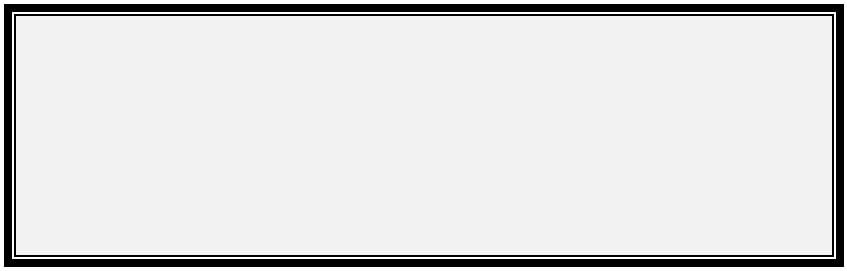
APPENDIX B-1

RECIPIENT INFORMED CONSENT

Informed Consent to Participate in Research



We invite you to participate in this research study. About 45 patients will participate at up to eight centers around the country. Your study participation will last about two years. This is a study for patients who are going to have an allogeneic (donor) peripheral blood stem cell transplant for acute myelogenous leukemia.

This consent form tells you about the study. The doctors in charge of this study (the investigators) or other staff will also discuss this study with you and answer any questions you might have. Before you decide to join this study, please read this information and ask any questions about things you do not understand. Some patients find it helpful to have a family member or friend with them to help ask questions and listen to information.

This study will give more information to doctors about future treatment choices for patients with leukemia. It is important to know that:

- You will not be paid to be in this study.
- You or your insurance company will pay for all medical bills for your treatment.
- You will not be charged for research tests – tests you would not normally have if you were not a part of this study.

Before you decide to join the study, please read the information below. Feel free to ask questions to understand your rights. It is your choice to take part in this study. You and your doctor will discuss other treatment options if you decide not to be in this study.

Your Name: _____

1. Title of Research Study

A Single Arm, Multicenter Phase II Trial of Transplants of HLA-Matched, $CD34^+$ Enriched, T cell Depleted Peripheral Blood Stem Cells Isolated by the CliniMACS System in the Treatment of Patients with AML in First or Second Morphologic Complete Remission

2. Principal Investigator Contact Information at your Institution

Name/Title/Phone number/

3. Contact Information for Emergencies After Hours or on Weekends or Holidays
Name/Phone number/

4. Study Sponsors
This study is sponsored by the National Institutes of Health (NIH) by providing financial support for this study through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

The device that removes T cells from the donor peripheral blood stem cells that is being used in this study is called the CliniMACS device. It is being supplied by Miltenyi Inc., the company that makes it. This company did not plan or design the study. In addition, they will have no part in analyzing the results of this study.

5. What is the purpose of this study?
A donor peripheral blood stem cell transplant has been offered to you because your doctors think it may improve the chances of curing your acute leukemia. Based on what we now know, when transplantation using a related donor is performed for patients with acute leukemia in remission, the chance of the leukemia returning is still present but less likely than with anti-cancer drugs alone. Anti-cancer drugs are usually called chemotherapy. Your doctor can discuss with you the results of other studies using chemotherapy alone without transplantation.

One of the possible complications of allogeneic stem cell transplant is graft-versus-host disease (GVHD). GVHD develops when T cells in the donor's peripheral blood stem cells (also called the graft), attack organs in your body, such as the skin, gastrointestinal tract (stomach and bowels), and liver. GVHD can also increase your risk of infection.

Signs of GVHD can include mild to severe skin rashes, yellowing of the skin (jaundice) due to liver disease, nausea and vomiting, mild to severe diarrhea and malnutrition and breathing problems. GVHD can be treated and often can be cured. Sometimes it continues despite treatment, but in a milder form. Although most of the time GVHD is treatable, sometimes patients can die because of complications due to GVHD.

Something must always be done to prevent GVHD, unless your donor is an identical twin. The most common approach to preventing GVHD is to give drugs to the patient receiving a transplant. This decreases the chance of getting GVHD and the severity of GVHD if it occurs. But it does not prevent GVHD in all patients. Approximately half of patients receiving donor transplants from a brother or sister still get GVHD.

Another method has been developed to remove T cells, the cells that cause GVHD, to prevent GVHD in more patients. If this is done, the patient does not have to receive drugs to prevent GVHD. T cells are removed in the laboratory, *after* the cells are collected from your donor, but *before* they are given to you. Several studies show that taking T cells out of the graft is good at preventing both the early and late forms of GVHD. This type of donor transplant is called a *T cell depleted transplant.*

It is possible that reducing your chances of getting GVHD by using T cell depletion may not improve your outcome after the transplant. Some methods of removing T cells from the donor cells have resulted in other bad outcomes. These outcomes include more patients rejecting the transplanted cells (graft failure), more patients' leukemia coming back after the transplant (relapse), an increase in potentially life threatening infections and possibly the development of another tumor. Previous studies in small numbers of patients using the device being tested in this study have not shown increased problems with graft rejection, leukemia relapse or new tumors. Your doctor can discuss these issues with you in more detail.

6. How will my treatment differ if I participate in this study?

The most likely treatment you would receive if you do not participate in this study would be a donor transplant from your brother or sister that has not had the T cells removed. The answer to this question lists what would be different for you if you participate in the study compared to that treatment.

a. You will receive a specific combination of medicines and irradiation to suppress your immune system prior to receiving your donor's cells. Although this combination has been used for this type of transplant for a long time, it is likely different from what you would receive if you do not participate in the study.

b. Most of the T cells will be removed from your donor's cells (the graft) before the graft is given to you. We will use the CliniMACS device to remove the T cells. This device uses a magnetic system to separate the stem cells away from the T cells that can cause GVHD.

c. You will not receive drugs after the transplant to prevent GVHD because GVHD should be prevented by removing the T cells from the donor graft using the CliniMACS device.

d. You will need to follow up with the doctors that do your transplant on a specific schedule for up to two years after your transplant.

7. What will be done if you take part in this research study?

The transplant process has many steps. You have been offered a T cell depleted peripheral blood stem cell transplant because you have a brother or sister that matches you and has agreed to be your donor. Both you and your donor will need to have tests done before you can have the transplant. You and your donor will need to give permission to join this study. Your donor may refuse to participate in this study, but continue to be available to donate cells for your transplantation**.** You may decide to have a transplant using this donor, but not join this study.

