Donor Informed Consent to Participate in Research

Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease

Your Name: _____

Study Title: Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease

Protocol: BMT CTN #1507

Co-Investigator: Allistair Abraham, M.D.
Children's National Medical Center
Assistant Professor Pediatrics
111 Michigan Ave NW
Washington, DC 20010
(O) 202-476-5772
aabraham@childrensnational.org

Principal Investigator: *[Insert local PI information]*

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 provide blood samples for research. You're being asked to join because you're a bone marrow donor for a family member who is going to receive a haploidentical (half-matched) transplant in the main study, BMT CTN 1507.

This consent form is about a research study to learn how patients' immune system recovers after they get cells from a donor (transplant). In order to do this study, we will need extra blood samples from you.

It's your choice to give blood samples. Even if you say 'no' to giving samples for this research study, your family member can still receive a transplant from you as part of the main study. If you agree to give blood samples, we will collect them at the time of your bone marrow donation.

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

Everyone who takes part in research at [insert facility name] should know that:

- Being in any research study is voluntary.
- You will not directly benefit from being in the study. Knowledge we gain from this study may benefit others.
- If you give blood samples for research, you can change your mind at any time.
- If you decide to quit the study, it will not affect your care or the care of your family member at [insert name of facility or institution].
- Please ask the study staff questions about anything that you do not understand, or if you would like to have more information.
- You can ask questions now or any time during the study.
- Please take the time you need to talk about the study with your doctor, study staff, and your family and friends. It is your decision to provide blood samples for research. If you decide to join, please sign and date the end of the Consent Form.

The National Institutes of Health (NIH), through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), are giving staff support and money for this research study.

The BMT CTN will lead the research study and, along with the NIH, will make decisions about how to manage the study.

2. Study Purpose

We are collecting extra blood samples because we want to learn more about how the immune system recovers in SCD patients that have received a haploidentical donor bone marrow 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 your rights as a study participant or you want to leave the study, please contact:

[insert contact info]

Giving blood samples for research is voluntary. You can choose not to give samples or change your mind at any time.

If you choose not to take part or change your mind, it will not affect your donation process or the treatment of your family member in the main study in any way.

If you change your mind, any unused blood samples will be destroyed. However, samples and information that have already been used for research cannot be taken back or destroyed.

Your study doctor and study staff will be available to answer any questions that you may have.

4. Study Treatments and Tests

If you agree to give blood samples, here is what will happen:

a.) We will collect an extra blood sample at the time of your bone marrow donation. The amount of blood collected from you will be 20 mL (about 4 teaspoons).

b.) The blood samples will be sent to the Children's Research Institute laboratory for processing. All samples will be given a unique bar code that cannot be linked to you by the researchers testing your samples.

5. Risks and Discomforts

There are no major risks to having your blood drawn. It can be uncomfortable to have your blood taken and it can sometimes leave a bruise. You might faint, but this is unlikely to happen. Only trained people will take your blood.

6. Possible Benefits

You will not directly benefit from taking part in this study. The information from this study will help doctors learn more about how well transplant recipients do with a haploidentical (half-matched) donor.

This information could help other people with SCD who may need a transplant in the future.

7. Privacy, Confidentiality and Use of Information

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

[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.

- The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI)

- U.S. government agencies that are responsible for overseeing research such as The Food and Drug Administration (FDA) and the Office of Human Research Protection (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
- The Data and Safety Monitoring Board (DSMB), not part of [Institution]
- Institutional Review Boards (IRBs) responsible for this study
- Blood and Marrow Transplant Clinical Trials Network Data and Coordinating Center (BMT CTN DCC), including:
    - The Center for International Blood and Marrow Transplant Research (CIBMTR)
    - The National Marrow Donor Program (NMDP)
    - Emmes, who is coordinating the studies of the BMT CTN
- Dr. Allistair Abraham and laboratory staff at Children's National Medical Center
- Study investigators

Individuals authorized by the organizations above 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 these inspections. You also consent to allow authorized individuals to copy 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.

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.

For questions about access to your medical records, please contact [name] at [number].

