Informed Consent to Participate in Research

Prospective Multi-Center Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic Hematopoietic Cell Transplant (HCT)

Your Name: _____

Study Title: Prospective Multi-Center Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic Hematopoietic Cell Transplant (HCT)

Protocol: BMT CTN #1202

Principal Investigator:

Principal Co-Investigator:

Transplant Center Investigator: _____
(Insert contact information for PI at your site)

Sponsor: The National Institutes of Health (NIH) is sponsoring this study by providing financial support through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

1. Introduction

We invite you to join this clinical trial, also known as a research study. We are doing this study because we want to learn more about what makes related and unrelated (allogeneic) bone marrow, blood stem cell and umbilical cord blood transplants work well.

This study will include at least 1,500 participants enrolled over a 4 year period. Your study participation will last for 2 years after your transplant.

Being in this study is voluntary. You may choose whether or not to take part in this study. If you choose not to take part or leave this study, it will not affect your regular medical care in any way.

This Consent Form will tell you about the purpose of the study, the possible risks and benefits, other options available to you, and your rights as a participant in the study.

2. Study Purpose

We invite you to join this research study because you are already receiving a transplant. For this study, we are collecting health information and extra blood samples from transplant patients, like you. If you agree to join the study, we will ask for: 1) information about your health after your transplant (such as graft-versus-host disease (GVHD)) and 2) samples of your blood before and after your transplant that we will use in future research studies.

We will use your health information and blood samples in future studies, but we don't know what the studies will be about right now. For example, we may use your health information and blood samples to learn more about graft-versus-host disease (GVHD) or cancers that come back (relapse). Your health information and blood samples may also be used for studies that aren't about transplant.

3. Right to Ask Questions and/or Withdraw

You have the right to ask questions about the study at any time. If you have questions about the study or you want to leave the study, please contact:

[insert contact info for site PI]

If you decide not to continue being in the study, you may choose not to allow future blood samples or data collection. You can also decide to have any blood samples you already provided destroyed; however, samples and information that have already been shared with other researchers cannot be taken back or destroyed.

Your study doctor and study staff will be available to answer any questions that you may have about taking part in or leaving this study.

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

Your study doctor may decide to remove you from being in the study without your permission if your study doctor feels it is in your best interest.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study

4. Your Health Information and Blood Samples

If you agree to provide your health information and blood samples for future research, here is what will happen:

a.) Your health information (this will not include personal information such as your name) will be collected during the 2 years you are participating and given to the BMT CTN. This information will be tied to your blood samples and will be made available to researchers for future studies.

b.) We will collect blood samples before and after transplant.

- Before your transplant: We will collect about 1 tablespoon of blood 1 time.
- After your transplant: We will collect about 2 tablespoons of blood 7 times over 90 days. Each blood draw will be about 1-2 weeks apart.
- The blood will be drawn either from a central line or from a vein in your arm.

c.) The blood samples will be sent to the BMT CTN Repository for processing and storage. A repository is a place that protects, stores and sends out samples for approved research studies. All research samples will coded. A small sample of your blood may be sent to a laboratory partnering with BMT CTN Repository to count and describe the different white blood cell types in the sample. This information will be sent back to the Repository and stored with the other sample-related information.

d.) Materials stored in the Repository will be used mainly by doctors and researchers in the BMT CTN network. In the future, the unused blood samples and health information will be made available outside of this network (see section ‘e’ below).

e.) Researchers can apply to study the health information and blood samples in the Repository. The BMT CTN Steering Committee and/or the BMT CTN Executive Committee must approve each request before they will share samples or information with researchers. This is to make sure that the investigators requesting the samples are qualified, and that the research is of high quality.

f.) DNA from your stored blood samples might be used in genome-wide association (GWA) studies for a future

project either done or supported by the National Institutes of Health (NIH). Genome-wide association studies are a way for scientists to find genes that have a role in human disease or treatment. Each study can look at millions of genetic changes at the same time.

If your coded samples are used in such a study, the researcher is required to add your test results and sample information into a shared, public research database. This public database is called the NIH Genotype and Phenotype Database and it is managed by the National Center for Biotechnology Information (NCBI). It is very unlikely that the NCBI could identify you, or link you to your information or research samples.

Your blood will be used only for research and will not be sold. The research done with your blood may help to develop new products in the future. You will not get paid for any samples or for any products that may be developed from current or future research.