To make the consent form easier to follow, side effects and risks related to the different parts of the study treatments are given later in the consent form, after the description of the overall process.

Your participation in this study is expected to last up to two years. Initially, you will undergo a series of tests that include drawing about 6 tablespoons of blood. These tests are standard and are done to be sure it is safe for you to have the transplant. Samples of your bone marrow will be taken to be sure that your acute leukemia is in first or second remission. Samples of the fluid that bathes everyone's brain and spinal cord [cerebrospinal fluid] may also be

checked before transplant in special situations. This fluid is obtained by inserting a small needle in the lower middle part of your back; or if you have had a device placed in your head (Ommaya reservoir) for this purpose, fluid may be obtained from this site. It is necessary to check this fluid if you have a history of leukemia in your spinal fluid. It is also necessary if you have had leukemia anywhere outside your bone marrow such as in your skin or gums. These tests are always done for patients with acute leukemia who will receive a transplant. They are not being done just for this study's purposes.

You will then be admitted to the hospital and will have a catheter placed in a large blood vessel in the chest. This catheter placement will be done under local anesthesia and is considered standard of care for transplant patients. This catheter will be used to draw blood and give transfusions and medications. Your hospitalization and period of recovery following transplant can be broken down into four major parts.

The first part is the treatment that you are given in order to kill any leukemia cells in your body. This part also allows your body to accept your donor's peripheral blood stem cells. All patients receiving transplant must receive some kind of treatment to do this. However, the treatment you will receive is considered research since it is not routinely given to patients having a conventional peripheral blood stem cell transplant. However, it is felt that all the radiation and drugs given in the treatment are needed so that you will not reject your donor's peripheral blood stem cells. The first four days of treatment you will be given radiation treatment to your whole body, three times a day. After this, you will receive four days of chemotherapy. On the first two days, you receive a drug called thiotepa. The next two days, you receive a drug called cyclophosphamide. Both of these drugs will be given through your catheter. On the sixth day of treatment you will also receive a medicine called antithymocyte globulin or Thymoglobulin through your catheter. After the treatments are given, you will have a day off treatment before you receive your donor's peripheral blood stem cells.

The second part of your hospitalization is the peripheral blood stem cell transplant itself. The transplant is necessary to restore blood production after the high-doses of chemotherapy and radiation. Prior to your transplant, blood stem cells will be collected from your donor. The cells that can cause GVHD, T cells, will be removed from your donor's blood in the laboratory using a machine called the CliniMACS device. This is called T cell depletion. This part of the study is considered research because it is not routine to have T cells removed from your donor's blood stem cells. After the T cells are removed, the rest of the donor's blood stem cells are given to you in the same way you receive a blood transfusion. They are slowly injected into your veins through your catheter. It is not put directly back into your bone. The cells will find their own way to your bone marrow where they begin to grow again. Your donor's blood stem cells may have to be given to you on more than one day, after each collection.

The third major part of your hospitalization is the time during which the donated blood stem cells begin to grow and provide normal blood cells for you. During this time, patients develop many of the problems that occur because of the treatment they received before the transplant [see Risks, below]. These problems are, for the most part, related to the period in which neither you nor your donated blood stem cells are making enough normal blood cells for you.

These problems occur with all transplants like this and are not specifically related to this study. You may also have severe irritation on the insides of your mouth, esophagus or swallowing tube, stomach, and intestines. Until your immune system recovers and is able to fight infection on its own, steps will be take to protect you from being exposed to too many germs. Until your blood counts reach safe levels, you will be given blood & platelet transfusions. Once your donated blood stem cells begin to grow enough normal cells, much of this treatment can be stopped, and most patients can go home.

The fourth major part of your treatment is your recovery period. Many patients have no further problems and remain at home. Patients typically see their transplant doctor in the clinic on a regular, usually weekly, basis until at least about 100 days after the transplant and less frequently after that. Other patients may develop problems that require re-admission to the hospital (see Risks, below), like a fever or pneumonia or the development of GVHD. You might think of yourself as a newborn baby with little or no resistance or immunity to many common, everyday infections. For this reason, you will need to take all the preventative medicines prescribed for you when you leave the hospital. You will also need to take all precautions explained to you to prevent or reduce your chances of getting a fever or infection. Above all, you will need to stay in close contact with your transplant doctor.

You may require transfusions of blood and/or platelets as an outpatient for several weeks (or rarely for months) after transplant. You will have bone marrow biopsies done at approximately 3, 6, and 12 months after the transplant to determine if you have adequately accepted the donor's blood forming cells and to monitor the status of your acute leukemia. These tests are important for your medical care and are not considered research.

The study coordinators at your center will collect information from your medical chart about you and your health over two years. They will collect information every week for 100 days, then at 3 months, 6 months, 1 year, and 2 years.

8. Will you provide blood samples for research?

You will provide samples for research to determine how your immune system is recovering after the transplant. This will involve drawing about one teaspoon of blood at about 1, 3, 6, and 12 months after the transplant.

You will also provide about one teaspoon of blood weekly up to 100 days and monthly to 6 months. These samples will be used to see if you have any evidence of a virus called Epstein-Barr virus or EBV. EBV is a virus that can cause a cancer of the immune cells. This cancer is called lymphoproliferative disease or LPD. This happens in less than 5% of patients. If untreated this complication can be serious or even cause death. It can be treated and reversed with a medicine called rituximab. This complication is more common after a T cell depleted transplant than a non-T cell depleted transplant. Screening for EBV is often done for patients getting a T cell depleted transplant. For this study the tests will be performed at a single laboratory and are considered part of the research.

Neither you nor your insurance company will be billed for these research tests.

9. What are the possible discomforts and risks?

Likely Side Effects	Less Likely Side Effects	Rare Side Effects
What it means: This type of side effect may occur in 10% or more of patients. This means that 10 or more patients out of 100 get this.	**What it means:** This type of side effect may occur in 3-9% of patients. This means that 3 to 9 patients out of 100 might get this.	**What it means:** This type of side effect does not occur very often, but can occur in less that 2% of patients. This means that 1 or 2 patients out of 100 might get this.

