RESEARCH PATIENT INFORMATION AND CONSENT FORM

TITLE: **A Phase 1, Non-Randomized, Open-Label/Phase 2 Randomized, Blinded Study of ProTmune™ (*ex vivo* Programmed Mobilized Peripheral Blood Cells) Versus Non-Programmed Mobilized Peripheral Blood Cells for Allogeneic Hematopoietic Cell Transplantation in Adult Subjects with Hematologic Malignancies**

PROTOCOL NO.: **PT-001**

SPONSOR: **FATE THERAPEUTICS, INC.**

INVESTIGATOR:

SITE(S):

STUDY-RELATED PHONE NUMBER(S):

SUMMARY

You are being asked to take part in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve experimental (investigational) drugs or procedures that are being tested for a certain condition or illness. An investigational drug is one that has not been approved by the U.S. Food & Drug Administration (FDA).

- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

You are invited to take part in a research study because you will be undergoing a mobilized peripheral blood transplant as treatment for your diagnosis of cancer of the blood. This research study is a way of gaining new knowledge about an investigational treatment called ProTmune (also known as ex vivo programmed mobilized peripheral blood cells). Investigational means that ProTmune is still being studied and that study doctors are trying to determine whether ProTmune causes side effects, and if it is effective for treating different types of blood cancers. It also means that the FDA (the U.S. Food and Drug Administration) has not yet approved this treatment.

ProTmune is prepared from blood cells that are collected from a matched unrelated donor. After the collection, these cells are modified using special chemicals, also called reagents. The modification of the blood cells is the investigational part of the study.

This study consists of two consecutive phases, Phase 1 and Phase 2. The Phase 1 portion of the study has completed. This consent form refers to the Phase 2 portion of the study only.

The purpose of the Phase 1 portion of the research study was to evaluate the safety of the ProTmune treatment on mobilized peripheral blood to be used in transplantation.

The purpose of the Phase 2 portion of the research study is to evaluate if ProTmune can prevent or reduce complications that frequently happen during transplantation, which include graft versus host disease (GvHD). Safety will also be evaluated in this phase of the study. For a period of time, after you receive your transplant and when your immune (self-defense) system recovers, you may be at a higher risk of infection.

Graft versus host disease happens when the transplanted donor blood cells attack the transplant patient's body. This happens in approximately 50% of transplant patients and the consequences can be very serious, and sometimes even life threatening.

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As part of the transplant procedure you will first receive chemotherapy and, sometimes, radiation. These standard treatments will help fight your blood cancer, and prepare your body to receive the donor cells. Further, these treatments are meant to prevent transplant rejection.

NUMBER OF PATIENTS AND LENGTH OF STUDY
Approximately 80 patients will take part in this study with a total of approximately 15-20 study sites participating in Phase 2 of the study. Your participation in the study will be approximately 26 months.

PROCEDURES
This research study consists of two phases. Phase 1 was the first in human experience, where safety results were the most important outcome. Phase 2 will evaluate the effectiveness of the study treatment, and further evaluate safety.

All Phase 1 patients received the modified cells called ProTmune. Since the initial 7 patients were the first human experience with this investigational treatment, the number of patients that entered the study were carefully managed by the Study Sponsor. In addition, the safety data for the study patients were monitored by an independent data monitoring committee (IDMC) which consisted of 2 independent physicians and a statistician. The IDMC met at the end of Phase 1 and approved the opening of Phase 2.

If you decide to participate in this study, you will be enrolled in Phase 2. For Phase 2 there are two study groups you may be assigned to. This assignment will be selected by a computer and you will be randomly assigned with a 50-50 chance (like the flip of a coin) to receive a transplant with the modified cells (study drug) or to receive the standard transplant (cells are not modified). Phase 2 of the study is blinded which means that you, your study doctor and the study sponsor will not know which treatment you will receive. In case of an emergency your study doctor will be able to find out your treatment assignment.

All patients that are considered to take part in this study will be screened and will be deemed qualified if they meet eligibility criteria that are defined in the study protocol.

