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Study Title: Molecular Evaluation of AML Patients After Stem Cell Transplant to Understand Relapse Events

Protocol: MEASURE

NCT #: NCT05224661

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Informed Consent to Participate in Research

Study Sponsor: NMDP	**Study Title:** Molecular Evaluation of AML Patients After Stem Cell Transplant to Understand Relapse Events
	Study Doctor: *[Enter name of site Principal Investigator]*

M·E·A·S·U·R·E
MOLECULAR EVALUATION OF AML PATIENTS AFTER STEM CELL TRANSPLANT TO UNDERSTAND RELAPSE EVENTS

Principal Investigator

(*Enter name/title of Principal Investigator*)

Contact Information for Emergencies

(*Enter name and phone number for emergency contact person(s)*)

Sponsors and Other Support

NMDP and (*Enter the name of local transplant center)

The ethics of this study have been reviewed and approved by the NMDP Institutional Review Board.

This Consent Form includes:

- ✓ The purpose of the research
- ✓ Possible risks and benefits
- ✓ Your rights if you join the study

1. Key Information

We are asking you to join this research study because you have acute myeloid leukemia (AML) and your doctor recommends you get a blood or marrow transplant (BMT).

We are doing this study to figure out what are the best tests that will tell doctors which AML patients who have a BMT (or are thinking of having a BMT in the future) may be more likely to have a relapse after transplant and how we can tell as early as possible if a relapse is happening.

There will be no special treatment on this study. The scientists who are taking part in this study are only gathering information to help people in the future who will get AML.

If you join, here is what will happen:

- You will be in the study for up to 3 years
- Your doctor will collect several small samples of your blood (up to 3 tablespoons)
- We will ask your doctor to provide some of the leftover bone marrow or tissue samples collected as part of your regular care
- Your health information and any leftover samples collected for the study will be shared for future research

This study does not include any treatments. Some possible harms and benefits of joining the study include:

Possible Benefits:

- No direct benefit to you, but the knowledge gained from this study may help future AML patients.

Possible Harms:

- You may have pain or bruising where the blood is drawn, and there is a small risk of fainting or infection when giving a blood sample.
- Your personal information, including your health information and DNA information, could become known to people other than the scientists on this study.

Whether or not you join the study, there will be no changes to the treatment plan you decide with your doctor.

Key points

- Being in any research study is **your** choice. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. No one can force you to join this study.

- You may or may not benefit from being in the study. Knowledge gained from this study may help 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 (*name of facility or institution*)
- This document can help you decide whether or not to join. Take time to read it and ask any questions before you agree to join.
- You can contact us at any time if there is anything you don't understand, if you want more information, or if you want to quit the study. See section 10 (page 8) for contact information.
- Take time to talk about the study with your doctor, study staff, and your family and friends.

If you decide to join, please sign the end of this Consent Form. You will get a copy to keep.

2. What's the purpose of the study?

Sometimes, when AML is treated with BMT, the AML comes back. This is called a relapse. The purpose of this research study is to see if by looking at your whole genome – all of the genes that make up your DNA – we can learn which genes tell us a patient is more likely or less likely to experience relapse after BMT for AML. If we can determine which biomarkers (indicators in DNA) to look for, we can develop tests or improve tests that already exist to help predict future relapse in AML patients.

Whole genome/exome tests result in a unique set of genetic blueprints that can be used to identify you (like a fingerprint) and possibly your near blood relations. In addition, whole genome sequencing can shed light on not only your risks of disease, but also the risks of disease of your close blood relations. Sometimes researchers just look at specific genes that they think might be related to either your condition or how you will respond to specific medicines.

The blood and leftover samples collected for the study will be used for the for the study tests. We want to see which of the tests we are doing is the most helpful to guess which patients will have a relapse and if we can tell as early as possible when a relapse is happening.

There will be about 1000 people in this study.

3. What will happen if I join the study?

You will actively be part of the study for up to 1.5 years after your transplant, then we will follow you to see how you are doing (for a total of up to 3 years after your transplant). During those 3 years, these are the things that will happen:

We'll test your blood
You will have blood samples taken for the study at these times:

- Before transplant
- At months 1, 2, 3, 4, 5, 6, 9, 12, 15, and 18 after transplant
- If your AML relapses after transplant

You will give a small amount of blood from your body at each of these times, **no more than 3 tablespoons at each time point**. The researchers will do DNA testing on each sample, including whole genome sequencing. You and your study doctor will not get the results of these tests.

We'll test your leftover samples
We will look at some of the tissue or bone marrow left over from the test when you were diagnosed with AML. If your doctor collects a bone marrow sample as part of standard testing before and/or after BMT, we will look at this leftover tissue, too. The researchers will do DNA testing on each sample, including whole genome sequencing. You and your study doctor will not get the results of these tests.

We'll collect information on how you're doing
We will look at information that is sent to CIBMTR as a standard part of following patients who have a BMT. We will look at this information for up to 3 years after your transplant. If you have an AML relapse, we will ask your doctor to give us information about the relapse.

