**18.0 RELATED DONOR MODEL CONSENT FORM**

# A Phase II Study of Reduced-Intensity Allogeneic Transplant for Patients with High-Risk Chronic Lymphocytic Leukemia

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to participate in this trial because you are being considered as a donor for a sibling, that is a brother or sister, that has been diagnosed with chronic lymphocytic leukemia (CLL). Donors that are identified as an HLA-identical sibling have the same type of bone marrow and can server as a good donor of "stem cells" for a family member diagnosed with leukemia.

## Why is this study being done?

You are being asked to take part in this study because you have a sibling that has been diagnosed with chronic lymphocytic leukemia (CLL), a form of cancer that originates from the lymphocytes, the cells that make up the immune system and that are located in the lymph nodes, bone marrow and most of the other organs of the body. Your sibling is considered to have CLL with high-risk features that may not respond to standard forms of treatment such as chemotherapy.

Instead, a transplant of some of sibling's "stem cells" may be effective treatment for these cancers. Stem cells are the original cells from which all the blood cells (including white blood cells which help fight infection, red blood cells which carry oxygen, and platelets which help the blood to clot) develop. After transplant into the patient, the donor's stem cells (cells that have the ability to develop into red blood cells, white blood cells, or platelets) appear to have the ability to recognize and kill the patient's leukemia cells. This powerful reaction performed by the donor's stem cells is known as the "graft-versus-leukemia," or GVL, effect. The use of chemotherapy to kill cancer cells in patients, along with the use of stem cells from a healthy sibling donor such as yourself, may improve the outcome of patients with this disease.

## How Many People Will Take Part in the Study?

As many as 86 people will take part in this study.

## What will happen if I take part in this research study?

If you take part in this study, you will undergo blood tests to insure that you do not carry any communicable diseases that could be transmitted through your blood (such as hepatitis, HIV, etc.). Other tests to determine your suitability as a donor may be necessary, as well.

**Treatment**

It is possible to stimulate the bone marrow to produce stem cells with a class of drugs known as colony stimulating factors (or CSFs for short). CSFs are commercially available and approved medications used in patients receiving chemotherapy for cancer to increase the number of white blood cells, the cells responsible for fighting infections. When CSFs are given to a healthy brother or sister who has been shown to have the same type of bone marrow as the patient with cancer, it is possible to obtain stem cells that can then be used for transplant in their siblings who have cancer. When combined with chemotherapy in the patient with cancer, the stem cells collected from the donor (that is, a brother or sister) may also aid in recognizing and destroying any cancer cells that may still be in the patient's body after the high dose chemotherapy.

Your sibling's study doctor will describe the specific treatment to be given to you to collect the stem cells. Generally, the CSF is given to you, the donor, for several consecutive days as a daily injection just underneath the skin (subcutaneous injection). You or a family member will be taught to give the injections at home. During the period in which you are receiving the CSF, your white blood cell count will increase. After you complete the CSF, a process known as leukapheresis will be performed where the stem cells will be taken from the blood stream of the donor.

The leukapheresis procedure is similar to the process of blood donation, where a needle is placed in the vein of the arm and blood is removed in a sterile fashion. In leukapheresis, the blood is removed and filtered (centrifuged) so that only the white blood cells, stem cells, and some plasma are removed. About one-half pint of blood cells are collected for the transplant. The rest of the blood (mostly red blood cells) is returned back into the blood stream of the donor through a second needle. The leukapheresis procedures will be performed on the fifth day and, possibly, the sixth day after you have been receiving the CSF. No more than three leukapheresis procedures should be necessary. Each collection of stem cells will then be transfused directly into the patient (your brother or sister) who in the meantime will have received chemotherapy.

A daily check of your blood counts will be performed on the days when you are undergoing leukapheresis. This will require about 1-2 teaspoons to be removed by blood draw from one of your veins.

Some or all of the stem cells that are collected from you during the leukapheresis procedure may be frozen to preserve them prior to infusing them into your sibling. Also, some of the cells that are frozen may not be needed by your sibling. If some or all of the cells are not used by your sibling, your cells will be stored. The remaining stored cells may be discarded if your sibling's study doctor determine that there is no clinical need for these cells.

If your sibling's disease should return during the course of their participation in this trial, there is a chance that your sibling's study doctor may request more cells from you. This would be done to further treat your sibling's disease.

## How long will I be in the study?

You will be in the study for about 5-6 days.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your brother or sister's doctor first. There may be no consequences to your health if you discontinue participation in this study, but it may have serious affects on the recipient (that is, your brother or sister) if they have already received chemotherapy for their transplant.

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

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the CSF. In some cases, side effects can be serious, long lasting, or may never go away.

