INTRODUCTION TO RESEARCH STUDIES

You are invited to voluntarily participate in a research study of the addition of a low dose of total body irradiation (TBI) to a standard preparation for transplant [total lymphoid irradiation (TLI) and anti-thymocyte globulin (ATG)], being conducted by Robert Lowsky, MD, at the Stanford Cancer Center. You were selected as a possible participant in this study because you have leukemia; lymphoma; myelodysplastic syndrome (MDS); or a myeloproliferative disorder. These are all cancers or cancer-related conditions.

This document is to be used as a guide for a discussion between you and your Study Doctor and the study team. This form, called an informed consent document, was designed to help you understand why this study is being done; what part of the study is “research” or “experimental;” what will be asked of you if you choose to participate; possible risks; any inconveniences or discomforts you may experience; and other important information. This form may also be helpful as a reference if you choose to participate, as a reminder of what your role in the study is, and who to contact if you have questions at any time during your participation. You are urged to discuss any and all questions you have about this study with members of the study team. If you wish, you can also discuss this study and your role with your family doctor or medical provider.

PURPOSE OF RESEARCH

All the procedures in this study, TBI; TLI; ATG, and donor (allogenic) peripheral blood stem cell (PBSC) transplant (aka, hematopoietic cell transplant, HCT), are established or approved procedures or drugs for cancer, but it is not known if this combination might be a better treatment for you. The study team hopes to learn if the addition of a low dose of total body irradiation (TBI) will improve the chance the transplanted donor cells will grow, and improve your overall treatment for your cancer. How well this treatment will work also depends on the healthy immune system of the donor, to help destroy the tumor cells in your blood and/or bone marrow.

Your normal medical care would also include medical exams and blood tests, and medical scans to check the status of your cancer such as positron emission tomography (PET); computed tomography (CT); or magnetic resonance imaging (MRI) scans. Your normal medical care might also include radiation treatments, depending on the details of your cancer.

A bone marrow examination will be done to see if you are eligible to participate in this study. A bone marrow examination is routinely done prior to HCT and not considered research.
If you decide to terminate your participation in this study, you should notify Robert Lowsky, MD at [redacted].

This research study is looking for about 50 people with leukemia; lymphoma; MDS; or a myeloproliferative disorder. The study is being done at Stanford University, and expects to enroll all research study participants.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

It is planned that each participant will take part in this study for about 1 year, ± 8 weeks. Per regular medical care for HSC transplant patients, all recipients will be followed long-term and tracked via the Stanford BMT patient database for overall survival, event-free survival, and late complications such as but not limited to relapse; late chronic GVHD; and infections.

Information about the end of your participation in the study is provided under “Withdrawal from the study.”

PROCEDURES

It may be harmful to enter this study while receiving some medications, therefore, you may need to stop taking certain medications. Your Study Doctor will review your medications and provide you with specific instructions.

Research studies are usually dividing into at least 3 parts, typically consisting of:

1. Testing to see if you are eligible to participate in the study (“Screening”);
2. Testing during study treatment to monitor your health and the effects of the study treatment (“Study Evaluation Procedures”); and
3. Testing after your treatment is complete (“Follow-up”). Testing/procedures for each of these parts are described separately below.

Some of these examinations, tests, or procedures may be part of your regular medical care, and/or and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated.
Before you join this study, Dr. Lowsky and/or the research study team will review this document with you, and ask you to sign this informed consent document. After you have signed this document, and received a signed copy, the study will begin with a Screening Visit.

**Screening Visit**

If you choose to participate, the first activity after informed consent will be screening. During the Screening Visit, you will be asked to have the following tests and activities or assessments. The Screening Visit should occur between Day -42 to Day -12 relative to the PBSC HCT.

**General information:** Information about you, such as date of birth; gender (sex); and ethnic origin (“demographic information”)

**Medical history:** Your complete medical history will be reviewed, including:

- Review of all medicines and/or supplements you are taking or have been taking
- Questions about any medical symptoms you are having
- Surgery and cancer history
- Tobacco and alcohol use
- Reproductive status

**Physical examination:** A complete physical exam will be performed, including:

- Your vital signs, including height; weight; breathing rate; heart rate; blood pressure; temperature; and other measurements
- General examination of your body systems, such as heart and lungs; ear, nose, and throat; skin; muscles and joints; stomach and gastrointestinal tract; and nervous system

**Donor evaluation:** The prospective donor for your HCT will be evaluated according to standard criteria. Your donor must be an adult and have substantially similar tissue to you, i.e., be an HLA-matched or single allele-mismatched sibling; half-sibling; or unrelated donor.

**Blood collection:** Blood collections will typically be from the central venous access port, or from a vein in your arm using a blood collection needle (“venipuncture”). Standard aseptic (clean) techniques will be used. Less than about 3 tablespoons (45 mL) of blood will be collected for:

- **Complete blood count (CBC) with differential**, including red blood cells (RBC, oxygen-carrying cells): white blood cells (WBC, infection-fighting cells); platelets; and other blood components.
Serum chemistry or “Comprehensive Metabolic Panel,” consisting of tests for blood chemicals that indicate how well your body and organs are working, and if you have any significant diseases. You may be asked to not drink or eat anything (“fast”) for several hours before the test.

Serum pregnancy test for beta-HCG (if you are a woman who can become pregnant). The pregnancy test must be negative to participate in the study.

Blood test the human immunodeficiency virus [“HIV;” the virus that causes acquired immunodeficiency syndrome (AIDS)]. People who are HIV-positive cannot participate. This test is required in order to participate in this study. If you test positive for HIV, counseling will be provided.

Notice pursuant to California Senate Bill 699 (April 2006): Health care providers and laboratories such as those involved in this study are required to confidentially report positive HIV test results by patient name to the San Mateo County Dept of Public Health and to the California Dept of Health Services. You have the right to refuse the test for these viruses, but you will not be able to be in this study. Additional important information is provided below.

- There are numerous treatment options available to the patient who tests positive.
- There is a risk of false negatives (a false negative is a test result that indicates a person does not have a condition, but they really do).
- There is a need for routine testing.
- For more information, see California Health and Safety Code 120990.

A blood sample for short tandem repeat (STR) analysis. STR analysis is a measure of how well the donor cells are engrafting. The sample collected at Screening is for comparison to later samples collected after treatment.

