Informed Consent to Participate in Research

A Multi-Center, Phase II Trail of Non-myeloablative Conditioning and Transplantation of Umbilical Cord Blood (UCB) from Unrelated Donors for Patients with Hematologic Malignancies

Your name:_____

Introduction
You are being invited to participate in a clinical trial. A clinical trial is a research study to answer specific medical questions. The information from this study may help future patients. This form tells you about the study. In addition, the study doctor (the person in charge of the research) will explain the study to you.

This is a consent form for a research study. You are being asked to take part in this study because you have leukemia or lymphoma that has failed other treatment or it is not likely to respond to other treatment. These diseases can be treated and sometimes cured with very high doses of chemotherapy and radiation therapy given to kill leukemia or lymphoma cells. However, this treatment also harms normal cells in the bone marrow. We and other transplant centers have the most experience using a donor who is a "perfect" or close to perfect "tissue match". However, tissue typing shows that a completely or partially matched donor is unavailable within your family. A completely matched unrelated donor transplant is an option, we either have not been able to find a good match or we are concerned that your disease may worsen in the time it takes to find one.

The bone marrow is the body's "blood factory." It makes the cells that circulate in the blood, including: red blood cells (which carry oxygen), white blood cells (which fight infection), and platelets (which prevent bleeding). The bone marrow can be fixed by giving "hematopoietic or blood stem cells" donated by someone else. This is called a hematopoietic stem cell transplant. Blood stem cells are the "parent cells" of the bone marrow that produce all the blood cells. For a transplant to be successful, the donor blood stem cells must have a tissue type that is completely or closely matched to the patient's tissue type. These genetic markers are like a "finger print" and help our immune system to determine which cells belong to the body and which do not. For patients needed a transplant that do not have a family donor who is a match (has the same tissue type), blood stem cells from unrelated donors can be used.

Blood stem cells are found in bone marrow and in umbilical cord blood. Umbilical cord blood is the blood left over in the placenta (afterbirth) after a baby is born. Usually this blood is thrown out with the placenta. Over the past 15 years, we have learned how to collect and freeze cord blood cells to be used for transplants at a later time. A cord blood unit is the cord blood cells

collected and stored from a single placenta. Cord blood units have been used for more than 6,500 transplants performed around the world.

This trial will use two cord blood units for transplantation to determine if disease survival is better using a non-myeloablative preparative regimen than using intense doses of chemotherapy and radiation therapy. Two cord blood units are being used as the numbers of blood cells in one unit are too few to allow successful growth of these cells.

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

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

Who is conducting this study?
The research in this study is paid for by the National Institutes of Health (NIH), which supports the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The BMT CTN will direct the research study. All decisions about how the study is done are made independently by the BMT CTN and NIH.

Why is this study being done?
Before a standard transplant, patients receive high doses of chemotherapy and possibly radiation therapy. This treatment is called a preparative regimen or a conditioning regimen. The preparative regimen destroys the diseased cells (such as cancer cells). It also destroys the patient's immune system so it cannot attack the donor's cells during transplant.

In contrast, the preparative regimen for a reduced-intensity transplant (sometimes referred to as a "mini-transplant") does not destroy many diseased cells. It is just strong enough to weaken the patient's immune system so it cannot attack the donor's cells. The donor's cells grow a new immune system. The new immune system destroys the diseased cells. The cells for a mini-transplant can come from a family member, an unrelated donor, or a cord blood unit.

The information collected from this study will help doctors and future patients make better treatment choices.

How many people will take part in the study?
A total of 50 patients will participate in this study. This study will be done many different medical centers in the United States, including [Center Name/Location].

What will happen if I take part in this research study?
Your treatment will start six days before you are to receive your double UCB transplant. You will begin taking a drug called fludarabine, by IV, once a day for five days. You will also receive cyclophosphaimide (Cytoxan®), another chemotherapy drug, by IV on the sixth day before transplant. On the day before transplantation you will receive a low dose of total body irradiation (TBI). The purpose of this treatment is to allow your body to accept the donor cells without rejecting them. After this treatment is completed, your donor's stem cells will be given to you through your central venous catheter.

