**Prospective Assessment of Allogeneic Hematopoietic Cell Transplantation**

**in Patients with Medicare Coverage**

# Adult Research Consent Form and Parent/Legal Guardian Permission Form

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

## **Invitation and Purpose**

We invite you to take part in a sub-study of the Research Database. You will be given a separate consent form with information about joining the Research Database. You may choose to join this sub-study without joining the Research Database. The Research Database and this sub-study are 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). The goal of this sub-study is to see how well bone marrow and PBSC transplants work to treat your disease.

We invite you to take part in this sub-study because:

* you have [patient’s disease],
* you plan to get a blood or marrow transplant (BMT) and,
* you have healthcare insurance coverage from Medicare.

Right now, the U.S. Centers for Medicare and Medicaid Services (CMS) will only cover BMT for your disease if the patient is participating in a research study approved by CMS. (This study is approved by CMS.)

The results of this study will help them decide if BMT for your disease will be covered by Medicare in the future.

### **What to Expect**

If you agree to take part in this sub-study, your doctor will send us your healthcare data about your diagnosis and treatment for at least 5 years. Your data will be combined with others who got a BMT for the same disease. Researchers will look at the data to see how well BMT works to treat your disease.

Your data may be shared with other researchers for future research studies related to Medicare coverage for your disease. However, the data will **not** include any information that could identify you.

1. **Possible Risks and Benefits**

There are no physical risks to you if you agree to take part in this sub-study.

There is a small risk that an unauthorized person could find out which data are yours. Your treatment 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.

By joining this sub-study, Medicare will provide coverage for your BMT, subject to deductibles, copayments, or other fees determined by Medicare. Future patients who have Medicare may also benefit from this study by having their transplant covered.

### **Confidentiality and Use of Information**

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

The CIBMTR, CMS, or other US government agencies may review your medical record and the data we have in order to make sure we have correct data. If you agree to take part in this study, 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](http://www.clinicaltrials.gov/) 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 directly 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:

* Center for International Blood & Marrow Transplant Research (CIBMTR)
* Institutional review board (IRB) or ethics committee
* Health Resources and Services Administration (HRSA)
* Centers for Medicare and Medicaid Services (CMS)
* 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.

### **Reimbursement and Cost**

You will not be paid for joining this sub-study. It will also not cost you anything to join this sub-study. If you join this sub-study, Medicare will cover the cost of your transplant. You may be responsible for paying other costs associated with transplant, like copays or deductibles.

### **Your Right to Join or Leave the Study**

It is up to you if you want to join this sub-study. If you choose to **not** be in this sub-study, you will still get health care.

However, if Medicare is your only way to receive insurance coverage for transplant, you will only receive a transplant if you join this sub-study. You may still receive a transplant if you have another way to pay for it. You also could decide not to have a transplant and your doctor can discuss other treatment options with you.

If you decide to join this sub-study, you may change your mind and leave at any time. This will not affect your relationship with your health care teamor the CIBMTR. However, any data already collected will still be used for the sub-study. And, if you leave, Medicare may not continue providing coverage for your transplant.

### **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 study, please contact:

* *(Treatment Center Physician)* at *(telephone number)*

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

For information or support, please contact the Be The Match® Patient Support Center:

* Call or text: 1 (888) 999-6743
* Email: patientinfo@nmdp.org

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

**I confirm that I:**

* Have read this consent form
* Have had the chance to ask questions
* Freely agree to join the study. My data may be used as defined in this consent form.

Printed Participant Name

Participant Signature (or Parent/Guardian Signature) Date (MM/DD/YYYY)

Printed Parent/Guardian Name (if participant is <18 years old)

**Healthcare Professional Certification**

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

Healthcare Professional Name

Healthcare Professional Signature Date (MM/DD/YYYY)

**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

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Witness Signature:

Printed Witness Name:

Date (DD/MM/YYYY):