APPENDIX B

Informed Consent to Participate in Research

A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Age 50 or Older with Intermediate-2 and High Risk Myelodysplastic Syndrome

Your Name: _____

Study Title: A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Age 50 or Older with Intermediate-2 and High Risk Myelodysplastic Syndrome

Protocol: BMT CTN #1102

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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 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 known as a research study. You are invited to join this study because:

1) You have **myelodysplastic syndrome (MDS)**, also called myelodysplasia;

2) Your MDS is at an advanced stage. This means that you are at medium (intermediate) to high risk for your MDS to become acute leukemia or cause death; and

3) Your doctor recommends that you have an **allogeneic stem cell transplant (transplant)** if a donor is found whose DNA or tissue type matches your DNA or tissue type.

We are doing this study because we want to find out if patients with MDS who have a matched donor and get a **reduced-intensity conditioning (RIC) transplant** do better than those who get drugs to treat their MDS (no transplant).

This study also wants to learn more about the cost-effectiveness of transplant and collect extra blood and tissue samples for future studies.

(See **Section 2. Study Background** for a definition of the bolded terms)

This study will take about 6.5 years and will include about 338 – 400 participants from around the United States. We will collect information on how you're doing (your health condition and how you feel) for **3 – 4 years.**

This Consent Form tells you about the purpose of the study, the possible risks and benefits, other treatment options available to you, and your rights as a participant 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 benefit from taking part on the study. Knowledge we gain from this study may benefit others.
- If you join the study, you can quit the study 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 discuss how to best treat your MDS. Joining this study will affect your treatment decisions. If you don't want to participate in this study, we will not collect information on your health condition or how you're feeling.

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.

Myelodysplastic Syndrome (MDS), also called myelodysplasia, is a disease where the bone marrow does not make enough normal blood cells for the body. This can lead to a fast-growing blood cancer called acute leukemia. It mostly affects people who are 50 or older.

There are different ways to treat MDS. Some treatments use blood transfusions and drugs. These treatments can improve MDS and slow it from becoming acute leukemia. However, drugs don't cure MDS.

Allogeneic stem cell transplant (transplant) is another treatment option for advanced stage MDS. A transplant uses blood-making cells from a family member or an unrelated donor to remove and replace your abnormal blood cells. It requires a close tissue match between you and the donor.

Your donor could be a sibling (a sister or brother) or an unrelated person. We use the Be The Match® Registry to find unrelated donors.

The best experience with transplant for MDS is with well-matched sibling or unrelated donors. If you do not have one of these donors there may be other potential donor options such as umbilical cord blood or mismatched donors. Since the outcome from transplant with these donors is not as good, only well-matched sibling and unrelated donors are being offered on this trial.

A transplant first uses chemotherapy and radiation to destroy the abnormal blood cells or stop them from growing. For your MDS and your condition, your doctor wants to use lower amounts of chemotherapy and radiation. This type of transplant is called **reduced-intensity conditioning (RIC)** or non-myeloablative. There are different combinations of RIC drugs and radiation. Your doctor will decide on the best combination for you.

Because of your age or health problems, you may have a higher chance of side effects and health problems from a standard transplant that uses very high doses of chemotherapy and radiation. The possible benefit of RIC is

a lower chance of side effects. The possible risk of RIC is that the transplant will not stop your disease from growing or cure it. Your doctor will explain all of the risks and side effects of your RIC treatment.

Transplant cures MDS for some patients, but not all patients. However, patients often have side effects after both standard and RIC transplants. The side effects can be very serious, sometimes even causing death. We don't know if patients with MDS in an advanced stage do better with transplant or with drug therapy only (no transplant). Both treatments are common.

If you don't find a donor whose DNA or tissue type is a close match, you might be able to get a transplant that uses a donor who isn't a close match or that uses an umbilical cord blood unit (CBU). However, other research studies showed that transplants that use a less-closely matched donor or a CBU don't treat the disease as well, so transplants with these donor types are not included in this study.

3. Study Purpose

We are inviting you to join this study because you have MDS and your doctor recommends reduced-intensity transplant as a treatment option for you (if you find or have a matched donor).

The main goal of this study is to learn if MDS patients who have a matched donor and receive transplant do better than other MDS patients who don't have a donor and only get drugs to treat their MDS (no transplant). We want to know how well you're able to do your normal activities after your treatment. We will ask you survey questions (health evaluations) by phone after you start your treatment.

We also want to learn more about the cost-effectiveness of transplant (see **Ancillary Cost-Effectiveness Analysis Informed Consent Form (Optional)**) and collect extra blood and tissue samples for future research (see **Section 17: Blood and Tissue Samples for Future Research**). These studies are optional. This means you can still be part of the main study (health evaluations by phone) if you say 'no' to these studies.

