

**The National Marrow Donor Program® (NMDP) and
Center for International Blood and Marrow Transplant Research® (CIBMTR®)**

Research Database for Hematopoietic Cell Transplantation and Cellular Therapies

Minor Allogeneic Recipient Parent/Legal Guardian Permission Form

I. *INVITATION AND PURPOSE*

The National Marrow Donor Program (NMDP) and the Center for International Blood and Marrow Transplant Research (CIBMTR) invite your child to take part in a research database. The NMDP/CIBMTR does research with medical 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 research is to find ways to make bone marrow and PBSC transplants and other cellular therapies work better.

The NMDP/CIBMTR is trying to learn more about what makes bone marrow, PBSC, and cord blood transplants and other cellular therapies work well. Although the exact studies for which Research Database data may be used is 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. *RESEARCH DATABASE PROCEDURES*

Medical data about your child's disease and his/her transplant or cellular therapy will be sent to the NMDP/CIBMTR. Your child's doctor will send data to the NMDP/CIBMTR before and after your child's transplant or cellular therapy, and once a year for the rest of his/her life. If your child agrees to participate, and you allow your child to take part in the Research Database, his/her data will be used in research studies.

Your child's transplant-related or cellular therapy-related data may be shared with investigators or other registries outside the NMDP/CIBMTR, but no identifying information will be given to those investigators. Additionally, all research studies using these data must first be approved by a group of scientists within NMDP/CIBMTR. NMDP will also review the proposed study 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 this study only involves sending medical data to the NMDP/CIBMTR, there are no physical risks to your child if he/she participates in the study.

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

Your child 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 child's treatment center and the NMDP/CIBMTR will not intentionally tell anyone that your child is taking part in the Research Database. The NMDP/CIBMTR has procedures in place so that no one outside the NMDP/CIBMTR will know which data are your child's data.

The NMDP/CIBMTR or the Food and Drug Administration (FDA) may ask your child's treatment center if they can look in your child's medical record. These data reviews are done from time to time to make sure that the data in the Research Database are correct. When your child agrees to take part in the Research Database, he/she is agreeing to these reviews, which may include copying parts of his/her medical record.

A description of this clinical study will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. (Identifier: NCT01166009)

V. REIMBURSEMENT AND COSTS

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

VI. VOLUNTARY PARTICIPATION IN AND WITHDRAWAL FROM THE RESEARCH DATABASE

Participating in this research study is up to you and your child. If your child chooses not to take part, or if you choose not to allow your child to take part in the Research Database, he/she will still be able to get healthcare or any other services that it is his/her right to receive. If your child does not participate, your child will not lose any benefits which he/she should receive.

If your child decides to take part in the Research Database, and you allow your child to participate, you or your child may change your mind at any time in the future. If your child quits the Research Database, your child's information will not be included in any future research studies. This will not affect your child's relationship with the treatment center or the NMDP/CIBMTR.

VII. ALTERNATIVE TO PARTICIPATION

Your child may choose not to take part in the Research Database, and you may choose not to allow your child to participate. If your child does not participate in the Research Database, your child will receive his/her transplant or cellular therapy as scheduled, but your child's data will not be included in research studies.

VIII. PERMISSION TO CONTACT FOR FUTURE CIBMTR RESEARCH STUDIES

Do you agree to give the CIBMTR permission to contact you in the future to tell you about research studies for which your child is eligible? These studies are different from the studies that use your child's medical data. These studies would involve your child directly, for example, asking you or your child to complete a survey. You may decide if you want your child to participate in a specific study when you are contacted. By checking the "AGREE" box below, you are only agreeing that the CIBMTR can contact you to tell you about the study.

Due to the need to follow-up with you after your child's transplant, please tell your transplant center if your contact information changes. If the contact information on file is no longer valid, it might be necessary to use an internet-based search service to find you.

By agreeing to be contacted for future studies, you authorize the CIBMTR to use such a service to search public and non-public information only for the purpose of trying to locate you.

- I **AGREE** to allow CIBMTR to contact me about future studies for which my child is eligible.
- I **DO NOT** want CIBMTR to contact me about future studies.

IX. QUESTIONS OR CONCERNS

If you have questions, concerns, or complaints about the Research Database, please contact (*Treatment Center Physician*) (*telephone number*) 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 child's 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 a Patient Services Coordinator with Be the Match® Patient Services at 1-888/999-6743 or patientinfo@nmdp.org. You will be given a copy of this consent form for your records.