Starting three days before your transplant, you will be given cyclosporine (also called Gengraf®) twice a day and Mycophenolate mofetil (also MMF or CellCept®) three times a day. Cyclosporine and MMF are given to prevent your body from rejecting your donor's stem cells and to help decrease the risk of developing a complication called graft-versus-host-disease (GVHD). GVHD is a condition where your donor's immune cells attack your skin, liver, intestines and potentially other organs. Some patients develop very severe GVHD, which can be fatal. In certain transplant centers patients may be given tacrolimus (also called FK-506 or Prograf®), another approved drug that helps prevent GVHD.

Because the chance of developing GVHD can persist many months after an unrelated double UCB transplant, you will continue to receive MMF for 30 days and cyclosporine or tacrolimus for 180 days after your transplant. While you are taking cyclosporine or tacrolimus, blood tests to monitor the amount of cyclosporine or tacrolimus in your blood will be done at least weekly for the first several weeks and your dose of cyclosporine or tacrolimus may be adjusted if necessary to maintain the proper level in your blood.

Blood tests will be performed frequently to evaluate your response to treatment and possible side effects of treatment. If necessary, platelet and red cell transfusions will be given to maintain adequate levels and antibiotics will be given to treat or prevent infection. You may also require intravenous nutritional support and pain medications during or after transplantation. You will be monitored closely for any signs and symptoms of GVHD.

You will receive treatment for any infections according to medical standards.

If, at any time during this study, your cancer worsens, you will be taken off study. Other treatment options will be discussed with you at that time.

How long will I be in this study?
Your treatment will last approximately 2-3 months at this center but possibly longer if there are complications. We would like to see you in clinic for follow-up at 6 months, if possible, and then one year post-transplant.

However, we would like to keep track of your medical condition for the rest of your life. We will do this by contacting you and the doctor providing your regular medical care by phone or mail once a year. Keeping in touch with you and checking on your condition every year helps us

know whether there are any unexpected long-term side effects of treatment. Many transplant centers include this type of long-term follow-up as part of their regular care.

Can I stop being in this study?
Yes. You can decide to stop at any time. If you wish, you may withdraw from the study but still receive UCB transplant. If you withdraw from the study after you have had some or all of the pre-transplant treatments and decide to have no transplant at all, then your blood counts may not return and you could die.

If you decide to withdraw from the study, we ask that you tell your doctor. If you withdraw, there will be no penalty or loss of benefit to which you are entitled and you will continue to receive medical care. The medical staff will continue to tell us about your progress for three years after your transplant. If you do not want this, you must specifically tell your doctor.

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

Can the Principal Investigator withdraw me from this research study?
You can be taken off the study (with or without your consent) for any of these reasons:

- The study treatment does not work for your type of cancer
- You develop a serious side effect that you cannot tolerate or that cannot be controlled with other medications
- You are unable to meet the requirements of the study (for example, you cannot take the medicine as prescribed or you refuse follow up)
- New information about the study drugs or other treatments for cancer becomes available.
- The study is cancelled

What side effect or risks can I expect from being in the study?

Likely Side Effects	What it means: This type of side effect is expected to occur in more than 20% of patients. This means that 21 or more patients out of 100 might get this side effect.
Less Likely Side Effects	What it means: This type of side effect is expected to occur in 20% of patients or fewer. This means that 20 patients or fewer out of 100 might get this side effect.
Rare Side Effects	What it means: This type of side effect does not occur very often – in fewer than 2% of patients – but is serious when it occurs. This means that 1 or 2 patients (or fewer) out of 100 might get this side effect.

