CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

A Multi-Center, Phase II Trial of HLA-Mismatched Unrelated Donor Bone Marrow Transplantation with Post-Transplantation Cyclophosphamide for Patients with Hematologic Malignancies

NCT02793544

Document date: 16Aug2018

Informed Consent to Participate in a Research Study

Throughout this document, references to "You" may stand for either the study subject or the parent/legally authorized representative of the study subject if the subject is younger than the legal age of majority under applicable law of the jurisdiction in which the research study will be conducted, or otherwise unable to legally give informed consent to participate in the research study.

The signature(s) at the end will clarify whether the study subject is signing this consent form on their own behalf or via a parent/legally authorized representative.

1. Title of Research Study

A Multi-Center, Phase II Trial of HLA-Mismatched Unrelated Donor Bone Marrow Transplantation with Post-Transplantation Cyclophosphamide for Patients with Hematologic Malignancies

2. Principal Investigator

[Enter name of Transplant Center Principal Investigator]

3. Contact Information for Emergencies After Hours or on Weekends or Holidays:

[Enter name(s) and phone number(s) for emergency contact person(s) at Transplant Center]

4. Sponsors and Source of Funding or Other Material Support

Be The Match® operated by the National Marrow Donor Program® (NMDP)

5. Introduction

This is a clinical trial, a type of research study. Clinical trials include only people who choose to take part. A clinical trial is a research study to answer specific medical questions. The information from this study may help future patients. This form tells you about the study. In addition, the study doctor (the person in charge of the research) will explain the study to you.

You are being asked to take part in this study because you have been found to have a cancer of the blood or lymph glands that may be treatable with stem cell transplantation (transplant) from a relative or unrelated donor. We and other transplant centers have the most experience using a donor who is a "perfect" or "close to perfect" tissue match to you. Tissue typing shows that you do not have a "perfect" or "close to perfect" relative or unrelated donor; however, you do have a mismatched unrelated donor (MMUD) who is a "partial match" to you.

You are being invited to participate in this study because your doctor has determined that the best option for treating your disease is a bone marrow transplant using a MMUD.

Please take your time to make your decision about taking part in this study. You may discuss your decision with your friends and family. You can also discuss it with the medical staff at the transplant center.

6. Purpose of the study

The purpose of this study is to see if using a MMUD is safe and effective in patients undergoing bone marrow transplant.

It is your choice whether or not you want to participate in this study. You and the medical staff at your transplant center will discuss other options before you make your decision about participating in this study.

As many as 80 patients will participate in this research study from medical centers throughout the United States.

7. Study Procedures

If you choose to participate in this study, your study doctor will check your general health to assure that you are eligible. Many of the tests and procedures listed below are part of your regular care. You may have had some of them done already. Your study doctor will determine if any of these tests or procedures will need to be repeated for you to participate in the study. Your participation in this study will end at approximately one year after your transplant.

Prior to transplant

A complete medical history and physical exam will be done before transplant. Other tests may include:

- blood tests (for both standard of care and research tests)
- urine tests
- breathing tests
- heart function test
- bone marrow tests
- CT/PET/MRI scans (only patients with lymphoma or Chronic Lymphocytic Leukemia)
- pregnancy test (for females of childbearing potential)

You will have a thin plastic tube (catheter) placed into a large vein in your chest (called a Hickman or central line). This will require surgery, and you will be asked to sign a separate consent form for this procedure. The catheter will be used for many of the drugs given in this study and for the required blood draws.

HIV-positive patients may have additional tests and evaluations performed prior to transplant. Some of the blood samples collected will be used for research.

Preparing for your transplant

The nurses and doctors count backwards from 6 to 0 when talking about the days before your transplant. Day -6 (minus 6) is the first day of the preparative regimen and Day 0 is the day of your transplant.

On this study, you will receive one of the three following treatments (as determined by your physician for your particular case):

Treatment A

- Fludarabine will be given by an intravenous infusion (through your vein) on Days -6 through -2.
- Cyclophosphamide (Cy) will be given by an intravenous infusion on Days -6 and -5.
- Mesna will be given by intravenous infusion before and after Cy on Days -6 and -5.
- Total body irradiation (TBI) will be given on Day -1.

Although a schedule is proposed above, the regimen can be given according to institutional standards.