Central venous catheter (Central line):

Less Likely Side Effects	Rare Side Effects
• Clotting of blood (treated with a medicine that dissolves clots) • Bleeding around the catheter • Infection in the tissues around the catheter or in the bloodstream • Skin redness at the catheter exit site, which may require treatment with an antibiotic	• A small chance of a puncture to the lung during placement of the catheter • A blood clot can form on the tip of the catheter, break off, and go into the lungs (pulmonary embolus), which could cause shortness of breath and pain

In general, patients do well with their catheters, but there are side effects. Even though local anesthetic is used while placing the central venous catheter in your body, this will cause some discomfort.

Blood samples are drawn frequently to follow the treatment and course of events. The risk is limited to the discomfort at the site of the needle insertion, although most of the time, blood will be drawn through the central venous catheter, which is generally painless.

Cyclophosphamide (Cytoxan):

Likely Side Effects	Less Likely Side Effects	Rare Side Effects
• Lower white blood cell count with increased risk of infection • Diarrhea (loose stools) • Vomiting (throwing up) • Liver damage • Lower sperm production in men • Hair loss • Nausea (feeling sick to your stomach) • Loss of appetite • Missing or stopping menstrual cycle in women • Infertility	• Bleeding from the bladder • Sores in mouth or on lips • Blood in urine • Decreased energy / tiredness, fatigue • Lower platelet count (mild) with increased risk of bleeding • Darkening of nail beds • Fetal damage if pregnancy occurs while taking Cyclophosphamide	• Lung fibrosis with cough and shortness of breath • Heart failure with high doses • Decrease in sodium level in the blood with high doses • Secondary cancers

Cyclophosphamide can cause bleeding in your bladder. Getting more fluid through a vein or your catheter and drinking extra liquids may prevent this. A drug called Mesna is given to prevent damage to the bladder, and the bladder may be irrigated (washed out) with a salt-water solution.

It is not know whether the use of Cyclophosphamide will cause additional side effects or problems with patient health in the future.

Total body Irradiation (TBI):

Likely Side Effects	Less Likely Side Effects	Rare Side Effects
• Diarrhea (loose stools) • Nausea (sick to the stomach) • Stomach cramps • Vomiting (throwing up) • Painful swelling of the parotid gland (salivary glands under the ears) for a few days • Short-term hair loss • Anemia • Infection • Bleeding • Cataracts • Sterility (inability to have children • Growth failure • Endocrinopathies (such as thyroid disease or diabetes) • Mouth sores	• Lung inflammation Pneumonia • Redness of the skin • Liver problems	• Risk of developing other cancers in the future as a consequence of having received the total body irradiation • Difficulty swallowing • Back problems • Kidney problems

Although TBI can theoretically cause abnormalities in children born to transplant survivors, the incidence of genetic abnormalities has not been reported to be greater than the general population. However, this is a potential risk and birth control should be used for a least one year after transplant to minimize risks of conceiving.

Thiotepa:

Likely Side Effects	Less Likely Side Effects	Rare Side Effects
• Lower white blood cell count with increased risk of infection • Diarrhea (loose stools) • Vomiting (throwing up) • Liver damage • Lower sperm production in men • Hair loss • Nausea (feeling sick to your stomach) • Loss of appetite • Missing or stopping menstrual cycle in women • Mouth/throat sores • Sterility (inability to have children)	• Liver abnormalities • Skin rash • Change in skin coloring • Risk of bleeding due to low platelet count	• Confusion • Disorientation

Antithymocyte Globulin (ATG): This is a preparation of antibodies that were produced by rabbits that were immunized with thymocytes (T cells) from human donors. As with any protein which comes from a different species (animal), injection of ATG may cause fever reactions. In earlier studies, some patients who developed GVHD and were given ATG at doses higher than doses given in this study developed an unusual lymphoma associated with a virus called EBV, and some patients died with this complication. The development of lymphomas has not been a problem in patients given lower doses of ATG before transplantation. Blood tests will be done in this study to monitor for the development of EBV infection. If the amount of EBV in the bloodstream is found to be above a certain level, a medication will be given to prevent the development of lymphoma.

Likely Side Effects	Less Likely Side Effects	Rare Side Effects
• Fever and chills • Lower platelet count that increases your risk of bleeding • Skin rashes	• Allergic reactions may include shortness of breath, fast heart rate, low blood pressure, and/or serum sickness (itching rash, facial swelling, lymph node swelling, joint pain, diarrhea, and nerve pain)	• There is also a rare risk of anaphylaxis, which is a severe and sometimes dangerous reaction to this drug. This may cause fainting, itching, skin rash or problems breathing. It could result in death. • There may also be other side effects that we do not know about

Bone Marrow Suppression: The main side effect of radiation treatment, thiotepa, and cyclophosphamide is the destruction of your own bone marrow. This is good to the extent that it kills the leukemia cells. But it also destroys the normal bone marrow that makes all the normal blood cells. This leads to increased chances of infection, bleeding, weakness, dizziness, difficulty breathing, and headaches and/or difficulty thinking clearly. The doctors taking care of you should be able to prevent and/or treat many of these problems with medicines and blood transfusions. This is sufficient for the majority of patients, until their blood cells begin to grow normally. If you do not receive a transplant after this treatment your own marrow would either not grow back at all or not grow back fast enough to prevent your death from bleeding and/or a lethal infection.

Graft Failure: The transplanted blood stem cells may fail to grow or be rejected by your body. The treatment you receive before your transplant has been designed to reduce the chance of rejection as much as possible. Recent measures used to prevent this problem have reduced the likelihood of rejection or early graft failure to less than 5%. If your donated stem cells fail to grow due to rejection, viral infection, or other causes, you may be offered a second transplant. This second transplant would be from the same donor. If your transplant fails and you could not receive a second transplant from your original donor, the result would probably be death except in the unlikely event that your own marrow recovered despite the high dose radiation treatment and chemotherapy. Second transplants are also used in rare cases to improve otherwise delayed recovery of normal immune function that helps you fight infections.