Cyclophosphamide (Cytoxan®)

Likely	Less Likely	Rare, but Serious
• Decreased white blood cell count with increased risk of infection • Temporary hair loss • Nausea • Vomiting • Loss of appetite • Sores in mouth of on lips • Diarrhea • Stopping of menstrual periods in women • Decreased sperm production in men • Decreased platelet count (mild) with increased risk of bleeding • Blood in urine	• Anemia • Temporary tiredness • Damage to the fetus if you become pregnant while taking drug	• Scarring of lung tissue, with cough and shortness of breath • Severe heart muscle injury and death at very high doses • Secondary cancers

Fludarabine (Fludara®)

Likely	Less Likely	Rare, but Serious
• Decreased white blood cell count with risk of infection • Decreased platelet count with increased risk of bleeding • Anemia • Tiredness • Nausea • Vomiting	• Diarrhea • Numbness and tingling in hands and/or feet related to irritation of nerves of the hand and/or feet • Changes in vision	• Pneumonia • Agitation/nervousness • Confusion • Cough • Difficulty breathing • Weakness • Severe brain injury and death

G-CSF (Neupogen®)

Likely	Less Likely	Rare, but Serious
• Ache or pain inside the bones • Increased levels of liver enzymes and uric acid in the blood • Low number of platelets in the blood • Headache • Tiredness	• Local irritation (skin) at the injection site • Nausea	• Allergic reaction • Low fever • Enlargement or rupture of the spleen • Worsening of pre-existing skin rashes

Mycophenolate Mofetil (MMF; CellCept®)

Likely	Less Likely	Rare, but Serious
• Miscarriage • Birth defects • Diarrhea • Stomach pain • Damage to unborn baby • Limited effectiveness of birth control • Upset stomach • Vomiting • Headache • Tremors • Low white blood cell count with increased risk of infection • Increased blood cholesterols • Swelling of the hands, feet, ankles, or lower legs	• Anemia • Rash • Difficulty falling asleep or staying asleep • Dizziness • Uncontrollable hand shakes	• Difficulty breathing • Unusual bruising • Fast heartbeat • Excessive tiredness • Weakness • Blood in stools • Bloody vomit • Changes in vision • Progressive Multifocal Leukoencephalopathy

Total Body Irradiation (TBI)

Likely	Less Likely	Rare, but Serious
• Fatigue • Nausea	• Vomiting • Cataracts • Low white blood cell count with increased risk of infection • Low platelet count with increased risk of bleeding • Anemia	• Diarrhea • Secondary cancers

Cyclosporine (Gengraf®)/Tacrolimus (Prograf®)

Likely	Less Likely	Rare, but Serious
• Kidney problems • Loss of magnesium, calcium, potassium • High blood pressure • Tremors • Increases in cholesterol and triglyceride	• Nausea • Vomiting • Liver problems • Changes in how clearly one can think • Insomnia • Unwanted hair growth • Confusion	• Seizures • Changes in vision • Dizziness • Red blood cell destruction

Most of the problems described above, we anticipate to be common are temporary and treatable.

Risks and Toxicities Related to Standard Transplant Procedures

Risks of Umbilical Cord Blood Transplantation

The following problems may occur as a result of transplantation of cord blood. These are risks that would be present whether such a transplant was done as part of the study or not:

1. **Slow Recovery of Blood Counts.** The red blood cells, white blood cells, and platelets can be slow to recover after bone marrow transplantation. Until your blood counts recover, you will need blood and platelet transfusions, and will be at risk for bleeding and infections. Although infections can be treated with drugs, they can be very dangerous or fatal.
2. **Graft Failure.** The umbilical cord blood cells (the "graft") may fail to grow inside your body. Past experience suggests that there can be up to a 15% chance of graft failure. If graft failure occurs, this may result in low blood counts for a long period of time. Graft failure can be fatal. Should this happen, you will NOT receive additional stem cells from the same cord blood donor. However, you may be able to receive a second transplant with stem cells from another person (e.g. different umbilical cord blood donor or an adult donor).
3. **Graft-versus-host Disease (GVHD).** This condition results from the bone marrow cells recognizing your body as foreign and attacking it. In most cases, GVHD can be successfully treated. Sometimes GVHD is severe or difficult to treat and may lead to death. You will be watched closely for this complication and given medication to prevent and/or treat it.