A daily check of your blood counts will be performed on the days when you are undergoing leukapheresis. The risks of the blood draw include bruising, inflammation in the vein, and infection. Care will be taken to avoid these complications.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to CSFs include those which are:

**Likely**

- Bone pain.
- Fatigue
- Muscle aches.

**Less Likely**

- Fever.
- Chills.
- Rash.

**Rare**

- Shortness of breath.
- Nausea.
- Vomiting.
- Diarrhea.
- Headache.
- Chest pain.
- Hair loss.
- Loss of appetite.
- Weakness.
- Low blood pressure.
- Increased liver function tests.
- In extremely rare cases, rupture of the spleen has been reported following CSF treatment. If you develop abdominal pain while taking CSF you should inform your doctor immediately.

The risks and side effects of the leukapheresis process have to do with the placement of the leukapheresis needles in the veins of the arms. These risks are similar to those involved in blood donation and include nausea, vomiting, dizziness, seizures (if you faint), blood loss, inflammation in the vein and infection. Also, with the leukapheresis process, the platelet count (the cells partly responsible for blood clotting) may drop. This drop in blood counts is temporary and should return to normal within one or two days.

**Risk of Testing for Infectious Illnesses:** Participation in this study will require that you be tested for hepatitis and HIV. Testing for HIV and for the hepatitis viruses may result in a diagnosis of infection with these viruses. In the event that you are diagnosed with hepatitis or HIV, you may be referred to a doctor who specializes in these illnesses. The diagnosis of HIV or hepatitis may result in earlier treatment and/or prevention of many complications from the illnesses. Efforts will be made to keep your personal information confidential. Awareness of a diagnosis of these illnesses may have serious personal and social consequences. Some of these consequences include possible difficulty obtaining health insurance or employment.

For more information about risks and side effects, ask your study doctor.

## Are there benefits to taking part in the study?

Although there is no direct benefit to the donor, the stem cell transplant is potentially life-saving to the recipient who is suffering from an otherwise fatal cancer.

## What other choices do I have if I do not take part in this study?

Your participation in this study is voluntary.

## Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Cancer and Leukemia Group B (CALGB)
- Blood and Marrow Transplant Clinical Trial Network (BMT CTN)
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people.

It may be necessary to contact you at a future date regarding new information about the treatment you have received. For this reason, we ask that you notify the institution where you received treatment on this study of any changes in address. If you move, please provide your new address to the following person: (name)_____ (title)_____ (address)_____ (phone number)_____.

The CALGB has received a Certificate of Confidentiality from the federal government, which will help us to protect your privacy. The Certificate protects against the involuntary release of information about you collected during the course of the study. The researchers involved in this project may not be forced to identify you in any legal proceedings (criminal, civil, administrative, or legislative) at the federal, state, or local level. However, some information may be required by the Federal Food, Drug, and Cosmetic Act, the U.S. Department of Health and Human Services or for purpose of program review or audit. Also, you may choose to voluntarily disclose the protected information under certain circumstances. For example, if you or your guardian requests the release of information about you in writing (through, for example, a written request to release medical records to an insurance company), the Certificate does not protect against that voluntary disclosure.

## What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of the CSF 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 what they will pay for.

You will not be paid for taking part in this study.

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 happens if I am injured because I took part in this study?

It is important that you tell your study doctor, _____ *[investigator's name(s)]*, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number]*.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

## 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 and 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 or changes in the study that may affect your health or your willingness to continue 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.

## Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* at _____ *[telephone number].*

For questions about your rights while taking part in this study, call the _____ *[name of center]* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *(telephone number).*

## Related Research Studies

Please note: This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be a part of the main study even if you say 'no' to taking part in any this additional study.

You can say "yes" or "no" to the following study. Please mark your choice for the study.

### About Using Blood for Research

During the course of determining whether you are a suitable donor, your sibling's doctor will obtain blood specimens to do some tests. The results of these tests will be given to you by your sibling's doctor and will be used to plan their care. We would like to collect an additional blood specimen (about 2 tablespoonfuls) at this time. This sample would be obtained when other routine laboratories are obtained so you will not need to undergo additional procedures to collect this specimen. We will analyze this sample in the laboratory to see if we can determine how the donor's cells recognize the patient's leukemia cells, and how the patient's immune system recovers after the transplant. The results of these blood studies are for research use only and the results will not be available or used to guide your treatment.

Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Your specimens will be used only for research and will not be sold. The research done with your specimens may help to develop new products in the future.

### Benefits

The benefits of research using specimens include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

### Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

### Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

No matter what you decide to do, it will not affect your care.

1. I agree that my specimens may be used for the research studies described above.

*Yes* *No*

## Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

## Signature

I have been given a copy of all _____ *[insert total of number of pages]* pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

**Participant** _____

**Date** _____