Bone marrow biopsy, consisting of a standard collection of a sample of the marrow from within a large bone, typically from the back (posterior) or front (anterior) part of your hip bone (pelvis). The complete tissue sample, called a “biopsy,” usually has a small piece of bone and a sample of the pulpy marrow material from within the bone, called the “aspirate.” The doctor will give you a local painkiller, and make an incision over the bone to be sampled, and a large needle will be used to collect the sample. Tell the doctor if you think this will make you very uncomfortable. The biopsy will be used for a type of microscopic evaluation called “cytogenetics” and other testing to determine or confirm your diagnosis.

Disease status assessment: The severity of your cancer will be assessed during the physical exam above, and by an evaluation by medical scan within 28 days of starting study treatment. These scans look at the blood flow and the extent and activity of your cancer, and are a part of your regular medical care (Standard-of-Care, SOC). The radiologic evaluation may be computed tomography (CT) scan; positron emission
tomography (PET) scan; magnetic resonance imaging (MRI), and/or an alternate scan as medically necessary. Regardless of which scan will be conducted, these scans are part of your regular medical care for a patient with cancer such as yours. These procedures are described below:

**Magnetic Resonance Imaging (MRI):** An MRI, which does not require a radiation exposure, may be used in place of a CT scan or other radiologic scan. The scan will take about 30 to 60 minutes. The MRI scan evaluates blood flow and the extent of the cancer. The MRI will be performed according to standard practice. MRI machines use a powerful magnet and radiofrequency fields to make images of the body interior. An MRI scanner is large, tunnel-shaped machine, and uses a strong magnet and radiofrequency magnetic fields to make images of the body interior. This magnet is very strong, and will strongly attract or pull on some metals and affect some electronic devices, including magnetic access cards, and the magnetic strip on credit / debit / ID cards. Do not bring any metal objects into the magnet room. Any metal objects that you are carrying or have in your body could be attracted by the magnet and be a hazard to you or others. Any metal objects, such as but not limited to watches; hearing aids or other removable medical devices; jewelry / rings; credit / debit / ID cards; access cards; should be removed before entering the MRI magnet room. You will be provided a way to secure these items. Because the magnetic field is so strong, **tell the study team now, and ALSO TELL the MRI operator before entering the MRI magnet room**, if any of the following apply to you.

- **IT IS VERY IMPORTANT THAT YOU IMMEDIATELY TELL THE STUDY DOCTOR AND THE MRI OPERATOR** if you have a cardiac pacemaker or any other biomedical device in or on your body.
- You have any other metal objects in or on your body, such as:
  - Metal plates; pins; screws; surgical clips
  - Medical devices, including hearing aids
  - Other implants
  - Metal fragments in your body, such as bullet fragments or shrapnel fragments
  - Piercings
- You have ever had a head or eye injury involving metal fragments;
- You have ever worked in a metal or fabrication shop;
- You have a history of severe allergies, or have previously had a reaction to a Gadolinium-based contrast agents.
- You have, or previously had, kidney problems, or
- You are or could be pregnant.
Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

In some cases, these could mean you should not have an MRI scan performed.

The scanning procedure is very much like an X-ray, but uses a strong magnetic field instead of X-rays. You will not be able to feel the magnetic field. You will be asked to lie on a long narrow bench for up to 45 minutes while the machine performs the scan. You will be asked not to move during the scan and to relax and breathe normally. During this time, you will not be exposed to X-rays, but rather the magnetic field. During the scan, the bench you are lying on will move into a narrow space in the scanner. Many steps have been taken to make the procedure comfortable, but you may still experience some discomfort or anxiety ("claustrophobia") from being in this confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. The scanner will make repetitive tapping noises, which can seem very loud inside the scanner. You may be provided with earplugs or headphones to wear.

A computed tomography (CT) scan (an "X-ray") may be performed according to standard practice. The CT scan will be used to look at the blood flow and the extent and activity of your cancer. This scan is part of your normal medical care. The scan will take about 30 to 60 minutes. You may be asked to not drink or eat anything ("fast") for several hours before the scan. You will need to remove all jewelry, piercings, and other metal items. A tourniquet will be applied to your arm or leg to help find a vein, and a contrast agent will be injected into a vein, or may be administered orally if needed. The entire scan procedure will take about 30 to 60 minutes. You will be asked to lie still on a long narrow bench, or scanner bed, for up to 45 minutes. You will be asked not to move during the scan and to relax and breathe normally. A strap and/or pillows may be placed across your body to prevent movement. You may experience some discomfort or anxiety from being in the confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. During the CT scan procedure, the scanner will rotate around you, and make clicking sounds, which is normal. Tell the CT technician immediately if you have any breathing difficulties; sweating; numbness; or unusual changes in your heart rate.

A positron emission tomography (PET) scan alone or in combination with a CT scan (PET/CT) may be performed according to standard practice. A PET scan is a computerized image that looks at blood flow and the extent and activity of the cancer in your entire body. This scan is part of your normal medical care. PET scans use a radioactive material called a "radio-isotope;" "radio-tracer;" or "radiolabel." A tourniquet will be applied to your arm or leg to help find a vein, and a small amount of
A standard radioactive tracer will be injected into a vein about 1 hour before the scan. The radiolabel accumulates in areas of the body that are metabolically active, and this accumulation is detected by the scanner. Tumors are usually very metabolically active, more so than normal tissues. You will be asked to lie on a long narrow bench for up to 45 minutes while the machine performs the scan. You will be asked to not eat or drink anything but water (ie, “fast”) for about 4 to 6 hours before the scan. The entire procedure will take about 30 to 60 minutes. You may experience some discomfort or anxiety from being in the confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. The camera will record the tracer’s signal as it travels through your body.

**Location:** The location of the Screening Visit will be at Bone Marrow Transplant (BMT) Clinic (Clinic F), 875 Blake Wilbur Dr, Stanford Cancer Institute of the Stanford University Medical Center, or an alternate location. The study team will confirm the location of the Screening Visit.

Medical imaging will be performed at the following clinic locations. The Study Team will let you know which of these locations, or a different location, that you need to go to.

