Official Study Title: INTEGRATION OF mHEALTH INTO THE CARE OF PATIENTS WITH SICKLE CELL DISEASE TO INCREASE HYDROXYUREA UTILIZATION – mESH study

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Sickle Cell Disease Implementation Consortium (SCDIC)

Integration of mHealth Into the Care of Patients with Sickle Cell Disease to Increase Hydroxyurea Utilization – mESH Study

NOTE: When we say "you" in this consent, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study or research protocol.

Key Information

To start we want to highlight the **risks and study requirements** that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more detail.

A. Why are you being asked to volunteer in this study?
   You are being asked to take part in this research study because you have been diagnosed with sickle cell disease and prescribed hydroxyurea.
B. What is the usual approach to Sickle Cell care?
   Following with a hematologist to monitor disease progression and hydroxyurea use, when applicable.
C. Why is this study being done?
   Hydroxyurea is a medicine used to treat sickle cell disease and reduce its complications. Evidence shows that it helps treat the disease. However, hydroxyurea is not used often. People avoid taking this medicine for many reasons. The most common are forgetfulness, lack of motivation, and not understanding the medicine's potential benefits. We want to study how well the *InCharge* app helps you take your medicine.
D. What will happen if you decide to take part in this study?
   You will download the InCharge app to your phone and use it. We will collect information from your medical records. At enrollment and when the study ends, you will be asked to complete a survey. You may also be asked to participate in a 45- to 60- minute interview. We will collect information related to your hydroxyurea prescription. You will participate in the study for 6 months and have 3 study visits: baseline, 12 weeks, and 24 weeks. After this time, we will collect follow-up data for 12 weeks.
E. What are the research risks and benefits of taking part in this study?
   Data on the phone app and your medical record information is at risk of loss of privacy. You might benefit from this study by taking your hydroxyurea more regularly, which may improve your health.
F. How many people will take part in this study?
   At least 45 participants will participate from each of the 8 sites.
G. What are your options?
   a. Taking part in this research study is completely your choice.
   b. If you decide to take part in this study, you can change your mind and stop at any time.
   c. If you decide not to take part in this study, you may still be able to receive care at St. Jude.
   d. You may choose no treatment or to seek treatment somewhere else.

If you are still interested in taking part in the mESH research study, more detail will be provided in the following pages.

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1. Why are you being asked to volunteer for this research study?

You are being asked to take part in this research study because you have been diagnosed with sickle cell disease and prescribed hydroxyurea. The SCDIC is a group of clinical centers. The centers work together to treat sickle cell disease and remove obstacles to receiving care. A data coordinating center, part of the SCDIC, will receive your data and help analyze it. The center is based at RTI International (formerly Research Triangle Institute). Please take your time in deciding and feel free to discuss it with your family, friends and St. Jude staff. Before agreeing, it is important that you read this consent form that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

2. Who is sponsoring this study?

This study is sponsored by the National Institutes of Health, under the U01 HL133996 grant.

3. What is the purpose of this study?

Hydroxyurea is a medicine used to treat sickle cell disease and reduce its complications. Hydroxyurea is taken once a day and is not expensive. Evidence shows that it helps treat the disease. However, hydroxyurea is not used often. People avoid taking this medicine for many reasons. The most common are forgetfulness, lack of motivation, and not understanding the medicine's potential benefits. This study is investigating whether a new phone app will help people with sickle cell disease take hydroxyurea more often. For this study, the *InCharge* app will have educational information about hydroxyurea. It will send reminders and alerts for you to take your medication. You can also use it to track how often you take hydroxyurea. We want to study how well the *InCharge* app helps you take your medicine.

4. What will be done in this study?

Use of InCharge App

You will download the InCharge app to your phone and it will be used as follows:

(a) Daily Reminders

The *InCharge* app will send you daily reminders to take the medicine. You will choose the message and when to receive it.

(b) Messages to Coaches

You can also choose a person to help you remember to take your medicine. This person can be your parent, a friend, or another relative. When you take more than 4 hours to mark that you took your medicine, this person will get a text message.

(c) Education

The app contains information about sickle cell disease and hydroxyurea.