If you are enrolled, then as part of this study you will receive transplant preparation with FDA approved drugs and radiation therapy. You will also receive immunosuppressive therapy with FDA approved drugs to help the transplant get accepted by your body. Following the transplant procedure all study patients will receive the same follow up visits and procedures to evaluate their disease status and transplant results.

Eligibility Assessment and Screening Procedures – Study Days -53 thru -11
If you would like to take part in this study, you will be asked to sign this consent form, and you will be required to undergo the following qualification assessments and procedures:

- Medical History and Concomitant Medications review
- Demographics information collection
- Physical Examination and Vital signs measurement including height, body weight, blood pressure, heart rate, respiratory rate, and temperature

- Blood draw for routine complete blood count, chemistry laboratory tests and to find the best matched, unrelated donor (about 3 teaspoons)
- Blood collection for baseline assessment for immune reconstitution. This blood will be sent to a central laboratory for future testing and analysis (about 3 tablespoons).
- Blood test for infectious disease evaluation and viral monitoring. This includes testing for HIV and hepatitis. You will be asked to sign a separate consent for HIV testing, and you will be counseled about the results. HIV – related information may be shared with other members of the research team besides the study doctor (about 2 teaspoons)
- If you are a woman who can become pregnant, a blood pregnancy test will be done (about 1 teaspoon)
- Bone marrow aspirate and biopsy: This is a procedure where a needle is inserted into your hip bone and a small amount of bone marrow cells and a sample of bone are removed (this test will only be done if you have disease that has spread to the bone marrow). If a bone marrow aspirate is required, you will be asked to sign another consent form for this test
- Electrocardiogram (ECG): A test of the electrical function of your heart
- Echocardiogram (sound wave study) of the heart, or a nuclear medicine test to measure the pumping function of your heart
- Pulmonary function tests to measure your how well your lungs work
- Performance status assessment, to see how well you are able to perform your daily activities

If you meet the study requirements you will be enrolled into the study.

Transplant Preparation and Hospital Admission – Study Days -10 thru -1

You will be admitted to the hospital as *per* your study doctor's recommendation. You will receive chemotherapy treatment and possibly radiation as part of conditioning (preparation) regimen for the transplant. This will be given to you to help destroy your cancer and to suppress your immune system so your body does not reject the transplanted cells.

The following procedures will be performed during this time:

- Medical History and Concomitant Medications review
- Physical examination
- Vital signs including weight, blood pressure, heart rate, respiratory rate, and temperature
- Blood draw for routine blood tests and viral reactivation of cytomegalovirus (CMV) will be obtained. Some of this blood will be sent to a Central laboratory (about 2 tablespoons)
- You will be asked about any side effects or illnesses you experience
- The preparatory/conditioning regimen and GvHD prophylaxis will be administered per your study doctor recommendation

Transplant – Study Day 0

In Phase 2 of this study you may be assigned to receive a transplant with the modified cells (study drug called ProTmune) or to receive the standard transplant (cells that are not modified). This assignment will be selected by a computer. You, your study doctor and the Study Sponsor will not know which treatment you will receive.

Prior to the transplant the following procedures will be performed:

- Physical Exam
- Vital signs including weight, blood pressure, heart rate, respiratory rate, and temperature (before, during and following the infusion)
- Electrocardiogram (ECG)
- Performance status assessment
- Blood draw for routine blood tests (about 3 tablespoons)

The transplant will be prepared in the hospital's laboratory and transfused to you through your central venous catheter (long, thin and flexible tube used to give medicines, fluids, food usually over a long period of time). You will be asked about any side effects or illnesses you experience during and after the infusion.

You will remain in the hospital until the cells engraft and you are strong enough to go home as per decision of your study doctor.

