

## Research Database for Hematopoietic Cell Transplantation and Cellular Therapies

### Adult Unrelated Donor Research Consent Form

#### 1. Invitation and Purpose

We invite you to take part in a Research Database. The Research Database is managed by the CIBMTR®. CIBMTR stands for Center for International Blood and Marrow Transplant Research. It is a research collaboration of the National Marrow Donor Program (NMDP)/Be The Match® and the Medical College of Wisconsin. The CIBMTR does research with healthcare data from patients who have had a transplant or other cellular therapy and donors who donate bone marrow or peripheral blood stem cells (PBSCs).

We are trying to learn more about what makes transplants and other cellular therapies work better. If you join, your data may be included in a variety of studies about transplant and cellular therapies. These studies look at things like:

- How well recipients recover from transplant or cellular therapy;
- How to make the recovery better;
- How a donor's or recipient's genetics affect recipient recovery;
- How patients can get better access to transplant or cellular therapy;
- How well donors recover from donating.

#### 2. What to Expect

When you donate, the doctor already sends data to us, including:

- Your blood and tissue type
- Your age, gender and race
- Results of testing your blood (for example, diseases, number of cells)
- Symptoms you have after donating

If you agree to take part in the Research Database, these data that have already been collected will be used in research studies. Your transplant-related or cellular therapy-related data may be shared with:

- Researchers,
- Partner organizations, or
- Other registries outside the CIBMTR.

The data that is shared will not include any information that could identify you. All research studies must be approved by us before using the data. The studies will also be reviewed to make sure the research matches the types of studies in section 1 above.

GRID: \_\_\_\_\_

### 3. Possible Risks and Benefits

There are no physical risks to you if you agree to take part in the study.

There is a small risk that an unauthorized person could find out which data are yours. Your donor center and the CIBMTR have procedures in place to keep your data private. No identifiable information about you will be given to the researchers, nor will it be published or presented at scientific meetings.

You will not benefit by taking part in the Research Database. You will not directly receive any results generated from this research. However, this research may help future patients who need a transplant or cellular therapy.

### 4. Confidentiality and Use of Information

Your privacy is important to us. We will make every effort to protect it. Your donor center and the CIBMTR will not intentionally tell anyone that you are taking part in the Research Database. Your donor center and the CIBMTR have procedures in place so that no one outside the CIBMTR will know which data are yours.

The NMDP/CIBMTR, the Food and Drug Administration (FDA), or other US government agencies may ask your donor center if they can look in your medical record. These data reviews are done from time to time to make sure that the data in the Research Database are correct. When you agree to take part in the Research Database, you agree to these reviews, which may include copying parts of your medical record.

A description of this clinical study is available on <http://www.ClinicalTrials.gov>, Identifier NCT01166009, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. You will not receive any results generated from this research.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers can protect your information if there is a court case. However, some of your healthcare 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.

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept confidential (private). However, we cannot promise total privacy.

To make sure the study is running ethically, some government agencies or other groups may need to access part of your medical records. For this study, those groups include:

GRID: \_\_\_\_\_

- Center for International Blood & Marrow Transplant Research (CIBMTR)
- Institutional review board (IRB) or ethics committee
- Health Resources and Services Administration (HRSA)
- Food and Drug Administration (FDA)
- U.S. government agency sponsor

Researchers may place some of your health information into research databases, where it is stored along with information from other studies. It can be accessed by researchers outside the CIBMTR, who study the combined information to learn more about health and disease. They may be able to see and use your information, but it will **not** identify you.

CIBMTR may sell the use of your data to other organizations such as drug companies. These organizations may use the data to help create new products or treatments for patients. Any data that are sold or shared outside the CIBMTR will **not** include any information that could identify you. Your data will always be combined with the data of other participants in the Research Database before it is shared or sold. Your data are only useful in research when combined with other data. You and other participants will not receive any money or other benefit from any products or therapies developed from research that included your data.

## 5. Reimbursement and Cost

You will not be paid for taking part in the Research Database. It will not cost you anything to take part in the Research Database.

## 6. Your Right to Join or Leave the Research Database

It is up to you if you want to join the Research Database. If you choose to **not** be in the Research Database, it won't affect your donor services or medical care in any way. You may still donate bone marrow or blood stem cells for a patient, but your data will not be included in research studies.

If you decide to join the Research Database, you may change your mind and leave at any time. If you leave, your information will not be included in any future research studies. This will not affect your relationship with your donor center or the CIBMTR.

To leave the Research Database, email or write a letter to:

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

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

GRID: \_\_\_\_\_

## 7. Questions or Concerns

You have the right to ask questions about the study at any time.

If you have questions, concerns, or complaints about the Research Database, please contact:

- \_\_\_\_\_ at  
\_\_\_\_\_

If you want to talk with someone not directly involved in the study, or have any complaints or questions about your rights as a research participant, please contact:

- The NMDP Institutional Review Board Administrator at: 1 (800) 526-7809
- Be The Match Donor Advocacy at: 1 (800) 526-7809, extension 8710

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

GRID: \_\_\_\_\_

**I confirm that I:**

- Have read this consent form
- Have had the chance to ask questions
- Freely agree to join the Research Database. My data may be used in research studies as defined in this consent form.
- I allow \_\_\_\_\_ to give the CIBMTR my demographic information (such as gender, age and ethnicity) and health information from the donation process (such as infectious disease and physical exam results) and product testing results to evaluate the Be The Match Registry and report to funders.

\_\_\_\_\_  
Printed Donor Name

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

\_\_\_\_\_  
Donor Signature

**Healthcare Professional Certification**

I certify that I have provided a verbal explanation of the details of the Research Database. I believe the participant has understood the information provided

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

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

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

GRID: \_\_\_\_\_

**Use of an Interpreter:** Complete if the subject is not fluent in English, an interpreter was used to obtain consent, and IRB approves a non-English short form to be used:

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

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

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

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.

**Use of a Witness:** Complete if the subject is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g. blind, physically unable to write, etc.) or when an interpreter was used but is not physically present (e.g. a language line is used):

**Declaration of witness:**

By signing below, I confirm I was present for the entire consent process. The method used for communication with the subject was

\_\_\_\_\_.

Witness Signature: \_\_\_\_\_

Printed Witness Name: \_\_\_\_\_

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

GRID: \_\_\_\_\_