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Study Title: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation

Protocol: BMT CTN #1702

NCT #: NCT03904134

Date: December 19, 2019

INFORMED CONSENT
Informed Consent to Participate in Research

Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation

Your Name: _____

Study Title: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation

Protocol: BMT CTN #1702

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(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 called a research study. You are invited because:

1) You have one of these diseases or disorders:
    - **Acute myeloid leukemia (AML)**
    - **Acute lymphoblastic leukemia (ALL)**
    - **Myelodysplastic syndrome (MDS)**
    - **Non-Hodgkin's lymphoma (NHL)**
    - **Hodgkin's lymphoma (HL)**
    - **Aplastic anemia (AA)**
    - **Sickle cell disease (SCD)**

2) Your doctor recommends that you have a transplant (**allogeneic stem cell transplant)** in the next 6 months.

We're doing this study to see how well patients do after transplant depending on whether they are very likely or very unlikely to find a matched unrelated donor.

We also want to learn about:

- Barriers patients and their doctors face when trying to get a transplant
- How many of the patients in this study get a transplant
- How well patients do after having a transplant depending on the type of donor used

You will be in the study for about **2 years**. This study will include about **1,732 people** from around the United States.

This consent form tells you about the reason for the study, the possible risks and benefits of joining, other treatment options for you, and your rights in the study. Please take your time to make your decision.

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

- Being in any research study is voluntary.
- You will not necessarily benefit directly from being in the study. Knowledge we gain from this study may benefit others.
- If you join the study, you can quit at any time.

- If you decide to quit the study, it will not affect your care at [*insert name of facility or institution*].
- Please ask the study staff questions about anything that you don't 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 be in the study. If you decide to join, please sign and date the end of the consent form.
- You and your doctor will always have the final say about your treatment, no matter what the study recommends.

2. Study Background

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

An **allogeneic transplant**, also called bone marrow or stem cell transplant, uses healthy blood-making cells from a donor to replace unhealthy ones. Your donor could be a relative or an unrelated person. **Human leukocyte antigen (HLA)** is used to match patients and donors. HLA is a protein marker found on most cells in your body. HLA markers are inherited (something that you are born with). You get half of your HLA markers from your mother and half from your father.

To prepare your body for the transplant, you'll get chemotherapy and possibly radiation to destroy the abnormal blood cells. This step is called the **conditioning regimen**. Then, when the conditioning regimen is done, you're given the donor cells.

Graft Versus Host Disease (GVHD) is a complication of transplant. It happens when the donor cells see your body as foreign (or different) and attack it. Your doctors will give you medicine to help prevent GVHD after your transplant (**GVHD prophylaxis**).

The best success with transplant is with HLA-matched sibling donors (brothers or sisters). For patients who do not have a matched sibling donor, it is not clear whether it is better to spend a longer time searching for a fully matched unrelated donor or move quickly to a different type of donor such as mismatched unrelated donor, half-matched (**haplo-identical**) family donor or

unrelated cord blood donor. A haplo-identical donor is someone whose HLA matches exactly half of yours. Parents are always a half-match for their children and vice versa.

Some of these other donor options are becoming more effective and safer than in the past, with similar results as matched unrelated donor transplants. Sometimes, patients and their doctors choose to wait to find an HLA-matched unrelated donor instead of having a transplant sooner with a half-matched family member, mismatched unrelated donor, or cord blood. But, it is unknown whether this is the best strategy because some people have a very low likelihood of ever finding a matched unrelated donor.

We are trying to improve the likelihood that people will get to transplant by using an algorithm to help guide the donor search. The algorithm is a system that figures out your chance of finding an HLA-matched unrelated donor. It uses your HLA type and race/ethnicity to calculate whether you a very likely, less likely, or very unlikely to find a match.

Your doctor will use the results of the algorithm to choose the best treatment option for you. If you are very likely to find a matched unrelated donor, your doctor would try to transplant you with an HLA-matched unrelated donor. If you are very unlikely to find a matched unrelated donor, then you would move quickly to a partially matched family donor, mismatched unrelated donor, or cord blood donor rather than pursuing a less than 10% chance of finding a matched unrelated donor. If you are less likely to find a matched unrelated donor, your doctor would follow the standard practices of your transplant center.

The algorithm gives a recommendation for treatment to your doctor, but your doctor does not have to follow it. They can choose what is best for you based on your unique situation.