After you are done participating in the study the following will happen:

We'll store your leftover study samples for future studies
If you choose to join this study, we will collect and store the DNA and any remaining samples collected for the study. This part of storing samples for future studies is called "biobanking." The biobank for this study is run by CIBMTR. This is a publicly funded study, which means we are required to share samples as broadly as possible. However, we will protect your privacy. We hope to help future studies that may improve people's health.

The biobank is a public research resource, with controlled access. This means that researchers who want to get samples and data from it must submit a request. The request says who they are and what their project is. Before getting the samples and data, researchers must agree to keep the data private, only use it for their project, and never use it to identify you.

Right now, we do not know what your blood and tissue samples will be used for in future studies. This means that:

- You will not be asked if you agree to be in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.

Future studies may look at the DNA in your cancer and compare it to your DNA. This can help researchers understand if the cancer can be passed down from parents to their children.

4. What are the benefits?

This study may not help you. You will not directly receive any results generated from this research. However, this study may help doctors understand how to predict which AML patients may relapse after BMT and learn things that may help other people in the future.

5. What are the potential harms?

The side effects of transplant are the same if you are in this study or not. You will not get any different treatment than other patients not in the study.

Blood Samples
There are no major risks with blood draws. A blood draw can hurt a little and may cause a bruise. In rare cases, people feel lightheaded or faint. Only trained people will draw your blood.

Data and Information
There is a small risk that an unauthorized person could find out which data are yours. Your treatment center and the CIBMTR/NMDP have procedures in place to keep your data private. No identifiable information about you will be given to the researchers, nor will it be published or presented at scientific meetings.

DNA
Since your DNA is unique to you, there is a small risk that someone could trace your samples back to you. Researchers accessing your information will do their best to protect your privacy and to keep your information confidential. We will not give information that could identify you to researchers, publish it or present it at scientific meetings.

Samples Collected by Your Doctor for Standard BMT Care
This study will use a sample of your tissue or bone marrow from when your doctor determined an AML diagnosis, and if your doctor collects bone marrow samples as part of standard care for BMT patients. Generally, if you have had a biopsy, your hospital will keep some of your left-over tissue after that test has been done. This left-over tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, it could be used up.

6. What are my costs? Will I be paid?

You will not be paid for taking part in this study. It will not cost you anything to take part in the study. If there is part of your stored blood sample left over after the study is completed that becomes part of the biobank, the CIBMTR may sell your blood sample to other organizations such as drug companies. Samples that are sold or shared outside the CIBMTR never include any information that could identify you. The organization may

use your blood sample to make products or therapies that benefit patients or are valuable to researchers. You will not receive any money or other benefit from any products or therapies that are developed from your blood sample.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at cancer.gov/ClinicalTrials/LearningAbout. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site.

NMDP Clinical Trial Search and Support financial assistance program may help qualified patients pay for the following travel costs:

- Air travel: for you and your companion
- Ground transportation: gas, parking, and public transit (bus/train/cab/etc.)
- Accommodations: hotel, temporary housing, and incidentals

Your medical team will need to complete and submit the application on your behalf. If you have any questions, please email patientgrants@nmdp.org or contact one of our Clinical Trials Navigators at **1 (888) 814-8610**.

7. What if I'm injured because of the study?

If you are injured because of being in this study, tell your study doctor right away. You will get medical treatment if you are hurt as a result of this study. You and/or your insurance company will be charged for this treatment. The study sponsor will **not** pay for medical treatment for injury.

You have the legal right to seek payment. Agreeing to take part in this study does **not** mean you give up these rights.

8. How will my privacy be protected?

Your privacy is very important to us. The study team (your study doctors and the researchers) will do their best to protect it. They will not share personal information about you outside of the study team. However, some of your medical information may be shared if required by law. If this happens, the study doctors will do their best to make sure that any information that goes out to others will **not** identify you.

Some of your health information, such as results of study tests, will be kept in a central research database. However, your name and contact information will not be put in the study database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your blood and DNA samples will be stored with a code. The study staff and future researchers do not have a link to this code. However, a link does exist. The link is stored at [insert center name here].

To expand research, it is helpful for researchers to share information. They do this by putting the information into one or more research databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease.

If you agree to take part in the study, some of your genetic and health information may be stored in a research database, such as the Genotype and Phenotype Database maintained by the National Institutes of Health (NIH). Researchers with an approved study may be able to see and use your information, and they also must agree that they will not try to find out who you are. Your name and other information that can identify you will never be put into the database and your personal information will not be given to anyone unless it is required by law. The CIBMTR restricts the use of the data to studies of BMT and cellular therapy.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and employers with 15 or more people to discriminate against you based on your genetic information. Health insurance companies and group health plans may **not** request your genetic information or use it to make decisions about your health insurance. This federal law will **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

To make sure the study is running ethically, some organizations can look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations.

