Survivor: Audit Edition

Be the Auditor: Informed Consent Review

- Date of HCT: 3/13/2015
- Type of HCT: Allogeneic
- Age of recipient: 14
- Primary language of parent/legal guardian: English
- Primary language of recipient: English

Research Database

Parent/legal guardian Permission Form
- Parental/legal guardian consent obtained on 3/2/2015
- IRB-approval periods:

<table>
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Assent Form (12-17)
- Recipient assent obtained on 3/2/2015
- IRB-approval periods:

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Sample Repository

Sample collected on 3/4/2015

Parent/legal guardian Permission Form
- Parental/legal guardian consent obtained on 3/2/2015
- IRB-approval periods:

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The National Marrow Donor Program® (NMDP) and Center for International Blood and Marrow Transplant Research (CIBMTR) Research Database for Hematopoietic Stem Cell Transplantation and Cellular Therapies

Minor Allogeneic Recipient Parent/Legal Guardian Permission Form

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 therapies 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, PBSC transplants and other cellular therapies work better.

The NMDP/CIBMTR is trying to learn more about what makes bone marrow, PBSC, 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.

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 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.

Initials MP
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 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.

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 audits 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 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: NCT01166229)

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.

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.
IRB #: 123456/ CR00001
Version: 7.1
Form Approval Date: 10/29/2014
Form Date of Expiration: 10/28/2015

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.

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.

QUESTIONS OR CONCERNS
If you have questions, concerns, or complaints about the Research Database, please contact Dr. CandyLand at (555) 555-5555.

If you have questions or concerns about your child's rights as a research subject or about potential risks and injuries, please contact the 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 the 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.
IRB #: 123456/ CR00001  
Version: 7.1  
Form Approval Date: 10/29/2014  
Form Date of Expiration: 10/28/2015

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.

Mary Poppins  
Parent/Legal Guardian's Signature  
3-2-2015  
Date

Mary Poppins  
Print Name of Parent/Legal Guardian

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.

John Campbell  
Counseling Healthcare Professional  
3-2-2015  
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.

v.7.1  
Page 4 of 4  
Initials MPP
National Marrow Donor Program® (NMDP) and 
Center for International Blood and Marrow Transplant Research (CIBMTR) 
Research Database for Hematopoietic Stem 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/cord blood transplant or other cellular therapy.

The NMDP/CIBMTR is trying to learn more about what makes bone marrow, blood stem cell/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 cannot 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.

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

Kevin McCallister

Minor's Signature

3-2-2015

Date

Kevin McCallister

Print Name of Minor

14

Age of Minor

v.7.1

Page 2 of 2

Initials KM
Contribution of a Blood Sample to the Research Sample Repository

Minor Allogeneic Recipient Parent/Legal Guardian Research Permission Form

SUBJECT'S NAME: Kevin McCallister
DATE OF BIRTH: 11/1/2001

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 invite your child 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 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 the 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 populations; for example, various racial and ethnic populations, to help develop methods to improve tissue matching between donors and recipients.

Investigators may conduct research studies with stored blood samples that have had all identifiers removed. CIBMTR may allow investigators to use these anonymous samples for many other kinds of studies. Any research project may be proposed for anonymous research, examples include:
- Studies that look at how certain genetic traits may affect transplant outcomes.
- Studies that look at biological factors that may predict relapse after transplant.

II. RESEARCH SAMPLE REPOSITORY PROCEDURES
If you allow your child to take part in the Research Sample Repository, a sample of blood (up to two tablespoons) will be collected from a vein in your child’s body. The blood will be collected just before your child starts his/her conditioning regimen to prepare for the transplant. Your child’s blood sample will be frozen and stored indefinitely for possible use in future research studies. Cells from
your child’s blood may be grown in the lab so there are more cells 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 these blood samples must first be approved by a group of scientists within CIBMTR as well as the Repository Oversight Committee. 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 SAMPLE REPOSITORY
Collecting the sample of blood will likely cause minor discomfort at the site where the blood is taken. For example, some bleeding and/or a small bruise may occur. Infection is rare, but could occur. If your child is uncomfortable at the sight of blood he/she may feel light-headed or faint.

