months, you may also be asked to complete surveys. The surveys will be mailed or emailed to you, and the study will pay for you to mail the completed surveys back to us. If you are

assigned to a patient navigator, your patient navigator may or may not visit you in your new location.

Significant new findings developed during the course of the study which may relate to your willingness to continue participation will be provided to you.

RISKS AND DISCOMFORTS

Although we do not anticipate any risk for participating in this study, sometimes talking about certain subjects causes people to become upset, nervous, or uncomfortable. You do not have to answer any questions you do not want to, and you may end your participation at any time.

The risks associated with blood draws may include bruising, discomfort, or irritation at the needle site.

BENEFITS TO YOU AND OTHERS

You may or may not get any direct benefit from this study, from the navigators and from HU. This project may help others by showing that navigators can help SCD patients by teaching you how importance in taking your HU, keeping your medical appointments, learning more about your SCD and helping to improve your overall health in dealing with your SCD.

COSTS

The cost of your care will not change because you are in the study.

PAYMENT FOR PARTICIPATION

You will receive $50 after completion of each of the three official "study visits" to assist you with transportation, childcare or other arrangements. Otherwise, you will not be paid to see your provider in the clinic. You will be asked to provide your social security number in order to receive payment for your participation. Your social security number is required by federal law. It will not be included in any information collected about you for this study. Your social security number will be kept confidential and will only be used in order to process payment.

If you relocate during the study and are asked to continue the study from your new location, you will receive $50 at 6 months and/or 12 months after your study site receives (1) your blood draws from your local doctor, (2) your completed surveys, and (3) signed forms with your social security to receive payment.

ALTERNATIVES

The alternative to this study is not to participate in this study.

CONFIDENTIALITY

All study staff are trained to protect you and your privacy, including the navigators. The surveys and study data will be coded with ID numbers, not names, in order to further protect confidentiality. Your confidentiality will be ensured by not including your name on any study materials that can directly link the material back to you. A name-to-ID number list will be maintained in a locked file cabinet or password protected computer in the study office, and only authorized study staff will have access to this material. Paper data will be stored in locked file cabinets, kept in locked rooms, and accessible only to project staff. Electronically scanned data will be kept in password-protected computers, on mainframe virtual hard drives, accessible only to appropriate members of study staff.

We will not tell anyone the answers you give us; however, if you tell us you're in danger of hurting yourself or someone else, or, if someone else is hurting you, we are required by law to let people in authority know. Furthermore, information from the study and information from your medical record and the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research, or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services.

What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

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

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of
Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you,
even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other
proceedings. The researchers will use the Certificate to resist any demands for information that would identify
you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States
Government that is used for auditing or evaluation of federally funded projects or for information that must be
disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family
from voluntarily releasing information about yourself or your involvement in this research. If an insurer,
employer, or other person obtains your written consent to receive research information, then the researchers
may not use the Certificate to withhold that information

ADULT CONSENT

STUDY PERMISSION

I agree to participate in this study.

YES ☐ NO ☐

PHARMACY INFORMATION

I give consent to release my pharmacy information. You may call my usual pharmacies to get dates and amounts of my Hydroxyurea prescriptions.

YES ☐ NO ☐

DATA REGISTRIES

1. I give consent for my data/tissue samples to be stored and used for research related to *sickle cell disease*.

YES ☐ NO ☐

2. I give consent for my data/tissue samples to be stored and used for future research about other health problems.

YES ☐ NO ☐

3. I want to be contacted prior to any future use of my data/tissue samples for research.

YES ☐ NO ☐

4. I give consent for you to call or contact me later about other studies.

YES ☐ NO ☐

PARENTAL PERMISSION

STUDY PERMISSION

I agree to participate in this study?

YES ☐ NO ☐

PHARMACY INFORMATION

I give consent to release my pharmacy information. You may call my usual pharmacies to get dates and amounts of my Hydroxyurea prescriptions.

YES ☐ NO ☐

DATA REGISTRIES

1. I give permission for my child's data/tissue samples to be stored and used for research related to *sickle cell disease*.

YES ☐ NO ☐

2. I give permission for my child's data/tissue samples to be stored and used for future research about other health problems.

YES ☐ NO ☐

3. I want to be contacted prior to any future use of my data/tissue samples for research.

YES ☐ NO ☐

4. I give permission for you to call or contact me later about other studies.

YES ☐ NO ☐

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information

The following people and/or groups may request my Protected Health Information:

- Principal Investigator and Research Staff
- Research Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law
- Study Sponsor
- Institutional Review Boards
- Government/Health Agencies
- Pharmacists

Authority to Release Protected Health Information

The VCU Medical Center (VCUMC) may release the information identified in this authorization from my medical records and provide this information to:

- Health Care Providers at the VCUMC
- Study Sponsor
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Principal Investigator and Research Staff
- Research Collaborators
- Institutional Review Boards
- Government/Health Agencies
- Pharmacists

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released

The following types of information may be used for the conduct of this research:

☒ Complete health record ☐ Diagnosis & treatment codes ☐ Discharge summary
☐ History and physical exam ☐ Consultation reports ☐ Progress notes
☐ Laboratory test results ☐ X-ray reports ☐ X-ray films / images
☐ Photographs, videotapes ☐ Complete billing record ☐ Itemized bill
☐ Information about drug or alcohol abuse ☐ Information about Hepatitis B or C tests
☐ Information about psychiatric care ☐ Information about sexually transmitted diseases
☒ Other (specify): Information about the dates and frequency of prescription fills from patient pharmacies.

Uses of Your Protected Health Information

Your health information as shown above will be used for the following reasons:

☒ To determine if you meet the requirements to be a participant in this study
☒ To be able to conduct the study
☒ For safety monitoring
☐ For regulatory issues
☐ Other (specify):

Expiration of This Authorization

☒ This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.
☐ This research study involves the use of a Data or Tissue Repository (bank) and will never

expire.
☐ Other (specify):

Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

IF AN INJURY OR ILLNESS HAPPENS

Virginia Commonwealth University, VCU Health System, Eastern Virginia Medical School (EVMS), and Children's Hospital of the King's Daughter (CHKD) do not have a plan to give long-term care or money if you are injured because you are in this study.

If you are injured by, or become ill, from participating in this study, please contact the study staff right away. Medical treatment is available at Virginia Commonwealth University Health System (VCU Health System), Eastern Virginia Medical School (EVMS), and Children's Hospital of the King's Daughter (CHKD). Your study doctor will arrange for short-term emergency care at one of these sites or for referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study.

To help avoid research-related injury or illness it is very important to follow all study directions.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study. There is no penalty or loss of care, service, or benefit for which you are entitled, or are receiving, or will receive in the future from any agency if you decide to withdraw from the study.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Dr. Wally Smith
Virginia Commonwealth University Health System
Department of Internal Medicine
1200 E. Broad St. Rm W10W-403
Box 980306
Richmond, Virginia 23298-0306

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research
Virginia Commonwealth University
800 East Leigh Street, Suite 113
P.O. Box 980568
Richmond, VA 23298
Telephone: 804-827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT (Adults)
I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed Participant signature Date

PERMISSION (Children)
I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing for my child to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Name of Child *[only include this line if needed]*

Name of Parent or Legal Guardian
(Printed)

Parent or Legal Guardian Signature Date

Name of Person Conducting Informed Consent
Discussion / Witness [3]
(Printed)

Signature of Person Conducting Informed Consent Discussion / Witness Date

Principal Investigator Signature (if different from above) Date