

**Informed Consent to Participate in Research  
Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular  
Therapies and Marrow Toxic Injuries**

**Adult Research Consent Form and Parent/Legal Guardian Permission Form  
Allogeneic Donor**

*The word “you” throughout this form refers to you or your child.*

## **1. Research Overview**

We ask for your permission to collect and store your blood samples for future research. Your blood has genetic information, called DNA. We want to study your blood and DNA to learn what makes blood or marrow transplants (BMT), cord blood transplants and other cell therapies work.

We’re asking you to participate because you are scheduled to be a bone marrow, blood stem cell, or cellular therapy donor.

Researchers may use your samples to learn more about:

- What affects transplant and cell therapy results
- The distribution of tissue type in populations
- How to match donors and patients for BMT

Researchers may also use your samples anonymously to learn about other things such as:

- The presence of traits linked to other diseases, like diabetes

## **2. What to Expect**

If you agree to give blood samples, here’s what will happen:

- Your doctor will collect a small sample of your blood (up to 2 tablespoons) before or shortly after your donation.
- Your blood and DNA will be stored. Your name will **not** be on the containers.
- We will keep the samples at the **Research Sample Repository** for future research. A repository - like a warehouse - is a place that protects, stores and sends out samples for research studies. The research studies must be approved by a group of scientists. Your samples may be stored and used for months, years or decades.

GRID (if applicable): \_\_\_\_\_

Your blood cells may be grown in a lab for approved research studies. Your research samples will be stored at the Repository until they are used up. In the future, we may ask you for another blood sample. At that time, you can choose to give another sample if you want to.

The DNA testing may include “whole genome sequencing”. Every cell in your body contains the genetic code for your DNA. Whole genome sequencing looks at the entire genome, or genetic code. All people have about 99.6% identical genomes. However, everyone is unique, and between any two people, there could be about 24 million places where the “spelling” of the code is different. Linking these differences in spelling (gene variants) with differences in BMT or cellular therapy outcomes may help us to understand how these variants are related to disease and treatment success.

### **3. Your Right to Leave or Not Join the Repository**

If you agree to be in the Repository, you can change your mind at any time. If you change your mind, please email or write to \_\_\_\_\_.  
See page \_\_\_\_\_ for contact information.

If you change your mind, we will destroy any unused samples.

If you choose not to participate in the Repository, there will be no change in your care. Your decision will not affect your relationship with your doctor, treatment center or the CIBMTR.

### **4. Risks and Benefits**

You will not benefit from giving samples to the Repository. This research may help future patients who need a transplant or cellular therapy.

There are no major risks with blood draws. A blood draw can hurt a little and may cause a bruise. In rare cases, people feel lightheaded or faint. Only trained people will draw your blood.

Since your DNA is unique to you, there is a small risk that someone could trace your samples back to you. Researchers accessing your information will do their best to protect your privacy and to keep your information confidential. We will **not** give information that could identify you to researchers, publish it or present it at scientific meetings.

GRID (if applicable): \_\_\_\_\_

## 5. Privacy, Confidentiality and Use of Information

Your privacy is important to us. We will make every effort to protect it.

Your blood and DNA samples will be stored with a bar code. The Repository staff and future researchers do not have a link to this code. However, a link does exist. The link is stored at \_\_\_\_\_.

To expand research, it is helpful for researchers to share information. They do this by putting the information into one or more research databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease.

If you agree to take part in the study, some of your genetic and health information may be stored in a research database, such as the Genotype and Phenotype Database maintained by the National Institutes of Health (NIH). Researchers with an approved study may be able to see and use your information. Your name and other information that can identify you will never be put into the database. The CIBMTR restricts the use of the data to studies of BMT and cellular therapy.

This research is covered by a Certificate of Confidentiality from the Health Resources and Services Administration (HRSA). Researchers can protect your information if there is a court case. However, some of your medical information may be shared if required by law. If this happens, the researchers will do their best to make sure that any information that goes out to others will **not** identify you.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and employers with 15 or more people to discriminate against you based on your genetic information. Health insurance companies and group health plans may **not** request your genetic information or use it to make decisions about your health insurance. This federal law will **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

The results of research done with your blood and DNA may be seen or used by:

- Center for International Blood & Marrow Transplant Research (CIBMTR)
- Health Resources and Services Administration (HRSA)
- Food and Drug Administration (FDA)
- U.S. government agency sponsor

The results of research done with your blood and DNA will **not** be shared with you.

GRID (if applicable): \_\_\_\_\_

## 6. Cost and Reimbursement

You will not be paid for taking part in the Research Repository. It will not cost you anything to take part in the Research Repository. The CIBMTR may sell your blood sample to other organizations such as drug companies. Samples that are sold or shared outside the CIBMTR never include any information that could identify you. The organization may use your blood sample to make products or therapies that benefit patients or are valuable to researchers. You will not receive any money or other benefit from any products or therapies that are developed from your blood sample.

### Physical Injury as a Result of Participation

Tell your donor center coordinator if you think you've been hurt because of joining the Repository:

Name: \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

You'll get medical treatment if you're hurt as a result of this study. Be The Match<sup>®</sup> will pay for this treatment for unrelated donors. For related donors you and/or your health insurance company will be charged for this treatment. If you're injured, you do **not** lose any of your legal rights to seek payment by signing this form.

## 7. For More Information

If you'd like more information about the Repository, contact:

Name: \_\_\_\_\_

Contact details: \_\_\_\_\_

For more information about your rights, please contact:

### **NMDP IRB Administrator**

Call: 1 (800) 526-7809

If you wish to speak to someone **not** directly involved in the study, you may contact:

### **Be The Match<sup>®</sup> Donor Advocacy**

Call: 1 (800) 526-7809 extension 8710

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

GRID (if applicable): \_\_\_\_\_

## 8. Statement of Consent to Participate in the Research Sample Repository

- I have read and understood this Consent Form. The purpose and description of the Repository has been explained to me.
- I have had the chance to ask questions and understand the answers I have been given. I understand that I may ask questions at any time.
- I freely agree to participate in the Repository.
- I understand that:
  - I will not benefit from being in the Repository.
  - My name and personal information will not be identified.
  - I can leave the Repository at any time and doing so will not affect my health care.
  - I will get a copy of this signed consent form.
  - I do not give up any legal rights by signing this form.

\_\_\_\_\_  
Donor/Subject Signature (if 18 years or older)

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

\_\_\_\_\_  
Print Name of Donor/Subject

\_\_\_\_\_  
Parent/Legal Guardian Signature  
(if donor/subject is <18 years old)

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

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

GRID (if applicable): \_\_\_\_\_

## Certification Healthcare Professional

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.

\_\_\_\_\_  
Healthcare Professional Name

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

\_\_\_\_\_  
Healthcare Professional Signature

\_\_\_\_\_  
Date

### Interpreter Certification

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

Interpreter Name: \_\_\_\_\_

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

Interpreter Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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 addendum for documentation.

GRID (if applicable): \_\_\_\_\_