- **Stanford Hospital**
  - MRI department, ground floor
  - 300 Pasteur Dr
  - Stanford, CA 94305
  - Phone [redacted]

- **Stanford Cancer Center**
  - Blake Wilbur Building
  - Radiology, ground floor
  - 900 Blake Wilbur Dr
  - Palo Alto, CA 94306
  - Phone [redacted]

- **Stanford Medicine Outpatient Center**
  - Pavilion B
  - 450 Broadway St
  - Redwood City, CA 94063
  - Phone [redacted]

  **Stanford Medicine Imaging Center**
  - 451 Sherman Ave
  - Palo Alto, CA 94306
  - Phone [redacted]

The study includes radiotherapy treatments, which will be administered in the radiotherapy suite (ground floor, ie, basement) at 875 Blake Wilbur Dr, Stanford Cancer Institute.

**Women of Childbearing Potential**

If you are pregnant or currently breast-feeding, you may not participate in this study. It is not known whether the Study Drug is safe for the fetus (unborn child) or a breast-fed baby.
Study Treatment Procedures

All participants in this study will receive the same treatment, consisting of transplant conditioning; and infusion of mobilized peripheral blood stem cells (PBSC) from an HLA-matched or single-mismatch donor, and transplant support. This procedure is called a hematopoietic cell transplant (HCT). Your PBSC donor may be a sibling; half-sibling; or unrelated. All agents or procedures used in this study are approved or medically established agents / procedures. This study uses those procedures in a different way.

Treatment Procedures

- **Days -11 to -1.** You will then receive the conditioning regimen which is a combination of total lymphoid irradiation (TLI) and anti-thymocyte globulin (ATG) to weaken your immune system sufficiently so that the donor’s hematopoietic cells (PBSC) will grow and function as your new immune system.
  - TLI will be administered on about 9 separate days before PBSC infusion starting on a Monday designated Day -11 continuing to Day -1, (Days -6 and -5 will be a Saturday and a Sunday, and are skipped).
  - You will receive 5 doses of ATG which will be administered intravenously through the central venous catheter.

- **Day -1.** For this research study, you will also receive a single, low-dose of total body irradiation (TBI). TBI will be administered on Day -1, (same day as the last TLI regimen).

  Overall, the TLI and TBI conditioning regimens are considered non-myeloablative conditioning, meaning that your own immune system will not be completely killed and replaced by the donor PBSC.

- **Day -3.** Treatment starts with tacrolimus. Tacrolimus can be taken as a pill or intravenously (through the catheter), and is used to try to prevent or minimize graft vs host disease (GvHD) by weakening the immune system. GvHD is an immune reaction where certain components of the donor’s PBSC attack your body tissues. Tacrolimus treatment will continue for at least 6 months, and treatment may need to be extended if GvHD develops.

- **Day 0.** The donor PBSC (hematopoietic cells) will be infused on Day 0, a Friday. The hematopoietic cell infusion is like a blood transfusion. These cells are often called stem cells. 2 to 4 weeks after the infusion of the PBSC, your blood counts should begin to recover.
Overall, this type of conditioning and PBSC is called a non-myeloablative allogeneic transplant. The donor cells will hopefully grow and replace your immune system. The success of this procedure depends on the donor’s immune system recognizing and destroying any residual malignant/diseased cells in your body.

- **Day 0.** Mycophenolate mofetil (MMF) treatment starts. MMF is another immune-suppressing agent that are intended to prevent or minimize GvHD. MMF will be given as a pill 2 or 3 times a day. If your donor is a sibling, MMF treatment will continue for approximately 1 month. If your donor is an unrelated volunteer, the mycophenolate mofetil will continue for approximately 3 months. MMF treatment may need to be extended if GvHD develops.

- Administration of supportive medications and blood transfusions, as needed.

**Location:** The location of the Study Treatment Visits will be in Bone Marrow Transplant (BMT) Clinic (Clinic F) or an alternate location, as described above.

Medical imaging will be performed at the locations described above.

The study includes radiotherapy treatments, which will be administered in the radiotherapy suite (ground floor, ie, basement) at 875 Blake Wilbur Dr, Stanford Cancer Institute.

**Study Evaluation Procedures**

The day of the PBSC infusion (HCT) procedure is considered Day 0 of the study. You will have routine assessments every week after the PBSC procedure.

You will have formal study visits to assess your progress and health status at 4 weeks (28 days ± 7); 8 weeks (56 days ± 14); and 90 days (± 14 days). The following procedures or assessments will occur.

**Medical history:** Your complete medical history will be updated, as described above.

**Physical examination:** as described above.

**Blood collection:** as described above, including for STR analysis. Less than about 2 tablespoons (30 mL) of blood will be collected.

- A blood sample for short tandem repeat (STC) analysis. STR analysis is a measure of how well the donor cells are engrafting. The sample collected at Screening is for comparison to later samples collected after treatment.

**Bone marrow biopsy,** as described above.

**Disease status assessment:** You will have a treatment response / disease status assessment at 90 days (± 14 days), as described above.
6 and 12 months after HCT

In addition, you may have a treatment response / disease status assessment as appropriate at 6 months (180 days ± 14 days) and 12 months (360 days ± 14 days). The exact assessment will be determined based on your type of disease, may include CT, PET, and/or MRI imaging, and bone marrow biopsy or aspiration, as described above.

Also at these timepoints, you will have a blood sample collected (2 tablespoons, about 30 mL) for STR analysis, as described above.

End-of-Study

The STR assessment at 12 months will be the end-of-study assessment.

Additional tests may be ordered by the doctor as determined medically necessary.

Location: The location of the End-of-Study assessment will be in Bone Marrow Transplant (BMT) Clinic (Clinic F) or an alternate location, as described above.

Medical imaging will be performed at the locations described above.

Your Tissue / Data Samples for Research and Genetic Testing

Testing of blood samples is an important way to try to understand human disease. Sometimes, this may include the testing and study of genes, also known as DNA, and related materials called RNA, proteins, and/or metabolites edit/specify if known. This type of testing is also called “genetic analysis” or called “pharmacogenomic research.” For this study, this testing, called short tandem repeat (STR) analysis, is part of your regular medical care for the transplant. You are being given this information because the Study Doctors want to include a sample of your blood in a research project and because they want to save the samples for future research.

There are several things you should know before participating in this study and allowing your blood to be studied. This subject is complicated, and there are many considerations. Ask for more information if you do not understand any part of this information.