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 or you want to leave the study, please contact:

[*insert contact info for site PI*]

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

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

5. Study Treatment and Tests

We will check your health condition before you start treatment and for 3 years after. You will not have to make any extra visits to your clinic or transplant center to be part of this study.

If you have not had a bone marrow biopsy within the last 60 days, you might need to have one before you join the study. Your doctor will tell you if you need a bone marrow biopsy.

Study Participation

If you join this study and you don't have a known sibling donor, your doctor will determine if you have a suitable matched donor. Your donor could be a sibling (sister or brother) or an unrelated person. If a donor is found within 90 days (about 3 months) of your consent to be on this study, you will have a transplant as soon as you and your doctor feel you are ready for it.

If we can't find a matched donor for you, you will continue to see your regular cancer doctor. Together, you and your doctor will decide on the standard treatment or a different treatment for your MDS. We will be in touch with you and your cancer doctor's office to collect information on how you're doing.

Once you and your doctor decide on your treatment, you will get more information about the treatment.

Health Evaluations

After you join the study, we will ask you questions about your health and how you're feeling over the phone.

We will also contact you by phone at:

- 6 months
- 1 year (12 months)
- 1 ½ years (18 months)
- 2 years (24 months), and
- 3 years (36 months)

These phone calls will take approximately 30 minutes each. These health evaluation follow-up phone calls are only for English- and Spanish-speaking participants.

Different treatments can work to treat MDS, but they can have different side effects. In this study, we want to find out how transplant makes people feel compared to how drug therapy only makes people feel.

We will use surveys to collect information on how you're doing. The surveys will ask you about:

- Your general health
- Any side effects you may have from your treatment
- How well you can do your normal activities
- Your feelings

You do not need to answer all of the questions or complete the surveys at all. It is okay to only answer the questions you feel comfortable answering. If any of the questions make you uncomfortable, you can skip them.

If your phone number 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]

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.

We will also give you the choice to provide a list of what you and your insurance company pay for your treatment (see **Ancillary Cost-Effectiveness Analysis Informed Consent Form (Optional)**) and extra samples of your blood and tissue for future research (see **Section 17: Optional Blood and Tissue Samples for Future Research**).

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. Your doctor will give you drugs to help ease side effects, such as feeling sick to your stomach (nausea). In some cases, side effects can be long lasting or never go away.

a) Risks and side effects of transplant

If you have a matched donor, the following general problems might happen from your transplant. Your doctor will explain the possible risks and benefits for the drugs used with your transplant before you get your transplant.

Anyone who has a transplant will experience the risks described below:

1. Slow recovery of blood counts. You will need blood and platelet transfusions after your transplant because red blood cells, white blood cells, and platelets can be slow to recover. This will make you at risk for bleeding and infections.

2. Graft failure. The peripheral blood or bone marrow stem cells (the "graft") may fail to grow inside your body. There is a low chance of this happening (about 1 out of 10 people), and can result in low blood counts for a long time. If your counts don't recover, you might need another transplant. Graft failure can be fatal.

3. Graft-Versus-Host Disease (GVHD). This happens when the graft sees your body as foreign and attacks it. Sometimes GVHD is serious or difficult to treat and may lead to death. In most cases, GVHD can be successfully treated.

Acute GVHD may produce skin rash, nausea, vomiting, diarrhea, stomach pain, abnormalities of liver function, and an

increased risk of infection. Chronic GVHD may produce skin rashes, hair loss, thickened dry skin, dry eyes, dry mouth, liver disease, weight loss, diarrhea, and an increased risk of infection. To diagnosis acute or chronic GVHD, you may need to have a biopsy (a small sample of your tissue for testing) of your skin, gut, or liver.

4. Damage to the vital organs in your body. The transplant could cause problems in any body organ such as the heart, lungs, liver, gut, kidneys and bladder, or brain. The kidneys and the liver are most likely to be damaged. Some patients will experience serious lung problems from infections, or the chemotherapy and radiation.

5. Serious infections. There is an increased risk of infections when your immune system is recovering. Most infections can be successfully treated, but some infections may result in death.

6. Relapse of MDS. Your MDS may come back even if the transplant is successful at first.

7. Risk to the unborn. Transplant has not been proven to be safe at any stage of pregnancy. If you are a woman and can become pregnant, it's very important that you aren't pregnant when you start the study and don't become pregnant while in the study.

8. Reproductive Risks. The drugs used in transplant may damage your reproductive organs, affect your ability to have children or possibly cause birth defects if you take them while you are pregnant. It is important that a woman is not pregnant or breast-feeding and does not become pregnant during the course of transplant.

- **If you are a woman and can become pregnant:**

  You will need to take a pregnancy test before you start transplant. You should discuss ways to prevent pregnancy while you are going through transplant.

- **If you are a man:**

  Your body may not be able to make sperm (become sterile). You should talk with your doctor about banking your sperm before having a transplant.

