Haploidentical Donor Informed Consent to Optional Research Samples

BMT CTN 2207

A Phase II Trial of Non-Myeloablative Conditioning and Transplantation of Haploidentical Related, Partially HLA-Mismatched, or Matched Unrelated Bone Marrow for Newly Diagnosed Patients with Severe Aplastic Anemia

Your Name: _____

Principal Investigator: *Insert local PI information*

Sponsor: This study is sponsored by the National Institutes of Health, through the Blood and Marrow Transplant Clinical Trials Network.

1. INTRODUCTION

We invite you to provide a blood sample for future research. You're being asked to join because you're a bone marrow donor for someone who is going to receive a transplant in the main study, BMT CTN 2207.

This consent form is for a research study to learn about patients with severe aplastic anemia (SAA) after they get cells from a donor (transplant). In order to do this study, we will need extra blood.

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

- These blood samples will be shipped on the day of collection to the BMT CTN Biorepository for processing and initial storage.
- Your name will be removed from the research sample and given a bar code. This bar code helps link your sample to de-identified data and other samples collected on this study by the Data and Coordinating Center for the Blood and Marrow Transplant Clinical Trials Network (BMT CTN DCC). Only the research team at your hospital and/or your donor center will be able to link you to the research sample.
- Your research samples may be stored in a repository designated by the BMT CTN and may be used for approved research studies by investigators in the broader scientific community. Samples will be kept until they are used up or until it is determined that they are not likely to be used for future research. You can change your mind and request to have your samples destroyed by

withdrawing from the study. If you stop being in the primary study before it is finished, upon your written request to [Insert site investigator] any remaining research samples you have given will be discarded when you tell us that you want to stop being in the study. Results we get before you stop being in the study will be kept.

- Your name and other information that could directly identify you (such as address or social security number) will not be used. Researchers have a duty to protect your privacy and to keep your information confidential.

Genetic Studies

DNA from your stored blood samples might be used in future genetic studies. We would like to test your DNA (or genes) to learn if some donor genes predict who will have serious complications of transplantation or other disorders. DNA is inherited information, like a blueprint about the structure and functions of human body traits that make up the color of our hair and eyes and may affect the way our bodies respond to things that happen outside the body such as smoking, an illness, or infections. We are interested in the possibility that there are genes that predict the outcomes of transplantation.

Genome-Wide Association Studies

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 hundreds of thousands 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). The NCBI will never have any information that would identify you, or link you to your information or research samples, although the results of genetic studies could theoretically include identifying information about you.

How can I find out about the results of the research?

You will not have any direct health benefits from providing your specimens for future research. It will probably take a long time for the research performed to be used to produce health-related information that we will know how to interpret accurately. For this reason, and because we will not know who the individual sample donors are, we will not be able to give you individual results from studies that may be conducted using the specimens. Knowledge from future research studies is likely to yield information that is more widely or generally applicable and not specific to an individual.

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.
- 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 an extra blood sample because we want to learn more about SAA patients that have received a 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 the patient 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:

- We will collect an extra blood sample prior to collection of your bone marrow donation. The amount of blood collected from you will be 20 mL (about 4 teaspoons).
- The blood sample will be sent to the BMT CTN Biorepository for storage. The sample 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.

Risks of Genetic Testing

In the course of these studies, we may find new genes that are inherited and predict the development of specific illnesses. Once we have obtained your DNA (or genes) from the white blood cells, we will put the DNA in tubes. These tubes will be labeled with a code and will have no markings to link the tube with you specifically. If we learn anything of importance to our research from this testing, we may publish the results in a medical journal. However, you will not be identified in the article as the patient who provided the blood sample for our testing.

In rare instances, it is possible that we could find out information about a specific gene that could affect you or other members of your family in terms of insurability, employability, or paternity. We will do everything possible to ensure that your identity and confidentiality will not be breached. As previously mentioned, the code linking your identifying information to the sample will be kept secure by the BMT CTN DCC staff in a password-protected file in a secure location.

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 patients with SAA do after a bone marrow transplant.

This information could help other people 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].
- NMDP Institutional Review Board (IRB) 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).
    - NMDP.
    - Emmes, who is coordinating the studies of the BMT CTN.
- 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 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.

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.
- 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 (if donating for a family member) 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 the blood sample 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 is standard for bone marrow donors and will be covered by the recipient's insurance.

You will not be charged for the collection of the optional sample 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 NMDP Institutional Review Board (a group of people who review the research to protect your rights) at [telephone number].

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 the recipient of my donation's current care or prevent them from receiving future treatment.
- I understand that I will be given a copy of this signed consent form.

_____
Patient Name

_____ _____
Patient's Signature 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

_____ _____
Signature of Counseling Physician/Staff Date

_____
Name of Interpreter

_____ _____
Signature of Interpreter Date