Graft-versus-host disease [GVHD]: GVHD is a disease in which the donor blood stem cells react against your own body organs and tissue. There are both early and late forms of this problem. GVHD may never appear, may be mild and temporary, or may lead to severe complications including death. Early GVHD can cause skin rash, diarrhea, or liver injury. In addition, late GVHD can also cause damage to many other organs including lungs and sexual organs. It may be severe enough to cause death in 15% of patients receiving non-T cell depleted transplants. Severe GVHD increases the chance of infections that may result in

death. Both forms of GVHD appear to occur less often in patients receiving T cell depleted transplants.

Low Number of Donor Blood Stem Cells: There is a small risk that the number of blood stem cells collected from your donor may not be enough cells for you to receive a fully T cell depleted peripheral blood stem cell transplant. A certain number of donor blood stem cells are necessary in order for the donor cells to start growing in your body. Your doctor can predict this based on tests done in the laboratory during the T cell depletion procedure. In such a situation, your doctor may decide it is in your best interest to receive a non-T cell depleted transplant. Should this occur, then you would receive medications to reduce the chances of developing GVHD. Medications are essential to prevent GVHD if you receive a transplant that has too many T cells.

Relapse of Leukemia: The leukemia may return at a later date even if the transplant is successful. Based on current information, this risk is lower than your chance of relapse or death from your disease without a transplant. The risk of relapse may be higher with a T cell depleted transplant compared to a conventional transplant, but we do not know this for sure.

Second Cancers: Anyone who has ever had cancer once is more likely to develop a second kind of cancer, than someone who has never had any cancer at all. You may develop a second type of cancer that is different from your leukemia because of the radiation and chemotherapy given for your transplant. Approximately 2% of patients alive 10 years and 7% alive 15 years after their transplant will have developed another cancer. Many of the second cancers can be successfully treated.

Sterility: The combination of radiation and chemotherapy given for the blood stem cell transplant will make you unable to have children [sterile]. This is usually permanent. Other sexual function, including the ability to have sexual relations, may also be affected. These side effects occur in non-T cell depleted transplants as well. If you want to maintain the possibility of having children later and are a man, ask for a referral to a sperm bank. The options for women are not as simple and may not be in your best interest due to the time required. Your doctor can discuss these with you and try to make referral. These options may or may not be feasible, depending on the type of chemotherapy that you have already received for your disease. Also, should any of this delay your transplant to an extent that would reduce your chances of success, your doctor will recommend that you proceed directly with the transplant.

Transfusion Risks: There are risks from transfusions of all blood products after transplant. These risks may include too much fluid, serious allergic reactions, and infections such as viral hepatitis B or C, cytomegalovirus infection, and AIDS. All blood products you receive will be screened against such diseases. The screening standards are set according to blood banking guidelines established by outside regulatory agencies and apply to all patients in this and other hospitals. Screening procedures and standards are constantly updated as new technology comes along. This helps to reduce the risks of transmitting disease by blood transfusions.

Potential Allergic Reactions to Murine Proteins: Mouse (murine) protein antibodies are used in the CliniMACS processing procedure. If you have a pre-existing allergy, you may be at risk for allergic reactions during infusion of the processed donor stem cells, although only very small amounts of mouse protein are present. To date, no allergic reactions are reported in patients receiving cells processed with the CliniMACS System. You should notify your physician if you have been told you have an allergy to mouse proteins or if you know that you have received a product containing mouse antibodies. Some patients that have previously been exposed to products containing mouse antibodies may develop their own antibodies against mouse proteins. These are called human anti-mouse antibodies or HAMA. The presence of HAMA may possibly make a person more likely to develop an allergic reaction to mouse proteins, but this is not proven. Unfortunately, there is no well accepted test for measuring HAMA and it is not known whether the presence of HAMA would let us know if you would have an allergic reaction to mouse proteins. Therefore, we will not be testing for HAMA in this study. In the event that you do have an allergic reaction, epinephrine (a drug used for cardiac arrest) and antihistamines (drugs used for allergic reactions) will be available at your bedside during the infusion.

Organ Damage: Damage to any of the major organs, including the brain, may occur. This can be caused by a number of things: high-dose radiation and chemotherapy, reaction to other drugs, other destructive processes such as infection, GVHD or a combination of these factors. Your doctors will use antibiotics and other medications to reduce the risk of this happening. Although severe organ damage may have a fatal outcome, less than 10% of people receiving a T cell depleted peripheral blood stem cell transplant die from this type of complication.

Risk of Infections: Your ability to fight infections in a normal way [normal immune function] may not occur until 1-2 years after your transplant. Until that time, you will be very susceptible to infection. The infections can include germs you catch from your family and friends. Infections can also come from things that are very common and around us all the time. These common things normally do not cause disease when you have a normal immune system. In order to reduce your risks of these infections, you will be asked to follow the guidelines that you will be taught before leaving the hospital. You will also be given certain medications where preventive treatment has been found to be effective. Unfortunately, even following all the guidelines and taking all the preventive medications does not guarantee that you will not develop a serious infection. If you get an infection you will require additional tests and treatment. You may need to return to the hospital. Many infections can be treated successfully, but some can lead to death in spite of hospitalization and treatment. Infections are a common problem for all transplants, but they might occur more often after a T cell depleted transplant.

Risk of Death: The risk of dying from a problem in the immediate period (approximately the first month) after your transplant is 5-10%. The risk of death during this period depends on many things. Things like your age, any other medical problems, or the amount of prior treatment you have had for leukemia effect your risk. The tests you have before your transplant are used by your doctor to see if you are at increased risk for serious complications including death from the transplant. We do not believe the risk of death will be higher with a T cell depleted transplant than with a non-T cell depleted transplant.

During the time you are in the study, you will be informed of any new findings that might affect your willingness to continue should they occur.

If you are injured as a result of your participation in this research study, emergency care, hospitalization, and outpatient care will be made available to you by [ ] and billed to you as part of your regular medical expenses. No money will be provided as compensation for a research-related injury.

As with any treatment, there may be yet unknown and/or unexpected side effects from a T cell depleted blood stem cell transplant.