  Please check with your doctor to understand more about these risks.

b) Risks and side effects of RIC drugs

Your doctor decided that a RIC transplant is the best treatment for you if you have a matched donor.

The drugs used in RIC transplants are likely to cause infection, bleeding, feeling tired (fatigue), feeling sick to your stomach (nausea), and throwing up (vomiting). You might also have diarrhea, feel numb in your hands and feet, or notice changes in your eyesight.

Other side effects that are very rare (but serious if they happen) include a lung infection (pneumonia), feeling confused, coughing and trouble breathing, serious brain damage, and death. Your doctor will tell you more about the side effects of the

specific RIC drugs you will receive before you get your transplant.

c) Risks and side effects of drug therapy for MDS (no transplant)

If you don't have a matched donor, you will be treated with drugs for MDS. Your doctor will discuss with you more details about the side effects, risks, and benefits of these drugs. Some of the drugs can cause low blood counts, nausea, and stomach upset. Drug treatments can improve MDS and slow it from becoming leukemia. However, because drugs alone don't cure MDS, the risk of your disease coming back is very high.

d) Risks of being in this study

The 3 main parts to this study are health evaluations, optional cost-effectiveness of transplant research, and optional blood and tissue samples for future research. Each of these studies has their own risks. These risks are described below:

1. **Health evaluations by phone** (see **Section 5**). You may feel uncomfortable about some of the questions on the surveys. If this happens, you can skip these questions. You can also decide not to take the entire survey.

2. **Ancillary Cost-Effectiveness Analysis (Optional)** (see **Ancillary Cost-Effectiveness Analysis Informed Consent Form**). The risks to participating in the cost-effectiveness study are small. A possible risk is the loss of confidentiality of your medical information, but the chance that this information will be given to someone else is very small.

3. **Blood and Tissue Samples for Future Research (Optional)** (see **Section 17**). The risk of injury from having your blood taken is very small. If your blood samples are collected from your arm, you may bleed a little bit and/or develop a small bruise. Infection from blood draws is rare, but it may happen. If you are uncomfortable at the sight of blood, you may feel light-headed or faint. The risk of injury from having your bone marrow taken also is small. You may feel stiff or sore for several days afterwards. You may bleed a little bit and/or develop a bruise. The risk of injury from having a cheek swab from the inside of your mouth is very small.

4. **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.

7. Alternative Treatments

It is your choice to join this study. If you choose not to take part, you may still receive an allogeneic transplant to treat your MDS. Your treatment and evaluations could be very similar to what you would receive if you join this study.

The best experience with transplant for MDS is with well-matched sibling or unrelated donors. If you do not have a matched donor, you might be able to get a transplant that uses a donor who isn't a close match or that uses an umbilical cord blood unit (CBU). Since the outcome from transplant with these donors is not as good, only well-matched sibling and unrelated donors are being offered on this trial.

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 will not benefit from taking part in this study. Your participation in this study allows us to collect specific information about your treatment for MDS. You can still receive the same or similar treatments if you don't take part in this study.

Information from this study will help doctors learn more about treatments for MDS. This information could help people with MDS who may need a transplant in the future.

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 and medical conditions.

10. Privacy, Confidentiality and Use of Information

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record will be kept private. However, we can't guarantee total privacy.

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 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.

Individuals authorized by the organizations below will have access to your research and medical information. They may use this information for inspections or audits to study the outcomes of your treatment. In agreeing to participate, you consent to 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, Ryotaro Nakamura, MD and Corey Cutler, MD MPH FRCP(C)

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

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, 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 need a medical treatment not allowed in this study.
- The study doctor decides that it would be harmful to you to stay in the study.
- You are having serious side effects.
- You become pregnant.
- You cannot keep appointments.
- The study is stopped for any reason.

Even if you withdraw from the study, the information collected from your participation will be included in the study.

12. Physical Injury as a Result of Participation

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 taking part in this study.

You and/or your health plan will be charged for this treatment. The study will not pay for this treatment.

In case you are injured in this study, you don't lose any of your legal rights to receive payment by signing this consent form.

13. Compensation or Payment

You will not be paid for taking part in this study. You will not be compensated or reimbursed for any extra costs (for example, travel and meals) from taking part 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 speak 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. Blood and Tissue Samples for Future Research (Optional)

This section of the consent form is about future research studies that will use blood and tissue (blood, cheek cells, and bone marrow) samples from people who are

taking part in the main study. You may choose to give blood and tissue samples for these future studies if you want to. You or your insurance will not be charged for these research samples.

You can still be a part of the main study (health evaluations by phone) even if you say 'no' to give blood and tissue samples for future studies.

The risk of injury from having your blood taken is very small. If your blood samples are collected from your arm, you may bleed a little bit and/or develop a small bruise. Infection from blood draws is rare, but it may happen.