5. Risks and Discomforts

The risk of injury while being in this study is considered small.

If your blood samples are collected from your arm (instead of your central line), you may bleed a little bit and/or develop a small bruise. Infection from blood draws is rare, but may happen. If you are uncomfortable at the sight of blood you may feel light-headed or faint.

A possible risk is the loss of confidentiality about your medical information. We will use safety measures with both your samples and health information to make sure that your personal information will be kept private. It's very unlikely that your personal information will be given to someone else (see the Privacy, Confidentiality and Use of Information section below).

6. Possible Benefits

Taking part in this study will not make your health better. You will not get any direct benefit from taking part in this study. The information from this study will help doctors and researchers learn more about how well unrelated transplant works as treatment for people with a blood disease.

This information could help people with a blood disease who may need a transplant in the future.

7. Privacy, Confidentiality and Use of Information

Your confidentiality is our main concern. We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. All your medical and demographic (such as race and ethnicity, gender and household income) information will be kept private and confidential. [insert 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 regulatory agencies.

Individuals authorized by the organizations below will have access to your research and medical information. They may use this information for inspections or audits to study the outcomes of your treatment. In agreeing to participate, you consent to such inspections and to the copying of parts of your records, if required by these organizations.

We may give out your personal information if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Some of your health information will be taken from another research database you signed up for called the "Research Database for Hematopoietic Cell Transplantation and Marrow Toxicities."

Information about your transplant from your original medical records may be seen by or sent to the following organizations:

- /Institution/
- The National Institutes of Health (NIH)
- The National Heart, Lung, and Blood Institute (NHLBI)
- The National Cancer Institute (NCI)
- Office of Human Research Protection (OHRP)
- The Food and Drug Administration (FDA)
- Institutional Review Boards (IRBs) responsible for this study
- Data and Safety Monitoring Board (DSMB), not part of /Institution/
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN), including the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP) and the EMMES Corporation who are coordinating the studies of the BMT CTN
- Study investigators and future researchers

Information that does not include personally identifiable information about this study has been or will be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registration, results, and other information about registered studies.

This data bank can be accessed by you and the general public at:

www.ClinicalTrials.gov. Federal law requires study information for certain studies to be submitted to the data bank.

8. Physical Injury as a Result of Participation

The risk of injury is considered small. However, it is important to tell your study doctor, _____ *[investigator's name(s)]* or study staff if you feel that you have been injured from taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number]*.

You will get all available medical treatment if you are injured from taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

In case you are injured in this study, you do not lose any of your legal rights to receive payment by signing this Consent Form.

9. Payment

You will not be paid for taking part in this study.

10. Costs and Reimbursements

It will not cost you anything to participate in this study. You or your insurance will not be charged for tests that are only done for this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. 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.

11. Questions about Your Rights

For questions about your rights while taking part in this study, call the _____[name of center] Institutional Review Board (a group of people who review the research to protect your rights) at _____ (telephone number).

12. HIPAA

Health Insurance Portability and Accountability Act 1 (HIPAA1) Authorization to use and disclose research purpose

A. Purpose:

As a research participant, I authorize the Principal Investigators and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research study:

Prospective Multi-Center Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic Hematopoietic Cell Transplant (HCT)

B. Individual Health Information to be Used or Disclosed:

My individual health information that may be used or disclosed to do this research includes:

- Demographic information (for example: date of birth, sex, weight)
- Medical history (for example: diagnosis, complications with prior treatment)
- Findings from physical exams
- Laboratory test results obtained at the time of work up and after transplant (for example: blood tests, biopsy results)

C. Parties Who May Disclose My Individual Health Information:

The researcher and the researcher's staff may collect my individual health information from:

[*List hospitals, clinics or providers from which health care information can be requested*]

D. Parties Who May Receive or Use My Individual Health Information:

The individual health information disclosed by parties listed in item c and information disclosed by me during the course of the research may be received and used by the following parties:

Principal Investigator and the researcher's staff

1 HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

Study Sponsors

- National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH),
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN), data coordinating center
- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)

U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments.

E. Right to Refuse to Sign this Authorization:

I do not have to sign this Authorization. If I decide not to sign the Authorization, I will not be allowed to participate in this study. My decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

F. Right to Revoke:

I can change my mind and withdraw this authorization at any time.