10. What other alternatives or treatments are available if you do not want to be in this study?

Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not affect current or future health care you receive at this hospital. You and your doctor will discuss any other treatment options available to you including:

- No treatment
- Chemotherapy
- A transplant using your own bone marrow or peripheral blood stem cells
- A transplant of bone marrow or blood stem cells from a relative without T cell depletion
- A transplant of bone marrow, blood stem cells or cord blood cells from a donor who is not related to you
- A transplant of bone marrow or blood stem cells from a relative using T cell depletion at another institution that is not participating in this study

11. What are the possible benefits to you?

If a T cell depleted transplant proves to be more effective in reducing the risk of GVHD without increasing the incidence of other serious side effect, you may benefit by participating in this study. On the other hand, you may receive no direct benefits from this study. You may or may not benefit from the scheduled medical assessments required for this study, and extra support from personnel working for this study.

12. What are the possible benefits to others?

You may be helping other patients get better treatment in the future.

13. If you choose to take part in this study, will it cost you anything?

You and/or your insurance company will pay all medical expenses relating to, or arising from the blood stem cell transplant. You or your insurer will not be charged for the T cell depletion of the blood stem cell graft since this is considered research. You or your insurer will not be charged for samples and tests that are considered research. For questions about your costs, financial responsibilities, and/or medical insurance coverage for your transplant and this study, please contact /Center/ Financial Counselor at /Number/.

14. Will you be paid for taking part in this research study?

No.

15. What if you are injured because of the study?

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

16. How can you withdraw from this research study?

You may decide to quit this study at any time, for any reason, without notice. However, if you quit after you have had some or all of the chemotherapy and radiation treatment but before your transplant is given, then your blood counts may not return and you could die. Even if you withdraw from the study after starting treatment, you will require medical follow-up to manage side effects of treatment you have received. If you decide to quit, we ask that you tell [the Principal Investigator] in writing (his/her address is on the front page of this form). You may also withdraw from the study by providing verbal notification to your physician and a witness. If you do take back your consent, there will be no penalty. You will not lose anything you are entitled to. You will continue to receive proper medical care. If you have any questions about your rights as a study subject, you may phone the Institutional Review Board (IRB) office at /number/.

17. If you quit the study, can information about you still be collected and used?

If you quit the study, we ask that you let us continue using all information that was already collected. We also ask that you let your doctor continue to tell us about your progress until two years after your transplant. You may say no at any time.

18. Can the Principal Investigator withdraw you from this research study?

You can be taken off the study (with or without your consent) for any of these reasons:

- Staying in the study would be harmful to you.
- You need treatment not allowed in this study.
- You do not follow directions.
- The study is cancelled.

19. How will your privacy and the confidentiality of your research records be protected?

The centers and doctors in charge of this study will keep your personal information as private as possible. They will do their best to see that it is shared only when required by state or federal law or the terms of this consent. It is impossible to promise total privacy. In addition to following state and federal law, the organizations listed below may read or copy your records to make sure the study information is correct. Your research and medical records will have your name on them. They will include things such as your medical history, results of your blood tests and exams, as well as reports about your treatment and office visits.

In order to understand the results of the study, people from the /Center Name/ and the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) will need to see medical records with your name on them. These people include:

- Doctors in the study
- Transplant center committees
- People (who are not doctors) who check the safety and progress of studies
- Members of the Institutional Review Board (this committee safe-guards the rights of persons taking part in research), and
- People from the government (the National Institutes of Health and the Food and Drug Administration)

Your research and medical records may be shown to these organizations:

- [Institution]
- Office of Human Research Protection (OHRP)

Information related to or resulting from your stem cell transplant will be reported to the Center for International Blood and Marrow Transplant Research (CIBMTR). The CIBMTR is a voluntary organization of basic and clinical scientists working together in an effort to gather information on results of stem cell and marrow transplants. This information is used to guide clinical decisions and identify ways to improve transplant outcomes. Scientific data or medical information (not identifiable with you) that could be useful to others may be presented at meetings and/or published in medical journals.

Data about your progress will be sent to the Blood and Marrow Clinical Trials Network Data Coordinating Center and the International Blood and Marrow Transplant Registry. Your name and other personal identifiers will NOT be sent to these organizations.

Summary data will be shared with Miltenyi, the company that is providing the CliniMACS materials to do the T cell depletion. They may also view your study record.

We will do all we can to keep your medical records private. Your name will not be used in any report of study results. Only study personnel will have access to your information. However, if any of your answers lead us to believe you are seriously depressed or in danger of hurting yourself, your doctor will be notified. For questions about access to your medical records, please contact /name / at/number/.

20. What is the expiration date for keeping your records?

Study records will be kept indefinitely by the transplant center for re-analysis and follow-up. If you have questions about the keeping of your research records or access to your files, please call /name/at /number/.

The data sent to the Blood and Marrow Clinical Trials Network Data Coordinating Center will be kept for 5 years after the study has ended.

21. How will the researcher(s) benefit from you being in this study?

The researchers have no money invested in this study. But, in general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in the scientific press. In addition, the Principal Investigator is being paid a small amount to cover the cost of the study.

22. HIPAA[1] authorization to use and disclose individual health information for research purposes

a. Purpose: As a research participant, I authorize the Principal Investigator and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research study entitled *A Single Arm, Multicenter Phase II Trial of Transplants of HLA-Matched, CD34$^+$ Enriched, T cell Depleted Peripheral Blood Stem Cells Isolated by the CliniMACS System in the Treatment of Patients with AML in First or Second Morphological Complete Remission.*

b. Individual Health Information to be Used or Disclosed: My individual health information that may be used or disclosed to conduct this research includes: demographic information (e.g., age, date of birth, sex, weight), medical history (e.g., diagnosis, complications with prior treatment), physical examination findings, and laboratory test results obtained at the time of work-up and after transplantation (e.g., bone marrow tests, blood tests, biopsy results).

c. Parties Who May Disclose My Individual Health Information: The researcher and the researcher's staff may obtain my individual health information from (*list hospitals, clinics or providers from which health care information can be requested*).