   There are two forms of GVHD: acute GVHD (occurs in the first 3 months after transplant) and chronic GVHD (after the first 3 months). Acute GVHD may produce skin rash, nausea, vomiting, diarrhea, abdominal pain, abnormalities of liver function, and an increased risk of infection. Chronic GVHD may produce skin rashes, hair loss, thickened dry skin, dry eyes, dry mouth, liver disease, weight loss, diarrhea, and an increased risk of infection. To confirm the diagnosis of acute or chronic GVHD, you may be asked to have a biopsy (i.e. taking a small sample of tissue to look at under the microscope) of your skin, gut, or, rarely, your liver.
4. **Genetic Disease within the Cord Blood Cells.** It is possible that certain genetic diseases (for example, thalassemia or immunodeficiency) may be passed through the umbilical cord blood stem cells. While these diseases are very rare, each umbilical cord blood unit can only be tested for a few of the many possible genetic diseases. To reduce this possibility, cord blood is not collected from babies that have genetic diseases running in their family.
5. **Incorrect Labeling of the UCB.** Though rare, it is possible that incorrect labeling of an umbilical cord blood unit could occur so that you receive the wrong unit. To avoid this, the umbilical cord blood unit is re-typed to ensure that the tissue type of the donor and you are as previously reported (i.e., when the donor unit is confirmed). If the umbilical cord blood unit does not have an attached segment for us to re-type, there are several ways the unit labeling can be confirmed.

6. **Other Complications.** Other complications that can result from the transplantation procedure not specifically related to one specific drug or the bone marrow stem cells or this study include:

   a. **Damage to the vital organs in your body.** This could result in problems in any body organ, such as heart, lungs, liver, gut, kidneys and bladder, brain, etc. The lungs and the liver are particularly vulnerable. Some patients will experience severe lung problems due to infections and/or due to a reaction of the lungs to the chemotherapy and radiation. Rarely patients can suffer veno-occlusive disease of the liver (VOD). This complication results from high doses of chemotherapy and/or radiation. Patients with VOD become jaundiced (yellowish skin), have liver function abnormalities, abdominal swelling, and abdominal pain. Although many patients recover completely, these complications may cause permanent damage or even death.

   b. **Serious infections.** Full and complete recovery of your immune system may take many months following the initial recovery of your cell counts. During this time, there is an increased risk of infections. You will be prescribed certain medications to reduce the chance of those infections. However, preventative treatments are not always effective. If you have an infection, you may have to stay in the hospital longer or be re-hospitalized after transplant. Although most infections can be successfully treated, some infections may result in death.

   c. **Recurrence of disease, or development of a new blood cancer.** Your leukemia or lymphoma may come back even if the transplant is initially successful. In rare cases (<2% of patients receiving a transplant) a blood cancer may arise from cells of the donor.

   d. **Risk to the unborn.** The treatments in this study have NOT been proven to be safe at any stage of pregnancy. Therefore, if you are pregnant or nursing, you are not eligible for this study. Women who have the potential of becoming pregnant must use some form of effective birth control while receiving chemotherapy, TBI, and GVHD prophylaxis. Effective birth control is defined as the following:

      1) Refraining from all acts of vaginal intercourse (ABSTINENCE)
      2) Consistent use of birth control pills
      3) Injectable birth control methods (Depro-Provera, Norplant)
      4) Tubal sterilization or male partner who has undergone a vasectomy
      5) Placement of an IUD (intrauterine device)
      6) Use, with every act of intercourse, of a diaphragm with contraceptive jelly and/or condoms with contraceptive foam.

   e. **Sterility and future childbearing potential for men and women.** Chemotherapy and/or irradiation may affect your ability to have children. Male patients may become sterile (unable to produce sperm) and should discuss with their doctor regarding sperm banking prior to transplantation. Female patients who have attained puberty may find that their menstrual cycle becomes irregular or stops permanently.

However, this DOES NOT MEAN THAT YOU CANNOT BECOME PREGNANT, and you must use some effective method of birth control during transplant and afterwards until you are off GVHD prophylaxis. Damage to reproductive tissue may result in infertility (inability to have children). It is not known if the damage could result in birth defects. You should discuss these risks and options in detail with your doctor before entering this study.