Genes are in every cell of your body. Your genes were inherited from your biological parents and carry instructions for the body to grow, develop, and survive. Genes are made of a substance called DNA. Most genes and DNA are identical among human beings, but there are small variations between different people. These small genetic differences are why people have their own unique characteristics, such hair color, eye color, height, and other characteristics. Some traits affected by genetics are not visible, such as why different people have different responses, including side effects, to the same drug, or are more likely to get certain diseases or conditions.
The proteins in your body were determined by your genes, and control how your body works. Differences in genes and therefore proteins can affect the way a disease develops, the way drugs or treatments act against the disease, or the way your body uses the drugs.

The purpose of this type of testing is to understand the cause of disease, such as cancer, or the body’s response to the treatments (such as safety findings), and evaluate how well the transplant has worked for you. In this study, the genetic research (STR analysis) is also part of the assessment to determine if the addition of a low dose of total body irradiation (TBI) will improve the chance the transplanted donor cells will grow, and improve your overall treatment for your cancer.

This genetic research sample may be used for additional research including: additional studies of leukemia and lymphomas; as a comparison sample (“control sample”) in other cancer studies or in a group of other patients’ samples to determine the natural difference in genes and proteins in groups of people with cancer; or to develop new gene research techniques. The results of future studies could trigger the need to test or re-test the genetic research samples; therefore the sample and data generated from them will be held by the study team and Stanford for many years. These samples, and the data generated from them, may be shared with other researchers or entered into databases, provided confidentiality is upheld (you are not identified), and they are used only for research on the topics described in this document. The information in these databases may be kept forever, however, information that could directly identify you will not be included in these databases.

The Study Team may try to re-contact you in the future. If you are re-contacted and want to know what the Study Doctors have learned about your tissue samples, you should understand the following:

- The information may be too limited to give you particular details or consequences
- You may be determined to carry a gene for a particular disease that can be treated
- You may be determined to carry a gene for a particular disease for which there is no current treatment
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene

Providing genetic information to others

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance
companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Be aware that that GINA 2008 does not specifically protect you against genetic discrimination by companies that sell life insurance; disability insurance; or long-term care insurance.

Handling of your Blood Samples

Your blood sample for the STR genetic analysis will be stored at Stanford. These samples will be identified by your unique study number ("study identifier") only, and not your name. This study identifier will be a series of numbers and/or letters. Donors of samples do not retain any property rights to the samples.

Authorization for STR Analysis of Blood Samples

You have the right to refuse to allow your tissues to be studied now or saved for future study. However, agreeing to provide this blood sample for STR analysis is required to participate in this study. If you decline to allow the use of blood sample for STR analysis, you will not be able to receive the TBI radiotherapy in addition to the TLI radiotherapy, and you would receive the TLI radiotherapy regimen alone. You may withdraw from this study at any time. The Study Doctors might retain the identified samples, eg, as part of your routine clinical care, but not for additional research.

Your decision regarding this genetic research will be recorded with the signatures at the end of this document.

Adverse event monitoring will be performed as part of the procedures described above. During the treatment period, the Study Doctors will monitor you for any potential side effects. If the side effects are severe, the Study Doctors may temporarily stop study medication; change the dosage of your study medication; or withdraw your medication completely.

If, at any time, you have any symptom; side effect; or injury affecting you physically or mentally during the study, you should tell the Study Doctors or nurses right away, even if you do not think it was caused by the study medication.

If you have to go to the hospital for any reason, please tell the hospital staff that you are participating on a research study, and give them the contact information for the study team. You may be provided with a card with the study team contact information.
PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study team.
- Be sure to tell the study team all of your present and past diseases, allergies and any drugs or medications you are taking. This is for your safety. Other drugs or medications includes all prescription drugs; over-the-counter (OTC) drugs; herbal preparations; and nutritional supplements. If any other medical provider prescribes new medications for you while you are on this study, please contact the study team before taking the new medicine, or have that medical provider contact the study team before prescribing it to you. You should not take any new non-prescription medicine while you are on this study unless you first check with the study team.
- Ask questions as you think of them.
- Tell the Study Doctor or study team if you change your mind about staying in the study.
- Tell the Study Doctor or study team about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Study Doctor or study team if you believe you might be pregnant or gotten your partner pregnant.
  - You must use a medically-approved method of birth control, for the duration of the treatment period and for at least 6 months after the last day you receive mycophenolate mofetil (MMF), one of the study agents.
- This study has magnetic resonance imaging (MRI) scans that may be required. Tell the Study Team or the MRI operator if you have any tattoos on your body, including eyeliner and other permanent makeup.
- Take the Study Drug as instructed.
- Maintain control of the Study Drugs, and keep them in a safe place where children cannot access them. Follow any additional storage instructions that you are provided with.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Study Doctor or research study team to reschedule as soon as you know you will miss the appointment.
About Pregnancy

In order to participate in this study, if you are able to become pregnant or get someone else pregnant, you must agree to use a highly-effective method of birth control. To ensure that you do not get pregnant, or get your partner pregnant, it is strongly recommended that 2 highly-effective methods of birth control be used, by either the man or woman, or both.

Your birth control method(s) must be reviewed by the Study Doctor and determined to be effective, as well as to not interfere with the study. In particular, use of a hormonal contraception must be approved by the Study Doctor before you begin taking the Study Drug. There is a risk that pregnancy could still happen despite the responsible use of a reliable method of birth control. You agree to notify the Study Doctor if you or your partner become pregnant.

Women of Childbearing Potential: If you are a woman capable of having children and choose to have sex, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent such as mycophenolate mofetil (MMF). MMF is known to cause birth defects. You should use an effective form of birth control while taking MMF and for 6 months after your last dose of MMF. The only certain way to be 100% certain you will not get pregnant is to not have sex. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you; the fetus (unborn child); or the child may be at increased risk. To confirm that you are not pregnant, you agree to have a pregnancy test done before beginning this research study.

You agree to notify the Study Doctor as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

During the study, if you become pregnant, or you think you may be, you must immediately tell your Study Doctor. If you become pregnant during the study, the study treatments may involve unforeseeable risks to the unborn baby, and your pregnancy will be followed to determine the outcome.