(d) Track and Submit Hydroxyurea Use and Pain Information

You will use the app to track your daily progress in taking your medicine and you can use it

to record your pain daily. The app also has a chart of your pain and your daily use.

(e) Links to Medical Chart and Doctors, Connection to Other Patients

The app has links to your medical chart and a website where you can talk to other patients. It includes links to call your doctors as well.

A research staff member will help you download the app. After the app is downloaded, the staff member will go over the features of the app. The staff member will cover these steps:

- Adding contact details for a person to help remind you to take your medicine (if you want to have a person help remind you to take your hydroxyurea)
- Adding your current hydroxyurea prescription details (such as your current dose and how many pills you take a day)
- Navigating through the pages and features on the app
    - Including calendar, hydroxyurea tracking, submission, and hydroxyurea education
- Setting up reminders and alerts

To make sure you understand how to use the app, the staff member will ask you to use the features. The staff member will give you materials on how to use the app. We will also give you a number to call with any questions.

Collection of Medical Chart Information

We will collect information from your medical records. This will help us understand whether the app helps you remember to take your hydroxyurea. Members of the study team will review your medical record. They will record your age, gender, race/ethnicity, medication use, laboratory test results, and other medical evaluations. They will review your records four times:

- When you enroll. This will include information from today and from the previous 6 months.
- At week 12.
- When the study ends (approximately 6 months from now).
- Three months after the study ends.

Questionnaires

At enrollment and when the study ends, you will be asked to complete a survey. The survey will ask about your quality of life and the pain you are in. It will also cover your ability to manage your sickle cell disease. Answering these questions will take about 20 to 30 minutes. You can refuse to answer any or all of the questions. You may also be asked to participate in a 45- to 60- minute interview. The interview will be one-on-one with a member of the research team. We will interview you either during the study or at the end of it. You may be asked to participate both times. You will be asked questions about the InCharge Health app. For example, how has the app helped you remember to take hydroxyurea? How could we improve the app? What did you like or dislike about it?

You may refuse to be interviewed. If so, you can still participate in the study and use the app.

Collection of Hydroxyurea Prescription Information

At enrollment, we will ask for the name, address, and phone number of the pharmacy that fills your hydroxyurea prescriptions. We will also ask you for this information for any other pharmacy that filled these prescriptions in the past 6 months. We will ask you again at week 12 and when the study ends (approximately 6 months from now). We will ask that you authorize your pharmacy(ies) to disclose to us your prescription information, including information about how often your hydroxyurea medication is refilled, how much they give you, and the name of the prescribing doctor. You will be presented with separate authorization form(s) to permit these disclosures.

5. What are the risks and benefits of taking part in this study?

a. <u>Risks</u>

Data on the phone app and your medical record information is at risk of loss of privacy. We will take several steps to prevent loss of privacy:

- We will assign a unique code to your data before sending it to the data coordinating center. We send them data that you entered in the app using the code. We also send data from your medical records using the code.
- We will only allow members of the study team to see your medical records.
- We will store electronic data only on protected computers. These computers will use a password and encryption software.
- We will report study results on the whole group. We will never identify one single person in any reports.

Information collected by the app is subject to its privacy policy. You should read the app's privacy policy carefully. If you are signing for your child, you should talk about the privacy policy with your child. Any app carries security risks.

We have developed the app for the current study and have worked to limit security risks. However, St. Jude Children's Research Hospital cannot guarantee that the app is risk-free. This app can access your contacts list. It will only access your contacts list if you allow it. This access will enable notification of accountability contacts. The app will not be able to access any other features of your phone. Similarly, other apps on your device will not have access to data entered into the study app. Information that you enter into the app will be stored in a Firebase cloud server hosted by Google (https://www.google.com/about/datacenters/inside/locations/index.html). The server can only be accessed by designated study members. For further information about security measures, please go to https://cloud.google.com/terms/.

You will be asked to create an account within the app. Your login will be a numerical code. None of your identifying information will be stored in the app. We recommend running a current operating system (OS) on your device. Review the privacy and security settings often. Restrict any unnecessary access. The app may run in the background of your device. Apps may have unexpected effects on your device. For example, the app may drain the battery. If you do not have an unlimited data/text plan, you may incur additional charges as described above.

b. Benefits

This app has many benefits. You might benefit from this study by taking your hydroxyurea more regularly. This may improve your health. The app may help you take hydroxyurea and monitor pain symptoms. You can also use it to communicate with your doctors and with other patients. The app will give you information about sickle cell disease too. However, the app is not meant to replace decisions you make with your doctors and health care providers.

