RECIPIENT consent form for allogenic CD8 memory T-cells
IRB-33058 / BMT288

Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

You are invited to voluntarily participate in a research study of a type of immune cells called “donor CD8 memory T-cells” being studied as an experimental (“investigational”) treatment for cancer, being conducted by Robert Lowsky, MD at the Stanford Cancer Center. You were selected as a possible participant in this study because you have a “blood cancer” that is suitable to be treated with a hematopoietic cell transplant from a sibling donor “Hematopoietic cells” are the blood-making cells that live in your bone marrow. The types of cancer that are eligible for this study are:

- Acute myeloid/myelogenous leukemia (AML)
- Chronic lymphocytic leukemia (CLL)
- Hodgkin’s lymphoma (HL)
- Non-Hodgkin’s lymphoma (NHL), either B- or T-cell
- Myelodysplastic syndrome (MDS)
- Myeloproliferative disorder (MPD)

Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

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

This study involves adding an infusion of donor cells that have been concentrated or "enriched" for a type of blood cell called T-cells that have a certain marker on the surface known as CD8, and do not have another marker called CD45RA (these enriched cells are called "CD8 memory T-cells"). The treatment with CD8 memory T-cells is unproven, and may or may not benefit you. The infusion of CD8 memory T-cells will occur 30 to 75 days after your transplant. . If at 1-2 months after the transplant test confirm that your blood shows a mixture of your (recipient) and donor blood cells (called "mixed chimerism"), there is a significant association with increased risk of disease (leukemia/lymphoma/MDS) relapse compared to patients who have achieved 100% (full donor chimerism) donor blood cells by 1-2 months after transplant. The study is designed to help determine if giving donor CD8 memory T-cells to patients with mixed chimerism will help convert them to complete chimerism and subsequently reduce their risk of relapse. Before receiving the CD8 memory T-cells you will receive a single dose of chemotherapy called cyclophosphamide (Cytoxan). The cyclophosphamide will help the CD8 memory T-cells work better.

One of the benefits of allogeneic transplant is the donor's cells are capable of recognizing residual tumor and destroying the tumor. This is called graft versus tumor effect. A risk of allogeneic transplant is the donor's cells can attack your body tissues and cause graft versus host disease, which can be a serious and life threatening problem. This study is trying to find a better balance between the anti-cancer benefit effect and the risk of graft versus host disease. .

Your recovery after treatment; symptoms; functional abilities; changes in the extent of disease; and laboratory results obtained after you receive the infusion will help the research team determine if CD8 Memory cells are safe for patients with your condition. A main cause for treatment failure following allogeneic transplantation (is disease relapse. The study team hopes to learn if the addition of the CD8 memory T-cells from your sibling donor will result in a decrease risk of relapse without increasing the risk of graft versus host disease or other transplant-related side effects.

If you do not participate in this study, you can still receive the transplant from your sibling donor but will not receive the CD8 Memory T cells. Other transplant researchers may use other investigational treatments to decrease the risk of disease relapse after allogeneic HCT that may involve the addition of a 2nd cell infusion that is not CD8 memory T-cells; additional radiation therapy; chemotherapy; and/or other investigational study drugs not approved by the FDA. At this point in time, it is unclear what treatment or combination of treatments is the most likely to achieve long-term

control of your cancer. The right treatments, and the right amounts of those treatments, are not completely understood. Of the currently available treatments, none are better than any other at controlling your cancer, and all have associated side effects ("toxicities").

The infusion of CD8 memory T-cells is an investigational procedure. The word "investigational" means that CD8 memory T-cells are not approved by the US Food and Drug Administration (FDA) to treat cancer. This study is being conducted under an application submitted to the FDA, called an "Investigational New Drug Application" or "IND."

If you decide to terminate your participation in this study, you should notify either Dr. Robert Lowsky or the study coordinator at [redacted] or [redacted] ; or your primary BMT doctor.

This research study is looking to treat 22 individuals with an infusion of CD8 Memory T Cells. This study is only being conducted at Stanford.

This study is being paid for by a National Institute of Health (NIH) program grant that has been peer-reviewed and endorsed by experts in the field.

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.

You will be informed of any significant new information about this study or CD8 memory T-cells that might affect your willingness to participate in this research study.

You will be told the results of tests that are part of your medical care, but you may not be told the results of the research tests.

DURATION OF STUDY INVOLVEMENT

Your participation in this research study is expected take about 6 months, but the study team will follow your health status indefinitely.