3. Study Purpose

The main goal of this study is to see if there is a difference in how people do if they are very likely or very unlikely to find an HLA-matched unrelated donor.

We also want to see:

- Barriers patients and their doctors face when trying to get a transplant
- How many of the patients in this study get a transplant
- How well patients do after having a transplant depending on the type of donor they use

We will also ask about your overall health, and how well you can do your everyday activities (quality of life), if you:

- Have AML or ALL in first remission (no signs of the disease)
  OR
- Have early stage MDS

  AND
- Receive transplant from a matched unrelated donor or half-matched family member
- Have specific types of **conditioning regimen and graft-versus-host disease (GVHD) prophylaxis**.

We'll ask about 33% of patients (those with AML, ALL and MDS as mentioned above) (1 out of 3), to let us contact them in 1, 2 and 5 years to see how well they're doing (**see Section 17: QOL Substudy**). If we receive additional money to support the study, we will collect additional blood for research. The amount of blood collected will be 30mL (about 6 teaspoons) if you are an adult. Children would have less blood drawn based on their weight. Answering these surveys and giving blood for research is optional. This means you can still be part of the main study (looking at how you do based on your chance of finding an HLA-matched unrelated donor) if you say 'no' to this Substudy.

4. Right to Ask Questions and/or Leave the Study

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*]

Being in this study is your choice. You can choose not to be in this study or leave this study at any time. If you choose not to join or to leave this study, it will not affect your regular medical care in any way.

If you leave the study, any information already collected from you will be included in the results, unless you specifically ask that it not be included.

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

5. Study Treatments and Tests

Study Participation

If you join the study, we'll check your health before, during, and for at least **2 years** after your transplant. We will ask you to sign this consent form and give you a copy of the signed form to keep.

If you join this study and you don't have a matched sibling donor, your doctor will check if you have another good donor. Your donor could be another family member or an unrelated person.

Group Assignment

We will look at your HLA type from the blood sample your doctors take for this purpose. Based on your HLA type, we will be able to tell your chance of finding an HLA-matched unrelated donor. Depending on whether you are very likely, less likely, or very unlikely to find an HLA-matched unrelated donor, you will be assigned to one of 3 groups:

- **Group 1: Very likely to find an HLA-matched unrelated donor**
  - Your doctor will try to find an HLA-matched unrelated donor for your transplant
- **Group 2: Less likely to find an HLA-matched unrelated donor**
  - Your doctor will follow the standard practices of your transplant center to find a donor for your transplant
- **Group 3: Very unlikely to find an HLA-matched donor**
  - Your doctor will try to find another donor option, such as a half-matched family member, mismatched unrelated donor or cord blood, for your transplant

Once a donor is found, you will have a transplant as soon as you and your doctor feel you are ready for it.

If a suitable donor can't be found for you, you will continue to see your regular doctors. Together, you and your doctor will decide on the treatment for you. You will still be a part of this study and your doctor's office will share information with us about how you are doing.

If you have AML or ALL in first remission or early stage MDS and had specific types of conditioning regimens and GVHD prophylaxis, we will give you quality of life surveys that ask how you are doing. We will give you the survey before transplant and at 1, 2 and 5 years after your transplant (see **Section 17: QOL Substudy)**.

We may also ask you to give blood samples if we get more funding to do research on these blood samples (see **Section 18: Blood Sample Substudy).**

6. Risks and Discomforts

The risks and side effects of transplant are the same if you join this study or if you don't join this study since you and your doctors will decide the type of conditioning regimen and GVHD prophylaxis you will receive. What is different is if you participate in this study, the protocol will help guide your doctors in choosing a donor for you, based on the likelihood that a matched unrelated donor can be found. It is possible that even though we think it should be easy to find a matched unrelated donor for you, this turns out not to be true and your transplant is delayed while your doctors search for a matched unrelated donor. It is also possible that we think it will be very difficult and take a long time to find a matched unrelated donor for you but it turns out that a matched unrelated donor does exist. In either of these cases, you may not do as well if your doctors follow the donor search algorithm. However, your doctors may choose to ignore our recommendation about whether to search for a matched unrelated donor if they think a different plan is better for you.

Unforeseen Risks:

New risks might appear at any time during the study. We may learn new things that might make you want to stop being in the study. We will let you know if this happens and you can decide if you want to stay in the study.

Your doctor will explain any risks of transplant to you. You will receive more information about the transplant process, including the risks and benefits. Your doctor will ask you to sign a separate consent form for the transplant itself.