6. What are the risks to pregnancy, to an unborn child and to the ability to have children when taking part in this study?

Female Risks:

There are no risks to pregnancy associated with the use of the app in this study. However, it is not recommended that hydroxyurea use be continued during pregnancy due to risk of birth defects.

Male Risks:

There are no risks to fertility associated with the use of the app in this study. However, it is possible that hydroxyurea use may lower sperm count.

7. Can you stop taking part in this study?

If at any time you feel uncomfortable and no longer want to participate, you may stop taking part in the study. You may refuse to be in this research study or stop at any time. The decision will not affect your care or your relationship with your doctor or St. Jude. If available, you may receive routine medical care at St. Jude Children's Research Hospital.

a. **Can you be taken out of this study without your consent?**

You may be taken out of the study without your consent for these reasons:

- The researcher decides that continuing in the study would be harmful
- You miss so many appointments that the data cannot be used in the study

8. What are your other options?

Your participation in the study is completely voluntary. If you choose not to participate, it will not affect your medical care.

9. How much will it cost you?

There is no cost for the participant to be in this study. However, the app can use data from your phone. Therefore, using data for this app could result in charges from your cell phone

service provider, as message and data rates may apply. You will not be reimbursed for any message or data charges that you incur as a part of this study.

10. Will you be paid for your time or expenses?

You will be paid for your time or expenses. You will be paid $25 for enrolling and for each of the two subsequent visits ($75 total).

11. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

12. How will you find out the results of this study?

The researcher will give you information about the overall results of this study. Whether you will know your personal test results will be discussed in another part of this document. St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters
- In medical or scientific journals
- In the media
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by the U.S. Law. This website 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.

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

13. Future contacts

Once the study has ended, your participation will be complete. Research team members will not contact you about this study after it ends. However, we would like your permission to invite you to join other studies. You would have a chance to learn more about any other studies before you agreed to participate.

Please check one of the boxes below

I agree that the research staff at St. Jude Children's Research Hospital can contact me for future research studies: ❒ Yes ❒ No

14. What about privacy and confidentiality?

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI (protected health information) may be used or given to someone outside the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. It may have changed since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude Internet website: www.stjude.org.

A decision to take part in this research means that you agree to let the research team use and share your PHI with other researchers for purposes of the study explained above. This information will be kept indefinitely. You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. However, research information may not be seen until the end of the study.

Federal agencies such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), the National Institutes of Health (NIH), and St. Jude Children's Research Institutional Review Board (IRB), your insurance company and other health benefits plan (if charges are billed to these plans), as well as other regulatory agencies, committees, or persons involved in overseeing research studies may review your research and medical record.

Study records that identify you will be kept private. This is required by law. The federal Health Insurance Portability and Accountability Act (HIPAA) guards the privacy and security of your records. It also limits access to them. Your protected records include your name, full address, phone number, medical record number, insurance number, and social security number. Other details that could identify you are also protected. Details that could identify you are known as "protected health information." HIPAA requires participating institutions to get permission from you to use or share this information. By signing this consent form, you allow us to use your protected health information for the research study. You also allow us to share your information in some cases. As part of this study, we may share your protected health information with these groups:

- Other research centers working with us on this project
- RTI International
- The sponsoring government agency (National Heart, Lung, and Blood Institute)
- The United States Department of Health and Human Services and the Office of Human Research Protection

RTI is responsible for collecting data from all the centers. The sponsoring government agency needs to confirm the accuracy of the results they receive. The agency also needs to confirm that government funds were used correctly.

Your data will be identified only by a unique code number. We will not include any information that directly identifies you. For example, we will not include your name, social security number, full address, or phone number. We will only share that information with others if we are required to by law. The key to the code will be kept in a password-protected

database on an internal server at St. Jude Children's Research Hospital.

Principal investigators who are not part of this study may request your data. In these instances, we will remove all information that could identify you. We will only send your data after doing so.

