Related Donor Informed Consent to Participate in Research

BMT CTN 1703

A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplant Cyclophosphamide/Tacrolimus/Mycophenolate Mofetil in Non-Myeloablative/Reduced Intensity Conditioning Allogeneic Peripheral Blood Stem Cell Transplantation

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BMT CTN 1801

Companion Study: Microbiome and Immune Reconstitution in Cellular Therapies and Hematopoietic Stem Cell Transplantation (Mi-Immune)

Your Name: _____

Study Title: A Randomized, Multi-Center, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplant Cyclophosphamide/Tacrolimus/Mycophenolate Mofetil in Non-Myeloablative/Reduced Intensity Conditioning Allogeneic Peripheral Blood Stem Cell Transplantation

Companion Study: BMT CTN 1801: Microbiome and Immune Reconstitution in Cellular Therapies and Hematopoietic Stem Cell Transplantation (Mi-Immune)

Protocol: BMT CTN 1703

Principal Investigator: *Insert local PI information*

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

Summary

The following document is a consent form regarding research for which you are eligible. Your participation in this study is completely voluntary. You do not have to consent to this study.

BMT CTN 1801 - Microbiome and Immune Reconstitution in Cellular Therapies and Hematopoietic Stem Cell Transplantation (Mi-Immune)

Purpose: The purpose of this study is to understand if the bacteria and proteins in the transplant patient's gut and body fluids can help the doctors predict transplant outcomes.

Procedures: We will collect blood, urine, and stool samples. We will also ask if the bag or syringe from your stem cell donation can be donated. The samples will be collected at the time of your evaluation or stem cell donation. Some of these samples will be stored for future research.

Risks: There are no foreseeable risks or discomforts.

Benefits: Information from this study may help doctors learn more about how the bacteria and proteins in a transplant patient's body could affect a transplant patient's outcome. This information could help to improve the outcomes for future transplant patients.

Duration: The samples will be collected one time.

1. Introduction

We invite you to join this clinical trial, also known as a research study and provide blood, urine and stool samples for research. You're being asked to join because you're a peripheral blood stem cell donor for a family member who is going to receive a transplant in the main study, BMT CTN 1703.

This consent form is about a research study to learn what makes allogeneic blood stem cell transplants work well. To do this study, we will need extra blood, urine and stool samples from you.

It's your choice to give blood, urine and stool samples. Even if you say 'no' to giving samples for this research study, your family member can still receive a transplant as part of the main study. If you agree to give the samples, we will collect them before you donate your peripheral blood stem cell donation. We would also like to collect the bag or syringe from which your peripheral blood stem cells were given to the patient. We will try to retrieve any remaining cells from the

bag or syringe for planned research studies. You would not need to do anything for this collection.

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. You will receive a different consent form to donate your stem cells.

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

- Being in any research study is voluntary.
- You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others.
- If you give the blood, urine and stool 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 the samples for research. If you decide to join, please sign and date the end of the Consent Form. You'll be given a signed and dated copy to keep. No one can force you to take part in this study.

2. Study Background

The National Institutes of Health (NIH), through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), are providing staff support and money for this research study. The BMT CTN will direct the research study. The BMT CTN and the NIH will make decisions about how to manage the study.

3. Study Purpose

We are collecting extra blood, urine and stool samples because we want to learn more about what makes allogeneic blood stem cell transplants work well.

4. 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, please contact:

[insert contact info for Principal Investigator or study team]

Giving 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 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.

Your samples will be used only for research and will not be sold. The research done with your samples 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.

If you change your mind, any unused blood, urine or stool 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 about taking part in or leaving this study.

5. Study Treatment and Tests

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

a. Before your peripheral blood stem cell donation, we will collect blood, urine and stool samples.
   - We will collect **41mL (about 8 teaspoons**) of blood.
   - We will collect **10-12mL (about 3 teaspoons**) of urine
   - We will collect **10-20mL (about 4 teaspoons**) of stool

b. We would also like to collect the bag or syringe from which your stem cells were given to the patient.