Treatment B

- Busulfan will be given by either an intravenous infusion or by mouth on Days -6 through -3.
- You will also be given <u>one</u> of the two following treatments:
    - Cy will be given by an intravenous infusion on Days -2 and -1.
        - Mesna will be given by intravenous infusion before and after Cy on Days -2 and -1.
    - Fludarabine will be given by an intravenous infusion on Days -6 through -2.

Although a schedule is proposed above, the regimen can be given according to institutional standards.

Treatment C

- Cy will be given by an intravenous infusion on Days -5 and -4.
- Mesna will be given by intravenous infusion before and after Cy on Days -5 and -4.
- TBI will be given on Days -3 through -1.

Although a schedule is proposed above, the regimen can be given according to institutional standards.

<u>During your transplant</u>

On your transplant day (Day 0), the bone marrow will be given to you through your catheter, like a blood transfusion. The cells will travel to your bone marrow where they will start to make healthy, new blood cells after several weeks.

<u>Treatment after transplant</u>

The nurses and doctors count forwards from Day 0 when talking about the days after your transplant. Since Day 0 is the day of your transplant, days after your transplant are called Day+ (plus). For example, 3 days after your transplant would be called Day+3.

After your transplant, you will receive the following treatments:

- Cy will be given by an intravenous infusion on Days+3 and +4
- Mesna will be given by intravenous infusion before and after Cy on Days+3 and +4.
- Sirolimus will be given by mouth from Day+5 through Day+180
- Mycophenolate mofetil (MMF) will be given by mouth from Day+5 through Day+35
- Granulocyte-colony stimulating factor (G-CSF) (filgrastim) will be given by an intravenous infusion, or as an injection from Day+5 until a type of white blood cell (neutrophil) has achieved a certain level for 3 consecutive days

<u>Evaluations after transplant</u>

The following tests will be done weekly after your transplant:

- complete medical history and physical exam
- blood tests (some of these samples will be used for research)
- GVHD assessment
- toxicity assessment
- infection assessment

A chimerism test of your blood (to determine how well your new cells are growing) will be done at 28 days, 56 days, 100 days, 180 days, and 1 year after transplant.

Bone marrow tests will be done at 100 days, 180 days, and 1 year after transplant. Some of these samples will be used for research.

Patients with lymphoma or Chronic Lymphocytic Leukemia will have imaging studies (e.g. CT, PET, MRI) done at 100 days, 180 days, and 1 year after transplant.

HIV-positive patients may have additional tests and evaluations performed after transplant. Some of the blood samples collected will be used for research. While your participation in this study will end at approximately one year after your transplant, HIV-positive patients may be contacted by researchers at the Sidney Kimmel Comprehensive Cancer Centre at Johns Hopkins regarding additional research requests after study completion. A separate consent would be required to participate in that research.

8. Possible Discomforts and Risks

There are risks involved in this study. There may be side effects from the drugs or study procedures. The side effects we know about are described below. They may vary from person to person. Many of the side effects will go away. However, sometimes side effects can be very severe and long lasting. Everything possible will be done to lessen the side effects. Your doctor may suggest that you take certain drugs to reduce some of the side effects. You should know that some complications can be fatal.

Table 1: Risks and Side Effects

Likely	What it means: This type of side effect is expected in more than 20% of patients. This means that 21 or more patients out of 100 might get this side effect.
Less Likely	What it means: This type of side effect is expected in 20% of patients or fewer. This means that 20 or fewer patients out of 100 might get this side effect.
Rare, but Serious	What it means: This type of side effect is expected in fewer than 10% of patients. This means that 10 or fewer patients out of 100 might get this side effect. It doesn't happen very often, but is serious when it does.

BUSULFAN

Likely (>20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Abdominal discomfort • Constipation • Diarrhea • Dizziness • Fluid retention	• Cough • Liver disease • High blood pressure • Imbalance in electrolytes (necessary	• Cataracts (clouding of the lens of the eye) • Lung fibrosis (scarring of lung tissue with cough and shortness of breath)

• Headache • Heartburn • Difficulty falling asleep and staying asleep • Lack of appetite • Mouth sores • Nausea and vomiting • Runny nose • Skin rashes/hives • Irregular or no menstrual cycles • Fast heartbeat	blood salts) • High sugar levels in the blood • Infertility (unable to become pregnant (women) or get a female partner pregnant (men)) • Low blood pressure • Seizures • Difficulty breathing and shortness of breath	