You may withdraw your agreement to continue to take part in this research study at anytime.

It is possible that you may not be able to receive the CD8 memory T-cell infusion. This might happen if:

- Your cancer becomes worse (tumor progression) shortly after the transplant, but before the CD8 memory T-cell infusion You have an adverse event such as significant graft versus host disease; uncontrolled infection; or organ toxicity before the planned CD8 T-cell infusion.

In general, your treatment in this study can continue until one of the following occurs:

- Your cancer becomes worse (tumor progression);
- You need a treatment that is not allowed in this study;
- You have a different illness that prevents study treatment;
- You or your doctor decides that the side effects are too severe;
- You are a woman and have become pregnant;
- The study is terminated; or

You are removed from the research study for any of the following reasons:

- You are unable to complete the required parts of the study.
- You do not follow the study team's instructions for the study.
- Your Study Doctor determines it is in your best interest.
  Other unanticipated; appropriate; and/or administrative reasons as determined by your doctor or the study sponsor.

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. 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 continued regular medical care. In addition, further treatment outside the study will be discussed with you.

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.

Before you begin the study, you will need to have certain medical examinations, tests, or procedures to find out if you can be in the study. This is called "Screening." These

examinations, tests, or procedures are generally part of your regular medical care, and are done even if you do not join the study.

Before you join this study, the Protocol Director Dr Lowsky and/or the research study staff 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, your enrollment in the study will begin the day you receive cyclophosphamide that is being given in order to prepare you to receive the CD8 memory T-cells.

General information: Information about you, such as date of birth; gender (sex); and ethnic origin ("demographic information") is obtained.

Medical history: Your eligibility will be determined based on a variety of routine standard blood tests that confirm mixed and not complete chimerism and no active infection or GVHD. This information will come from a review of your electronic medical record in combination with discussions with the medical team involved in your care.

Location: The location of your follow-up will be at the Stanford Cancer Institute in the BMT clinic area. The testing to check your progress after the transplant and for your care during the first 100 days after transplant will be done at Stanford. These before and after transplant examinations, tests, or procedures are part of your regular medical care, and are done even if you do not join the study.

The Study Team will let you know which Stanford locations you may need to go to and may include any of the following:

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

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

Stanford Cancer Institute
Infusion Therapy Center
875 Blake Wilbur Dr
Stanford, CA 94306

Women of Childbearing Potential
If you are pregnant or currently breast-feeding, you may not participate in this study.

Study Treatment and Schedule
This study adds an infusion of CD8 memory T-cells to a standard allogeneic sibling transplant (HCT), which is an established medical procedure. There are no additional planned clinic visits as a result of participation in this trial that are above and beyond the standard number of clinic visits for a standard transplant patient. There are no additional study specific blood tests needed beyond standard of care.

Twenty-five to seventy days post transplant: In order to prepare you to receive the donor CD8 memory T-cells you will receive an intravenous infusion of cyclophosphamide administered over 90-120 minutes. Because cyclophosphamide may be associated with some nausea during or shortly after the infusion, you will receive some anti-nausea medications. Three to five days after the cyclophosphamide you will receive the donor CD8 memory T-cells.

Thirty to seventy-five days post transplant: You will receive the CD8 memory T-cells as an infusion over about 20 minutes. The study team will tell you the exact date, which will be based on your status after the initial HCT transplant. The CD8 memory T-cells will be infused through a central venous catheter or as a peripheral IV infusion. The infusion of CD8 Memory T cells is investigational. You will be monitored for side effects for at least 2 hours. If necessary, you may receive medications to minimize the potential for an allergic reaction. .

Further Study Rationale
A standard transplant does not include the infusion of CD8 memory T-cells. A main reason for the transplant "not working" or "not being successful" is because at some point in time after transplant the cancer recurs and/or progresses (disease relapse). If your cancer should relapse/progress after transplant it may be difficult for your doctors to gain long-term control of your cancer. A goal of the current research study is to determine if an infusion of CD8 memory T-cells will decrease the risk of cancer recurrence/progression, and not cause significant graft versus host disease reactions or other toxicity.

Prior studies done at Stanford have shown that the infusion of CD8 memory T-cells in patients who suffered disease relapse after transplant were safe and did not cause graft versus host disease reactions. The CD8 Memory T cells were associated with apparent meaningful graft versus tumor reactions in some patients. The idea in the current trial is not to wait for disease relapse to occur, but instead to infuse the CD8 memory T-cells shortly after transplant (30-75 days) and before disease relapse.