Men: If you are a man and your partner is able to become pregnant, you must:

- Prevent pregnancy in your female partners. You and your partner must use adequate contraception while you are participating in the study and for 6 months after you stop taking mycophenolate mofetil (MMF), which is known to cause birth defects.
- Inform your female partners of the potential for harm to her or a fetus. They should know that if pregnancy occurs, they should promptly notify their doctors
- Not donate sperm for at least 6 months after your last dose of Study Drug

Participant ID:
Tell the Study Team immediately if your partner becomes pregnant

Your doctor will discuss with you whether your preference for birth control is considered adequate.

WITHDRAWAL FROM THE STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Robert Lowsky, MD at [redacted]. Any information collected before you withdraw will be kept and used to complete the research. Depending on when you choose to withdraw, there may be significant health consequences. If you withdraw after starting treatment, your Study Doctor will need to check on your health status afterwards. If you do not want the Study Doctor to check on your health status after withdrawing from the study, you should say so.

To help you safely finish your participation in the study, the Study Doctors may ask you to have more tests and you will be asked to come into the clinic for an End-of-Study Visit. If your participation in the study is ended, you must return all study-related supplies, including unused Study Drug.

If you withdraw from the study, or the study medication is stopped for any reason:

- Any consequences might depend on when you discontinued participation.
- Your cancer may get worse.
- Your health may be compromised if you do not continue with medically necessary parts of the transplant treatment.
- The Study Doctor will discuss with you the different withdrawal opportunities and their timing, including your options for continued treatment.
- To help you leave the study safely, the Study Doctors may ask you to have more tests.
- The Study Doctors may also ask if you wish to take part in the follow-up portion of the study. If you agree to continue with the follow-up portion of the study, information about your health will continue to be collected as described above in the Follow-up Procedures section.
- If your participation in the study ends, you must return all study-related supplies, including unused Study Drug.
Data and information from your participation may not be removed from the research study database and may continue to be used to complete the research analysis. This is discussed in more detail under the heading “Authorization To Use Your Health Information For Research Purposes” on the following pages.

Your treatment in this study can continue until one of the following occurs:

- You withdraw your agreement to continue to take part in this research study;
- The Study Doctor withdraws you from the study, and the study medication is stopped, with or without your consent, for one or more of the following reasons:
  - Failure to follow the instructions of the Protocol Director and study team
  - The Study Doctor decides that continuing your participation could be harmful to you, or otherwise not in your best interest
  - If you have bad side effects during treatment, or if you or your doctor otherwise decide that the side effects are too severe or undesirable
  - You need treatment with drugs or procedures not allowed in the study.
  - You have become pregnant
  - The study is stopped (cancelled)
  - Other administrative reasons
  - Unanticipated circumstances

When your participation in this study ends, you may be asked to return for a final visit to have some end-of-study evaluations or tests, or to allow medical information to be collected about your health after the trial treatment is stopped. After you finish the study, or stop treatment for any other reason, you may continue to be checked regularly (physical exams; blood tests; tumor measurements; X-rays; other scans, etc) if you continue to have significant side effects from the treatment. This is called follow-up. Your Study Doctor will follow your progress, in accordance with good medical care, for as long as it is felt to be necessary by both you and the doctor, unless you ask otherwise. Many if not all of these procedures will be part of your regular continued medical care. In addition, further treatment outside the study will be discussed with you.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. This section describes the reasonably foreseeable risks; discomforts; and inconveniences that you may experience. In addition, because this is a research study, there may be risks that are not yet known (“unforeseeable”), including a risk of death due
to unknown risks. These deserve careful thought. You should talk with the Study Doctor if you have any questions.

You must tell the Study Doctor or study team about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study. Your Study Doctor may give you medications to try to help lessen some of the side effects. All patients in the study will be monitored for side effects. If you experience serious problems, you may be asked to return to the study center for more tests or treatment.

**Anticipated Side Effects of the Study Treatment and Study-specific Procedures**

- **Total body irradiation (TBI):** This radiation exposure is part of the study-related anti-cancer treatment and procedures. Total body irradiation side effects include nausea; vomiting and diarrhea; temporary hair loss; painful swelling of the salivary glands for a few days; cataracts (a clouding of the vision); thyroid dysfunction; possible infertility; and early menopause for women. This radiation exposure will be 80 cGy, and is considered study-related because it would not normally be performed for someone also receiving TLI.

- **Bone marrow biopsy:** Bone marrow biopsies can be painful. The most common side effects, which are usually minor, include pain; discomfort; bleeding; redness and swelling; scarring; bruising; infection; and fever. You may experience dizziness or fainting. Pain and discomfort can last for a couple of hours to a couple of days after the sample is taken. To reduce these risks, the site of the biopsy will be numbed and sterile techniques will be used. In extremely rare cases, an allergic reaction to the local anesthetic used to numb the biopsy site can occur. This is a routine procedure, and established institutional procedures will be followed.

**Anticipated Side Effects Associated with the Hematopoietic Stem Cell Transplant (HSC) and related procedures or treatments**

- **Total lymphoid irradiation (TLI):** This radiation exposure is part of your regular medical treatment (you would be expected to receive this exposure regardless of participating in this study). This radiation exposure consists of 9 exposures over 11 days, of 120 cGy each, for a total of 1080 cGy, and is considered part of your regular medical care. The side effects of TLI include nausea and diarrhea. Radiation will lower the blood counts with the associated risks of infection, bleeding and anemia. Radiation may cause infertility and there is a risk of genetic damage to children conceived after transplantation. Radiation has also been associated with 2nd malignancies and hypothyroidism. There is an increased risk of viral infections within 2 years following this type of radiation.
• **Mycophenolate mofetil (MMF):** Side effects of mycophenolate mofetil include a decrease in the blood counts, which is usually reversible when the drug is stopped. Other side effects include nausea; vomiting; diarrhea; and abdominal discomfort and bleeding. MMF works by weakening the immune system therefore if you are taking tacrolimus you are more susceptible to infections. These infections can sometimes be life-threatening. Immune-suppressing medications are also associated with the development of secondary malignancies. Mycophenolate mofetil may cause birth defects. You should avoid becoming pregnant or getting your partner pregnant during treatment, and for at least 6 months after you stop taking the mycophenolate mofetil. It is recommended that you use 2 effective forms of birth control to avoid pregnancy.