7. Alternative Treatments

It is your choice to join this study. If you choose not to join, you may still receive a transplant to treat your disease.

Your study doctor will talk with you about your options. If you decide not to join this study, your medical care will not be affected in any way.

8. Possible Benefits

You may not benefit directly from being in this study. You can still receive the same or similar treatments even if you don't join this study. Your participation allows us to collect specific information about your transplant experience.

Information from this study will help doctors learn more about how patients find a donor for transplant and how they do after transplant with different types of donors. It will also help

doctors understand how transplantation with different types of donors affects patient's Quality of Life. This information could help people who may need a transplant in the future. If you are unlikely to find an HLA-matched unrelated donor, it's possible you may have a transplant more quickly with another type of donor than if you waited, depending on your transplant center's current standard practices. Earlier transplantation may improve how well you do.

9. New Information Available During the Study

During this study, the study doctors may learn new information about the risks and benefits of the study. If this happens, they will tell you about the new information.

The new information may mean that you can no longer take part in the study, or that you may not want to continue in the study.

If this happens, the study doctor will stop your participation and offer you all available care to meet your needs for your medical conditions.

10. Privacy, Confidentiality and Use of Information

Your privacy is very important to us. The study doctors will do everything they can 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 to others will not identify you.

All your medical and demographic information (such as race and ethnicity, gender and household income) will be kept private and confidential. *(Name of Transplant Center)* and the organizations listed below will not share that you are in the study in any way, except with your written permission, or unless required by law.

Individuals authorized by the organizations below will be able to see 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 agree to such inspections and to the copying of parts of your records, if required by these organizations.

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept confidential (private). However, we cannot promise total privacy. We may have to 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.

Information about your transplant from your original medical records may be seen or sent to national and international transplant registries, including:

- */Institution/Transplant center*
- 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, Stefan Ciurea, MD and Stephanie Lee, MD, MPH

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 site will include a summary of the results. You can search this site at any time.

For questions about access to your medical records, please contact */name/at/number*

11. 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.

If we ask you to leave the study, we will tell you why. Possible reasons your participation in this study could end include:

- You do not meet the study requirements.
- You need a medical treatment not allowed in this study.
- The study doctor decides it would be harmful to you to stay in the study.
- The study is stopped for any reason.

If you leave the study, any information already collected from you will be included in the results, unless you ask that it not be included.

12. Physical Injury as a Result of Participation

Participation in this study and use of the donor search algorithm is unlikely to cause any direct physical injury. We think that guiding centers to use your likelihood of finding a matched unrelated donor to quickly identify a donor so you can get to transplant will be helpful because we believe that the success of transplant is the same no matter which donor is used, but we do not know if this will be true.

Whenever you participate in a study, it is important to tell your study doctor *[investigator's name(s)]* or study staff if you feel that you have been hurt or injured from taking part in this study. You can tell the doctor in person or call *[telephone number]*.

You will get all available medical treatment if you are injured from being in this study.

You and/or your health plan will be charged for the donor search and your transplant care. The study will not pay for this treatment.

13.Compensation or Payment

You will not be paid for taking part in this study. You will not be given money for any extra costs (for example, travel and meals) for being in this study. We do not think there will be any extra costs to you from being in this study.

14. Costs and Reimbursements

The clinic visits for this study are standard medical care for transplant or the standard treatment. You and/or your health plan/insurance will need to pay for the costs of transplant or standard treatment in this study.

Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out if they will pay.

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://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.

15. For More Information

If you want more information about this study, or if you have problems while taking part in this study, you can contact the study doctor or study staff.

They can be reached at the telephone numbers listed here:

[*Insert contact information for site PI*].

16. Contact Someone about Your Rights

If you wish to talk to someone not directly involved in the study, or if you have any complaints about the project, or any questions 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 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)*.

17.QOL Substudy

(*Optional for patients with AML or ALL in first remission or early stage MDS – if you do not have a diagnosis of one of these diseases, please skip forward to page 17 and check the N/A box)*

Please note: This section of the consent form is about an additional research study that will be done with some people taking part in the main study. To be in the QOL Substudy, your doctor will determine if your disease, conditioning regimen and GVHD prophylaxis fit the Substudy criteria. You must also be at least 8 years old and able to complete surveys in either English or Spanish.

You may take part in this additional study if you want to. You can still be a part of the main study even if you say 'no' to this additional study.