At the end of this study, identifying information will be removed from all data. The de-identified data will be stored at the National Heart, Lung, and Blood Institute data repository or another NIH data storage facility. Your data will also be stored at St. Jude Children's Research Hospital.

If you sign this form, you are giving us permission to collect, use, and share your protected health information. If you do not want to give that permission, you should not sign this form. Note that you cannot participate in the study without signing this form. Your decision on whether to participate will not affect the care you receive here.

You are granting us permission only for the length of the research study. We will not use or share your data after the study ends.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

To help us protect your privacy, the study has been granted a Certificate of Confidentiality from the federal government. With this Certificate, the researchers cannot be forced to give out your personal information, document or specimen, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other process. The researchers will use the Certificate to block any demands for information or specimens that would identify you, except in the cases listed below.

The Certificate cannot be used to resist a demand for information, documents or specimens from the United States Government, if that information is used to audit or check federally funded projects or to meet the needs of the U.S. Food and Drug Administration (FDA).

You should know that a Certificate of Confidentiality does not keep you or a member of your family from choosing to give out information, documents or specimens about you or your part in this research. If an insurer, employer, or other person gets your written consent to receive research information, documents or specimens, then the researchers cannot use the Certificate to keep that information private.

The Certificate of Confidentiality will not keep researchers or hospital staff from making reports required of them. These include reports about suspected child abuse, about diseases that spread from person to person, or about possible threat of harm to yourself or others.

15. Permission to Use Your Data/Information: Authorization/HIPAA

If you sign this document, you give permission to the mESH study team at St. Jude Children's Research Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information listed in the previous section may be used by and/or disclosed (released) to all researchers and their staff at St. Jude Children's Research Hospital.

St. Jude Children's Research Hospital is required by law to protect your health information. By signing this document, you authorize St. Jude Children's Research Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

** Where a covered entity conducts the research study, the Authorization must list ALL names or other identification, or ALL classes, of persons who will have access through the covered entity to the protected health information (PHI) for the research study (e.g., research collaborators, sponsors, and others who will have access to data that includes PHI). Examples may include, but are not limited to the following:

- Other research centers working with us on this project
- RTI International
- The sponsoring government agency (NHLBI)
- The United States Department of Health and Human Services and the Office of Human Research Protection

You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This Authorization does not have an expiration date.

16. Further Information and Contact Details for Questions about This Research Study

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor.

If there is anything you do not understand, or have any other questions, please contact the researcher listed below.

IF AT ANY TIME DURING THE STUDY YOU EXPERIENCE ANY DISCOMFORT OR UNUSUAL SYMPTOMS, OR SIDE EFFECTS, PLEASE CONTACT ANY OF THE DOCTORS LISTED BELOW.

Principal Investigator, Researcher:
Dr. Jane Hankins
St. Jude Children's Research Hospital
262 Danny Thomas Place
Memphis, TN 38105
Tel: (901) 595-3300

If you require any medical or surgical treatments outside of St. Jude such as with your local doctor or another hospital during this study, your researcher and their team would need to be informed.

You can get more details about your rights as a research participant by calling the St. Jude Institutional Review Board at 901-595-4357 or the Research Participant Advocate at 901-595-4644 or 901-595-1139. The Research Participant Advocate is an individual who is not part of the research study team and is available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team. If you are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE-IRB).

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

PARENT/GUARDIAN STATEMENT (Required for participants younger than 18 years):

I have read this document or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give permission for my child to be in this research study.

_____ _____ _____AM/PM

Parent/Legal Guardian Signature Date Time (circle one)

RESEARCH PARTICIPANT STATEMENT (14-17 years old and Adult Participants 18 years and older):

I have read this document or it was read to me. I have been encouraged to ask questions and all my questions were answered. I agree to take part in this study.

_____ _____ _____AM/PM

Research Participant Signature Date Time (circle one)

RESEARCHER/DESIGNEE STATEMENT: I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this form has been given to the participant or his/her representative.

_____ _____ _____AM/PM

Research/Designee Signature Date Time (circle one)

_____

Print Name

PLEASE FAX CONSENT FORM TO CLINICAL TRIALS OPERATIONS
SCAN and EMAIL to: protocoleligibilityoffice@stjude.org or FAX to: (901) 595-6265