***Informed Consent to Participate in an Access Study***

1. **Title of 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***

1. **Principal Investigator**

<< Enter name/title of Principal Investigator*>>*

1. **Contact Information for Emergencies After Hours or on Weekends or Holidays:**

*<< Enter name and phone number for emergency contact person(s)>>*

1. **Sponsors and Source of Funding or Other Material Support**

National Marrow Donor Program (NMDP)/Be The Match

Center for International Blood and Marrow Transplant Research (CIBMTR) – NMDP

Center for International Blood and Marrow Transplant Research (CIBMTR) – Medical College of Wisconsin

<< Enter name of local transplant center*>>*

Throughout this document, references to “You” may stand for either the study subject or the parents or legal guardians of the study subject if the subject is under 18 years of age, or otherwise unable to legally give informed consent to participate in the study.

The signature(s) at the end will clarify whether the study subject is signing this consent form on their own behalf or via a legal guardian or legal personal representative.

1. **Introduction**

We are asking you to be in a research study. This study includes only people who choose to take part.

You are being asked to take part in this study because you and your doctor have agreed that the best option for treating your disease is a cord blood transplant. In October 2011, the Food and Drug Administration (FDA) began considering cord blood as a biological drug. In the United States, drugs must meet standards set by the FDA to make sure they are safe and effective. Cord blood units not meeting FDA requirements or not yet approved by the FDA may be used for transplant if the transplant is done as part of a study.

Since 1989, cord blood banks have been established in six continents and over one million cord blood collections have been performed. Approximately 10,000 cord blood transplants have been performed in children and adults, for malignant and non-malignant conditions.

*Most of the cord blood units that are currently available in cord blood banks in the United States and other countries were collected before the FDA set these new standards. Although these cord blood units may not meet FDA standards, they do meet similar standards set and followed by the NMDP for years.*

This consent form gives information about taking part in the study. Please read this form carefully. You do not have to be in this study. Please take your time to make your decision about taking part in this study. You mays discuss your decision with your friends and family. Ask your study doctor about any questions you have.

**6. Study Information**

You are being asked to take part in this study because you are going to have a cord blood transplant and one or more of the cord blood units that are considered by your doctor to be the best choice for your transplant may not meet all the new FDA standards. This study will allow your doctor to use these cord blood units for your transplant. Cord blood units used for transplant on this study must meet standards set by the NMDP. If a cord blood unit meets NMDP standards this means that the cord blood unit is suitable for use. This does not however guarantee that the cord blood unit(s) will be successful in treating your disease.

These standards include:

* Making sure the hospital where the cord blood units are collected follows safe procedures to prevent the cord blood units from coming into contact with germs.
* Making sure the cord blood units are stored and labeled in a certain way.
* Making sure the cord blood units are tested for certain viruses and bacteria that could cause illness in the patient.

The primary purposes of this study are to:

* Provide access to cord blood units for patients whose best choice for a cord blood unit(s) do not meet all FDA standards, but do meet standards set by the NMDP on this study.
* Assess how well and how quickly blood counts return to normal after transplant in patients on this study.

An unlimited number of patients will participate in this study from medical centers throughout the United States.

**7. Study Procedures**

The cord blood unit(s) will be infused into one of your veins. Receiving the cord blood unit transplant and allowing your medical data to be collected are the procedures involved in this study. Your participation in this study will end one year after your cord blood transplant. Your doctors will send data to the CIBMTR on the outcomes of your transplant. These data will be used to answer the study questions.

# Your doctors will continue to follow your condition post-transplant according to the hospital's standard procedures for transplant patients.

**8. Possible Discomforts and Risks**

There is no known difference in patient outcomes between transplants that use cord blood units that meet the new FDA standards and transplants that use cord blood units that meet NMDP standards.

