IRB Approved Consent for Understanding and Addressing the Social Determinants of Health for Families of Children with Sickle Cell Anemia within Pediatric Hematology

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BOSTON MEDICAL CENTER AND THE
BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH AND DENTAL MEDICINE

RESEARCH CONSENT FORM

Basic Information

Title of Project: Understanding and Addressing the Social Determinants of Health for Families of Children with Sickle Cell Anemia within Pediatric Hematology

IRB Number: H-38214

Sponsor: NIH/National Heart, Lung, and Blood Institute (NHLBI)

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Study Phone Number: (617) 414-3817

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to see how pediatric hematology clinics provide a new program called WE CARE, and how this program affects children with sickle cell anemia (SCA). WE CARE may help doctors' offices ask you about things you may need (like food, housing, or childcare), and tell you about places where you can get help with these things if you want it.

If you agree, you will take one survey today, and another survey in about 1 year. We will also ask you to provide small samples of your hair today and in about 1 year. You will also be interviewed over the phone in 3 months, 6 months, and 9 months. You will be in the study for 1 year if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are loss of confidentiality and emotional discomfort when discussing or completing questionnaires about your family life. You will find more information about risks later in this form.

You might benefit from being in the study because it might help you find resources for things you may need (like food, housing, or childcare), and might help improve the health of your child with sickle cell anemia. You will find more information about benefits later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in the study.

You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

Purpose

We want to see how the doctors of children with SCA provide a new program called WE CARE. We also want to see if WE CARE affects the health of children with SCA. WE CARE may help doctors' offices ask about things your family may need, like food or housing. If you do have needs and want help meeting them, your child's doctor may give you information about places where you can get help.

What Will Happen in This Research Study

You are being asked to participate in this research because your child is receiving care for their SCA at this hematology clinic. If you choose to join the study, you will complete a 20-minute questionnaire today, and another 20-minute questionnaire in about 1 year. These questionnaires ask about your background, your family's needs, and how well you and your child are coping with your child's SCA. We will also ask you to provide small samples of your hair today and in about 1 year. These hair samples will help us measure your stress level. You will complete both questionnaires and provide both hair samples here at your child's doctor's office. We will also call you 3 times this year to briefly interview you. These phone interviews take about 5-10 minutes, and will occur in about 3 months, 6 months, and 9 months. The phone calls will help us understand needs your family may have, and whether you have contacted any resources to help you meet these needs. Today, we will also ask you to give us permission to look at your child's electronic medical record. This would help us understand how your child's SCA affects their health.

Some families who join this study will fill out an extra 5-minute survey on things they may need, such as food, housing, and utilities. If they would like help, these families might also receive information from their doctor's office about resources that help families meet these needs. Other families will not answer this survey or receive resource information during the study, but will receive resource information from the research team at the end of the study, if they would like it.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form. You will be one of approximately 100 parents or caregivers who will be asked to be in the study.

Risks and Discomforts

The risks from participating in this study are minimal. The questionnaires, phone interviews, and hair sample testing have been used in other low-risk research studies. You may feel emotional or upset when discussing or completing questionnaires and phone interviews about your family life. If you feel this way, you can skip questions or stop the questionnaire or interview at any time. You can also tell the interviewer if you are feeling sad or upset, and if you want help, our research team's licensed clinical psychologist can help you find someone to talk to about how you are feeling.

Potential Benefits

The benefits of being in this study may be: connecting to resources for things your family may need, like food, housing, childcare, education, employment, or utilities; improving the health of your child with SCA; and helping your doctor's office and other offices provide more help to families. However, you may not receive any benefit. Your being in the study may help the investigators learn how doctors who treat children with SCA provide the WE CARE program, and how WE CARE affects the health of children with SCA.

Alternatives

The alternative to participating in this study is to not participate. Not participating in the study will not affect your child's care at their doctor's office.

Costs and Payment

There are no costs to you for being in this research study. You will receive up to $175 for participating in all of the study procedures over the next year. You will receive $50 for completing the questionnaire and providing a hair sample today, and $50 for completing a questionnaire and providing a hair sample 1 year from now. You will also receive $25 each time you complete a phone interview (in 3 months, 6 months, and 9 months). You will receive these payments on a reloadable gift card called a 'ClinCard', which you can use anywhere that accepts MasterCard.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store biological samples taken from your body (such as the hair samples) in plastic vials labeled by an ID number uniquely linked to you. The vials will be stored in a locked file cabinet. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC**.** The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Your hair samples will be sent to Dr. Jerrold Meyer's laboratory at the University of Massachusetts, Amherst for processing. The people in Dr. Meyer's laboratory are expected to protect your information and biological samples in the same way we protect it.
- Any people who you give us separate permission to share your information.

We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records. Here are some reasons why we might need to disclose your records:

> **Reporting child or elder abuse:** If, during your participation in this study, we have reasonable cause to believe that child or elder abuse is occurring, the research team must report this to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.
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> **Reporting Suicidal Risk:** If, during your participation of this study, we have reason to believe that you are at risk for suicide or otherwise harming yourself, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not able to assure confidentiality.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.
- Using biological samples in future studies, done by us or by other scientists.

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 Web site will include a summary of the results. You can search this Web site at any time.

Use and Disclosure of Your Child's Health Information

The research team has to use and share your child's health information to do this study, including information that may identify you or your child. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your child's health information as described in this form.

Health information that might be used or given out during this research includes:

- Information that is in your child's hospital or office health records. The records we will use or give out are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or given out to others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to give out any information from you about child abuse or neglect, elder abuse, or harm to yourself or others.

The people and groups that may use or give out your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor of the research study, listed on the first page, and people or groups they hire to help them do the research
- Public health and safety authorities who receive our reports about child abuse or neglect, elder abuse, or harm to yourself or others.

We ask anyone who gets your child's health information from us to protect the privacy of your child's information. However, we cannot control how they may use or share your child's health information. We cannot promise that they will keep it completely private.

The time period for using or giving out your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and give out your child's health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits for you or your child.
- You have the right to withdraw your permission to use or share your child's health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org or at Boston University at HIPAA@BU.EDU.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

________Yes______No You may contact me again to ask for additional information related to this study

Yes No You may contact me again to let me know about a different research study

________Yes______No You may contact me again to ask for additional biological samples related to this study

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Arvin Garg at (617) 414-3817.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject:

Printed name of subject

Researcher: ____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

____ ___________
Signature of person conducting consent discussion Date