This study attempts to provide a benefit to patients, but this is not known and is not guaranteed.

The dose of CD8 memory T-cells infused will be adjusted to 5 x 10^6 per kg body weight and the cells will be collected from your sibling donor 1 to 2 days before the planned infusion. Your sibling will not be required to receive any medications or treatments prior to the cell collection. The cells are collected from the blood during a 3-hour apheresis which is similar to what was involved for the collection of cells for initial transplant.

If, at any time, you have any symptom, side effect, or injury affecting you physically or mentally during the study, **you should tell your transplant doctors and team right away**, even if you do not think it was caused by the study medication (infusion of CD8 memory T-cells).

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Be sure to tell the study staff 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 drugs; herbal preparations; and nutritional supplements. These may interact with the treatments you will receive. If any other medical provider prescribes new medications for you while you are on this study, please contact the study staff before taking the new medicine, or have that medical provider contact the study staff 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 staff. Come to the Study Visits as scheduled.
- Take the medications as instructed.
- Ask questions as you think of them.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the transplant team or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or study team if you change your mind about staying in the study.
- Tell the Protocol Director or study team about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director 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, preferably a barrier method, for the duration of the treatment period and for at least 1 month after the last day you receive the injection of Study Drug.

About Pregnancy
In order to participate in this study, you must agree to avoid sexual intercourse, or to use a birth control method that the Study Doctor agrees will be effective at preventing pregnancy, and that will not interfere with the proposed research. The Study Doctor can discuss with you what methods of birth control are considered adequate.
Your signature on this document means you agree to these requirements.

There is a risk that pregnancy could still result despite the responsible use of a reliable method of birth control. You agree to notify the investigator 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.

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 the known risks of radiation as well as a potentially dangerous agent with unknown risk. 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 exposed to unknown risks as well as the risks of birth defects due to the radiation therapy and treatment drugs. To confirm that you are not pregnant, you agree to have a pregnancy test done before beginning this research 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 CD8 Memory T cells may involve unforeseeable risks to the unborn baby, and your pregnancy will be followed to determine the outcome.

Men: If you are a man, you must
- Prevent pregnancy in your female partners
- You should 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
- If your partner becomes pregnant, you need to tell the Study Team and her physician immediately

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 Dr. Lowsky or the study coordinator at. 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 a final Study Visit. The Study Doctor will discuss your treatment options with you at this time.

- If you withdraw from the study after receiving the transplant on Day 0, but before receiving the CD8 memory T-cell infusion, Dr Lowsky or his designate will discuss your medical options with you.

The Protocol Director may also withdraw you from the study and the CD8 memory T-cell infusion may be not be administered, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The initial transplant on Day 0 failed to show any donor cells by day 28 after transplant (failure to engraft).
- You have active graft versus host disease reactions before the planned CD8 memory T-cell infusion.
- Test results taken on days 28 or 56 after transplant that confirm you have achieved > 90% donor-type cells.
- You are not strong or healthy enough.
- You have other medical conditions that prevent the CD8 memory T-cell infusion.
- The sibling donor is unable to or unavailable to provide cells for the CD8 memory T-cell collection.
- If your tumor worsens (tumor progression).
- You have become pregnant.
- You need, or have received, treatment not allowed in the study.
- The study is stopped by the study sponsor Dr Lowsky; the Stanford Institutional Review Board (the IRB, a group of people who review the research to protect your rights); or by a regulatory agency such as the US FDA.
- Other administrative reasons.
- Unanticipated circumstances.

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. These deserve careful thought. While the transplant is considered a standard of care procedure, it is also a part of this research study and is associated with risks.

Possible Side Effects of Cyclophosphamide (Cytoxan)
Cyclophosphamide is a chemotherapy drug that will be administered intravenously (into your catheter), given 3-5 days prior to receiving the donor CD8+ memory T cells. Side effects may include nausea, vomiting, diarrhea, sores in the mouth and throat, skin changes, loss of appetite, irritation and possibly bleeding of the bladder lining and lowered blood counts. Cyclophosphamide may also damage the heart which in rare instances can be fatal.