FLUDARABINE

Likely (> 20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Decreased white blood cell count with risk of infection • Suppression of the immune system • Tiredness • Nausea and vomiting • Mouth sores • Fever • Skin rash/hives	• Diarrhea • Numbness and tingling in hands and/or feet related to irritation of nerves of the hand and/or feet • Changes in vision	• Pneumonia (inflammation in lungs, often from infection) • Agitation or nervousness • Confusion • Cough • Difficulty breathing and shortness of breath • Weakness • Severe brain injury and death • Coma

CYCLOPHOSPHAMIDE (Cy)

Likely (>20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Diarrhea • Damage to male (testes) and female (ovaries) sex glands • Fluid retention • Hair loss • Infertility (unable to become pregnant (women) or get a female partner pregnant (men)) • Irregular or no menstrual cycles • Loss of appetite • Nausea and vomiting • Suppression of the immune system • Decreased platelet count and increased risk of bleeding	• Bleeding in the bladder • Low red blood cell count • Damage to the fetus if you become pregnant while taking the drug • Abdominal pain • Skin rash/hives	• Allergic reaction • Lung fibrosis (scarring of lung tissue with cough and shortness of breath) • Severe heart muscle injury and death • Secondary (new) cancers

MESNA

Likely (>20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Diarrhea • Nausea and vomiting • Headache • Weakness	• Abdominal pain • Skin rash/hives • Low blood pressure • Joint and/or limb pain • Altered taste	

MYCOPHENOLATE MOFETIL (MMF)

Likely (>20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Diarrhea • Limited effectiveness of birth control • Abdominal pain • Nausea and vomiting • Headache • Tremors • Decreased white blood cell count, red blood cell count, and platelets with increased risk of infection • Suppression of the immune system • Increased blood cholesterols • High sugar levels in the blood • Imbalance in electrolytes (necessary blood salts) • Swelling of the hands, feet, ankles, or lower legs • Leg cramps	• Low red blood cell count • Skin rash/hives • Difficulty falling asleep or staying asleep • Dizziness • Altered taste • Joint and/or limb pain • Low blood pressure • High blood pressure • Damage/birth defects to the fetus if you become pregnant while taking the drug • Miscarriage	• Difficulty breathing and shortness of breath • Unusual bruising • Fast heartbeat • Weakness • Blood in stool • Bloody vomit • Change in vision • Allergic reaction • Progressive Multifocal Leukoencephalopathy (a rare disorder caused by a virus that damages the material that covers and protects nerves in the white matter of the brain (myelin))

SIROLIMUS

Likely (>20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Headache • High blood pressure • Suppression of the immune system • Fever • Nausea • Diarrhea • Constipation • Tremors • Kidney dysfunction	• Chest pain • Difficulty falling asleep or staying asleep • Vomiting • Skin rash/hives • Decreased platelet count and increased risk of bleeding • Low white blood cell count with increased	• Low blood pressure • Asthma • Cough • Fast heartbeat • Lack of appetite • Lung fibrosis (scarring of lung tissue with cough and shortness of breath) • Pneumonia (inflammation in lungs, often from infection)

• Back pain • Abdominal pain • High cholesterol • High triglycerides (type of fat found in blood) • High sugar levels in the blood • Swelling of the hands, feet, ankles, or lower legs • Low red blood cell count • Acne • Joint and/or limb pain	risk of infection • Itchiness • Difficulty breathing and shortness of breath • Heartburn • Mouth sores • Imbalance in electrolytes (necessary blood salts) • Abnormal liver tests • Urinary tract infection • Upper respiratory infection • Delayed wound healing • Abnormal amount of protein in urine • Increased blood clotting in small blood vessels throughout the body (called TTP) • Abnormal premature destruction of red blood cells (called HUS and TMA)	• Kidney disease • Congestive heart failure • Skin cancer • Weakened bones • Bone tissue death • Flu-like syndrome • Fluid around abdomen • Excessive growth of lymphatic cells • Muscle pain • Fluid around lungs • Fluid around heart

TOTAL BODY IRRADIATION (TBI)

Likely (>20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Weakness • Hair loss • Infertility (unable to become pregnant (women) or get a female partner pregnant (men)) • Loss of appetite • Nausea and vomiting • Fever	• Cataracts (clouding of the lens of the eye) • Inflammation of the salivary gland • Skin pigmentation (reversible) • Stunted growth • Low white blood cell count with increased risk of infection • Low red blood cell count • Suppression of the immune system	• Diarrhea • Lung fibrosis (scarring of lung tissue with cough and shortness of breath) • Secondary (new) cancers