7. **Unknown or Unexpected Side Effects.** As with any treatment, there may be unknown and/or unexpected side effects from a non-myeloablative double UCB transplant. We many learn new things about non-myeloablative UCB transplants that might make you want to stop being in the study. We will let you know if this happens and you can decide if you want to continue in the study.
8. **Additional information regarding MMF**
    a. MMF could be damaging to an unborn baby if you are pregnant or become pregnant while receiving the drug.
    b. MMF can limit the effectiveness of birth control pills and thus increase your chances of becoming pregnant while you are taking it.
    c. In this trial you will be assigned to receive MMF for approximately 5 weeks and therefore you should not become pregnant during that time. If you think you might be pregnant or could be become pregnant during the upcoming 5 weeks, you should not enroll in this trial.

Are there benefits to taking part in the study?
This research study is examining the treatment results of non-myeloablative preparative regimen along with UCB transplantation in unrelated donors. The knowledge gained from this study may help future patients who need a umbilical cord blood stem cell transplant, but there is no expectation that you will benefit from participating in the study.

As a result of the umbilical cord blood transplant, your disease may be put in remission or continue in remission.

What other choices do I have if I do not take part in this study?
Participation in this study is entirely voluntary. You don't have to be in this study. What you decide will not affect current or future health care you receive at this institution. Before you decide to be in this study, you and the medical staff will discuss other options available to you, including:

- Chemotherapy
- A bone marrow transplant from a tissue-typed partially mismatched related donor
- Transplantation from an adult unrelated donor, if one can be identified that would be a good match for you
- No therapy to try to control your leukemia/lymphoma but treatment to make sure you remain comfortable for the remainder of your life

What are the costs of taking part in this study?
You and/or your insurance company will pay all medical expenses relating to, or arising from, UCB transplantation. You will not be billed for tests that are only done for research purposes.

You will not be paid to be in this study.

Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out if they will pay.

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/.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What if I am injured as a result of being in this study?
In the event that this research activity results in an injury, treatment will be available. This treatment includes first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed to your insurance company. If you think you have suffered a research related injury, let the study doctors know right away. Unexpected side effects or accidents might result in your getting sicker than anticipated. All available medical care will be provided to you, but you and your insurance company are responsible for the costs of all such care.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. You will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information that may affect your health or your willingness to stay in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Will my medical information be kept private?
Your participation in this research study will be kept private and confidential. All your medical and demographic (such as race and ethnicity, gender and household income) information will be kept private and confidential. *(Name of Transplant Center)* and the organizations listed below will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission, or unless required by federal, state or local laws, or regulatory agencies.

Individuals authorized by the organizations below will have access to your research and medical information. They may use this information for inspections or audits to study the outcomes of your treatment. In agreeing to participate, you consent to such inspections and to the copying of parts of your records, if required by these organizations.

Organizations with access to your research and medical records:

- /Institution/
- The National Institutes of Health (NIH)
- The National Heart, Lung, and Blood Institute (NHLBI)
- The National Cancer Institute (NCI)
- Office of Human Research Protection (OHRP)
- The Food and Drug Administration (FDA)
- Institutional Review Boards (IRBs) responsible for this study
- Data and Safety Monitoring Board (DSMB), not part of /Institution/
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN), including the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP) and the EMMES Corporation who are coordinating the studies of the BMT CTN
- Study investigators

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

Information related to or resulting from your transplant will be reported to the CIBMTR. The CIBMTR is a voluntary organization of basic and clinical scientists working together to gather 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.

For questions about access to your medical records, please contact /name/ at /number/.

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 Multi-Center, Phase II Trial of Non-Myeloablative Conditioning (NST) and Transplantation of Partially HLA-Mismatched Bone Marrow for Patients with Hematologic Malignancies*

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., 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)

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

- Principal Investigators and the researcher's staff at the University of Minnesota.
- Staff/laboratories identified in the protocol for the evaluation of other laboratory samples
- National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH), study sponsors
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN), including the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP) and the EMMES Corporation who are coordinating the studies of the BMT CTN
- 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)

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 public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments.
- Others:

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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.

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Is there an expiration date for keeping my 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/.