Some of these organizations are:

- The study sponsor, NMDP, and any company supporting the study now or in the future
- Center for International Blood and Marrow Transplant Research (CIBMTR)
- National Institutes of Health (NIH)
- The Institutional Review Board (IRB) responsible for this study
- Office of Naval Research (ONR), the primary funding source for this study
- The U.S. Food and Drug Administration (FDA)
- The U.S. Department of Health and Human Services (DHHS)

These organizations may also see or use the results of research done with your blood, leftover samples, and DNA. These results will **not** be shared with you.

Data from this study may be used in future research. If you join this study, you allow your data to be used in future research, without your personal information. The results of the study may be compared to results from future studies. The Study Sponsor and

people who work with the Study Sponsor may use the results of this study for other research, including:

- Looking at the safety of a treatment or how well it works
- Looking at other treatments for patients
- Learning more about a disease
- Making future clinical trials better

9. What if I don't want to be in the study? Can I leave once I've joined?

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 to not join or leave this study, it won't affect your regular medical care in any way.

If you decide to leave, let your study doctor know as soon as possible.

You may also be told to leave the study for reasons such as:

- New information becomes available and the study will no longer benefit you, or may harm you. Your doctor will tell you about new information.
- Your doctor no longer thinks a transplant is the best option.
- Your doctor is not able to share the tissue or bone marrow left over from the test when you were diagnosed with AML.
- You do not follow the study rules, like keeping appointments.
- The study is stopped for any reason.

If you choose to leave the study, the information already collected from you may still be used in the research. If you do not want your information to be used, or if you want any unused samples destroyed, you **must** let your study doctor know. The study staff and sponsor will still have access to your medical records collected before you left the study.

10. Where can I go with questions?

A description of this clinical trial will be available on 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.

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

(*Treatment Center Physician*)
Call: (*telephone number*)
Email: (*email, if appropriate*)

If you want to talk with someone **not** directly involved in the study, or have any complaints or questions about your rights as a research participant, please contact:

NMDP IRB Administrator at 1-800-526-7809

If you want to talk to someone outside this study about general concerns or questions about living with your AML and/or being a transplant patient, please contact:

NMDP Patient Support Center
Call or text: 1 (888) 999-6743
Email: patientinfo@nmdp.org

(*Transplant center to enter office of research subject advocacy contact information*)

You will be given a copy of this consent form for your records.

11. Optional Studies

If you decide to join this study, we would like to share your information with the Survey Research Group (SRG) at CIMBTR who may invite you to an optional survey study.

If you agree, we will share your name, email, mailing address and phone number(s) with the SRG. The SRG will then contact you to describe and obtain your consent to the separate survey study. They may contact you very soon after joining the main study.

You can choose to join optional studies, which are separate from the main study. The optional studies will not benefit your health. We hope these results will help other transplant patients in the future.

The SRG's contact information is listed below. They will always contact you from these addresses or phone numbers. The team members will always say that they are contacting you about the survey study and are from the Survey Research Group.

Phone: 1-888-298-6714
Email: PRO-Surveys@nmdp.org
Mailing address: 500 N 5th Street, Minneapolis, MN, 55401-1206

Your hospital will share your contact information with the SRG. If your contact information changes (for example, emails to you bounce back to us), the SRG may ask your transplant center or search online for updated contact information.

Please circle your answer below to show if you would or would not like to be contacted about this optional study:

Please circle your answer: I choose to share my contact information with the NMDP SRG and allow them to contact me.

Yes No

Please write your initials and today's date: _____

This is the end of the optional studies section.

My signature on this page means I agree to join the study

My signature below means that:

- I have read this consent form or it has been read to me and I understand the information in this form.
- 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 have had the chance to talk about joining the study with a family member or friend, if I want.
- I have been given enough time to think about the study, its procedures, risks, and my options.
- My consent does not release the sponsor from its obligations and my legal rights will not be affected.
- I understand that...
    - I may not directly benefit from being in the study.
    - The study sponsor, regulatory authorities, and the IRB may have access to my medical records.
    - My name and personal information will not be shared even if information from the study is published.
    - Information about me, including test results will be stored in a research database. Researchers can see this for future studies.
    - I can leave this study at any time, and doing so will not affect my rights.
    - I will be given a signed and dated copy of this document.
- I agree to…
    - Go to my appointments

_____ _____

Participant Signature Date

_____

Printed Participant Name

Certification of Healthcare Professional Obtaining Consent

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered.

_____ _____

Healthcare Professional Signature Date (DD/MM/YYYY)

_____

Printed Healthcare Professional Name

Use of an Interpreter: Complete if the subject is not fluent in English, an interpreter was used to obtain consent, and IRB approves a non-English short form to be used:

Interpreter Signature: _____

Printed Interpreter Name: _____

Date (DD/MM/YYYY): _____

An oral translation of this document was administered to the subject in _____ (state language) by an individual proficient in English and _____ (state language). See the attached short form for documentation.

Use of a Witness: Complete if the subject is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g. blind, physically unable to write, etc.) or when an interpreter was used but is not physically present (e.g. a language line is used):

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication with the subject was

_____.

_____

Witness Signature: _____

Printed Witness Name: _____

Date (DD/MM/YYYY): _____