Post-Transplant Follow-up Visits
Daily Assessments thru Day 28

- Blood draw for routine complete blood count (about 1 tablespoon) – it will be collected until the donor cells engraft, which may be sooner than Day 28)
- You will be asked about any side effects or illnesses you experience

Weekly Assessments until Day 100

- Physical Exam and Vital Signs
- Concomitant Medication review
- Routine blood tests (about 4 tablespoons) at every visit. Some of this blood will be stored for future viral testing at a central laboratory.
- Blood draw for engraftment and chimerism assessment (a check to see if whether your cells or the donor's cells are making new blood cells) (about 1 tablespoon) – it will be collected when there are signs of engraftment, as determined by the results of routine blood tests and the study doctor, and also on **Days 28 and 100**.
- Bone marrow aspirate and biopsy on **Day 21 (if white blood cell count is <500), and additional assessments will be done only if your study doctor requires it**.
- Blood draw for chimerism on study **Day 28 and Day 100 only**
- Performance status to see how well you are able to perform your daily activities
- You will be asked about any side effects or illnesses you experience
- Echocardiogram (ECG) on **Day 100 only**

After you leave the Hospital: You will be required to come back for monitoring and routine care. This is standard after transplant procedure. You will be asked to return to the clinic at least once a week for approximately the first 3 months after transplantation. After the first three months, you will be asked to return to the clinic at Day 100 and at 6, 9, and 12 months from the date of your transplant, however, it is likely that you will require more frequent visits than these for routine clinical care.

Month 6, 9 and 12 Visit Assessments

- Physical Exam and Vital Signs
- Blood tests for standard, post-transplant studies (about 4 tablespoons). Some of this blood will be stored for future testing at a central laboratory
- Blood draw for chimerism study at Visits 6 and 12 months only
- Performance status to see how well you are able to perform your daily activities
- You will be asked about any side effects or illnesses you experience, and any medications that you are taking

Month 24 Assessment

- You will be contacted by phone and asked about any side effects or illnesses you have experienced since your last visit.

Blood Tests for Immune System Recovery: You will have blood drawn (about 3 tablespoons) to assess how well your immune system is recovering after transplantation. The first (baseline) sample will be collected before you receive medications and radiation therapy to prepare you for transplant procedure. Additional samples will be drawn after transplantation while you are still in the hospital, or on days that you are visiting the clinic for routine blood tests. These blood samples will be collected on study Days 7, 14, 28, 56, 91 and study Visits at 6, 9 and 12 months after transplant. These blood samples will be shipped to a central laboratory and some of it may be stored for future testing or analysis.

Unscheduled Visits: You may be asked to come to the clinic for an unscheduled visit to perform additional testing for your safety.

Blood Samples for Research

Blood samples will be taken from you and used for the purposes of this trial. Any additional blood samples that are collected and any leftover blood or tissue may be provided to the Sponsor and other researchers and may be stored for re-testing or future use or testing. This may include testing or use in research studies related to the immune recovery and effectiveness of ProTmune, and development of assays to help understand ProTmune better. The samples may also be used or tested to learn about, prevent, or treat other health-related problems, and some of this research may include genetic testing. Information obtained from testing the samples will be used only for purposes of research and development, and it is not the aim of this research to provide you with information that could be used to guide you or your physicians in making health care decisions.

These samples will be transferred to the Sponsor or their contracted laboratory for long-term storage. Samples will be retained for at least two years following FDA (or other country) approval of ProTmune, or until the program is discontinued, whichever occurs first. Only your study-assigned subject number and the date and time of the blood draw will be associated with the samples. The Sponsor and labs will not have access to any other information about you.

RISKS AND DISCOMFORTS

There are risks to taking part in any research study. Many of these risks are the same as these for any person undergoing a stem cell transplant without the investigational modification of the cells. To better manage these risks, there will be an independent medical monitoring committee

made up of doctors who will oversee the safety of the patients in this study and make recommendations regarding the study, including whether it should continue or not.

Phase 1: Risks Related to ProTmune Stem Cell Transplant (Experimental portion of the trial)

The risks of ProTmune are largely unknown at this time. Seven patients were treated and evaluated for safety in Phase 1 of this study. In all cases ProTmune was successfully made and all patients receiving ProTmune in Phase 1 successfully engrafted.