Other risks associated with the cord blood transplant itself will be discussed with you by your physician and you will be asked to sign a separate transplant consent form documenting that you understand these risks. The infusion risks are the same for patients receiving *any* cord blood unit and may include changes in heart rate or rhythm, changes in blood pressure, high blood pressure, fever, chills, sweats, nausea/vomiting, diarrhea, abdominal cramping, fluid overload, headache, difficulty breathing, allergic reaction, acute renal failure, and in rare cases infusion reaction resulting in death. Any serious toxicity potentially associated with the infusion will be reported to the CIBMTR. You may also experience slow blood count recovery, prolonged risk of infection, and rarely, the potential for acquiring a rare or genetic disease. These are standard risks associated with all cord blood transplants and will be discussed again in detail in the separate transplant consent form.

As with any research study, there might be risks and side effects that are unknown at this time. You will be monitored for the occurrence of side effects and should report any unusual events to the study staff.

There is a small risk that an unauthorized person could find out which data are yours. Your transplant center and the CIBMTR will take every precaution to make sure that this does not happen. Your data will only be labeled with a number code.

1. **Possible Benefits to Being in the Study**

You may not receive any benefit from participating in this study. The knowledge gained from this study may help medical science and future patients who havecord blood transplants.

**10. Alternatives if You Do Not Want to be in the Study**

Participation in this study is voluntary; however, if you choose **not** to be in this access study, you **cannot** get a transplant using the cord blood unit(s) your doctor believes to be the best choice. Your choice will not affect current or future health care you receive at this institution. Before you decide to be in this study, you and the medical staff will discuss other options available to you, including:

* Getting a transplant from an unrelated, volunteer donor, if one is available.
* Using licensed cord blood units, if available.
* Getting treatment that will control your symptoms without treating your underlying disease.
* Participation in another study.
* No treatment at this time.

Talk to your doctor about your choices before you decide if you will take part in this study.

**11. Cost of Participating in the Study**

You or your insurance company will have to pay for the cord blood unit as well as all costs associated with your cord blood transplant and medical care. Your participation in this study should not result in any costs other than those associated with the treatment of your disease. Some tests and procedures that are provided as part of regular care will not be paid for by the study sponsor. You or your insurance carrier will be charged or held responsible for the costs of that care. Some insurance companies or government health care programs may limit what they will pay for certain routine services that are performed in a research study, in which case, you may be responsible. For questions about your costs, financial responsibilities, and/or medical insurance coverage for your transplant and this study, please contact [Insert Transplant Center name] [Insert Financial Counselor name] at [Insert Financial Counselor phone number].

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute’s Web site at <http://www.cancer.gov/clinicaltrials/learningabout>. You can print a copy of the “Clinical Trials and Insurance Coverage” information from this web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

1. **Reimbursement for Participating in the Study**

You will not be paid for your participation in this study. You will not receive compensation or reimbursement for any extra expenses (travel, meals, etc.) you may incur through your participation in this study.

**13. In the Event of Injury While Participating in the Study**

If you are injured or become ill while taking part in this study, medical care will be provided at this center. If you think you may have experienced a research-related injury please contact your doctor, or one of the people listed at the top of this form. No funds have been set aside to pay you if you are injured. You or your insurance company will be charged for ongoing medical care and/or hospitalization.

However, the sponsor or [Insert Transplant Center name] may be responsible if any injury or illness is caused by negligence (mistake) on the part of them, their employees or agents. Your study [Insert Principal Investigator or Center Contact Name] can provide you with information about the general liability policies of [Insert Transplant Center name], to determine if compensation may be available from that source.

You do not give up any legal rights by signing this form.

**14. Protection of Your Privacy and Confidentiality of Your Study Records**

Your participation in this study will be kept as private and confidential as possible within the law.Your medical information including demographic information (such as race and ethnicity, gender and household income) will be kept private and confidential. *(<<Enter Name of Transplant Center>>)* and the organizations listed below will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission, or unless required by federal, state or local laws, or by a regulatory agency.

Individuals authorized by the organizations below may request access to your study and medical records for inspections or audits. In agreeing to participate, you consent to such inspections and to copying of excerpts from these records, if required by their authorized representatives.

