

THE OHIO STATE UNIVERSITY

## **ASSENT TO INVESTIGATIONAL TREATMENT OR PROCEDURE**

I, \_\_\_\_\_ give my permission Michael A. Caligiuri MD or associates or assistants of his choosing to perform the following treatment or procedure, on \_\_\_\_\_ (myself/ name of subject).

The research portion of the treatment is:

Collection and storage of venous blood (the blood from a blood vessel), the liquid inside the bone know as bone marrow and products of white blood cell filtering (Leukopheresis).

I have been asked to take part in this research study because I have a cancer or other disorder of my blood system. My doctors, working with other researchers here at The Ohio State University and at other institutions, want to better understand the causes of these types of diseases. I am being asked to allow my doctors to obtain a sample of my blood, the liquid that is inside my bones, also known as bone marrow, or my white blood cells. Leukapheresis is the medical procedure during which my blood is filtered to remove extra white blood cells. These tissue samples will be stored frozen until they are needed for research.

**This is done as part of an investigation entitled:**

**The OSU Comprehensive Cancer Center Leukemia Tissue Bank**

### **1. Purpose of the procedure of treatment**

To work on a cure for cancer, doctors very often use blood samples, bone marrow or white blood cells that come from patients with cancer of the blood cells or lymph glands. The lymph glands are special organs inside my body that help my body fight infections. These materials come directly from their patients here at the Arthur G. James Cancer Hospital. This information sheet is to ask that I give up to two teaspoons of blood, one teaspoon of liquid bone marrow and/or white blood cells obtained from leukapheresis to be stored for research. My doctors will store it by freezing it.

### **2. Possible appropriate alternative procedure of treatment (not to participate in the study is always an option).**

There are no good substitutes for the blood, bone marrow or white blood cells that come from patients with cancer. If I do not wish to donate these tissues, I may choose not to participate in the study. If I agree to take part in this study, it is my own free choice and only with the permission of my parent or legal guardian. Approximately 200 patients will participate in this research study each year.

The study should last at least 5 years, and the researchers hope to store many samples from different patients. They may ask for more samples from me (no more often than once every 2 months). I am free to refuse having my blood or bone marrow drawn or release my white blood cells for the purposes of storage now or anytime, even if I sign this. After one year, my doctor will ask me to read and sign the assent again.

### **3. Discomforts and risks reasonably to be expected.**

What are the risks to me if I agree to participate in this study? If I am being treated by the blood filtering process called leukapheresis, in order that OSU Tissue Procurement Services will give my white blood cells to Dr. Caligiuri or specially selected assistant, the only thing required is that I sign this assent. There are a few things to consider if I agree to let the doctor obtain a sample of my blood. The doctor will take blood from a blood vessel in my arm by inserting a small needle. Possible side effects of taking blood this way may include tenderness, pain at the site where the needle entered the arm or the spot where the needle entered my arm may become black and blue (bruising). But this will be gone in a few days. It would be very unusual that I would get an infection, faint or feel faint because of having blood taken in this way.

There are also a few things to consider if I agree to let the doctor obtain a sample of my bone marrow. The doctor will have me lie down on my stomach and will put some sterile iodine over the area of skin between my hip and my backbone. In order to get a sample of bone marrow, the doctor must put a needle through my skin and into the bone. Before doing this, the doctor will give me a numbing medicine that will sting, but will numb the area where the needle is placed into the bone. This should make it so that I do not feel the needle going into the bone, but will only get a sense of pushing or pressure. Once the needle is put into the bone, the doctor will then pull back and draw out the marrow. This will take approximately 5 seconds and will be painful. The doctor will collect between 1-2 teaspoons of liquid bone marrow. The doctor will not remove any bone. If my parent or guardian and I have agreed to allow the doctor to obtain one bone marrow sample from me, then the doctor will immediately withdraw the needle and place some gauze over the needle site for 5 minutes. The doctor will then place a bandage over this site. I must keep the bandage on for the whole next day. I may be left with a very small scar at the site where the needle was inserted. This would be no greater than one tenth of an inch in length.

It should take no more than 20 minutes to get the bone marrow sample, from start to finish. The numbing medicine will wear off in 1-2 hours and after that the site may be sore for the next 1-2 days. After that the pain should go away completely. There is a possibility however; it will take longer for the pain to go away. In very rare cases (less than 1 in 1000) the nerve near where the needle went in to get bone marrow may be injured so that the patient is often bothered by pain. This is very unlikely. There is a small possibility of some bleeding where the needle was stuck, and this can lead to bruising, pain, and swelling. This does not happen often, and I would need to tell my parent or guardian who would call the doctor immediately if I notice any increased pain, swelling, bruising, or bleeding at the site. The other possible complication from this procedure is infection. This is rare. Should I notice that I have any fever or drainage from the injection site then I should tell my parent or guardian who would call the doctor

immediately. My parent or guardian will be given a sheet of paper with emergency numbers to call and the names of individuals to speak to in case any problems arise.

It is possible that I could have a reaction to the numbing medicine. This would cause me to get a rash or make it hard for me to catch my breath. These reactions can be taken care of by the doctor immediately. If I have had numbing medicine (Lidocaine or Novocaine) before without problems, it would be extremely unusual for me to have a reaction to this medicine at this time. If I know that I have had a reaction to this numbing medicine before, I will not give a bone marrow sample.