• **Pregnancy / Reproductive Risk:** MMF, a component of regular medical care that will be used in this study, has known birth defect risks to a fetus (unborn child) or the pregnant woman, even if it is the man participating in this study. The radiation procedures in this study (TBI and TLI) also have known birth defect risks. There may be other risks. There is a risk that pregnancy could still result despite the responsible use of reliable method of birth control. Detailed information about preventing pregnancy is given elsewhere in this document.

• **Tacrolimus:** Common side effects include nausea, vomiting, high blood pressure, shaking of the hands, increased hair growth, temporary darkening of the skin, kidney damage, and liver damage. Less common side effects include changes in mental function, a process of destruction of red blood cells, and seizures. These side effects generally go away when the dose of the medication is decreased. Tacrolimus works by weakening the immune system therefore if you are taking tacrolimus you are more susceptible to infections. These infections can sometimes be life-threatening. Immune-suppressing medications are also associated with the development of secondary malignancies.

• **Anti-thymocyte globulin (ATG):** Side effects of ATG include fever; chills; rash; allergic reactions; muscle and joint aches; and a decrease in platelet counts. ATG weakens the immune system leaving you more susceptible to infections. Serious life-threatening allergic reactions, although rare, may occur with this medication.

• **Allogeneic hematopoietic cell transplant (HCT infusion):** The HCT infusion is like a blood transfusion. In most cases, the HCT infusion occurs without side effects. In rare instances, a severe life-threatening allergic reaction can occur. 2 to 4 weeks after the HCT, your blood counts will begin to recover.

• **Graft-vs-Host Disease (GvHD):** After the HCT graft (donor’s hematopoietic cells) begins to function, there is a risk of a reaction of the donor’s cells against your tissues. This reaction is called graft vs host disease (GvHD). Acute GvHD generally develops within the first 3 months following transplant. The most common organs affected by
acute GvHD are the skin with a rash, blistering, and sloughing; the gastrointestinal tract (stomach and intestines) with diarrhea, cramping and bleeding; and the liver with inflammation and/or failure.

Chronic GvHD may occur anytime in the first 2 years after transplantation and may involve any tissue. The symptoms of chronic GvHD will depend on what tissue is involved. Chronic GvHD may be mild or severe. In severe cases, it may affect your physical functioning, and negatively impact your quality of life.

Both acute and chronic GvHD may become severe enough to result in death. The risk of GvHD is higher if you have an unrelated donor compared to a related donor. The treatment with tacrolimus and mycophenolate mofetil is intended to prevent or minimize GvHD. If you develop GvHD you will be given additional medications, and prolonged treatment may be required to suppress the reaction. These drugs that treat GvHD work by weakening the new (donor) immune system, but you will be more susceptible to infections.

- **Low blood counts:** Both the TLI and ATG (described above) will lower your blood counts. When your white blood cell (WBC) count is low, you are at risk for infections. You will be asked to follow many guidelines to protect yourself from infections, including wearing a special mask; frequent, vigorous hand-washing; some diet restrictions; special mouth care; taking medications to prevent infections; and avoiding ill people. Infections can be caused by a virus, bacteria or fungus and in some cases, be life threatening. When your platelet count is low; there is a risk of bleeding. Rarely, this bleeding can be life-threatening. You will receive transfusions of platelets to minimize the risk of bleeding. When your red blood cell (RBC) count is low; you are anemic and will feel tired. You will receive transfusions of red blood cells, or possibly some medications, to treat the anemia. In some individuals, the need for transfusions lasts for many months following transplant.

- **Graft Rejection** (standard of care) There is a risk that the donor’s hematopoietic cells will not grow following infusion. If the donor’s cells fail to grow, it is anticipated that your own blood counts would recover. However, if the donor’s cells do not grow and your blood cells do not recover, this is a fatal complication.

- **Donor Lymphocyte Infusions:** In some cases, if the cancer persists or returns, it may be necessary to give you additional cells from your donor. These cells are called lymphocytes, and the procedure is called a donor lymphocyte infusion (DLI). These lymphocytes are capable of destroying cancer cells. The major risk associated with donor lymphocyte infusions is increased risk of development of acute or chronic GvHD (as above). In addition, low blood counts have been observed in patients who have received donor lymphocyte infusions. The low blood counts are due to an immune reaction of the donor cells against the marrow, and may last for several weeks. Low blood counts due to DLI are associated with those risks described above.
• **Organ Damage and Other Side Effects:** It is possible you may experience life-threatening heart; lung; kidney; brain; or liver damage following transplant. There may be long-term effects upon heart; lung; brain; kidney; and liver. There may be unknown side effects and risks associated with allogeneic transplant.

• **Infertility and Sexual Functioning:** It is possible that this therapy will leave you unable to have children in the future. It is advised that you continue to use birth control however to avoid an unplanned pregnancy. If you are a woman, this therapy may also induce menopause. In most cases, sexual functioning is not affected, although both men and women often report less interest in sexual activity for many months following treatment. In some cases, men report difficulty with erections and women report pain with sexual intercourse.

• **Secondary Malignancies:** There is a risk you may develop a 2\textsuperscript{nd} cancer including leukemia because of the radiation; ATG; and/or immunosuppressive therapy.

• **Relapse:** Despite receiving an allogeneic HCT, there remains a risk that your cancer could return.

**Anticipated Side Effects of General, Regular Medical Care Procedures**

The following are general risks associated with this type of medical care.

• **Allergic reactions:** All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. You should get medical help and contact the Study Doctors immediately if you think you have any of the following symptoms of a serious allergic reaction:
  o Wheezing or trouble breathing,
  o Swelling of the face, mouth, lips, gums, tongue or neck.
  o Dizziness and fainting
  o Rash, hives, or blisters
  o Increased heart rate (a fast pulse or tachycardia);
  o Abnormal or increased sweating

• **Blood draws:** A blood draw may cause fainting; inflammation of the vein; stinging, discomfort, or pain; bruising; discomfort; redness; burning; or bleeding at the site where the needle is placed to draw the blood. There is a slight chance of infection. You may feel dizzy or you may faint. If you feel faint, you should immediately lie down to avoid falling.