If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

G. Potential for Re-disclosure:

My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected.

Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

H. Genetic Information Nondiscrimination Act (GINA)

A new federal law (2009), called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information.

Health insurance companies and group health plans may not request your genetic information that we get from this research. This means that they must not use your genetic information when making decisions regarding insurability. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

I. This authorization does not have an expiration date.

13. Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, please indicate your choice below.

If you have any questions, please talk to your doctor or nurse, or call our research review board at _____.

Statement of Consent for Research Samples

The purpose of storing blood samples, the procedures involved, and the risks and benefits have been explained to me. I have asked all the questions I have at this time and I have been told whom to contact if I have more questions. I have been told that I will be given a signed copy of this consent form to keep.

I understand that I do not have to allow the use of my blood for research. If I decide to not let you store research samples now or in the future, it will not affect my medical care in any way.

I voluntarily agree that my blood and health information can be stored indefinitely by the BMT CTN Repository for research to learn about, prevent, or treat health problems.

- ❑ I agree to allow my health information and blood samples to be stored for research.
- ❑ I do not agree to allow my health information and blood samples to be stored for research.

_____ _____

Signature Date

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with donation of blood samples to the BMT CTN 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).

Pediatric Assent to Participate in Research

Study Title: Prospective Multi-Center Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic Hematopoietic Cell Transplant (HCT)

Protocol: **BMT CTN 1202**

A. Why am I here?

We invite you to join this research study because you are already receiving a transplant. For this study, we will ask you for information about your health (health information) and extra blood samples.

B. Why are you doing this study?

We are collecting health information and blood samples from transplant patients, like you, to learn more about what makes transplants work well. We will use your health information and blood samples in future research studies.

C. What will happen to me if I join the study?

If you say you want to be in the study, we will ask you for a few things:

- Information about your health after your transplant.
- Some blood samples before and after your transplant.
  - Before your transplant: We will collect about 1 tablespoon of blood 1 time.
  - After your transplant: We will collect about 2 tablespoons of blood 7 times over 90 days. Each blood draw will be about 1-2 weeks apart.

We will use a small needle to collect the blood from a vein in your arm or we will collect it from your central line.

You will be in the study for about 2 years after your transplant. The study will include at least 1,500 people.

D. Will the blood draw hurt?

If we collect your blood from a vein in your arm, it may feel like a pinch. It will hurt for a minute and the place where the needle went may be red and sore. You may get a little bruise from the needle, but it will go away in a few days.

E. What if I have questions?

You can ask any questions that you have about the study. If you forget to ask a question and think of it later, you can call me:

[*insert office number*].

You can also ask your question the next time you see me.

You can call the study office at any time to ask questions about the study.

F. How will you use my health information and blood samples?

We will use your health information and blood samples in future studies, but we don't know what the studies will be about right now. Doctors may use your health information and blood samples to learn more about how people respond to transplant. Your health information and blood samples may also be used for studies that aren't about transplant.

G. Who will use my health information and blood samples?

Your blood samples will be used by doctors and researchers with the BMT CTN. If your blood samples aren't used, other researchers can ask for permission to use them. The BMT CTN will say if your blood samples can be used by other researchers. They do this to make sure your blood samples are being used correctly.

H. How will you store my health information and blood samples?

Your blood samples will be kept at a place called the BMT CTN Repository. A repository is a place that protects, stores and sends out blood samples for research studies.

All research samples will be tied to a number. This number will not be linked to your name or other identifying information.

I. Will the study help me?

This study will not help you, but it may help other people who need a transplant in the future.

J. Will I be paid to be in the study?

No, you will not be paid to be in the study. It will not cost you anything to be in the study either.

K. Do I have to be in this study?

If you do not want to be in the study, you need to tell us and your parent or guardian.

Your doctor will not be angry or upset if you do not want to join. You will still need to have treatment for your disease.

You can say yes now and change your mind at any time.

Please talk this over with your parents before you decide if you want be in the study. We will also ask your parents to give their permission for you to join this study.

Writing your name on this page means that you agree to be in the study and know what will happen to you.

If you decide to quit the study, all you have to do is tell the person in charge.

You and your parent or guardian will get a copy of this form after you sign it.

_____	_____
Signature of Child	Date
_____	_____
Signature of Researcher	Date