My doctor will take extra precautions to protect my privacy. Once the doctor receives a sample of my blood, bone marrow or white blood cells my name will be removed from the tube and the sample(s) will be given a special code. That code is used when the researchers work with my samples, so that no one knows my name. In this way, no one will know me by my name when working with my samples. The researchers who use my samples will not know who I am. Only Dr. Caligiuri will know both my name and the special code for my samples. Records of my bone marrow donation may be made available to a special office at OSU that checks on all studies like this one at OSU. This office is called the Office of Responsible Research Practices and the OSU Institutional Review Board. The people who work for these offices will review the records of this study to make sure that my privacy is protected.

It may be necessary for the researchers who do this research to look at the information in my medical records. They may need to know more about my disease. It may also be necessary to contact my parent or guardian and me in writing or by phone in order to obtain this information. This would be done under the direction of Dr. Caligiuri and only the doctors and nurses Dr. Caligiuri asks to get the information would know about this. Only doctors and nurses who work at The Ohio State University Hospital in the Division of Hematology-Oncology would be allowed to see my patient records. The doctors and nurses might use some of this information in a scientific report. My name or initials would not identify my sample; only my special code number would be used.

#### **4. Possible benefits for subjects/society.**

At this time, there is no direct payback to me for helping with the study. I will not be paid for the donation of these samples. By allowing researchers to store my blood, bone marrow or white blood cells for their laboratory research, it is possible that new discoveries for cancer will be made that may help other children like me. My doctor may explain this further. The information researchers will get from doing the research on my frozen samples may be used in scientific meetings or published in scientific articles. In either case, my name would never be used to identify me, only my special code. If the research leads to an important discovery about my disease that could affect me or my other family members, my doctor would break the code and notify me of their finding, if I want them to.

#### **5. Anticipated duration of subject's participation.**

I will be asked to be part of this study for at least one full year. Ideally, I will agree to be in the study for the whole time I'm being treated at OSU. The doctor may ask me to give my samples as much as 6 times a year. The doctor will only ask for white blood cells if they decide that I must have my blood filtered. At the end of one year, my doctor will ask

me again to agree to be in this study. I can either stop giving my samples at the end of one year, or I can continue to be in this study. If I agree to continue, I will sign another agreement form just like this one. My parent or guardian will also have to sign a new consent form for me. I may refuse to have samples taken from me at any time, even if I or my parent or guardian as already signed the forms.

I agree that \_\_\_\_\_ (to be filled in at the time of assent) has provided information about the procedures described above, about my rights as a patient in this study, and he/she has answered all questions to my satisfaction. I understand that I may contact her/him at phone no. 614-293-7521 should I have additional questions. He/She has explained the chances of any problems that may happen and I understand them.

An office of the United States government that controls medicines that can be used in this country called the US Food and Drug Administration may want to look at my records for this study. I also understand and agree that my records that may contain my name may be given to the organization that is paying for this study. Beyond this I understand that my participation will remain secret.

I understand that I can change my mind and not be part of this study at any time. My parent or guardian will let Dr. Caligiuri know if I don't want to be in the study any longer.

I understand in signing this form that I'm only agreeing to be a part of this study and that doesn't change any legal rights that I have. I am not releasing the doctors, the sponsor, OSU, or its agents from any legal liability for damages that they might otherwise have.

In the event of injury resulting in my being in this study, I also understand that if I need immediate medical treatment I can go to University Hospitals of The Ohio State University and that the costs of such treatment will be at the expense of my parent or guardian; financial payment beyond what the law says is necessary is not available. If I or my parent or guardian has a question about this, he or she should contact the Office of Responsible Research Practices at 614-688-4792.

I have read and understand the assent form. I sign it because I want to. A copy has been given to me.

Date \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM Signed: \_\_\_\_\_  
(Subject – Required)

Date: \_\_\_\_\_ Signed: \_\_\_\_\_  
(Witness, if required)

I certify that I have personally completed all blanks in this form and explained them to the subject or his/her representative before requesting the subject or his/her representative to sign it.

Date: \_\_\_\_\_ Signed: \_\_\_\_\_  
Signature of Project Director or his/her Authorized Representative)

## **INSTRUCTIONS FOR VOLUNTEERS FOLLOWING DONATION OF BONE MARROW AND VENOUS BLOOD**

It is likely that you will have some discomfort over the following 1 or 2 days. It should not be very bad and should not keep you from doing any of the things you usually do each day. It should not keep you from going to school, participating in sports or work if you have a job. You may take two Tylenol tablets (or Children's Tylenol tablets, depending on age of the child) every six hours for pain, if necessary (if you're not allergic to Tylenol. Your parent or guardian will decide this). You do not have to take Tylenol if you don't have any pain. If the discomfort is not decreased after 2 days, tell your parent or guardian. The doctor wants your parent or guardian to call him or her at the numbers listed below.

If you notice that the place where the needle went into the skin is swollen or black and blue this could mean that you're bleeding a little under the skin, and we want you or your parent or guardian to call the doctor immediately. If feel, like you have a fever, tell you parent or guardian to take your temperature. If your temperature is 100 degrees, or higher, you may have an infection and your parent or guardian should call the doctor immediately at the numbers listed below.

Keep the bandage on for the next day. After that the bandage can be taken off and you can take a shower. You shouldn't take a bath while the bandage is on but you can take a quick shower.

The nurse or doctor who takes your blood or bone marrow will give you with a number your parent or guardian can use to call him or her during the day. If your parent or guardian doesn't know which number to call during the day, please call 614-293-7521 and ask to speak with Dr. Caligiuri. If Dr. Caligiuri is not in his office, please ask his secretary to page him. If you have a problem after 5:00 in the evening or during a weekend you should page Dr. Caligiuri at 614-736-7688.