• **Central Venous Catheter:** Potential problems with the catheter include pain and bleeding at the insertion site; infection; poor functioning; blood clots; and rarely, a puncture of the lung (pneumothorax). In some cases, these problems lead to the need to remove the catheter. Generally, the catheter remains in place until you are eating...
and drinking adequately able to maintain a good nutritional state and no longer requiring transfusions, which will be about 3 months.

- **MRI**: The very strong magnetic fields of the MRI machine do not cause generally cause harmful effects at the levels used in the machine. However, there are some important considerations. The magnet in the MR scanner will attract or even move some metals and affect or damage some electronic devices. Exposure of the following to MRI magnetic fields may cause harm to you or others.
  - If you have a cardiac pacemaker; an artificial heart valve; or any other biomedical device in or on your body, these devices could malfunction when exposed to the very strong magnetic field.
  - If you have surgical clips; a metal plate; pin; screws; metallic fragments; or any other metallic object or implant in your body, these pieces of metal could move while in your body, causing possible serious injury or death.
  - If you have tattoos, these could become warm and irritated during the scan and remain so for several days.

- **If any of these apply to you, it is very important that you tell the operator/investigator immediately. In some cases, these risks could mean you should not have an MRI scan performed.**

In addition, when you are in the MRI scanner, you may experience discomfort or anxiety due to being in the small space inside the machine, or from the loud noises the MRI scanner makes. You may receive a medication to calm you if you need help with this.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is “not unexpected” (anticipated as a possible reaction), and should not be painful. However, you may have the scan stopped at any time if this occurs.

- **Medical Imaging: Injection of contrast agents**: A contrast agent or dye may be injected for the medical scans (eg, MRI; CT; and/or PET scans). If you have a history of severe allergies (eg, bee-sting reaction, food, shellfish, or nut reactions), or have previously had a reaction to medications or contrast agents, in particular Gadolinium-based contrast agents, you may be at risk of a serious reaction, which can be severe and/or life-threatening, including breathing difficulty; sweating; numbness; or heart palpitations. Tell the study team or technician **immediately if you experience these.** Following are the risks associated with injection of contrast agents.
  - Allergic reaction, which can be severe and/or life-threatening.
  - Kidney problems or kidney failure, especially if you are taking Glucophage (metformin, a common medicine for diabetes).
After the injection, there is a risk of pain, discomfort, or a burning sensation at the injection site; a flushing sensation; a salty or metallic taste in the mouth; a brief headache; or nausea/vomiting.

- If you are a smoker or exposed to cigarettes or nicotine, you may experience spasms in the arteries of your heart.
- Gadolinium-based contrast agents (GBCA), which may be used for MRIs, may remain in the brains of some people who undergo 4 or more contrast-enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects. You should talk to the study doctor if you have any questions about the use of GBCAs with MRIs.

**Radiologic imaging: X-ray / CT scans.** A CT scan exposes you to radiation. This exposure is part of your regular medical care. There are no radiation risks that are “more” than SOC. When you are in the scanner, you may experience discomfort or anxiety due to being in the small space inside the machine, or from the loud noises the scanner makes. If you become anxious or concerned in tight spaces, or from loud noises, tell the study team or technician before the scan. You may receive a medication to calm you if you need help with this.

**Radiologic imaging: Injection of radiotracers.** A radioactive tracer (radiotracer) will be injected for the PET scans. These scans are part of your regular medical care, and are not specifically part of this research study. There are no radiation risks that are “more” than SOC.

**Genetic research risks:** This research involves genetic studies and information. Procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you. However, even without your name or other identifiers, your genetic information is unique to you, and there is a remote possibility that someone could trace the information in a central database back, and identify you. If a genetic disorder is discovered in your genes, there is a remote possibility this information could become public and affect you or your family in an unfavorable way, including a possible risk of discrimination by employers or insurance providers.

It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study treatment or procedures. Contact the Study Team via the Nurse Coordinators at [number] (24 hours). If you are unable to reach anyone at the number(s) listed above, and you feel you may need medical attention, call 911 or go to the nearest emergency room.
POTENTIAL BENEFITS

☐ Allogeneic transplant has the potential to cure your underlying disease: It is possible that your health or medical condition may improve because of your participation in this study. The use of the study treatment, total body irradiation, increase the chance of your health improving. However, there is no guarantee that you will benefit in this or any other way.

☐ Although you may not directly benefit from participation in this study, information learned from this study may help other people in the future, including other people with cancer.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

You do not have to be in this study to receive treatment for your cancer (leukemia; lymphoma; myelodysplastic syndrome (MDS); or a myeloproliferative disorder). Instead of taking part in this study, you may choose to:

☐ Receive total lymphoid irradiation (TLI) and donor PBSC infusion, but without total body irradiation (TBI).

☐ Receive treatment with an experimental agent, such as a targeted therapy, if available. Targeted therapies recognize specific features of cancer, and focus the treatment effect on those cells.

The effectiveness and side effects of other treatments may be different for different people. The Study Doctors will discuss with you the risks and benefits of these alternatives, including which other treatments might be suitable for you.

While your type of cancer may be treatable with currently approved and available medications and procedure, another alternative is to receive only comfort care, also called “palliative care,” like painkillers. These types of treatments do not treat your cancer (ie, “are not curative”), and only make you comfortable (“symptom relief;” pain reduction; reduce tiredness, help with appetite problems or other problems caused by cancer). If you think you might prefer comfort care, please discuss this with your family, friends, and doctor. **NOTE:** The Study Doctors do not recommend this decision for you at this time, although it is and will remain your decision.

If you decide that you do not wish to take part in this study and wish to pursue any of these, or other alternatives, this will not change your regular medical care or the other treatment choices in any way.
PARTICIPANT’S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You can also tell any other member of the study team.

You will be told of any significant new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study. After you hear about this information, you have the right to withdraw from the program.

You will be told the results of tests that are part of your medical care.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Your research records may be disclosed outside of Stanford, including in computer databases and by other electronic methods, but you will only be identified by your unique study identifier, and not your name. Information linking your study identifier to your name will be kept in a secure location at Stanford and access will be limited to the Study Doctor and authorized members of the Study Team.