The researchers want to understand how finding a donor and how transplant goes for patients with AML or ALL in first remission or early stage MDS and who receive specific types of conditioning regimens and GVHD prophylaxis.

You can still be a part of the main study (looking at how you do based on how likely you are to find an HLA-matched unrelated donor) even if you don't answer questions about your quality of life.

If you agree to complete optional quality of life surveys, here is what will happen:

After you join the study, we will ask you questions about your health and how you're feeling. These questions can be answered either via an online survey or a paper survey mailed or given to you. The CIBMTR will collect the survey data, and will reach out to you if surveys are not completed to ensure you got the online link or paper survey and answer any questions you have.

We will ask you to complete surveys:

- One month or less before transplant
- 1 year (12 months) after transplant
- 2 years (24 months) after transplant, and
- 5 years (60 months) after transplant.

Each survey will take 15-30 minutes to complete.

The survey will ask about your physical, emotional, and social well-being including:

- How well you can do your everyday activities
- If you have pain and how much pain affects daily life
- Fatigue (feeling tired) and how well you are sleeping
- How much you worry or feel nervous or have symptoms of depression
- How much you are able to participate in social roles and social activities
- How much you are bothered by specific symptoms to parts of your body
- Demographics, such as your race and ethnicity, level of education, work status, income, current state and ZIP code where you live, and health insurance coverage.

This information will be used for research purposes. You can skip any questions you want. You can also stop the survey at any time.

If you want to stop participating (withdraw) in the optional QOL Substudy, let your study doctor know in writing. If you withdraw, you can choose whether we can still use your information or not.

If your phone number or email address changes, it's important that you let us know your new number so we can reach you. You can call:

[Insert contact information for site PI]

The CIBMTR will send you the online or paper surveys, and then follow up by phone and email with you. If we can't reach you by phone, we may use an Internet search service to find you. By agreeing to join this study, you are giving us your permission to use search firms to find your contact information. The service uses public and non-public information to reach you.

Privacy, confidentiality and use of information: Your privacy is very important. We'll do our best to make sure that your medical and personal information in your study record is kept private. However, we can't promise total privacy.

Your personal information will only be labeled with a number code. No information that would let others know who you are or that you were in the study will be published or presented at scientific meetings.

We'll only share your medical and personal information if you request it in writing or agree in writing to share it, or if we are required by law.

A possible risk is the loss of confidentiality about your medical information. We will do our best to make sure that your personal information is kept private. The chance that this information will be given to someone else is very small.

Risks to participating in QOL Substudy:

There are few risks from taking the quality of life surveys. Some of the questions or topics may make you feel uncomfortable or emotional. Talk to your doctor about your feelings.

There is a small risk that a person who shouldn't be able to see your survey could find out which answers are yours. Your transplant center and the CIBMTR will do everything possible to stop this from happening.

The survey isn't meant to find depression or other emotional health issues. We won't look at your information for signs or symptoms of distress. If you have any concerns about your feelings, thoughts, or emotional health during this study, tell your doctor right away. Your doctor will talk to you about your options.

Payment and costs: You will not get paid for participating in the QOL Substudy. You will not be charged for taking part in this study.

Right to ask questions and/or withdraw: You do not have to be part of the QOL Substudy. Your participation is voluntary. If you decide not to be part of the QOL Substudy, it will not affect your regular medical care or services. You can quit the QOL Substudy at any time. If you want to stop participating in the QOL Substudy (withdraw), let your study doctor know in

writing. If you withdraw from the QOL Substudy, you can choose whether we can still use your quality of life information or not.

18. Blood Samples Substudy

(*Optional for patients with AML or ALL in first remission or early stage MDS – if you do not have a diagnosis of one of these diseases, please skip forward to page 17 and check the N/A box)*

Please note: This section of the consent form is about an additional research study that will be done with some people taking part in the main study. To be in the Blood Samples Substudy, your doctor will determine if your disease, conditioning regimen and GVHD prophylaxis fit the Substudy criteria. You must also be at least 8 years old and able to complete surveys in either English or Spanish.

You may take part in this additional study if you want to. You can still be a part of the main study even if you say 'no' to this additional study.

The researchers want to study blood samples from patients with AML or ALL in first remission or early stage MDS and who receive specific types of conditioning regimens and GVHD prophylaxis.

You can still be a part of the main study (looking at how you do based on how likely you are to find an HLA-matched unrelated donor) even if you don't provide blood samples.