_____

_____

_____

d. Parties Who May Receive or Use My Individual Health Information: The individual health information disclosed by parties listed in item "c." above and information disclosed by me during the course of the research may be received and used by the following parties:

- Principal Investigator and the researcher's staff
- Dr. Steven Devine, Study Chairperson and staff/laboratories at Ohio State University
- Dr. Richard O'Reilly, Study Chairperson and staff/laboratories at Memorial Sloan-Kettering Cancer Center
- National Heart, Lung and Blood Institute (NHLBI) and National Cancer Institute (NCI), both of the National Institutes of Health (NIH), study sponsors
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN), data coordinating center

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

- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)
- U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments

e. Right to Refuse to Sign this Authorization: I do not have to sign this Authorization. If I decide not to sign the Authorization, I will not be allowed to participate in this study or receive any research-related treatment that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

f. Right to Revoke: I can change my mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

g. Potential for Re-disclosure: My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected. Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

h. This authorization does not have an expiration date.

23. Subject's Consent

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

I voluntarily agree to participate in this study.

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

_____ _____
Signature of Subject Date

_____
Print Name of Subject

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this study have been explained to the above individual and that any questions about this information have been answered.

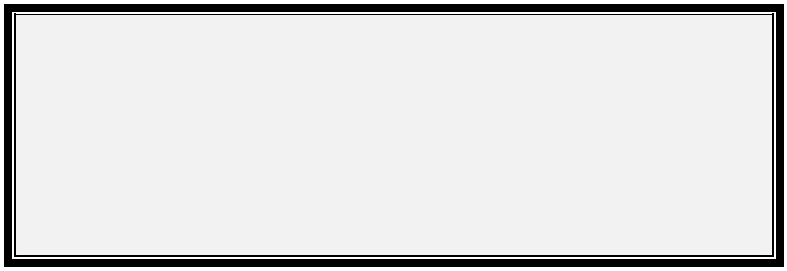
_____ _____
Signature of Counseling Healthcare Professional Date

_____
Print Name of Counseling Healthcare Professional

APPENDIX B-2

DONOR INFORMED CONSENT

- **Donor Informed Consent to Participate in Research**
-



This is a consent form for a research study. This form is to help you decide if you want to participate in this study.

Your family member has acute leukemia and may be treated with a blood stem cell transplant using blood stem cells donated by a family member like you. This type of transplant is called a peripheral blood stem cell transplant. The goal of this study is to see if transplant patients have better results when the cells that can cause a serious complication called graft-versus-host disease (GVHD) are removed from the donor's stem cells prior to transplantation.

This consent form tells you about the study. The doctors in charge of this study (the investigators) or other staff will also discuss this study with you and answer any questions you might have. Before you decide to join this study, please read this information and ask any questions about things you do not understand. Some people find it helpful to have a family member or friend with them to help ask questions and listen to information.

This study will give more information to doctors about future treatment choices for patients with leukemia. It is important to know that:

- You will not be paid to be in this study.
- You, your medical insurance company or the patient's medical insurance company will pay for all medical bills for your treatment.
- You will not be charged for research tests – tests you would not normally have if you were not a part of this study.

Before you decide to join the study, please read the information below. Feel free to ask questions to understand your rights. It is your choice to take part in this study.

1. Title of Research Study

A Single Arm, Multicenter Phase II Trial of Transplants of HLA-Matched, $CD34^+$ Enriched, T cell Depleted Peripheral Blood Stem Cells Isolated by the CliniMACS System in the Treatment of Patients with AML in First or Second Complete Remission

2. Principal Investigator Contact Information at your Institution
Name/Title/Phone number/

3. Contact information for emergencies after hours or on weekends or holidays:
Name/Phone number/

4. Sponsors and Source of Funding or Other Material Support
This research study is paid for by the National Institutes of Health (NIH). The Blood and Marrow Transplant Clinical Trials Network (BMT CTN) will direct the research study. A company called Miltenyi will provide the CliniMACS system for doing the T cell depletion. This study will be done at many different medical centers, including [Center Name/Location].

5. What will be different for you as a donor of peripheral blood stem cells if you choose to participate in this study?
If you plan to donate blood stem cells to the patient, participating in this study does not change how you will donate blood stem cells. The donation process for you is the same for this study as it would be if the patient was receiving a standard transplant.

6. What is the purpose of this study?
The purpose of this study is to determine if radiation therapy and chemotherapy followed by transplantation of T cell depleted stem cells donated by you can effectively treat your family member's acute leukemia. The research portion of this study involves the process of removing of the T cells from your stem cells (T cell depletion) since this process is not routinely performed.

7. What will be done if you take part in this research study?
In order to determine whether you are medically able to donate blood stem cells you will have a complete medical history and physical and some laboratory tests will be performed. This physical will include an EKG (tracing of your heartbeat), blood tests (approximately 1-2 tablespoons), urine test and a pregnancy test (if female). These are standard tests to evaluate a person who may be a blood stem cell donor.

Granulocyte Colony Stimulating Factor (G-CSF) Injections
If the tests indicate you are eligible to be a stem cell donor, you will receive a drug called G-CSF. G-CSF is normally made by the body to help the bone marrow make white blood cells that fight infection. When given in larger doses than normally found in the body, G-CSF helps the cells needed for a transplant move from the bone marrow to the bloodstream. G-CSF is sold under the name Neupogen.

G-CSF is given as an injection under the skin. The first time you receive G-CSF, it will be given to you at the clinic. For the remaining shots, you may learn how to give them to yourself, have a family member or friend learn how to do it, have a visiting nurse do it or return to the clinic for them on a daily basis. You will continue to receive daily G-CSF shots under the skin for between five and seven days. You will be asked to return to the clinic on the morning of the 5th day of G-CSF treatment to start collecting your blood stem cells.

Apheresis
Blood stem cells are collected using a process called apheresis. Apheresis involves placing 2 catheters into blood veins in your arms. These catheters are then connected to the apheresis machine. The apheresis machine takes blood from your body, removes the stem cells from your blood, and returns the rest of the blood back to you. The apheresis procedure is done daily until enough stem cells are collected. This may involve up to three days of collections. Each session will last approximately 6 hours. During the session you will be lying down in a reclining chair. Since blood is being drawn through the catheter, there will be no additional needle sticks. However, if the catheter becomes clogged or otherwise fails to work, another catheter will be started. Your blood counts will be monitored during the process. Apheresis will be stopped if it is felt that continuing would harm your health.

