INFORMED CONSENT
Informed Consent to Participate in Research

Composite Health Assessment Risk Model for Older Adults: Applying Pre-transplant Comorbidity, Geriatric Assessment and Biomarkers to Predict Non-Relapse Mortality after Allogeneic Transplant

Participant's Name: _____

Study Title: Composite Health Assessment Risk Model for Older Adults: Applying Pre-transplant Comorbidity, Geriatric Assessment and Biomarkers to Predict Non-Relapse Mortality After Allogeneic Transplant (CHARM)

Protocol: BMT CTN #1704

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Transplant Center Investigator: _____
(Insert contact information for PI at your site)

Sponsor: The National Institutes of Health (NIH) is sponsoring this study through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

1. Key Information

We invite you to join this clinical study, also called a research study, because you:

- Are 60 years or older
- Were offered an allogeneic stem cell transplant (transplant) to treat your blood cancer

We are doing this study to learn how well patients do after transplant, based on their health before transplant.

You will be in the study for about **1 year**. This study will include approximately **880 people** from around the United States. Before transplant, you will take:

- Physical tests, for example of your grip strength and speed walking
- A test of your thinking, including your memory, attention and language skills

Within 1 year after transplant, you will take the physical tests 3 more times and the test of your thinking one more time. You will take the tests in the hospital or clinic.

This consent form tells you about the reason for the study, the possible risks and benefits of joining, and your rights in the study. We encourage you to take some time to think this over and discuss it with other people. You can ask questions now and at any time in the future.

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

- Being in any research study is voluntary (your choice). If you choose not to join this study, you may still receive a transplant to treat your disease.
- We think most of the benefits from the study will be for people who receive transplant in the future.
- Risks of participating in this study are potential emotional distress or loss of confidentiality when completing surveys; neither of which are very likely to happen to you. If any new risks appear during the study, we will be sure to tell you about them.
- 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*]. If you decide to quit the study, we will still use the information we collected from you so far in our final research. We will also use information collected from the charts about your health till the end of one year in our final research. However, once you quit the study, you will not take any more surveys or tests for this study.

- 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 and at 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 paying 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.

You have a type of blood cancer that can be treated with transplant. Some patients have complications after transplant such as infections and graft-versus-host disease (GVHD). GVHD happens when the donor's cells see your cells as different and attack them. These complications can make patients less able to do their daily activities. Some older patients are not offered transplant because doctors are concerned that the risk of life-threatening side effects from transplant might be too high. We are working on a way to predict transplant risks and results in your age group by studying your health before and immediately after the transplant.

The researchers will use the results of the tests to find out which factors are most important for predicting your health in the year after your transplant. Researchers will create a scoring system of the most important factors for future patients. Information from this study may help doctors in the future to determine how patients will do after transplant.

3. Study Purpose

The goal of this study is to learn how to predict health after transplant, based on test results before transplant. The results may help doctors see if there is a way to tell which patients will have better health after transplant.

This study does **not** include any experimental procedures.

Through online or paper surveys, we will also ask about:

- Your physical health, including your daily activities, overall health, and energy

- Your emotional health such as feelings of anxiety or depression
- If you have fallen recently
- Medications you take
- Weight loss
- Demographics, such as race, education and income

Your doctor's team will also ask you to do these physical tasks:

- 4-meter walk: Your doctor will record how long it takes you to walk 4 meters (13.1 feet)
- Grip strength: You will be asked to grasp a dynamometer (a hand-held device used to test strength) with your hands
- A test of your thinking, including your memory, attention and language skills, called the Montreal Cognitive Assessment (MoCA)
- Blood draw for laboratory testing at the time of your routine blood tests

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.

Your doctor and study staff will 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 evaluate your health before, during, and for approximately **1 year** after your transplant. We will ask you to sign this consent form and give you a copy of the signed form to keep.

Scheduled Study Visits and Surveys

A study visit is an in-person meeting that you have with a member of the research team or your care team at [*insert name of facility or institution*]. You will need to have four study visits over about one year. These visits will include a walk speed test, grip strength test and test of your thinking. The in-person study visits will be scheduled with your regular clinic visits, so you don't have to make an extra trip to the clinic. If you are not seen in-person for regular clinic visits after you receive your transplant, or if the research team is unable to see you in-person during your regular clinic visits, you may be asked to complete the walk speed test and test of your thinking over the telephone or video teleconferencing. In addition to the study visits, you will be asked to complete surveys four times over around one year. These surveys can be done online or on paper. At your first in-person study visit, you will get either a link to complete the survey online or a paper version. For the later surveys, the research team will email you a link or mail you a paper version with a stamped return envelope. A member of the research team may call or email you to make sure you got the survey.