8. Ending Your Participation

The study doctor or the study sponsor may stop the study at any time, and we may ask you to leave the study. We may ask you to leave the study if you do not follow directions or if you suffer from side effects of the blood draw. The study sponsor may decide to end the study at any time. If we ask you to leave the study, the reasons will be discussed with you.

Possible reasons to end your participation in this study include:

- You do not meet the study requirements.
- You become unable to donate bone marrow to your family member.
- The study is stopped for any reason.

9. Physical Injury as a Result of Participation

It's important that you tell your doctor, [investigator's name(s)], or study staff if you feel that you have been injured because you provided blood samples for research. 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 as a result of providing blood samples for research.

You, your health plan, or your family member's health plan will be charged for this treatment for injury. The study will not pay for medical treatment.

In case of injury resulting from providing blood samples for this study, you do not lose any of your legal rights to seek payment by signing this form.

10. Payment and Study Costs

You will not be paid for your participation in the research study or for providing blood samples for research.

You will not be compensated or reimbursed for any extra costs (for example, travel and meals) from taking part in this study.

The visit at which this sample will be collected are standard for bone marrow donors and will be billed to your family member's insurance company.

You will not be charged for the collection of these optional samples or for the research tests done with these samples. The costs of shipping your blood samples will be paid by the BMT CTN.

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.

11. For More Study Information

If you need more information about providing blood samples for research, or if you have problems while you are participating in this study, you can contact the study doctor or his/her staff. They can be reached at the telephone numbers listed here:

[Insert name and contact details].

12. Contact Someone About Your Rights

If you wish to speak to someone not directly involved in the study, if you have any complaints about the study, or would like more information about your rights as a research participant, you may contact:

[Insert appropriate contact details].

The ethical aspects of this research study have been reviewed and approved by [name of IRB].

For more information about your rights when providing blood samples for research, call the [name of center] Institutional Review Board (a group of people who review the research to protect your rights) at [telephone number].

Health Insurance Portability and Accountability Act (HIPAA)[1] Authorization to use and disclose research purposes:

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, *Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease*.

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
- Findings from physical exams
- Laboratory test results obtained at the time of work up

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 Investigators and the researcher's staff:
  - Dr. Robert Brodsky, Co-Principal Investigator
  - Dr. Michael DeBaun, Co-Principal Investigator
  - Dr. Adetola Kassim, Co-Principal Investigator
  - Dr. Mark Walters, Co-Principal Investigator
- Dr. Allistair Abraham and laboratory staff at Children's National Medical Center
- Study Sponsors:

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

- 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.
- The Data and Safety Monitoring Board (DSMB), not part of [Institution]
- Institutional Review Boards (IRBs) responsible for this study

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 or receive any treatment related to research that is provided through the 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 by sending a written notice to the Principal Investigator to inform the researcher of my decision.

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 for abuse or neglect, judicial proceedings, health oversight activities and public health measures.

H. This authorization does not have an expiration date.

TITLE: BMT CTN 1507: Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease

Principal Investigator: Name: Phone:

Address 1: Fax:

Address 2: Email:

For donors under 18, consent must be provided by the Legally Authorized Representative and Donor Assent is required (see **Assent Section** on the next page).

- I have had the chance to ask questions, and understand the answers I have been given. I understand that I may ask questions at any time during the study.
- I freely agree to be a participant in the study.
- I understand that I will not directly benefit from taking part in the study.
- I understand that, while information gained during the study may be published, I will not be identified and my personal results will stay confidential.
- I have had the chance to discuss my participation in this research study with a family member or friend.
- I understand that I can leave this study at any time, and doing so will not affect my family member's current care or prevent my family member from receiving future treatment.
- I understand that I will be given a copy of this signed consent form.

_____ _____

Participant Name Date

_____ _____

Participant's Signature (if 18 years or older) Date

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

_____	_____
Name of Counseling Physician/Staff	Date
_____	_____
Signature of Counseling Physician/Staff	Date
_____	_____
Name of Interpreter	Date
_____	_____
Signature of Interpreter	Date