Usually, the apheresis procedure can be done by inserting catheters into your veins as described above. However, if your veins are too small you may need to have a special catheter placed in a large blood vessel in your neck or chest. This is a routine procedure. It will be done in an operating or procedure room on an outpatient basis. A specially trained surgeon or radiologist will do the procedure.

At the end of two days, we will know if we have enough stem cells. If not, you will need to undergo one more apheresis procedure

If your family member fails to recover blood counts within a reasonable period of time after transplant, you may be asked to donate more blood stem cells or bone marrow. Bone marrow collection is done in the operating room. It will be explained to you in detail if it becomes necessary.

T Cell Depletion
The blood cells collected from you will have the T cells removed by a process called T cell depletion. The device used to do this is called CliniMACS. CliniMACS is an experimental device. This means it is not yet approved by the US Food and Drug Administration.

8. How long will I be in the study?
You will be in the study for up to several months from the time you sign the consent until approximately one month after stem cell collection. The actual process of taking G-CSF and then collecting your stem cells though takes less than a week. You will be contacted by phone approximately 30 days after initiation of G-CSF. You will be asked to answer questions about your health since your stem cells were collected.

9. Will you provide blood samples for research?
You will not be asked to provide blood samples for research.

10. What are the possible discomforts and risks?
Central Venous Catheter (Central line): If catheters cannot be placed in the blood veins in your arms, a central venous catheter will be needed. When a central venous catheter is put into one of the large veins in your chest, it may cause bleeding or infection. Rarely, one of your lungs could collapse. If this happens, another tube will be put into your chest until the

lung is fully re-expanded. While you have a central line in place, you have an increased chance of infection around it or in your blood. If this occurs, it will be treated with antibiotics. In some cases, the catheter may need to be removed and replaced with another catheter. Rarely, a blood clot can form on the tip of the catheter, break off, and go into the lungs (pulmonary embolus), which could cause shortness of breath and pain. This is very unlikely but if it did occur, your doctors may need to treat you with blood thinning medication.

Blood Drawing: You may experience discomfort, swelling, bruising and or bleeding at the site of the needle insertion. Less common side effects include dizziness, infection at the site of the catheter or feeling faint.

G-CSF: You will likely experience bone pain, feelings of tiredness, muscle aches, and headache. Less common side effects include low-grade fever, chills, and skin rash. Rarely, shortness of breath, wheezing, low blood pressure, and increased liver function tests occur. In extremely rare cases, rupture of the spleen has been reported following G-CSF treatment.

Leukapheresis (Apheresis): Apheresis is a procedure routinely used to collect platelets and other blood products from volunteer donors. However, rarely (less than 1% chance) side effects occur and include high or low blood pressure, muscle cramping, chills and fever, loss of red blood cells leading to anemia, and loss of platelets which may lead to easy bruising and bleeding. Transfusions of red blood cells and/or platelets may be necessary (less than 1% chance). The medicine used to prevent blood from clotting in the machine can cause tingling or numbness around your mouth, feet or hands and in rare cases bleeding. If these symptoms occur they go away quickly. You will be monitored closely during apheresis.

Participation in this study may cause some or all of the side effects listed above. Some of the side effects, if serious enough, may cause death. However, the risk of death is very small. The investigator is willing to discuss any questions you might have about the severity, frequency, and duration of these risks and discomforts.

Breach of Confidentiality: Medical records are considered confidential. These records are kept in a secured area accessible to people involved in the conduct of the study. You will not be identified by name in any publication or presentation of the results of this study. All data entered into a computer will be coded. No data that may be linked to you will be entered on any network computer that could allow access to confidential information. The master list will be stored off-line and available only to the principal investigator and his or her designee(s). Although we will make every effort possible to maintain confidentiality, there is however, a slight risk of loss of confidentiality.

11. As with any treatment, there may be yet unknown and/or unexpected side effects from donating peripheral blood stem cells.

Donating blood stem cells is routinely done and is not considered research. Unanticipated side effects may occur that have not been previously reported. If you have any unusual symptoms, you should report them immediately to your doctor.

In an attempt to avoid side effects, your doctor will examine you and obtain laboratory test (blood tests, chest x-ray, etc.) to determine the effects of the treatment and alter the drug doses if necessary.

12. What other alternatives are available if you do not want to be in this study?

Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time. Your choice will not at any time affect the commitment of your health care providers to provide care to you or the patient. There will be no penalty or loss of benefits to which you or your relative are otherwise entitled. Alternatives to participating in this research include donating your bone marrow to your relative, donating your blood stem cells for a transplant that is not part of this research study, or deciding not to donate either your bone marrow or blood stem cells. The investigator can discuss with you the other treatment options available to the patient should you decide not be a donor.

13. What are the possible benefits to you?

You will not benefit directly from participating in this research. You may receive indirect benefit from knowing that you may be helping your family member or other donors and patients in the future.

14. What are the possible benefits to others?

You may be helping other patients get better treatment in the future.

15. If you choose to take part in this study, will it cost you anything?

Normally the insurance company of the patient covers the medical expenses associated with collecting your blood stem cells. This will be reviewed with the patient's insurance company prior to collecting your stem cells. Neither you nor the insurance company will be charged for the T cell depletion of the peripheral blood stem cell graft since this is considered research. You will not be reimbursed for any direct or indirect personal expenses related to participation in the study. For questions about your costs, financial responsibilities, medical insurance coverage, donation, and/or this study, please contact /Center/ Financial Counselor at /Number/.

16. Will you be paid for taking part in this research study?

No.

17. What if you are injured because of the study?

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

18. How can you withdraw from this research study?

You may decide to quit this study at any time, for any reason, without notice. If you decide to quit, we ask that you tell [the Principal Investigator] in writing (his/her address is on the front page of this form). You may also withdraw from the study by providing verbal notification to

your physician and a witness. If you do take back your consent, there will be no penalty. You will not lose anything for which you are entitled. You will continue to receive proper medical care. If you withdraw from the study and do not donate either peripheral blood stem cells or bone marrow for your brother or sister after they have received their chemotherapy and radiation in preparation for the transplant, they will likely die from irreversible bone marrow damage.