Side effects that the treating doctors considered as possibly related to ProTmune included:

- chest discomfort,
- nausea, and
- vomiting.

These occurred while receiving the ProTmune infusion.

Other side effects that were observed but that the treating doctor thought were due to the stem cell transplant procedure in general included the side effects noted below.

The five most common side effects reported in the study:

- low red blood cells,
- low white blood cells,
- low blood clotting cells (platelets),
- high blood pressure,
- inflamed mouth and lips, and
- changed sense of taste.

Other side effects that were less common but more serious:

- temporary kidney injury,
- temporary brain swelling,
- viral infection of the colon (the final section of the digestive system),
- donor cell attack of the colon,
- too much fluid in the lungs,
- irregular and rapid heartbeat,
- bacterial infection in blood, and
- bleeding in the colon.

An independent group of experts reviewed all of the safety data from Phase 1 of this study and all agreed that Phase 2 could start.

Phase 2: Risks Related to Blinded Portion of the Study (ProTmune or Standard Stem Cell Transplant)

As of January 24, 2019, fifty-one (51) subjects have been treated in Phase 2 of the study. In all cases, ProTmune or the Standard Stem Cell Transplant were made successfully. Of the 51 subjects treated, there was 1 reported case of primary engraftment failure. Not all standard transplants will be successful and approximately 2 standard transplants in every 100 performed

will fail based on results from a large clinical trial (refer to results on www.clinicaltrials.gov for NCT00075816).

Side effects that occurred in Phase 2 while receiving the infusion of study cells included:

- chest pain,
- nausea,
- vomiting,
- chills,
- flushing (warm sensation),
- tremors,
- high blood pressure,
- low blood pressure,
- fast heart rate (tachycardia), and
- cold feeling with shivering (rigors).

The most common side effects reported in 20% or more of the treated Phase 2 subjects include:

- inflamed mouth and lips,
- low red blood cells,
- fatigue,
- fever with low neutrophils (type of white blood cell),
- nausea,
- low blood clotting cells (platelets),
- high blood pressure,
- low neutrophils (type of white blood cell),
- diarrhea, and
- inflammation of the mucosa.

Potential risks with study participation, but considered rare:

- Allergic reaction to Human Serum Albumin, a solution added to the stem cells after study manufacturing.
- Damage to the blood cells either during processing or when transplanted, preventing it from engrafting. If this occurs, it is possible that the cell unit will not engraft. A back-up donor will be identified for you in the event that you need another transplant. However, if none of the units engraft, a condition known as "graft failure" will occur. This can be life-threatening due to the risk of infections.

More people will need to be studied to know if ProTmune might affect the general risks associated with any transplant.

Risks Related to Standard Stem Cell Transplant

Please discuss the risks associated with standard of care transplant with your doctor. Some of the risks associated with transplant include:

- the transplant not working and the cells do not engraft
- complications associated with the chemotherapy and radiation used to prepare you for the transplant

- complications with routine procedures such as taking blood, bone marrow biopsies etc.
- Increased risk of infection
- Allergic reaction
- Rash
- Nausea
- Chills
- Flushing (redness)
- Abdominal pain
- Cough
- Risk of graft versus host disease (GVHD). It is a common complication of all types of stem cell transplantation, with a risk of 50-60% in transplants with matched, unrelated donors

  Acute GVHD may occur during the first 100 days or later following transplantation and is usually associated with:
  - Diarrhea
  - Abnormal liver function tests, which may be a sign of liver inflammation
  - Skin rash
  - Any combination of above symptoms

  Chronic GVHD usually occurs after 100 days can last a lifetime and can have symptoms similar to acute GVHD. It could also involve other organs (lungs, joints, eyes, and/or mouth for example).

  If you develop chronic GVHD, you may experience:
  - Dryness and irritation of the eyes
  - Joint pain and stiffness
  - Toughening of the skin
  - Inflammation of the lungs, which may cause shortness of breath

  These symptoms can be mild, moderate or severe and life-threatening and fatal. There are medications used to treat GVHD, such as steroids and other immune suppressive drugs.