FILGRASTIM (G-CSF)

Likely (> 20%)	Less Likely (≤ 20%)	Rare, but Serious (<10%)
• Ache or pain inside the bones • Headache • Tiredness • Difficulty falling asleep or staying asleep	• Local irritation (skin) at the injection site • Nausea and vomiting • Low number of platelets in the blood	• Allergic reaction • Low fever • Enlargement or rupture of the spleen • Worsening of pre-existing skin rashes

RISKS OF BONE MARROW TRANSPLANTATION IN GENERAL:

Graft vs. Host Disease (GVHD): This occurs when the donor's white blood cells recognize your body as "foreign." The donor's cells then attack the cells of your body. GVHD can be mild or severe. In the most severe cases, it can cause death. You will be watched closely for this complication and given specific treatment to prevent and treat it. GVHD is treated with drugs that weaken the immune system. This makes you more likely to get infections. Treatment of GVHD may last from months to years. One of the most common treatments for GVHD is prednisone. Prolonged treatment with prednisone may result in cataracts, bone loss, diabetes, high blood pressure, bone fracture, and muscle loss.

There are 2 forms of GVHD: acute (early) and chronic (late) GVHD. Chronic GVHD occurs most commonly in patients who have had acute GVHD, but may occur in patients who did not have any acute GVHD.

Symptoms of Early or Acute GVHD (seen in 60-70% of subjects)
• Skin rash • Diarrhea • Nausea and vomiting • Abdominal pain or cramping • Increased risk of infection • Liver disease (inflammation of the liver and yellowing of the skin)

Symptoms of Late or Chronic GVHD (seen in 30-40% of subjects)	
• Skin rash • Hair loss • Thickened skin • Dry mouth • Dry eyes	• Diarrhea • Increased risk of infection • Liver disease or inflammation • Lung disease (scarring of the lungs)

Graft Failure: This occurs when your body does not accept the transplanted cells. Graft failure may occur in 5-10% of subjects. We do not know how likely graft failure is in a protocol like this one that does not completely kill the marrow before transplant. It is also possible that the blood stem cells will grow, but not work normally. This will result in low blood counts for a long period of time. If graft failure occurs, you may be able to have a second transplant with cells from the same donor or from another donor, if another donor is available. Graft failure may result in death from infections, low red blood cell count or bleeding.

Damage to the vital organs in your body: This could affect any organ in your body such as heart, lungs, liver, gut, kidneys and bladder, brain, etc. Some subjects will experience severe lung problems due to infections and/or due to a reaction of the lungs to the chemotherapy and/or radiation. Some subjects can suffer veno-occlusive disease of the liver (VOD). VOD is damage to the liver that can occur as a result of transplant. Symptoms and signs include yellowing of the skin (jaundice), a swollen and painful liver, fluid retention, weight gain and abnormal liver tests. In severe cases, VOD can lead to liver failure or even cause death.

Serious Infections: Your immune system will be not be normal for many months after the transplant, and the white blood cells that fight infection will be very low or not functioning well. During this time, there is an increased risk of viral, fungal or bacterial infections. You will be prescribed certain medications to reduce the chance of those infections. However, preventive treatments are not always effective. If you develop an infection you may have to stay in the hospital longer or be re-hospitalized after transplant. Infections can be very serious or cause death.

Recurrence of cancer: There is a chance that the transplant will not cure your disease or that it returns even if the transplant is initially successful.

REPRODUCTIVE RISKS

For pregnancy/risk to fetus (For Women): The treatments in this study have not been proven to be safe at any stage of pregnancy. **You should not become pregnant or nurse your baby while on this study**. If you are sexually active you and your male partner(s) must use a combination of two methods of birth control or you must not have sexual intercourse. Effective birth control methods include: 1) refraining from all acts of vaginal intercourse (abstinence); 2) consistent use of birth control pills; 3) injectable birth control methods (Depo-Provera); 4) tubal sterilization or male partner who has undergone a vasectomy; and 5) use of a diaphragm with contraceptive jelly and/or condoms with contraceptive foam, with every act of intercourse. You will have to use birth control or abstain from having sexual intercourse the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

For pregnancy/risk to fetus (For Men): Causing a pregnancy while receiving treatment on this study can affect a fetus. If you are sexually active you and your female partner(s) must use a combination of two methods of birth control or you must not have sexual intercourse. Effective birth control methods include: 1) refraining from all acts of vaginal intercourse (abstinence); 2) consistent use of birth control pills; 3) injectable birth control methods (Depo-Provera); 4) tubal sterilization or male partner who has undergone a vasectomy; and 5) use of a diaphragm with contraceptive jelly and/or condoms with contraceptive foam, with every act of intercourse. You will have to use birth control or abstain from having sexual intercourse the whole time you are on therapy on this study. If a sexual partner becomes pregnant during the research study, please tell the investigator and ask your partner to tell her doctor immediately.