Study Visits and Surveys

1. First visit: This will happen 0-21 days before starting your conditioning regimen (the chemotherapy and possibly radiation that you receive before transplant). At the time of the first visit you will also complete the first survey (13-20 minutes), do the walk speed test, grip strength test, memory test and have your blood drawn. The total time of the first visit will be up to 50 minutes.
2. Second visit: This will happen at around three months (100 days) after your transplant. The visit will last about 10 minutes in the clinic. You will repeat the walk speed test, grip strength test and memory test. At the time of the second visit, the research team will send you the second survey (7-10 minutes) by email or on paper through the mail.
3. Third visit: This will happen around six months (180 days) after your transplant. The visit will last about 10 minutes in the clinic. You will repeat the walk speed test and grip strength test. At the time of the third visit, the research team will send you the third survey (11-17 minutes) by email or on paper through the mail.
4. Final visit: This will happen one year (365 days) after your transplant. The visit will last about 10 minutes in the clinic. You will repeat the walk speed test and grip strength test. At the time of the final visit, the research team will send you the final survey (11-17 minutes) by email or on paper through the mail.

Your total length of study participation will be about 1.5 to 2 hours spread over the course of 1 year. Once you finish your last visit around one year after transplant, we will not contact you again.

You will **not** be able to access your study results before the study is done. This helps keep the study results accurate and trustworthy.

When the study is complete, you can ask your study doctor for your health information from the study. **By signing this Consent Form, you agree to ask for your results only after the study is done.** You will still have access to your regular medical records.

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

6. Risks

The risks and side effects of transplant are the same if you join this study or if you don't join this study. This is an observational study, meaning we don't treat you any differently than patients not on study. We will observe how you do with the transplant. We do not want to add any risk to you. However, there may be risks that we did not plan for.

Loss of Confidentiality:

We want to keep your data confidential (private). However, confidentiality of your medical information could be lost. We will do everything we can to protect your privacy, but we cannot guarantee complete confidentiality of the study data. Medical information created by the research study will not become part of your medical record and will be stored in a study research file with a specific study code without your name.

Your individual answers to the survey questions will remain confidential. The study team plans to publish the results of this research study and when we do, we may be asked to share data with other researchers. Your personal information will only be labeled with a code, not your name. No information that would let others know who you are or that you were in the study will be shared publicly.

Emotional Distress:

There are very few risks from doing the surveys. There is some risk that you may experience some anxiety or distress when answering survey questions about your illness, quality of life, or symptoms. If this happens, please tell your doctor and they will help you. You may also skip any survey questions for any reason.

If you feel upset by any part of the study, the research team and your doctor will be available to talk to you. You can also ask your doctor to arrange for you to meet with a social worker for counseling and support if needed.

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 health before and after your transplant. This information may tell doctors how to better help future patients like you know about transplant risks and benefits for older adults. We hope to use this knowledge to provide better care to patients 60 years and older.

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. We'll do our best to make sure that your medical and personal information is kept private. The study doctors can protect your records if there is a court case. 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.

Your personal information will 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 conferences or scientific meetings.

The research team will send you the online or paper surveys. They will also follow up by phone over the course of the study. To do that, *(Name of Transplant Center)* will securely share your contact information, including your name, address, email, and phone numbers, with the research team. Only the members of the CIBMTR research team who will be contacting you will have access to this information. If the research team 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.

Individual responses from your surveys will not be sent to your doctor or medical care team. However, if you complete the first visit survey on paper at *(Name of Transplant Center)* your doctor and medical care team may be able to see the results of that survey.

All your medical and demographic information (such as race and ethnicity, gender and 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.

People 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. If you agree to participate, you agree to such inspections and to the copying of 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.

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 Andrew Artz, M.D., M.S. and Mohamed Sorror, M.D., M.Sc.

Data collected during the study may be used for future research. If the study team does this, any private information will not be attached to you or your name in any way and results of the research done with these data will not be given to you.

A description of this clinical trial will be available on *https://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.

Data about your health, including follow up after one additional year may be obtained by the BMT CTN from the CIBMTR, which captures information on all US transplants.

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 other 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

This is an observational study and is unlikely to cause any injury as a result of your participation.

However, 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 this treatment. 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

Taking part in this research study will not lead to added costs to you or your insurance company. You and/or your health plan/insurance will still need to pay for the costs of the transplant or standard treatment that you will be receiving after transplant as part of your regular clinical care.

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 want 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 can 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)*.

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:

Composite Health Assessment Risk Model for Older Adults: Applying Pre-transplant Comorbidity, Geriatric Assessment, and Biomarkers to Predict Non-Relapse Mortality After Allogeneic Transplant(CHARM)

B. Individual Health Information to be Used or Disclosed:

My 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. Andrew Artz, Co-Principal Investigator

  Dr. Mohamed Sorror, Co-Principal Investigator

- The 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 oversee research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)
- U.S. government agencies that oversee 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: Composite Health Assessment Risk Model for Older Adults: Applying Pre-transplant Comorbidity, Geriatric Assessment and Biomarkers to Predict Non-Relapse Mortality After Allogeneic Transplant (CHARM)

PROTOCOL NUMBER: BMT CTN 1704

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 may not directly benefit from taking part in the study.
- I understand that the sponsor/sponsor representatives, IRB/EC and/or regulatory authorities may have direct access to my medical records.
- 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 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 have answered any questions the subject has asked, and I believe they have understood the information provided.

Name of Counseling Physician Date

Signature of Counseling Physician Date

Use of an Interpreter: *Complete if the subject is not fluent in English and an interpreter was used to obtain consent.*

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

Name of Interpreter Date

Signature of Interpreter Date