

Pediatric Donor Assent to Participate in Research

Study Title: **Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease**

Protocol: **BMT CTN 1507**

A. Why am I here?

If you give us your permission, we would like to have an extra sample of your blood. We would collect the extra sample at the same time you donate your bone marrow.

B. Why are you doing this study?

We are collecting blood samples from donors, like you, to learn more about SCD patients do after their transplants. Your name will not be on the samples.

C. What will happen to me if I join the study?

If you say you want to be in the study, we will ask you for:

- **1 extra blood sample:** We'll collect about 4 teaspoons of blood 1 time.

We will use a small needle to collect the blood from a vein in your arm.

D. Will the blood draw hurt?

When we collect your blood from a vein in your arm, it may feel like a pinch. It will hurt for a minute and the place where the needle went might be red and sore. You might get a little bruise from the needle but it goes away in a few days. We will collect the extra sample at the same time as you have other blood tests done.

E. What if I have questions?

You can ask any questions that you have about this study. If you forget to ask a question and think of it later, you can call me at: **[insert office number]**.

You can also ask your question the next time you see me. You can call the study office at any time to ask questions about the study.

F. How will you use my health information and blood samples?

Your blood samples will be used for a study about transplant in patients with sickle cell disease.

G. Where will my blood samples be sent?

Your blood samples will be sent to a laboratory at Children’s Research Institute.

All research samples will be tied to a number. This number will not be linked to your name or other identifying information.

H. Will the study help me?

This study will not help you or your family member, but it may help other SCD patients who have a transplant in the future.

I. Will I be paid to be in the study?

No, you will not be paid to be in the study. It will not cost you anything to be in the study.

J. Do I have to be in this study?

If you don’t want to be in this study, you need to tell us and your parent or guardian.

Your doctor will not be angry or upset if you do not want to join. You can still give bone marrow to your family member who needs it. They will still get the exact same care.

You can say yes now and change your mind at any time.

Please talk this over with your parents before you decide if you want to give an extra blood sample for research. We will also ask your parents to give their permission for you to give an extra sample for research.

TITLE: BMT CTN 1507: Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease

Principal Investigator:

Name: _____ Phone: _____

Address 1: _____ Fax: _____

Address 2: _____ Email: _____

Writing your name on this page means that you agree to give an extra blood sample and know what will happen.

If you want to quit the study, all you have to do is tell the person in charge.

You and your parent or guardian will get a copy of this form after you sign it.

Signature of Child _____ Date _____

Signature of Person Conducting Assent _____ Date _____