Possible Side Effects of the CD8 T-cell Infusion
The CD8 memory T-cell infusion is planned for 30 to 75 days after transplant. The risks of the CD8 memory T-cell infusion may include nausea; discomfort in the chest; facial flushing; or lightheadedness. These side effects if they occur generally resolve quickly. In rare instances, it is possible that a severe life-threatening allergic reaction may occur. In addition, you may develop graft versus host disease because of the CD8 memory T-cell infusion. It will be difficult to know how much of graft versus host disease will be due to the CD8 memory T-cells versus how much was from the initial transplant.. Overall, the risk of developing graft versus host disease reactions within 120 days of transplant following a standard transplant using TLI/ATG is generally low (less than 20%). If graft versus host disease is seen more frequently for the 22 transplant recipients on this study (more than about 7 or 8 participants of the 22) than it is reasonable to assume this higher risk would be a result of the CD8 memory T-cell infusion.

Late graft versus host disease (late is typically defined as more than 180 days after transplant) may occur anytime in the next few years, and may involve problems with the eyes; mouth; lips; skin; throat; lungs; lining of the heart and lungs; vagina; muscles; nerves; and/or liver.

Both early and late graft versus host disease may become severe enough to result in death. If you develop GVH reactions, you will be given drugs to help manage the symptoms by weakening the immune system. Just as with the early graft versus host disease, late graft versus host disase may be a consequence of transplant or from the

CD8 memory T-cell infusion. About 35% of patients develop late graft versus host disease after a standard transplant using TLI/ATG.

In addition, there are other risks and possible discomforts you might experience from the study procedures, including:

- **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
- **Personal anxiety**: Following are some common concerns that research subjects may have.
  - You may be asked sensitive or private questions which you normally do not discuss. It may be necessary to answer some of these questions related to your health and medical status.
  - You may feel embarrassed during the physical exam. You may request that the physical exam be done by a clinician of the same gender.
  - You may be concerned about your personal information being revealed. Although the Study Team, the NCI, and FDA does their best to protect your personal information, this cannot be absolutely guaranteed.
- **Other risks**: Since CD8 memory T-cell infusions are investigational, there may be other risks that are unknown ("unforeseeable") at this time.

It is important that you report <u>all symptoms and side effects</u> that you experience <u>as soon as</u> they occur, whether or not you think they are caused by the Study. 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

It is possible that the infusion of donor CD8 memory T-cells may reduce or completely eradicate your 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. Possible alternative treatments and side effects of these treatments depend on the characteristics of your cancer, and the stage and location of your cancer. The effectiveness and side

effects of other treatments may be different for different people. Instead of taking part in this study, you may choose:

- To receive allogeneic transplantation (cells form another person) using TLI and ATG conditioning but without the second infusion of CD8 memory T-cells.
- To receive allogeneic transplantation using other agents, ie, not TLI plus ATG, to attack the cancer and prepare you for the transplantation.
- To receive treatment with other investigational therapies.
- While your type of cancer is/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). 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.

The Study Doctors will discuss with you the risks and benefits of these alternatives, including which other treatments might be suitable for you.
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 staff.

You will be told of any important 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.

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, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

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 donor CD8 memory T-cells. The results will be provided to 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?

This study may help determine if donor CD8 memory T-cells are a good medical therapy. Information from this study will be submitted to the FDA and possibly international regulatory agencies. 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 Drive, 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; sex; race; ethnicity; and medical record number (MRN). 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 cancer assessments, any medical scans; 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 (includes hospital record from the Stanford Cancer Institute 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
- ☐ Research Staff
- ☐ The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

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 Office for Human Research Protections (OHRP) in the US Department of Health and Human Services (DHHS)
- ☐ The Food and Drug Administration (FDA) and/or other state or international regulatory authorities
- ☐ Stanford Data Safety Monitoring Committee (DSMC)
- ☐ International Bone Marrow Transplant Registry (IBMTR)
- ☐ Autologous Bone Marrow Transplant Registry (ABMTR)
- ☐ Foundation for the Accreditation of Cellular Therapy
- ☐ National Institutes of Health (NIH)

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 31 December 2065 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).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
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).

FINANCIAL CONSIDERATIONS

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the 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.

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.

The National Institutes of Health (NIH) are providing some financial support for the facility and staff where part or all of the study is taking place.

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 staff will assist you in obtaining appropriate 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 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 ask the Protocol Director, Dr Lowsky at You should also contact him 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 fell 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 You can also write to the Stanford IRB, Stanford University,
[redacted]El Camino Real, Palo Alto, CA 94306
.

Appointment Contact: If you need to change your appointment, please contact the study staff at [redacted]

Alternate Contact: If you cannot reach the Protocol Director, please contact the study staff at [redacted]

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**

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

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

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

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant (e.g., parent, guardian or conservator)

_____ _____
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, or other person who speaks both English and the participant's language)

- *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.*