Risks Related to the Transplant Conditioning Regimen

All the treatments given in the pre- and post-transplant periods are part of standard care for patients undergoing this transplant procedure; each medication is FDA-approved and is associated with side effects, some of which may be very serious. Your doctor will explain these side effects and risks to you and answer any questions you may have about these medications.

Your doctor will select the best transplant preparation for you, and you may receive one of the following combinations of chemotherapy with or without total body irradiation: Fludarabine and busulfan; busulfan and cyclophosphamide; cyclophosphamide and total body irradiation; etoposide and total body irradiation; or fludarabine and melphalan. Many of the side effects are similar between these chemotherapy drugs and are summarized below.

Common side effects observed with at least one of the chemotherapies/irradiation:

- Low blood counts (with or without fever) that can put you at increased risk for infection, anemia and/or bleeding.
- Nausea, vomiting, diarrhea, and loss of appetite

- Hair loss
- Loss of fertility, which is your ability to have a child
- General discomfort, tiredness, and weakness
- Inflamed and sore mouth
- Swelling in tissues

Serious side effects that may occur (events include, but not limited)

- An allergic reaction, which can be as minor as a skin rash/itching (includes effect from irradiation) to life-threatening (shortness of breath; closing of your throat; difficulty breathing; swelling of your lips, face, or tongue; or hives)
- Injury to the liver resulting from blockage of veins in the liver
- Heart/blood vessels (Blood clots, inflammation of the heart, heart failure, or changes in heart rhythm), urinary tract (inflammation of the kidney or bladder with or without blood in urine); gastrointestinal (inflammation and/or bleeding); lung tissue damage (infections, difficulty breathing, inflammation); and central nervous system (including visual disturbances and changes to sensation)
- A group of symptoms and complications when large amounts of tumor cells are killed at the same time by the treatment.
- Secondary cancers
- Toxicity to an unborn child

GVHD prophylaxis (preventive) medications

Methotrexate – is a drug used in the treatment of certain cancers or other diseases. It will be given to you as an intravenous (vein) infusion.

Common side effects include:

- Ulcers in the mouth
- Nausea and abdominal pain
- Feeling tired and weak
- Chills and fever
- Dizziness
- Increased chance of infection

Serious side effects include:

- Toxicity to an unborn child
- Liver damage after long use
- Lung damage
- Metabolic abnormalities when large amounts of tumor cells are killed at the same time by the treatment
- Severe, sometime deadly, skin reactions
- Sometimes deadly infections
- When given with radiation may increase the risk of skin/bone damage

Tacrolimus - is an immunosuppressive drug, given to prevent rejection of transplanted cells. It can be given intravenously or as a pill to prevent graft-versus-host disease. Side effects, which may be treatable, include:

Common side effects include:

- Headache, tremor, difficulty sleeping, and burning/prickling in hands and feet
- Diarrhea, nausea, constipation, loss of appetite, and increased liver enzymes.
- High blood pressure
- Abnormal kidney function
- Blood electrolyte changes and increased blood sugar
- Anemia and decreased white blood cells
- Pain, abdominal pain, back pain
- Rash and itching of the skin

Serious side effects include:

- Insulin-dependent diabetes mellitus
- Brain and nervous system toxicity (tremor, headache, and other changes in motor function, mental status, and sensory function)
- Kidney toxicity (when used in high doses)
- Increased potassium levels in blood
- An allergic reaction (shortness of breath; closing of your throat; difficulty breathing; swelling of your lips, face, or tongue; or hives;)

Your blood level of tacrolimus will be monitored to make sure the drug is being administered in the right dose for you.

Risks Related to other Study Procedures

Risks of Transfusions: You will sign a separate consent to receive blood and platelet transfusions during your transplant. This consent form describes the risks associated with the transfusion of blood and blood products.