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

- We'll take the blood samples from your catheter or by a vein in your arm. We'll collect this sample when you have your checkup before your transplant and up to 6 times during the first 2 years after your transplant.
- We will collect 30mL (about 6 teaspoons) if you are an adult. Children would have less blood drawn based on their weight.
- 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 research studies. Each research sample will be coded with a unique code. The codes themselves do not contain information that could identify you, however, 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 research.
- Samples 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. Researchers can apply to study the health

information and 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.

- 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.

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 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.

Genetic Information Nondiscrimination Act:
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.

Things to Think About:

- The choice to let us have blood for future research is up to you. No matter what you decide to do, it will not affect your care.

- If you decide now that your blood can be kept for research, you can change your mind at any time. Just contact your study doctor and let him or her know that you do not want us to use your blood. Then any blood that remains will no longer be used for research.

- In the future, people who do research on these blood samples may need to know more about your health. While the study doctor or others involved in running this study may give the researchers reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

- Sometimes blood is used for genetic research (about diseases that are passed on in families). Even if your blood is used for this kind of research, the results will not be put in your health records.

- 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.

- Reports about research done with your blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Benefits:
The research that may be done with your blood is not designed specifically to help you. The benefits of research using blood include learning more about what causes your or other diseases, how to prevent them, and how to treat them.

Risks to Participating in Blood Sample Substudy:
There is a small risk of an infection or fainting from the blood draw. 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.

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

The results of this study will be published, but your personal information (for examples, name and address) will remain confidential (private). BMT CTN may also use the information from this study for future medical research.

Right to ask questions and/or withdraw: You do not have to be part of the Blood Sample Substudy. Your participation is voluntary. If you decide not to be part of the Blood Sample Substudy, it will not affect your regular medical care or services. You can quit the Blood Sample Substudy at any time. If you want to stop participating in the Blood Sample Substudy (withdraw),

let your study doctor know in writing. If you withdraw from the Blood Sample Substudy, your blood samples will be discarded.

For more information: Contact [contact name and info]

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: *[contact information for site PI]*.

No matter what you decide to do, it will not affect your care.

Statement of Consents for QOL and Blood Samples Substudies (Optional)

The purpose of the QOL Substudy and the Blood Sample Substudy, the procedures involved (quality of life surveys and blood samples), 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 participate in either substudy. If I decide to not participate, it will not affect my medical care in any way.

For those without a diagnosis of AML or ALL in first remission or early stage MDS:

❑ N/A – I do not have a diagnosis of AML or ALL in first remission or early stage MDS and therefore will not participate in either substudy.

For those <u>with</u> a diagnosis of AML or ALL in first remission or early stage MDS:

Quality of Life Surveys

❑ I agree to take part in quality of life surveys.

❑ I do <u>not</u> agree to take part in quality of life surveys.

Blood Samples

❑ I agree to give blood samples for research related to transplantation.

❑ I do <u>not</u> agree to give blood samples for research related to transplantation.

_____ _____

Participant Signature (or Parent/Guardian) Date

Health Insurance Portability and Accountability Act 1 (HIPAA1) 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:

Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D)

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:

My individual health information from the research may be received and used by the following parties:

- Principal Investigator and the researcher's staff:

  Dr. Stefan Ciurea, Co-Principal Investigator

  Dr. Stephanie Lee, Co-Principal Investigator
- National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH),

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

- Study sponsors: Blood and Marrow Transplant Clinical Trials Network (BMT CTN), Data and 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 consent form. If I decide not to sign the consent form, 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 consent form 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 my consent at any time by sending a written notice to the Principal Investigator to inform the researcher of my decision.

If I withdraw my consent, 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 as required by law and would no longer be 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 consent form does not have an expiration date.

TITLE: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation

PROTOCOL NUMBER: BMT CTN 1702

PRINCIPAL INVESTIGATORS:

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- I have read and understood this consent form. The purpose of the research study has been explained to me.
- I have had the chance to ask questions, and I understand the answers I have been given. I understand that I may ask questions at any time during the study.
- I freely agree to take part 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 if I want.
- I understand that I can leave this study at any time, and doing so will not affect my current care or prevent me from receiving future treatment.
- I understand that I will be given a copy of this signed consent form to keep.

_____ _____
Participant Name (or Parent/Guardian) Date

_____ _____
Participant Signature (or Parent/Guardian) 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	Date
Signature of Counseling Physician	Date
Name of Interpreter	Date
Signature of Interpreter	Date