The 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 studies. The samples will be labeled with unique codes that do not contain information that could identify you. A link to this code does exist. The link is stored at the Data and Coordinating Center for the Blood and Marrow Transplant Clinical Trials Network (BMT CTN DCC). The staff at the Repository where your sample is being stored does not have a link to this code. Your research samples will continue to be stored at the BMT CTN Repository until they are used up for approved future research.

6. 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.

There are no major risks to collecting your urine or stool samples.

7. Possible Benefits

You will not directly benefit from taking part in this study. The information from this study will help doctors learn more about what causes GVHD, cancer and other diseases, how to prevent them, and how to treat them.

8. Privacy, Confidentiality, and Use of Information

Your privacy is very important to us. The study doctors will make every effort to protect it. This study has a "Certificate of Confidentiality," which means 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 you.

Representatives from government agencies, including the U.S. Food and Drug Administration ("FDA"), institutional review boards, the Sponsors and/or the Sponsors' authorized representatives may need access to your original medical records and study records to check information collected for the study. By signing this Consent Form, you authorize this access.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your study number (code) is not related to your name, social security number, or medical record number at [insert facility name]. Coded study information may also be used for unexpected medical projects and research in the future. These projects could be related to **your family member's disease or similar diseases, and development of the study drug.** At all times the projects will follow the law.

[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:

- Data and Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN DCC), including the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP)/Be The Match registry and The Emmes Corporation, who are coordinating the studies of the BMT CTN

- The Food and Drug Administratrion (FDA) and National Institutes of Health (NIH), which includes the National Heart, Lung and Blood Institute (NHLBI) and the National Cancer Institute (NCI)
- Office of Human Research Protection (OHRP)
- Data and Safety Monitoring Board (DSMB), not part of [Institution]
- Institutional Review Boards (IRBs) responsible for this study

We won't identify you by name in any publications or reports that come from these organizations or agencies.

9. Ending Your Participation

The study doctor or the study sponsor may stop the study at any time. We may ask you to leave the study if you do not follow directions or if you suffer from side effects of the sample collection. 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 peripheral blood stem cells to your family member.
- The study is stopped for any reason.

10. Physical Injury as a Result of Participation

It is important that you tell your doctor or study staff if you feel that you have been hurt or injured because you provided blood, urine or stool samples for research.

You will get medical treatment if you are injured as a result of providing the samples for research. You, your health plan, or your family member's health plan will be charged for this treatment. The study sponsor will not pay for medical treatment.

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

11. Compensation or Payment

You will not be paid for participating in this study. You will not get paid or reimbursed for any extra expenses (such as travel or meals) from your participation in this study.

12. Cost and Reimbursement

The visits at which these samples will be collected are standard for peripheral blood stem cell donors and will be billed to your family member's insurance company.

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

For questions about your costs, financial responsibilities, and/or medical insurance coverage for your family member's transplant and this study, please contact [Center/Financial Counselor at phone #].

13. Ethical Review

The ethical aspects of this research study have been reviewed and approved by National Marrow Donor Program IRB.

14. For More Information

If you would like more information about providing blood, urine or stool samples for research, or if you have problems while you are participating in this study, you can contact the study doctor or staff.

[*Insert name and contact details*]

A description of this clinical trial will be available at 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.

15. Independent Contact

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

[Insert appropriate contact details]

Health Insurance Portability and Accountability Act 1 (HIPAA[1]) Authorization to use and disclose individual health information for 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:

[List PI and research staff]

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 Investigators and the researchers' staff

BMT CTN 1703: Drs. Javier Bolaños-Meade and Shernan Holtan, Co-Principal Investigators

BMT CTN 1801: Drs. Ami Bhatt, Leslie Kean and Miguel Perales, Co-Principal Investigators

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), 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
- 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 deparmtnets
- 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 or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

H. **This authorization does not have an expiration date.**

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COMPANION STUDY: BMT CTN 1801: Microbiome and Immune Reconstitution in Cellular Therapies and Hematopoietic Stem Cell Transplantation (Mi-Immune)

Principal Investigator(s)

Name: Phone:

Address: Fax:

Email:

- I have read and understood this Consent Form. The nature and purpose of the research study has been explained to me.
- 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 may 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

_____

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 Person Obtaining Consent	Date
Signature of Person Obtaining Consent	Date