***Information Sheet for Minors to Participate in a Research Study***

You are being asked to be in a research study. A research study is a way to test new ideas and learn new things. This form will tell you about the study. Dr. [Insert site Principal Investigator (PI) name] will talk to you about the study and answer all of your questions.

**What is the name of this research study?**

*A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications*

**Why am I being asked to be in this research study?**

You are being asked to be in this study because you are going to have a cord blood transplant. The Food and Drug Administration (FDA) has made new rules for cord blood that will be used in a transplant. The FDA is a part of the United States government. The job of the FDA is to make sure medicines are safe. The FDA now considers cord blood to be a medicine and this is why they made new rules. The National Marrow Donor Program (NMDP) also has a set of rules that it follows to make sure cord blood is safe to use in a transplant.

Over the past 20 years, more than one million cord blood units have been given to cord blood banks around the world, where the blood is stored until needed. Cord blood transplant has now become a standard treatment for children and adults with certain cancers and other illnesses.

The cord blood that your doctor thinks is the best choice for you may not meet all the new rules put in place by the FDA. Because of this, the only way to get this cord blood for a transplant is to be on a research study. While the cord blood may not meet all the rules set by the FDA, it does meet rules set and followed by NMDP. A few examples of the rules that must be followed for getting and storing cord blood are:

* Asking medical questions of the Mom before she gives the cord blood to make sure she is healthy, which makes it more likely that the cord blood will be healthy
* Testing the cord blood to make sure it does not carry any bad germs
* Storing the cord blood in a certain way.

*Most of the cord blood that is in cord blood banks in the United States and other countries was collected before the FDA set these new rules. Although the cord blood may not meet FDA rules, it does meet similar rules set and followed by the NMDP.*

This study will look at how well your new blood cells grow after a transplant with this cord blood.

**What will happen to me on this research study?**

On this study, you will receive a cord blood transplant and medical information about your transplant will be shared with the Center for International Blood and Marrow Transplant Research (CIBMTR). Your doctors will watch how you are doing before and after your transplant as they would with any other transplant patient.

**Will any good things happen to me if I’m a part of this research study?**

We do not know if good things will happen to you if you are a part of this research study. What we learn from this study might help patients who havecord blood transplants in the future.

**Will it hurt to be a part of the research study?**

Your doctor will talk to you about the things that could happen that might hurt you during your cord blood transplant. We do not know of any extra things that might hurt you if you have a transplant with the cord blood that does not meet all the new rules put in place by the FDA.

If you have any questions or you don’t understand something, please ask the doctor. We want you to understand what is going on. You can keep a copy of this form at home.

*Print Name of Minor Age of Minor*

**Certification of Counseling Healthcare Professional**

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered.

#### Counseling Healthcare Professional Date