Authorized individuals from organizations that may have access to your study and medical records include:

* 1. <<Enter Transplant center nam*e>>*
  2. Institutional Review Boards ( IRBs) responsible for this study
  3. National Marrow Donor Program (NMDP)/Be The Match
  4. Center for International Blood and Marrow Transplant Research (CIBMTR)
  5. NMDP Donor and Patient Safety Monitoring Advisory Group (DPSM), not part of <<*transplant center’s name>>*
  6. U.S. Food and Drug Administration (FDA)
  7. U.S. Department of Health and Human Services (DHHS)

Scientific and medical findings resulting from a study may be presented at meetings and published so that the information can be useful to others. You will not be identified in these presentations or publications.

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.

**15. Voluntary Participation in and Withdrawal from the Study**

It is up to you if you want to participate in this study, however if you choose **not** to be in this access study you **cannot** get a transplant using the cord blood unit(s) your doctor believes to be the best choice. If you choose not to participate in this study, this decision will not affect your right or access to health care or any other services that you are entitled to receive. If you do not sign this form, you will not be in the study.

If you decide to participate, you may withdraw at any time. There will be no penalties if you withdraw from the study. You will not lose any benefits to which you are entitled, and you will continue to receive medical care.

If you choose to withdraw from the study, please tell [Insert Transplant Center PI name] at [Insert Transplant Center PI phone number]. Your study doctor may ask to continue to follow you to monitor your safety outside of the study.

If you withdraw from this research study, the study doctor will keep your study data that has already been collected.

[Insert Transplant Center PI name], the Sponsor (NMDP/Be The Match), the Institutional Review Board, or the FDAmay stop the study at any time. The investigator(s), your doctor, or the NMDP may remove you from the study at any time without your permission.

You will be informed of any new findings that may affect your health, welfare, or willingness to stay on the study.

**16. Questions or Concerns about the Study**

If you have questions or concerns about this study, please contact:

|  |  |  |
| --- | --- | --- |
| <Study Doctor or other title/role> | < insert name > | < insert phone number > |

If you have questions or concerns about your rights as a study subject or about potential risks and injuries, please contact:

|  |  |  |
| --- | --- | --- |
| <Study Doctor or other title/role> | < insert name > | < insert phone number > |

If you have questions about your rights as a study subject, please contact:

|  |  |  |
| --- | --- | --- |
| <Study Doctor or other title/role> | < insert name > | < insert phone number > |

If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact a Patient Services Coordinator with Be the Match® Patient Services at 1-888-999-6743 or [patientinfo@nmdp.org](mailto:patientinfo@nmdp.org).

[Insert Transplant Center office of research subject advocacy contact information].

You will be given a copy of this consent form for your records.

**17. Subject’s Statement of Consent**

My signature below means that:

* I have read this consent form or it has been read to me.
* I have been given time to consider the study-related procedures and risks, as well as the alternatives. All of my questions were answered to my satisfaction.
* I understand my participation is voluntary. There is no penalty if I refuse to participate. I understand that I can withdraw my consent at any time without any legal consequences and without any penalty or loss of benefits to which I am entitled.
* I agree to comply with the requirements of the study, follow my doctor’s instructions and let my doctor know about any medical issues I have during the study.
* My consent does not release the sponsor from its obligations and my legal rights will not be affected.
* I agree that the sponsor and/or representative, regulatory authorities and IRB representatives will be granted direct access to my original medical records or copies.
* I understand that I will be given a signed and dated copy of this document for my records.

*Signature of Subject Date*

*Print Name of Subject*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

*Parent/Legal Guardian (Signature) Date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

*Parent/Legal Guardian (Signature) Date*

**Certification of Counseling Healthcare Professional**

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

#### Counseling Healthcare Professional Date

**Use of an Interpreter:** Complete if the subject is not fluent in English and an interpreter was used to obtain consent:

Print name of interpreter: Date:

Signature of interpreter:

An oral translation of this document was administered to the subject in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (state language) by an individual proficient in English and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (state language). See the attached short form for documentation.