Informed Consent to Participate in Research

1. Title of the Research Study
   Natural History and Biology of Long-Term Late Effects Following Hematopoietic Cell Transplant for Childhood Hematologic Malignancies

2. Principal Investigator
   Christine Duncan, MD
   K. Scott Baker, MD
   [insert name of transplant center PI]

3. Contact Information for Emergencies After Hours or on Weekends or Holidays:
   [Enter name and phone number for emergency contact person(s)]

4. Sponsors and Source of Funding or Other Material Support
   St. Baldrick’s Foundation
   National Marrow Donor Program® (NMDP)
   Center for International Blood and Marrow Transplant Research® (CIBMTR)
   Pediatric Blood and Marrow Transplant Consortium (PBMTC)

5. Introduction
   This is a clinical trial, a type of research study. Clinical trials include only people who choose to take part.

   If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word “you” in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate.

   You are being invited to participate in this study because:
   
   - You have leukemia or lymphoma (types of cancers)
   - You intend to undergo a stem cell transplant.

   Please take your time to make your decision about taking part in this study. You may discuss your decision with your friends and family. You can also discuss it with the medical staff at your transplant center.
6. **Purpose of the study**

This clinical trial is being done to collect information about various long-term effects commonly seen in children who survive a stem cell transplant. In particular, information about renal (kidney), cardio-metabolic (heart disease and diabetes) and skeletal (bone) long-term effects will be collected for two years after transplant.

This clinical trial will also collect blood samples (approximately 2 teaspoons) from patients at the following times: before transplant, and at 30 days, 100 days, 1 year and 2 years after transplant to establish a biologic sample repository. The researchers will later analyze these samples for biomarkers (substances in the blood that can be measured through a blood test). Certain biomarkers may be useful to doctors in the future by helping them predict which children are at a higher risk for developing kidney problems, heart disease, diabetes and/or bone problems following a transplant.

As many as 340 patients will participate in this research study from medical centers throughout the United States.

It is your choice whether or not you want to participate in this study.

7. **Study Procedures**

If you choose to participate in this study, you will have certain tests and procedures done. Most of these are considered “Standard of Care” (meaning they are already part of your regular care). You may have had some of them done already. Others are being done for purposes of this study only.

<table>
<thead>
<tr>
<th>Review of:</th>
<th>Before your transplant</th>
<th>30 days after your transplant</th>
<th>100 days after your transplant</th>
<th>180 days after your transplant</th>
<th>1 year and 2 years after your transplant</th>
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</table>
| • Any treatments, such as radiation or chemotherapy, you have received prior to preparing for your transplant  
• Any diseases or conditions you have  
• Any medications or supplements you are taking | X | | | | |
| Review of: | | | | | |
| • Any new injuries or diseases you have had or developed since your last visit  
• Any new treatments or therapies you have had since your last visit  
• Any new medications or supplements you have had since your last visit | | | | | X |
8. Possible Discomforts and Risks

There are not expected to be any risks to your health if you choose to participate on this clinical trial.

Possible side effects of blood draws

*Common*

- Bruising where the needle was put in
- Fainting

*Rare*

- Infection where the needle was put in

There is small risk that an unauthorized person could find out which data are yours. Your transplant center, the CIBMTR and the PBMTC will take every precaution to make sure that this does not happen. Your data will only be labeled with a number code.

9. Possible Benefits to Being in the Study

It is unlikely you will benefit directly from participating in this study. However, the knowledge gained from this study may help future patients who have undergone a stem cell transplant during their childhood.

10. How long will I be in the Study

You will have screening studies and blood collection for two years following stem cell transplant. Blood samples will be stored in the TLEC Study Sample Biorepository and available for research for as long as the repository is in existence or until your sample is completely used.

After two years the study investigators may want to follow you for a longer period to learn more about late effects that develop at later times. After this study is completed, if funding for longer follow up is available, then you may be asked for your permission to continue to gather data about your post-transplant health.
11. Alternatives to Participation

Participation in this study is voluntary. You do not have to be in this study. Your choice will not affect current or future health care you receive at this institution, including your stem cell transplant.