If you are uncomfortable at the sight of blood, you may feel light-headed or faint. Only trained people will draw your blood.

The risk of injury from having your bone marrow taken is small. You may feel stiff or sore for several days after the aspiration. You may bleed a little bit and/or develop a bruise. Only trained people will collect your bone marrow.

The risk of injury from having a cheek swab from the inside of your mouth is very small.

If you agree to provide blood and tissue samples, this is what will happen:

a.) We will collect 1 extra blood sample at the same time you have routine blood tests done before you start your treatment. We will collect about 4 tablespoons (50 mL). If you weigh less than 110 pounds (50 kg), the amount of blood we collect will be based on your weight.

b.) We will also collect cells from your mouth by gently rubbing a cotton swab on the inside of your cheek.

c.) Additionally, if you are going to get a transplant, we will also collect about ¼ teaspoon (1 mL) of bone marrow fluid and cells through a needle put into your bone (aspiration, if you and your doctor choose to perform this procedure) before you get your transplant.

The skin will be cleaned with a special solution and a medicine (local anesthetic) will be used to numb the area. Then the aspiration needle will be put through your skin and into your bone to reach the bone marrow. During an aspiration, you may feel a quick, shooting pain as the sample is taken.

d.) If you get a transplant and your MDS comes back:

a. We will collect another blood sample (no more than 4 tablespoons).
b. We will collect another ¼ teaspoon (1 mL) of bone marrow fluid and cells through a needle put into your bone (if you and your doctor choose to perform this procedure).

e.) The blood and tissue 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. All research samples will be

given a number that cannot be linked to you.

f.) Samples stored in the Repository will be used mainly by doctors and researchers in the BMT CTN network. In the future, the unused blood and tissue samples and health information will be made available outside of this network (see sections 'g' below).

g.) Researchers can apply to study the health information and blood and tissue 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.

h.) DNA from your stored blood and tissue 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 millions of genetic changes at the same time.

If your coded samples are used in such a study, the researcher is required to add your test results and sample information into a shared, public research database. This public database is called the NIH Genotype and Phenotype Database and it is managed by the National Center for Biotechnology Information (NCBI). The NCBI will never have any information that would identify you, or link you to your information or research samples although the results of genetic studies could theoretically include identifying information about you.

Your name and other information that could directly identify you (such as address or social security number) will not be placed into any scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is small, but may grow in the future. Researchers have a duty to protect your privacy and to keep your information confidential.

Some general things you should know about letting us store your blood and tissue samples for research are:

- We will only store samples from people who give us permission.
- Research is meant to gain knowledge that my help people in the future. You will not get any direct benefit from taking part. Additionally, you or your doctor will not be given results and they will not be added to your medical record.
- A possible risk is the loss of confidentiality about your medical information. We will use safety measures with both your samples and health information to make sure that your personal information will be kept private. It's very unlikely that your personal information will be given to someone else.

- Your blood and tissue 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. You will not get paid for any samples or for any products that may be developed from current or future research.

You can change your mind at any time about allowing us to use your samples and health information for research.

If you do not want us to use your blood and tissue samples or health information for research, we ask that you contact: *[Principal Investigator]* in writing. The mailing address is on the first page of this form.

However, samples and information that have already been shared with other researchers cannot be taken back or destroyed.

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 Consent for Optional Blood and Tissue Research Samples

The purpose of storing blood and tissue samples, the procedures involved, 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 allow the use of my blood and tissue for research.

If I decide to not let you store research samples now or in the future, it will not affect my medical care in any way.

I voluntarily agree that my blood, tissue, and information can be stored indefinitely by the BMT CTN and/or NHLBI Repositories for research to learn about, prevent, or treat health problems. I also understand that my DNA and clinical information may or may not be used in genome-wide association studies.

Blood and cheek samples

❑ I agree to allow my blood and cheek samples to be stored for research.

❑ I do not agree to allow my blood and cheek samples to be stored for research.

Bone marrow samples

❑ I agree to allow my bone marrow samples to be stored for research.

❑ I do not agree to allow my bone marrow samples to be stored for research.

_____ _____

Signature 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:

A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Age 50 or Older with Intermediate-2 and High Risk Myelodysplastic Syndrome

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 Investigator and the researcher's staff:

  Dr. Ryotaro Nakamura, Co-Principal Investigator

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

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

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 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 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 authorization does not have an expiration date.

TITLE: A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Age 50 or Older with Intermediate-2 and High Risk Myelodysplastic Syndrome

PROTOCOL NUMBER: BMT CTN 1102

PRINCIPAL INVESTIGATORS:

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- I have read and understood this Consent Form. The nature and purpose of the research study has been explained to me.
- I understand that I will have a transplant if a matched donor is found. If I don't have a matched donor, I will get the standard treatment.
- 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.
- 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 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