If you have any questions about your rights as a study subject, you may phone the Institutional Review Board (IRB) office at /number/.

19. If you quit the study, can information about you still be collected and used?

If you quit the study, we ask that you let us continue using all information that was already collected. You may say no at any time.

20. Can the Principal Investigator withdraw you from this research study?

You can be taken off the study (with or without your consent) for any of these reasons:

- Staying in the study would be harmful to you.
- You need treatment not allowed in this study.
- You do not follow directions.
- The study is cancelled.

21. How will your privacy and the confidentiality of your research records be protected?

The centers and doctors in charge of this study will keep your personal information as private as possible. They will do their best to see that it is shared only when required by state or federal law or the terms of this consent. It is impossible to promise total privacy. In addition to following state and federal law, the organizations listed below may read or copy your records to make sure the study information is correct. Your research and medical records will have your name on them. They will include things such as your medical history, results of your blood tests and exams, as well as reports about your treatment and office visits.

In order to understand the results of the study, people from the /Center Name/, and the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) will need to see medical records with your name on them. These people include:

- Doctors in the study
- Transplant center committees
- People (who are not doctors) who check the safety and progress of studies
- Members of the Institutional Review Board (this committee safe-guards the rights of persons taking part in research), and
- People from the government (the National Institutes of Health and the Food and Drug Administration) might also need to see medical records with your name on them.

Your research and medical records may be shown to these organizations:

- [Institution]
- Office of Human Research Protection (OHRP)

We will do all we can to keep your medical records private. Your name will not be used in any report of study results. Only study personnel will have access to your information. However, if any of your answers lead us to believe you are seriously depressed or in danger of hurting yourself, your physician will be notified. For questions about access to your medical records, please contact /name / at/number/.

22. What is the expiration date for keeping your records?

Study records will be kept indefinitely by the transplant center for re-analysis and follow-up. The information sent to the Blood and Marrow Clinical Trials Network will be kept for five years following the closure of the study. If you have questions about the keeping of your research records or access to your files, please call /name/at /number/.

23. How will the researcher(s) benefit from you being in this study?

The researchers have no money invested in this study. But, in general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in the scientific press. In addition, the Principal Investigator is being paid a small amount to cover the cost of the study.

24. HIPAA[1] authorization to use and disclose individual health information for research purposes

a. Purpose: As a research participant, I authorize the Principal Investigator and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research study entitled *A Single Arm, Multicenter Phase II Trial of Transplants of HLA-Matched, CD34$^+$ Enriched, T cell Depleted Peripheral Blood Stem Cells Isolated by the CliniMACS System in the Treatment of Patients with AML in First or Second Morphological Complete Remission.*

b. Individual Health Information to be Used or Disclosed: My individual health information that may be used or disclosed to conduct this research includes: demographic information (e.g., age, date of birth, sex, weight), medical history (e.g., diagnosis, complications with prior treatment) and physical examination findings.

c. Parties Who May Disclose My Individual Health Information: The researcher and the researcher's staff may obtain my individual health information from (*list hospitals, clinics or providers from which health care information can be requested*).

_____

_____

_____

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

d. Parties Who May Receive or Use My Individual Health Information: The individual health information disclosed by parties listed in item "c." above and information disclosed by me during the course of the research may be received and used by the following parties:

- Principal Investigator and the researcher's staff
- Dr. Steven Devine, Study Chairperson and staff/laboratories at Ohio State University
- Dr. Richard O'Reilly, Study Chairperson and staff/laboratories at Memorial Sloan-Kettering Cancer Center
- National Heart, Lung and Blood Institute (NHLBI) and National Cancer Institute (NCI), both of the National Institutes of Health (NIH), study sponsors
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN), data coordinating center
- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)
- U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments

e. Right to Refuse to Sign this Authorization: I do not have to sign this Authorization. If I decide not to sign the Authorization, I will not be allowed to participate in this study or receive any research-related treatment that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

f. Right to Revoke: I can change my mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

g. Potential for Re-disclosure: My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected. Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

h. This authorization does not have an expiration date.

25. Donor's Consent

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

I voluntarily agree to participate in this study.

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

_____ _____
Signature of Donor Date

_____
Print Name of Donor

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this study have been explained to the above individual and that any questions about this information have been answered.

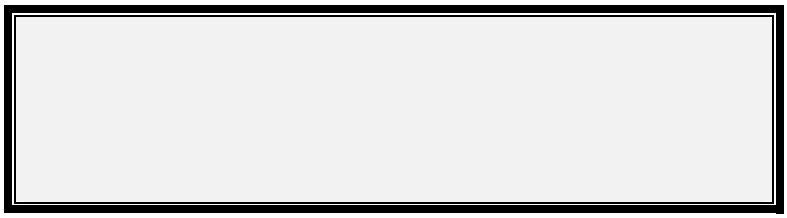
_____ _____
Signature of Counseling Healthcare Professional Date

_____
Print Name of Counseling Healthcare Professional

APPENDIX B-3

DONOR ASSENT

Donor Informed Assent to Participate in Research



This is a form for a research study. This form is to help you decide if you want to participate in this study.

Purpose of the Research Study
Your family member has acute leukemia and may be treated with a transplant of peripheral blood stem cells from a matched family member. The goal of the study is to see if patients have better results using a peripheral blood stem cell transplant in which the cells that can cause a serious complication called graft versus host disease (GVHD), are removed from the donor's peripheral blood stem cells prior to transplantation.

You are being asked to be in the study because you are a match for your brother or sister and can donate peripheral blood stem cells to them. Joining this study does not change how you will donate peripheral blood stem cells for your brother or sister. Your doctor or another person on the study team will explain to you what you must do if you are going to donate peripheral blood stem cells for your brother or sister. The team will also follow you closely to see if you are having any side effects while donating peripheral blood stem cells on the study.

If you have any questions, ask your doctors and make sure you understand their answers.

Your parents (or a guardian) are also asked for their permission for you to join this treatment study.

I agree to donate peripheral blood stem cells in this study.

_____ _____
Signature of Donor Date

_____
Print Name of Donor

_____ _____
Signature of Doctor Date

_____
Print Name of Doctor