X. PARENT/LEGAL GUARDIAN'S STATEMENT OF PERMISSION

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

Parent/Legal Guardian's Signature

Date

Print Name of Parent/Legal Guardian

NATIONAL MARROW DONOR PROGRAM®
INSTITUTIONAL REVIEW BOARD

**CONSENT FORM APPROVAL DATE:
JULY 30, 2013**

Do not sign this form after the
Expiration date of: **July 29, 2014**

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with submitting 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

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.

**National Marrow Donor Program® (NMDP) and
Center for International Blood and Marrow Transplant Research® (CIBMTR®)
Research Database for Hematopoietic Cell Transplantation and Cellular Therapies
Minor Allogeneic Recipient Assent Form (7 to 11 years of age)**

You are being invited to be in a research project with the NMDP and CIBMTR. The research project is about what makes transplants and cellular therapies work. You can talk to your parents about this project. If you have questions, ask your parents or your doctor.

If you agree to be in this research project, your doctor will tell the NMDP/CIBMTR about how your transplant or cellular therapy goes. Being in this research project is not about getting your transplant or cellular therapy. You will have a transplant or cellular therapy anyway.

Letting the NMDP/CIBMTR know how you are doing will not help you. Some things your doctor can tell the NMDP/CIBMTR about you, may help other kids or adults who are sick and need a transplant or cellular therapy.

You don't have to let the NMDP/CIBMTR know about your transplant or cellular therapy. Your doctors and nurses will not be mad at you if you don't want to be in this research project.

Sign your name on the line below if you want to be in the research project. Remember, you can change your mind at any time. You can keep a copy of this form at home.

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**CONSENT FORM APPROVAL DATE:
JULY 30, 2013**

Do not sign this form after the
Expiration date of: **July 29, 2014**

Minor Assent

Minor's Signature

Date

Print Name of Minor

Age of Minor

**National Marrow Donor Program® (NMDP) and
Center for International Blood and Marrow Transplant Research® (CIBMTR®)**

Research Database for Hematopoietic Cell Transplantation and Cellular Therapies

Minor Allogeneic Recipient Assent Form (12 to 17 years of age)

The National Marrow Donor Program (NMDP) and the Center for International Blood and Marrow Transplant Research (CIBMTR) invite you to be in a medical research database. You are being asked to participate in this database because you are getting a bone marrow, blood stem cell or cord blood transplant, or cellular therapy.

The NMDP/CIBMTR is trying to learn more about what makes bone marrow, blood stem cell, or cord blood transplants and other cellular therapies work well. The NMDP/CIBMTR does research with medical information collected from people who have had a transplant or other cellular therapy. Your doctor, or one of the medical staff at your hospital, will talk to you about what it means to be in a research database. You can talk to your parents about this research database. You should ask your doctor and your parents all of the questions you have.

The NMDP/CIBMTR would like your doctor to collect information from your medical chart about your transplant or cellular therapy and how you do after the transplant or cellular therapy and send it to the NMDP/CIBMTR to be stored in a computer (Research Database). Every few months your doctor will send medical information about how you are feeling to the NMDP/CIBMTR. Your information will be saved in the database with information from other patients to look at ways to make transplants and cellular therapies work better. You will have a transplant or cellular therapy for your disease, whether or not you agree to be part of this database.

Letting the NMDP/CIBMTR use your medical information for research will not help you. You or your parents will not get money for being in the study. Your medical information may help doctors figure out how to make transplants and other cellular therapies work better in the future.

You don't have to let the NMDP/CIBMTR use your medical information. Your doctors or your parents will not make you be in the research database if you don't want to be. If you agree to be in the research database but change your mind about it later, you can stop being in the research database. Your doctors and nurses will not be mad at you if you don't want them to send your medical information to the NMDP.

If you sign your name on this form, it means you agree to be in this research database. You will be given a copy of this form to take home and keep.

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**CONSENT FORM APPROVAL DATE:
JULY 30, 2013**

Do not sign this form after the
Expiration date of: **July 29, 2014**

If you agree to be in this study, sign here:

Minor's Signature

Date

Print Name of Minor

Age of Minor