Sterility and future childbearing potential for males and females: Chemotherapy and/or radiation may affect fertility. Male subjects may become sterile (unable to produce sperm). Female subjects may find that their menstrual cycle becomes irregular or stops permanently. However, this does not mean that you cannot become pregnant, and you must use some effective method of birth control. Damage to reproductive tissue may result in birth defects or permanent inability to father a child or become pregnant. You should discuss these risks and options in detail with your doctor and the investigator before entering this study.

OTHER RISKS

There is small risk that an unauthorized person could find out which data are yours. Your transplant center and the Center for International Blood & Marrow Transplant Research (CIBMTR) will take every precaution to make sure that this does not happen. Your data will only be labeled with a number code.

As with any research study, there might be side effects that are unknown at this time. You will be monitored for the occurrence of side effects and should report any unusual events to the study staff.

9. Possible Benefits to Being in the Study

It is not known if you will benefit from participating in this study. The knowledge gained from this study may help future patients who have a stem cell transplant using a mismatched unrelated donor (MMUD).

10. Alternatives to Participation

Participation in this study is voluntary. You do not have to be in this study. Your choice will not affect current or future health care you receive at this institution. Before you decide to be in this study, you and the medical staff will discuss other options available to you. Your other choices may include:

- Treatment with other drugs, radiation, or a combination of drugs and radiation without a transplant.
- A bone marrow, blood stem cell, or cord blood transplant that is not part of this study.
- Participation in another study.
- No treatment at this time.

Talk to your study doctor about your choices before you decide if you will take part in this study.

11. Cost of Participating in the Study

You will not be responsible for any additional costs related to study procedures. Your participation in this study should not result in any costs other than those associated with the treatment of your disease. Some tests and procedures that are provided as part of regular care will not be paid for by the study sponsor. You or your insurance carrier will be charged or held responsible for the costs of that care. Some insurance companies or government health care programs may limit what they will pay for certain routine services that are performed in a research study, in which case, you may be responsible. For questions about your costs, financial responsibilities, and/or medical insurance coverage for your transplant and this study, please contact *[Enter Transplant Center financial counselor name] at [Enter Transplant Center financial counselor].*

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://www.cancer.gov/clinicaltrials/learningabout. 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.

12. Reimbursement for Participating in the Study

You will not be paid for your participation in this research study. You will not receive compensation or reimbursement for any extra expenses (travel, meals, etc.) you may incur through your participation on this trial.

13. In the Event of Injury While Participating in the Study

If you are injured or become ill while taking part in this study, medical care will be provided at this center. If you think you may have experienced a research-related injury please contact your doctor, or one of the people listed at the top of this form. No funds have been set aside to pay you if you are injured. You or your insurance company will be charged for ongoing medical care and/or hospitalization.

You do not give up any legal rights by signing this form.

14. Protection of Your Privacy and Confidentiality of Your Research Records

Your participation in this research study will be kept private and confidential. Your medical information including demographic information (such as race and ethnicity, gender and household income) will be kept private and confidential. *[Enter Transplant Center name]* 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 by a regulatory agency.

Individuals authorized by the organizations below may request access to your research and medical records for inspections or audits. In agreeing to participate, you consent to such inspections and to copying of excerpts from these records, if required by their authorized representatives.

a. *[Enter Transplant Center name]*
b. Institutional Review Boards (IRBs) responsible for this study
c. National Marrow Donor Program (NMDP)
d. Center for International Blood and Marrow Transplant Research (CIBMTR)
e. CIBMTR Data and Safety Monitoring Board (DSMB), not part of [*Enter Transplant Center name]*
f. Sidney Kimmel Comprehensive Cancer Centre at Johns Hopkins (HIV-positive patients only)

Scientific and medical findings resulting from a study may be presented at meetings and published so that the information can be useful to others. You will not be identified in these presentations or publications.

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.