Risks of Central Venous Catheter: You will sign a separate consent to undergo placement of a central venous catheter. This consent form will describe the risks associated with a central venous catheter.

Risks of Bone Marrow Aspiration and Biopsy: You will sign a separate consent to undergo bone marrow aspirate and biopsy. This consent form will describe the risks associated with bone marrow aspiration and biopsy.

Risks of Venous Puncture: Side effects very likely to occur with venous puncture (a needle inserted into a vein in your arm) may include:

- Bleeding
- Bruising or soreness
- A serious infection may result, but is unlikely.

Radiation Risks Associated with Scans and X-Rays: While you are in this research study, x-rays, CT scans and PET/CT scans may be used to evaluate your disease. The frequency of these exams is similar to that which you would receive as standard care. There is thought to be a small but increased risk of cancers associated with radiation in the long term over many years.

Reproductive Risks

The chemotherapy treatment used in this study may cause unforeseeable risks to pregnant women or to unborn babies. Because of the unknown side effects of ProTmune (modified cells) on pregnant women, fetuses, newborn children, and sperm, women who are pregnant or breast-feeding and men who are seeking to father children, should not participate in this study.

Women must:

- Have a negative pregnancy test before they start the study and agree to avoid becoming pregnant while taking it (i.e. through use of an effective contraceptive), and immediately inform their study doctor should they become pregnant.

Men must:

- Agree to use an effective contraceptive to avoid impregnating a woman and
- Immediately inform their study doctor should they impregnate a woman.

There may be additional side effects that are not known at this time.

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you think you may be pregnant during the study, you must inform your study doctor immediately.

Men who are in this research study should not get a sexual partner pregnant. The effect of the study treatment on sperm is not known.

Other Risks

Your condition may not get better or may get worse during this study.

NEW INFORMATION

You will be informed about any new information that becomes available while you are in the study and may be asked to sign a new consent form if this occurs.

BENEFITS

Your blood cancer may improve while you are in this study and you may have less complications, such as GVHD and infectious diseases as compared to patients who do not get this experimental treatment; however, this cannot be promised. The results of this study may help people with blood cancer in the future.

COSTS
Fate Therapeutics will provide the reagents and supplies that are necessary to prepare the study treatment free of charge. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

You or your insurance company may be billed for any standard medical care given during this research study.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

PAYMENT FOR PARTICIPATION
You will be reimbursed $*[amount]* for costs such as transportation to the clinical for study visits. You will only receive that reimbursement for the visits you have completed.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there might be other choices available. Ask the study doctor to discuss these alternatives with you.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:
- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:
- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,

- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board® (WIRB®) or a local IRB

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
You will not be able to participate in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission? You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Confidentiality Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study treatment may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;
- Medpace, Clinical Research Organization, an agent for the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA,
- Department of Health and Human Services (DHHS) agencies,
- governmental agencies in other countries, and
- Western Institutional Review Board® (WIRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

COMPENSATION FOR INJURY

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance company will be billed, if appropriate, for the costs of the care you receive, but you may also be responsible for some of them. If an injury was caused by the investigational treatment, then the Sponsor will pay the reasonable costs for necessary medical treatment that is not covered by your medical insurance, provided you have followed the directions of the study doctor. This commitment does not include treatment for any other complications or illness that you may experience during this study which are not caused by the investigational treatment, including medical complications that are a part of the natural course of the primary disease or that are caused by the standard treatment for such disease.

There are no plans for [Insert Institution Name] or the Sponsor to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- In the event that the incoming stem cell product does not meet ProTmune or Control processing requirements, you will come off the study and receive a standard of care transplant.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

SOURCE OF FUNDING FOR THE STUDY

The sponsor, Fate Therapeutics, will pay for this research study.

QUESTIONS

Contact _____*[name]*_ at ____*[number(s)]*_____for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study drug, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research patient or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above

By signing this consent form, I have not given up any of my legal rights.

_____
Patient Name (printed)

_____ _____
Signature of Patient Date

_____ _____
Printed Name of Person Conducting the Informed Consent Discussion Position

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date