12. Cost of Participating in the Study

You will not be responsible for any additional costs related to study procedures. Your participation in this study should not result in any costs other than those associated with the treatment of your disease. Some tests and procedures that are provided as part of regular care will not be paid for by the study sponsor. You or your insurance carrier will be charged or held responsible for the costs of that care. Some insurance companies or government health care programs may limit what they will pay for certain routine services that are performed in a research study, in which case, you may be responsible. For questions about your costs, financial responsibilities, and/or medical insurance coverage for your transplant and this study, please contact /Center/ Financial Counselor at /Number.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://www.cancer.gov/clinicaltrials/learningabout. You can print a copy of the “Clinical Trials and Insurance Coverage” information from this web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

13. Reimbursement for Participating in the Study

You will not be paid for participating in this study.

14. In the Event of Injury While Participating in the Study

Although it is extremely unlikely, if you are injured or become ill while taking part in this study, medical care will be provided at this center. If you think you may have experienced a research-related injury please contact your doctor, or one of the people listed at the top of this form. No funds have been set aside to pay you if you are injured. You or your insurance company will be charged for ongoing medical care and/or hospitalization. You do not give up any legal rights by signing this form.

15. Protection of Your Privacy and Confidentiality of Your Research Records

Your participation in this research study will be kept private and confidential. Your medical information including demographic information (such as race and ethnicity, gender and household income) will be kept private and confidential. [Enter Name of Transplant Center] and the organizations listed below will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission, or unless required by federal, state or local laws, or by a regulatory agency.

Individuals authorized by the organizations below may request access to your research and medical records for inspections or audits. In agreeing to participate, you consent to such inspections and to copying of excerpts from these records, if required by their authorized representatives.

a. [Enter Transplant center name]
b. Institutional Review Boards (IRBs) responsible for this study
c. National Marrow Donor Program® (NMDP)
d. Center for International Blood and Marrow Transplant Research® (CIBMTR)
e. Data Safety and Monitoring Committee (DSMC) of the Pediatric Blood and Marrow Transplant Consortium (PBSC), not part of [transplant center’s name]

Scientific and medical findings resulting from a study may be presented at meetings and published so that the information can be useful to others. You will not be identified in these presentations or publications.

A description of this clinical trial 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.

16. Voluntary Participation in and Withdrawal from the Study

It is up to you if you want to participate in this study. If you choose not to participate in this study, this decision will not affect your right or access to health care or any other services that you are entitled to receive.

If you decide to participate, you may withdraw at any time. There will be no penalties if you withdraw from the study. You will not lose any benefits to which you are entitled, and you will continue to receive medical care.

If you choose to withdraw from the study, please tell _______________ at [Transplant center to enter information].

[PI name], the Sponsor [sponsor name], or the Institutional Review Board, may stop the study at any time. The investigator(s), your doctor, or the NMDP, CIBMTR or PBMTC may remove you from the study at any time without your permission.

You will be informed of any new findings which may affect your health, welfare, or willingness to stay on the study.

17. Questions or Concerns about the study

If you have questions, concerns or complaints about this study, please contact: _______________ at _______________ [Transplant center to enter information]

If you have questions or concerns about your rights as a research subject or about potential risks and injuries, please contact: _______________ at [Transplant center to enter information]

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 and Health Professional Services at 1-888-999-6743 or patientinfo@nmdp.org.

[Transplant center to enter office of research subject advocacy contact information]

You will be given a copy of this consent form for your records.
Subject’s Statement of Consent

I have been informed about this research study’s purpose, procedures, possible benefits and risks. I have been given a chance to ask questions and have had them answered to my satisfaction. I understand that I can ask more questions at any time.

I voluntarily agree to participate in this study.

By signing this consent form as a subject in a research study, I have not given up any of the legal rights which I otherwise would have.

_____________________________________  ______________________________
Signature of Subject  Date

_____________________________________
Print Name of Subject

Parent/Legal Guardian Signature (if applicable)

_____________________________________
Parent/Legal Guardian Signature  Date

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 participation in this research study have been explained to the above individual and that any questions about this information have been answered.

_____________________________________
Counseling Healthcare Professional  Date

NATIONAL MARROW DONOR PROGRAM®
INSTITUTIONAL REVIEW BOARD

CONSENT FORM APPROVAL DATE: JULY 10, 2016

Do not sign this form after the Expiration date of: July 09, 2017
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:  _____________________________________________________

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.