There is a small risk that an unauthorized person could find out which blood sample is your child’s. Your child’s transplant center and the CIBMTR have procedures in place to keep your child’s data private. No identifiable information about your child will be published or presented at scientific meetings.

Your child will not benefit by taking part in the Research Sample Repository. However, this research may help future patients who need a transplant.

IV. CONFIDENTIALITY
Your child's transplant center and the CIBMTR will not intentionally tell anyone that your child is taking part in the Research Sample Repository. The CIBMTR has procedures in place so that no one outside the CIBMTR will know which blood sample is your child’s.

V. REIMBURSEMENT AND COSTS
You and your child will not be paid for taking part in the Research Sample Repository. It will not cost you anything for your child to participate in the repository.

VI. VOLUNTARY PARTICIPATION IN AND WITHDRAWAL FROM THE RESEARCH SAMPLE REPOSITORY
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 Sample Repository, your child will still be able to get all healthcare or any other services he/she has a 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, and if you allow your child to participate in the Research Sample Repository, you or your child may change your mind at any
time. If your child quits, your child’s blood sample will be destroyed. This will not affect your child’s relationship with the transplant center or the CIBMTR.

VII. ALTERNATIVE TO PARTICIPATION
Your child may choose not to take part in the Research Sample Repository and you may choose not to allow your child to take part in the Research Sample Repository. If your child does not participate in the Research Sample Repository 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 your child is considered small. However, if an injury does occur, treatment (including first aid, emergency treatment and other necessary care) will be available. Please call your child’s Transplant Center Coordinator immediately at 555-555-5555 if your child is injured.

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

IX. QUESTIONS OR CONCERNS
If you have questions, concerns, or complaints about the Research Sample Repository, please contact Dr. Candy and at (555)555-5555.

If you have questions or concerns about your child’s rights as a research subject or about potential risks and injuries, please contact the IRB Administrator at 555-555-5555. 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 and Health Professional 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 Sample Repository. My child’s blood sample may be collected and used in sample repository research studies related to transplant or other research as defined in this consent form.

[Signature]
Parent/Legal Guardian Signature

[Date]

[Signature]
Print Name of Parent/Legal Guardian

Initials MP
IRB #: 123456/ CR00001
Version: 8.0
Form Approval Date: 2/10/2015
Form Date of Expiration: 2/9/2016

Certification of Counseling Healthcare Professional

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

John Candyland  3-2-2015
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.
Contribution of a Blood Sample to the Research Sample Repository
Minor Allogeneic Recipient Assent Form (7 to 11 years of age)

SUBJECT’S NAME: Kevin McCallister DATE OF BIRTH: 1/11/2001

You are being invited to be in a research project with the CIBMTR, the research program of the National Marrow Donor Program (NMDP)/Be The Match. The research project is about what makes transplants work. You can talk to your parents about this project. If you have questions, ask your parents or your doctor.

If you want to be in this research project, someone will take a small amount of your blood (up to 2 tablespoons). Your blood sample will be used to do research. Letting the CIBMTR use your blood is not about your transplant. You will have a transplant anyway.

The blood sample will most likely come from your catheter. If the blood comes from your catheter, it will not hurt. There is a chance the blood may have to come from a vein. If this happens it will probably hurt a little. You may bleed or get a bruise.

Letting the CIBMTR use your blood sample for research projects will not help you. Tests on your blood may help other kids or adults that are sick and need a transplant.

You don’t have to let the CIBMTR use your blood. Your doctors and nurses will not be mad at you if you decide not to let the CIBMTR use your blood.

Sign your name on the line below if you agree to give a small amount of blood for research. Remember, you can change your mind at any time. You can keep a copy of this form at home.

Minor Assent

Kevin McCallister 3-2-2015
Minor’s Signature Date

Kevin McCallister 14
Print Name of Minor Age of Minor

v.8.0 Page 1 of 1
Initials KM