

# THE NATIONAL MARROW DONOR PROGRAM®

## Contribution of a Blood Sample to the National Marrow Donor Program's Research Sample Repository

### Adult Allogeneic Donor Research Consent Form

#### *I. INVITATION AND PURPOSE*

The National Marrow Donor Program and the Center for International Blood and Marrow Transplant Research (CIBMTR) invite you to take part in the Research Sample Repository. A repository is a place where blood samples are frozen and stored. The blood samples are used for research.

The NMDP/CIBMTR is trying to learn more about what makes bone marrow, blood stem cell and cord blood transplants work well. Although the exact studies for which Research Repository samples may be used is not known at this time, the following are types of studies in which these samples may be included. Studies to:

- Improve the understanding of tissue matching for related and unrelated donors and recipients;
- Determine and evaluate the factors that affect transplant outcome;
- Study the distribution of tissue types in different populations; e.g., study tissue typing differences between different racial and ethnic populations to help develop methods that will improve tissue matching between donors and recipients.

In addition, it is possible investigators may request to use your samples for anonymous research studies. If your sample is used for anonymous research, all identifiers will be removed. There will be no way for the sample to be linked to you. Investigators may ask to use samples for any kind of anonymous study. The study may not be one of the types of studies listed above, or related to transplantation in general.

#### *II. PROCEDURES*

If you agree to take part in the Research Sample Repository, a sample of blood (up to two tablespoons) will be collected from a vein in your arm. The blood will be collected either just before your bone marrow or blood stem cell donation, or shortly after your donation. Your blood sample will be used to look at ways to improve how patients are matched with their donors. Cells from your blood may be grown in the lab so there are more of them that can be used in research studies. DNA, the genetic portion of the cells, may be used in some of the studies.

All research studies using blood samples must first be approved by a group of scientists. The studies will also be reviewed by the NMDP Institutional Review Board (IRB) to make sure the research is consistent with the types of studies described above. An IRB is a group of people who protect the rights of research participants.

#### *III. POSSIBLE RISKS AND BENEFITS TO PARTICIPATING IN THE RESEARCH SAMPLE REPOSITORY*

Collecting the sample of blood will likely cause minor discomfort at the site where the blood is taken from your arm. For example, some bleeding and/or a small bruise may

occur. Infection is rare, but could occur. If you are uncomfortable at the sight of blood you may feel light-headed or faint.

There is a small risk that an unauthorized person could find out which blood sample is yours. Your donor center and the NMDP/CIBMTR have procedures in place to keep your data private. Your blood sample will only be labeled with a number code. Your name will never be used in any research studies that are published or presented at scientific meetings.

You will not be helped by taking part in the Research Sample Repository. However, this research may help future patients who need a transplant.

*IV. CONFIDENTIALITY*

Your donor center and the NMDP/CIBMTR will not intentionally tell anyone that you are taking part in the Research Sample Repository. The NMDP/CIBMTR will try hard to make sure no one outside the NMDP/CIBMTR will know which sample is yours.

*V. REIMBURSEMENT AND COSTS*

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

*VI. VOLUNTARY PARTICIPATION IN AND WITHDRAWAL FROM THE RESEARCH SAMPLE REPOSITORY*

It is up to you if you want to participate in the Research Repository. If you choose not to take part, you will still be able to get all donor services 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 Sample Repository you may change your mind at any time in the future. If you quit, your blood sample will be destroyed. This will not affect your relationship with your donor center or the NMDP/CIBMTR.

*VII. ALTERNATIVE TO PARTICIPATION*

You may choose not to take part in the Research Sample Repository. If you choose not to participate in the Research Sample Repository your bone marrow or blood stem cells will still be used in a transplant for the intended recipient, but a blood sample will not be collected or sent to the Research Sample Repository.

*VIII. IN THE EVENT OF INJURY DURING BLOOD DONATION TO THE RESEARCH SAMPLE REPOSITORY*

The risk of injury to you is considered small. However, if an injury does occur, treatment (including first aid, emergency treatment and other necessary care) will be available. The NMDP will pay for this treatment. Please call your donor center coordinator immediately at \_\_\_\_\_ (telephone number) if you are injured.

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

*IX. QUESTIONS OR CONCERNS*

If you have questions or concerns about the Research Sample Repository, please contact

\_\_\_\_\_ (*Medical Director*) at \_\_\_\_\_ or \_\_\_\_\_ (*Coordinator*) at \_\_\_\_\_.

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

*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 Sample Repository. My blood sample may be collected and used in sample repository 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, 2007**

Do not sign this form after the  
Expiration date of: **July 29, 2008**

**Certification of Counseling Healthcare Professional**

I certify that the nature and purpose, the potential benefits, and possible risks associated with the donation of a blood sample to the Research Sample Repository 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: \_\_\_\_\_ 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.