Will researchers benefit from me being in this research study?
Your doctors have no money invested and will not get any financial gain from this study. Presenting research results may help the career of a doctor. Therefore, the doctors running this research study may benefit when the results are presented at scientific meetings or in the scientific press.

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Consent for Treatment:

I have been informed about 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

_____
Signature of Legally Authorized Representative *Date*

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.

_____ _____
Counseling Healthcare Professional *Date*

Use of an Interpreter: Complete if the subject is not fluent in English and an interpreter was used to obtain consent:

Print name of interpreter: _____ Date: _____

Signature of interpreter: _____

An oral translation of this document was administered to the donor in _____ (state language) by an individual proficient in English and _____ (state language). See the attached short form addendum for documentation.

ASSENT FORM

A Multi-Center, Phase II Trial of Non-Myeloablative Conditioning and Transplantation of Umbilical Cord Blood (UCB) from Unrelated Donors for Patients with Hematologic Malignancies

You have leukemia or lymphoma. Leukemia and lymphoma are cancers of the blood cells made in your body's "blood factory", which is called the bone marrow. These cancers are treated with special medicines. These medicines are called chemotherapy. They kill cancer cells. If chemotherapy doesn't kill all of the cancer cells, a special and stronger treatment called a transplant may be needed.

During some transplants, you receive a very large amount of chemotherapy medicines and radiation therapy to kill the cancer cells in your body. These chemotherapy drugs are so strong that they also kill many normal cells in your blood and bone marrow. In a mini-transplant you will still get chemotherapy medicines and radiation therapy, but you will get smaller doses of these medicines. A smaller amount of your cancer cells will be killed, but your body will be able to heal itself faster and attack the cancer cells. Your doctors think that a mini-transplant is the best treatment for you. They believe that it will increase your chance of cure.

You can be transplanted with blood cells from a baby's umbilical cord. Umbilical cord blood is the extra blood left over after a baby is born. It used to be thrown away. We know now that it contains blood-forming cells like the ones found in bone marrow. Cord blood can be collected after a baby is born and stored for future use. Collecting cord blood does not hurt the baby or Mom. When a patient, like you, needs a transplant, cord blood can be removed from storage and sent to your hospital for your transplant. There have been many transplants using umbilical cord blood.

Transplant Procedure
Before the transplant, you will be given the drugs cyclophosphamide and fludarabine. These drugs will be given through a central line – an IV that will be placed in your chest. If you do not already have a central line, we will put one in as a surgical procedure. A central line makes it easier for you to receive drugs and for drawing blood for tests. You will also get radiation to your whole body the day before your transplant. After you have received these drugs and radiation, new blood cells from umbilical cord blood will be given through your central line. When the blood gets into your body, you may feel sick to your stomach but that will go away quickly. You will be in the hospital for about four weeks after the cord blood cells are given to you while we are waiting for the cord blood cells to grow up inside your body and for you to recover from the chemotherapy and radiation. You will need to be on a number of medications during your transplant, which will either be given through your line or will be taken by mouth.

It will be necessary to check your blood and bone marrow after the transplant to make sure the cord cells are growing in your body. Your doctors will do blood tests and bone marrow tests. Blood tests will usually be done by taking blood through your line.

Risks/Discomforts
The drugs and radiation may cause hair loss, nausea and vomiting, and diarrhea. Your blood counts will fall and you may get fevers, infections or start bleeding. You may also get mouth sores. These are temporary and you will feel better as your new bone marrow grows.

During the period your new bone marrow is growing back after the cord blood transplant, you may need to get antibiotics since you will not be able to fight infections. You may also need to get blood transfusions since your new bone marrow will not be making new blood cells right away. It is possible that your new bone marrow will not grow back. This is unlikely but if it did happen, it may even be necessary to do a second transplant. You may get graft-versus-host disease (GVHD), which happens when transplanted cells attack your body causing skin rash, vomiting, diarrhea and liver problems. These problems could be mild, or they could be very serious. Your doctors will do their best to make you feel better and keep you safe.

The above information has been explained to me. My questions have been answered.

I agree to participate in this study.

_____ _____
Patient Parent

_____
Physician

_____ _____
Witness Date