CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Research Database for Hematopoietic Cell Transplantation and Cellular Therapies

Adult Donor Research Consent Form

I. INVITATION AND PURPOSE

The Center for International Blood and Marrow Transplant Research (CIBMTR), the research program of the National Marrow Donor Program (NMDP)/Be The Match, invites you to take part in a Research Database. The CIBMTR does research with medical data from patients who have had a transplant or other cellular therapy and donors who donate bone marrow or blood stem cells. The goal of this research is to find ways to make bone marrow and blood stem cell transplants and other cellular therapies work better. Although the exact studies for which Research Database data may be used are not known at this time, the following are types of studies in which these data may be included. These are studies to:

- Determine how well recipients recover from their transplant or cellular therapy;
- Determine how recovery after a transplant or cellular therapy can be improved;
- Determine how access to transplant or cellular therapy for different groups of patients can be improved;
- Determine how well donors recover from the collection procedures.

II. PROCEDURES

As part of your donation, data about your blood and tissue type, race, gender and age, and infectious disease tests will be sent to the CIBMTR. Your cells may be tested to find out the number and types of cells, to make sure that the product is sterile, and to learn other things that may be important to the transplant or cellular therapy. Additionally, you will be contacted after the donation and asked questions to see if you are having pain or other symptoms related to the donation. If you agree to take part in the Research Database, these data that have already been collected will be available to researchers through the CIBMTR.

All research studies using data must first be approved by a group of scientists within the CIBMTR. The proposed study will also be reviewed to make sure the research is consistent with the types of studies described above.

III. POSSIBLE RISKS AND BENEFITS TO PARTICIPATING IN THE RESEARCH DATABASE

Since taking part in the Research Database study only involves sending medical data to the CIBMTR, 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 be helped by taking part in the Research Database. However, this research may help future patients who need a transplant or cellular therapy.

IV. *CONFIDENTIALITY*

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 CIBMTR or the Food and Drug Administration (FDA) 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 will be available on 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. (Identifier: NCT01166009)

V. *REIMBURSEMENT AND COSTS*

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.

VI. *VOLUNTARY PARTICIPATION IN AND WITHDRAWAL FROM THE RESEARCH DATABASE*

It is up to you if you want to participate in the Research Database. If you choose not to take part, you will still be able to get all donor services that you have a right to receive, and you will not lose any benefits which you should receive.

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

VII. *ALTERNATIVE TO PARTICIPATION*

You may choose not to take part in the Research Database. If you choose not to take part in the Research Database you may still donate bone marrow or blood stem cells for the intended recipient, but your data will not be included in research studies.

VIII. QUESTIONS OR CONCERNS

If you have questions, concerns, or complaints about the Research Database, please contact _____ *(Donor Center Medical Director)* at _____ or Dr. Douglas Rizzo, Associate Scientific Director at the CIBMTR. He can be reached at 1-414-805-0700.

If you have questions or concerns about your rights as a research subject or about potential risks and injuries, please contact Roberta King, NMDP IRB Administrator at 1-800/526-7809. If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact 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.

You do not waive any legal rights by signing this form.

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IX. AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION FOR RESEARCH PURPOSES

The CIBMTR collects some data on all donors. This helps the CIBMTR make sure it is doing the best job it can and learn how to improve where needed. By signing this consent form, you allow _____ (Donor Center) to give the CIBMTR your demographic information (for instance: gender, age and ethnic background) and health information that was taken as part of the donation process (for instance: results from infectious disease testing and the physical exam and information on healing from the donation). This information will be used by the CIBMTR to evaluate operation of the registry, to report to its funding agencies, and to conduct research.

This authorization does not have an expiration date. You have the right to cancel this authorization at any time by notifying Be The Match or the CIBMTR in writing that you are canceling the authorization. The address for Be The Match is 500 N. 5th Street, Minneapolis, MN 55401. If you cancel this authorization, any identifiable health information will not be used for research studies. If you cancel your authorization, this will not affect your right or access to healthcare or any other services you are entitled to receive at _____ (Donor Center).

X. DONOR'S/SUBJECT'S STATEMENT OF CONSENT

I have read this consent form and I have been given the opportunity to ask questions. I voluntarily agree to take part in the Research Database. My data may be used in research studies as defined in this consent form.

_____ _____
Donor/Subject Signature *Date*

_____
Print Name of Donor/Subject

NATIONAL MARROW DONOR PROGRAM®
INSTITUTIONAL REVIEW BOARD

CONSENT FORM APPROVAL DATE:
JULY 30, 2016

Do not sign this form after the
Expiration date of: **July 29, 2017**

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with the submission of data to the Research Database have been explained to the above individual and that any questions about this information have been answered.

_____ _____
Counseling Healthcare Professional *Date*

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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: _____ 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.