

## Assent to Participate in Research (7 to 11 years of age)

[Insert site logo and/or address]

**Study Title:** A Multi-Center, Phase 2 Gene Transfer Study Inducing Fetal Hemoglobin in Sickle Cell Disease

**Protocol:** BMT CTN 2001

**Principal Investigator:** [Insert site PI]

**Source of Support:** This study is co-sponsored by the National Heart, Lung and Blood Institute, a part of the National Institutes of Health, and the California Institute of Regenerative Medicine.

### A. Why am I here?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about our research and the choice that you have to take part in it. We want you to ask us any questions that you have. You can ask questions any time.

### Important things to know...

- You get to help decide if you want to take part.
- You can say 'No' or you can say 'Yes'.
- No one will be upset if you say 'No'.
- If you say 'Yes', you can always say 'No' later.
- You can say 'No' at any time.
- We will still take good care of you no matter what you decide.

### B. Why are we doing this research study?

We are doing this research to find out more about sickle cell disease. Your sickle cell disease often makes you have pain or problems breathing. Sometimes you need to stay in the hospital to get strong pain medicines or even blood transfusions to help you feel better. There is a new treatment

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called gene therapy that can change your sickle cells to healthy cells, which are blood cells that are round and not curved like sickled cells.

### **C. What will happen if I join this research study?**

If you decide to be in the research, you will be asked to do these things:

- You will have visits with the study doctors.
- You will give some blood that your doctors will use to help change your sickle cells into healthy blood cells.
- You will get a strong medicine to help make room for your new healthy blood cells in your bone marrow, which is where your blood cells are made.
- You will get the healthy blood cells back, which is like having a blood transfusion.
- You will stay in the hospital when you get the healthy blood cells. Your doctors will watch you in the hospital until the healthy blood cells begin to grow. This takes about 4 weeks.
- After you go home, you will need to go back to see your doctor for check-ups.

The study will last about 2 years, which is counted from the time you receive the healthy blood cells and final doctor visits.

### **D. Will it hurt?**

Some of the tests might hurt and some of the medicine might make you feel sick. For example, you might get mouth sores, have a sore throat, or have an upset stomach for a short time after you get your cells back. The medicines you get might also make you sick to your stomach or throw up. Your doctor and nurses will give you medicine if you have pain and will also give you medicine if you feel sick. You might also feel tired. Your doctor might give you a blood transfusion to help you feel better. These problems will get better after a while. You will lose your hair, but this will grow back a few months after you are done taking your medicines. Your doctors and nurses will try their best to help you when you don't feel well.

Before your treatment, you will get a small, bendable tube, which is a special kind of IV, put in your chest in the operating room. The doctors will give you some medicine so that you sleep while it is being put in. The small tube makes it easier for you to get your medicines. The small tube also lets your doctors take blood without poking you each time, which will be easier and less painful for you. When you begin to feel better and no longer need medicines, we will take out the tube.

### **E. Could the research study help me?**

We are doing the study to see if we can make you better. But it is possible that your sickle cell pain will come back. If this happens, your doctor will find another way to help you.

### **F. What should I know about this research study?**

You should talk about this study with your parent or guardian before you decide if you want to be in the study. If you don't want to be in the study, you need to tell your parents or guardian. We will also ask your parents or guardian to give their permission for you to join this study.

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If you don't do the study, your doctors and nurses will still take good care of you, and no one will be angry or upset if you don't want to join the study.

You will not be paid to be in this study.

You can ask questions any time. You can talk to your doctor or nurses and ask any questions you have. Take the time you need to make your choice.

**G. Is there anything else to know?**

If you want to be in the research after we talk, please write your name below. We will write our name too. This shows we talked about the research and that you want to take part.

If you change your mind later and decide to quit the study, you or your parent or guardian can tell your doctor.

We will give you a copy of this form after you sign it.

\_\_\_\_\_  
Participant Name (To be written by child/adolescent)

\_\_\_\_\_  
Printed Name of Parent/Legal Guardian

\_\_\_\_\_  
Parent/Legal Guardian Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)

\_\_\_\_\_  
Printed Name of Parent/Legal Guardian #2 (*Optional*)

\_\_\_\_\_  
Parent/Legal Guardian #2 Signature (*Optional*)

\_\_\_\_\_  
Date (MM/DD/YYYY)

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**Physician certification**

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

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Printed Name of Counseling Physician

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Counseling Physician Signature

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Date (MM/DD/YYYY)

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**Interpreter certification (if needed)**

I certify that I have provided an accurate interpretation of this consent form. I believe the participant has understood the information provided.

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Printed Name of Interpreter

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Interpreter Signature

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Date (MM/DD/YYYY)

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