15. Voluntary Participation in and Withdrawal from the Study

It is up to you if you want to participate in this study. If you choose not to participate in this study, this decision will not affect your right or access to health care or any other services that you are entitled to receive.

If you decide to participate, you may withdraw at any time. There will be no penalties if you withdraw from the study. You will not lose any benefits to which you are entitled, and you will continue to receive medical care.

If you choose to withdraw from the study, please tell *[Enter Transplant Center PI name] at [Enter Transplant Center PI phone number]*.

[Enter name of Transplant Center Principal Investigator, the Sponsor, the Institutional Review Board may stop the study at any time. The investigator(s), your doctor, or the Sponsor may remove you from the study at any time without your permission.

It may be necessary to stop taking part in this study if:

- Your condition does not change or gets worse.
- You are not able to follow the study requirements.
- The research study is no longer safe for you.
- Another treatment may be more helpful.
- The study stops for safety reasons.
- *[Enter Transplant Center name]* is no longer taking part in the study

If you withdraw or you are removed from the study for any reason, the study doctor may ask to continue to follow you in order to monitor your safety.

Even if you leave the study, the information collected from your participation will be included in the study results, unless you specifically ask that it not be included.

You will be informed of any new findings which may affect your health, welfare, or willingness to stay on the study.

16. Questions or Concerns about the study

If you have questions, concerns or complaints about this study, please contact:
[Enter Transplant Center study contact name] at [Enter Transplant Center study contact phone number].

If you have questions or concerns about your rights as a research subject or about potential risks and injuries, please contact: [*Enter Transplant Center Research Subjects Protection Office contact name]* at *[Enter Transplant Center Research Subjects Protection Office contact phone number].*

If you wish to contact an independent third party not connected with this study about problems, concerns, questions, information, or input, please contact a Patient Services Coordinator with the Be the Match Patient Services at 1-888-999-6743 or patientinfo@nmdp.org.
[*Enter Transplant Center office of research subject advocacy contact information].*

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

Subject's Statement of Consent

I have been informed about this research study's purpose, procedures, possible benefits and risks. I have been given a chance to ask questions and have had them answered to my satisfaction. I understand that I can ask more questions at any time.

I voluntarily agree to participate in this study.

By signing this consent form as a subject in a research study, I have not given up any of the legal rights which I otherwise would have.

_____ _____

Signature of Subject *Date*

_____

Print Name of Subject

Parent/Legally Authorized Representative Consent

_____ _____

Signature of Parent/Legally Authorized Representative *Date*

_____

Print Name of Parent/Legally Authorized Representative

Certification of Counseling Healthcare Professional

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.

_____ _____

Signature of Counseling Healthcare Professional *Date*

_____

Print Name of Counseling Healthcare Professional

NATIONAL MARROW DONOR PROGRAM®
INSTITUTIONAL REVIEW BOARD

CONSENT FORM APPROVAL DATE:
AUGUST 16, 2018

Do not sign this form after the Expiration date of: **August 15, 2019**

Use of an Interpreter: Complete if an interpreter was used to obtain consent from the subject/parent/legally authorized representative

Subject/parent/legally authorized representative who is not fluent in English:

☐ An oral translation of this document was administered to the subject/parent/legally authorized representative in _____ [language understood by subject/parent/legally authorized representative] by an individual proficient in English and _____ [language understood by subject/parent/legally authorized representative]. See attached short form for documentation.

Subject/parent/legally authorized representative who is deaf or hard-of-hearing requiring sign language communication:

☐ A sign language interpretation of this document was administered to the subject/parent/legally authorized representative by an individual proficient in sign language.

Print name of Interpreter: _____ Date: _____

Signature of Interpreter: _____

English-speaking subject/parent/legally authorized representative who is illiterate and/or legally blind

I attest to the following:

☐ Consent document was read to the subject/parent/legally authorized representative.

☐ Subject/parent/legally authorized representative can understand and comprehend spoken English, but is physically unable to talk or write.

☐ Subject/parent/legally authorized representative is competent (i.e. able to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally) and able to indicate approval or disapproval for study participation by other means.

Method used for communication with subject/parent/legally authorized representative:

_____

Specific means by which the subject/parent/legally authorized representative communicated agreement to participate in the study: _____

Print name of Witness*: _____ Date: _____

Signature of Witness: _____ Time: _____

****A witness is a person who is independent from the trial or a member of staff who not involved in obtaining consent.***