

THE OHIO STATE UNIVERSITY

CONSENT TO INVESTIGATIONAL TREATMENT OR PROCEDURE

I, _____ hereby authorize or direct Michael A. Caligiuri MD or associates or assistants of his choosing to perform the following treatment or procedure, upon _____ (myself/ name of subject).

The experimental (research) portion of the treatment or procedure is:

Collection and storage of venous blood, bone marrow and products of leukapheresis

I have been asked to take part in this research study because I have a cancer or other disorder of the blood system. My doctor, 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 doctor to obtain a sample of venous blood, bone marrow or products of a leukapheresis. Leukapheresis is the medical procedure during which my blood is filtered to remove excess white blood cells. These tissue samples will be stored in the frozen state until they are needed for research purposes.

This is done as part of an investigation entitled:

The OSU Comprehensive Cancer Center Leukemia Tissue Bank

1. Purpose of the procedure of treatment

In order 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. These materials come directly from their patients here at the Arthur G. James Cancer Center. This information sheet is to request that I give up to two teaspoons of blood, one teaspoon of liquid bone marrow and/or white blood cells obtained from my leukapheresis to be stored for the purposes of research. My doctor 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 venous 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 of my own free choice. 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 thousands of samples. They may request additional samples from me (no more frequently than once every 2 months). I am free to refuse having my blood or bone marrow drawn or release my white blood cells from leukapheresis for the purposes of storage now or anytime, even if I sign this. After one year, my doctor will request that I read and sign the consent again.

3. Discomforts and risks reasonably to be expected.

What are the risks if I agree to participate in this study? If I am being treated by leukapheresis, in order that OSU Tissue Procurement Services will release my white blood cells to Dr. Caligiuri or authorized representative, the only thing required is that I sign this consent. There are a few things to consider if I agree to give the doctor a sample of my blood. The doctor will take blood from a blood vessel in the arm by inserting a small needle. Possible side effects of taking blood this way may include tenderness, pain and bruising at the site where the needle entered the arm, but this will be gone in a few days. Infection, lightheadedness or fainting is rare.

There are also a few things to consider if I agree to give the doctor 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 backbone. In order to get a sample of my bone marrow; the doctor places the needle into my bone. Before doing this, the doctor will give me a numbing medicine that will sting, but will numb the area where the doctor place the needle into my 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 I have agreed to give one bone marrow sample, then the doctor will immediately withdraw the needle and place gauze over the needle site for 5 minutes. The doctor will then place a bandage over this site, which he or she will ask me to keep on for the next 24 hours. 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 extremely rare cases (less than 1 in 1000) people experience nerve damage and are persistently bothered by pain, although again, it is unlikely. Other complications include the 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 notify 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 any fever or drainage from the injection site then I should call the doctor immediately. I 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 an allergic reaction to the numbing medicine, which would result in rashes, hives, or shortness of breath, all of which can be treated 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 have a known allergy to this medicine I may not give a bone marrow sample.

My doctor will take extra precautions to protect my privacy. Once they receive a sample of venous blood, bone marrow or white blood cells from me, my name will be removed from the tube and my sample will be given a special code. That code is then used when the researchers work with my particular sample, so that no one knows my name. In this way, no one can identify me by my name when working with my samples. The researchers who use my samples(s) will not have knowledge of my identity. Only Dr. Caligiuri will have routine access to both the code and my name. Records of my bone marrow donation may be made available to the Office of Responsible Research Practices (ORRP) and the Institutional Review Board (IRB) at The Ohio State University.

It may be necessary for the purposes of the proposed research to conduct a review of my medical records in order to obtain additional information such as my disease status and survival. It may also be necessary to contact me in writing or by phone in order to obtain this information. These actions would be performed under the direction of Dr. Caligiuri and confidentiality would be maintained at all times. Access to my patient records would be limited to physicians and nurses employed by the Division of Hematology Oncology. Information obtained in this manner might be used in the preparation of scientific manuscripts, however name or initials would not be used, but instead a unique patient identification number would identify me.

4. Possible benefits for subjects/society.

At this time, there are no direct benefits to me. I will not be compensated for the donation of my blood, bone marrow or white blood cells. By allowing researchers to store my blood, bone marrow or white blood cells for their laboratory research, it is possible that new discoveries relating to patients with cancer will be made that may ultimately help with diagnosing or treating this disease. My doctor may explain this further to me. The information researchers will get from doing the research on my frozen blood, bone marrow or white blood cells may be used in scientific meetings or published in scientific articles. In either case, this material would not reveal my name. If their research led to an important discovery about my disease that could affect me or my family members, my doctor would break the code and notify me of their finding, if I so desire.

5. Anticipated duration of subject's participation.

I will be asked to participate in this study for at least one full year. Ideally, I will participate for the entire period of time during which I will be treated at the Arthur G. James Cancer Hospital. I may be asked to give blood or bone marrow as frequently as once every two months or six times in one year. My white blood cells will be taken only when leukapheresis treatment is necessary. This will be determined by my doctor. At the end of one year, my doctor will ask me to reconsider my involvement with this study. I can either decide to stop donating specimens at the end of one year, or I may decide to continue with these procedures. If so, I will then sign another consent form. In addition, I may refuse to have samples taken at any time.

I hereby acknowledge that _____ (to be filled in at the time of consent) has provided information about the procedures described above, about

my rights as a subject, and he/she has answered all questions to my satisfaction. I understand that I may contact him/her at phone no. 614-293-7521 should I have additional questions. She/He has explained the risks described above and I understand them; she/he has also offered to explain all possible risks or complications.

I understand that, where appropriate, the US Food and Drug Administration may inspect records pertaining to this study. I understand further that records obtained during my participation in this study that may contain my name or other personal identifiers may be made available to the sponsor of this study. Beyond this I understand that my participation will remain confidential.

I understand that I am free to withdraw my consent and participation in this project at any time after notifying the program director without prejudicing future care. No guarantee has been given to me concerning this treatment or procedure.

I understand in signing this form that, beyond giving consent, I am not waiving any legal rights that I might otherwise have, and I am not releasing the investigator, the sponsor, the institution, or its agents from any legal liability for damages that they might otherwise have.

In the event of injury resulting in participation in this study, I also understand that immediate medical treatment is available at University Hospitals of The Ohio State University and that the costs of such treatment will be at my expense; financial compensation beyond that required by law is not available. Questions about his should be directed to the Office of Responsible Research Practices at 614-688-4792.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

Date _____ Time: _____ AM/PM Signed: _____
(Subject)

Witness (es) _____
If _____ (Person Authorized to Consent for
Required _____ Subject 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 24-48 hours. This should be relatively minimal and should not keep you from doing any of your usual daily activities. It should not keep you from going to work. You may take two Tylenol tablets every six hours for pain, if necessary (provided you do not have any allergy to Tylenol). You do not have to take the Tylenol if you are not experiencing any pain. If the discomfort is not decreased after 48 hours, the doctor would like you to call him or her at the numbers listed below.

If you note an increase in either swelling or bruising at the needle site, this could mean that you are having some bleeding beneath the skin, and the doctor asks that you call him or her immediately. If you feel warm, the doctor would ask that you take your temperature. If you have a temperature of 100°F (or higher), this could indicate a possible infection and you should contact the doctor immediately at the numbers listed below.

The doctor asks that you keep your bandage on for the next 24 hours. Following that the bandage can be removed and you can shower. You should not take a bath with the bandage in place, only a quick shower.

The nurse or physician performing this procedure should provide you with a number you can use to call him or her during the day. If you are uncertain as to 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.