Patient information may be provided to Federal and other regulatory agencies as required. The US FDA, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of adding a single dose of total body irradiation to a standard allogeneic transplant; the results will be provided to the sponsor; the Food and Drug Administration (FDA); and other federal and regulatory agencies as required.
Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this research is to continue to understand and improve outcomes in the field of blood and marrow transplantation. Information about you and your treatment will be used to understand outcomes in blood and marrow transplantation. The results from this research study are expected to be presented at scientific or medical meetings or published in scientific journals. You will not be personally identified in the publications, although representatives of the sponsor and FDA and other international regulatory agencies may need to know who you are.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any
revocation, your health information will no longer be used or disclosed in
the study, except to the extent that the law allows us to continue using your
information (eg, necessary to maintain integrity of research). If you wish to
revoke your authorization for the research use or disclosure of your health
information in this study, you must write to:

Robert Lowsky, MD
300 Pasteur Dr, H0101
Stanford, CA 94305

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in
connection with this research study, including, but not limited to identifiers
such as your name and initials; address including ZIP code;
phone numbers; dates including date of birth; age; biological gender
(your sex); race; ethnicity; medical record number (MRN); and other
numbers or codes such as your unique study identifier that might identify
you. During the study, researchers will also obtain information about your
health status, life-style choices, medical history, and medical diagnoses,
including family medical history and allergies; your current and past
medications or therapies; your physical examination results including
height and weight, blood pressure readings, heart rate, breathing rate and
temperature; your laboratory test results including blood, urine, and
pregnancy tests; results of procedures, such as tumor measurements or
assessments, medical scans including MRI or CT scans, bone marrow
aspiration/biopsy; results of genetic and biomarker testing; and
medical reports, such as the discharge summary and radiology,
post-operative, and pathology reports. The researchers will also get
information from your medical record (including hospital records from the
Stanford Healthcare and your referring physician’s records).

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health
information in connection with this research study:

☐ The Protocol Director, Robert Lowsky, MD
Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Food and Drug Administration (FDA) and/or other state or international regulatory authorities
- The Office for Human Research Protections (OHRP) in the US Department of Health and Human Services (DHHS)
- The Center for International Blood and Marrow Transplant Research (CIBMTR, a research program of the National Marrow Donor Program® / Be the Match and the Medical College of Wisconsin
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported
- The Stanford University Administrative Panel on Human Subjects in Medical Research (Stanford IRB) and any other unit of Stanford University as necessary

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on 1 January 2100 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (eg, if included in your official medical record).
Protocol Title: Very Low Dose Total Body Irradiation in Combination with Total Lymphoid Irradiation and Anti-thymocyte Globulin to Improve Donor Engraftment in Patients Undergoing Non-Myeloablative Hematopoietic Cell Transplantation (330_TLI_ATG_TBI)

Printed Name of Adult Participant

Signature of Adult Participant

Date

If authorization is to be obtained from a legally authorized representative, eg, parent(s), legal guardian or conservator - signature line(s) for representative(s) must be included on the authorization, as well as a description of his/her authority to act for the participant:

If needed: Printed Name of LAR

Signature of LAR

Date

LAR’s Authority to Act for Participant
(eg, parent, guardian, or conservator)
FINANCIAL CONSIDERATIONS

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the Study Visits.

You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance.

Some insurance companies or other 3rd-party payers may not pay for standard-of-care procedures or laboratory tests, including hospitalization, when they are done as part of a research study. You should consult with your health benefit plan to determine whether your medical costs associated with your care during this study are covered.

Payments

You will not be paid to participate in this research study. There is no reimbursement offered for any expenses related to your participation in this study.

This study includes the collection of research samples. Any of your samples which are used in research may result in new products; tests; or discoveries. In some instances, these products may have commercial value, and may be developed and owned by the study team; Stanford University; and/or others. However, donors of samples do not retain any property rights to the samples or data derived from them. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Sponsor OR Funding Source

Stanford is paying for (sponsoring) this study, and providing the study treatment (TBI) extra bone marrow biopsies) and/or other materials for this study.

Consultative or Financial Relationships

None.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study team will assist you in obtaining appropriate care.

Participant ID:
medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, **you may be responsible for these costs.** If you are unable to pay for such costs, the Protocol Director and/or the research study staff will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

**CONTACT INFORMATION**

**Questions, Concerns, Complaints, or to Report an Injury or Side Effect:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should contact Dr Lowsky at [---------]. You should also contact her at any time if you feel you have been hurt by being a part of this study.

If you are unable to reach anyone at the number(s) listed above, and you feel you may need medical attention, call or go to the nearest emergency room.

**Independent Contact:** If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at [----------------] or toll-free at [----------------]. You can also write to the Stanford IRB, Stanford University.

**Appointment or Alternate Contact:** If you need to change your appointment, or if you cannot reach the Study Doctor, please contact the Study Team via the Nurse Coordinators [----------] (24 hours).
EXPERIMENTAL SUBJECT’S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any attendant discomforts and risks reasonably expected;
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- Be given an opportunity to ask questions concerning the experiment or the procedures involved;
- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- Be given a copy of the signed and dated consent form; and
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ___ Yes ___ No

Authorization for genetic research:
Please make your choice regarding the genetic research described above, and initial one of the statements below.

_____ (initials) I agree (consent) to provide the blood sample for described pharmacogenomic research. The data from the blood sample may be used in future pharmacogenomic research.

_____ (initials) I DO NOT agree (consent) to provide the blood sample for described pharmacogenomic research.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_______________________________________________
Printed Name of Adult Participant

Signature of Adult Participant __________________________ Date __________________

Signatures continue on next page.

_______________________________________________
Signature of Legally Authorized Representative (LAR) (e.g., parent, guardian or conservator) __________________________ Date __________________

____________________________   __________
Print Name of LAR

LAR’s Authority to Act for Participant (e.g., parent, guardian or conservator)
(If available) Signature of Other Parent or Guardian  Date

Print Name of Other Parent or Guardian

Authority to Act for Participant

Signature of Person Obtaining Consent  Date

Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

Signature of Witness  Date

Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form (referred to as the "Summary Form" in the regulations):
  - Must be signed by the witness AND the Person Obtaining Consent (POC).
  - The non-English speaking participant/LAR does not sign the English consent.
  - The non-English speaking participant/LAR should not sign the HIPAA participant line
If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR’s Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant’s wishes, as they are understood during the consent process.