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IF LABEL NOT AVAILABLE, WRITE IN PT NAME & MR#

AUTOLOGOUS DONOR CONSENT FOR BONE MARROW HARVEST

A. CONSENT FOR BONE MARROW HARVEST

I have been asked to donate some of my bone marrow cells by a process called BONE MARROW HARVEST in preparation for my autologous hematopoietic stem cell transplant. This consent form gives me information about BONE MARROW HARVEST. Once I fully understand the procedure, and agree to have the procedure, I will be asked to sign this consent form and be provided with a copy.

I understand my diagnosis to be:

I authorize _____ to perform BONE MARROW HARVEST to collect stem cells for transplant.

I understand that my doctor may need to perform other urgent procedures that may be unanticipated. I consent to the performance of any additional procedures determined during my original procedure to be in my interests and where delay might cause additional harm.

The bone marrow collection will be performed by an attending hematologist/oncologist and an assistant. I understand that other qualified practitioners, including nurse practitioners, physician assistants, hematology fellows or residents (doctors who have finished medical school and are getting more training), may be chosen to do or help with procedures. All qualified practitioners will only perform tasks for which they have been granted clinical privileges or permission to practice based upon demonstrated competency. *Your attending physician will be present during key parts of the procedure but may not be present for the entire procedure. Prior to the procedure, he/she will discuss with you the roles of the members of the team and the key parts of the procedure for which he/she will be present.*

I understand that for some kinds of medical equipment a representative from the equipment manufacturer may be present, providing consultation or performing checks on the equipment.

I have been told about what results to expect, which includes information about the chances for the expected results and about problems that might occur. I know that results cannot be guaranteed. The details of these are discussed below and I have had the opportunity to ask questions and have had them answered to my full understanding.

I understand that photographs and/or video or electronic recordings may occur during my procedure and may be used for internal performance improvement or educational purposes.

B. WHAT IS INVOLVED IN BONE MARROW HARVEST?

Bone marrow stem cells will be extracted from your hip bones. Collecting your cells and freezing them will keep them protected while you receive high-dose chemotherapy. After the chemotherapy, they can be re-infused back into your body to recover your white blood cells, red blood cells and platelets.

The amount of bone marrow you will be asked to donate depends on the number of stem cells required for an upcoming transplant. The amount of marrow collected will also be limited based on your weight, to avoid excessive blood and red cell loss. The bone marrow will be extracted from your pelvic bones by multiple needle aspirations (needle sticks). Only a small portion of your total bone marrow volume will be extracted. There will be no decline in your white blood cells or platelets as a result of the harvest procedure.

Bone marrow collection procedure is performed under general or spinal anesthesia in an operating room. You may also receive local anesthesia administered by the attending hematologist/oncologist performing the bone marrow harvest, to decrease post-donation pain and bleeding. Please inform us if you have any known adverse reactions to general or local anesthesia.

Storage of Bone Marrow:

All of the cells that are collected from you during the bone marrow harvest will be frozen to preserve them prior to your stem cell transplant. If some or all of the cells are not used by your doctors during your transplant, two things may happen: (i) your cells will continue to be stored in our freezers, or (ii) the remaining stored cells will be discarded if the your transplant doctor determines that you have no clinical need for these cells and you consent to the destruction of the cells. If your cells remain in our freezers, you may, at any time, request in writing that we transfer the cells to another facility of his/her choice.

C. CONFIDENTIALITY, USE AND SHARING OF HEALTH INFORMATION:

Strict confidentiality is maintained for all client information and records. No information will be disclosed to anyone outside UVAHS without your written consent. Your information may be given if required by law, your insurance company, or regulatory agencies.

D. TESTS PEFORMED AND THE RIGHT TO REVIEW THE TEST RESULTS

I understand that I will have tests and procedures performed to protect my health. Some of the tests and procedures include

- Complete medical history and a physical exam, including specific questions to assess the risk of infectious illnesses, through completion of the Health History Questionnaire. These include my travel history, questions about my sexual practices and questions about high risk behaviors and personal habits.
- My prior medical records may be obtained as deemed appropriate and necessary by the donor services team
- Laboratory studies to assess my general health and studies to screen for multiple diseases that can be transmitted through blood, such as Hepatitis B and Hepatitis C viruses, HIV (human immunodeficiency virus; the virus that causes AIDS), HTLV (Human T-lymphotropic virus), CMV (Cytomegalovirus), Chagas (a parasitic blood disease), syphilis and West Nile Virus
- For female donors, a pregnancy test is performed. I may not serve as a stem cell donor if I am pregnant.
- An electrocardiogram (EKG), chest X-ray or other tests if necessary, depending on my health history and/or age
- An evaluation at the Preadmission Evaluation and Treatment Center (PETC) and, if necessary, with the anesthesia staff at the University of Virginia medical center

I understand that the results of any test which may be an implication for my health will be shared with me and/or my legally authorized representative, and that I and/or my legally representative have the right or review the test results. None of these results will be shared with anyone else without my consent.

E . RISKS OF BONE MARROW HARVEST PROCEDURE

Serious problems from bone marrow collection are rare but can occur. The risks associated with bone marrow collection include the following:

The <u>more common</u> risks:

- Pain, bruising and discomfort at the aspiration sites
  - Note that you may be given medication to help decrease this pain. See the above description of the bone marrow harvest procedure for more information.
- Anemia (low red blood cell levels) that will cause you to feel tired or fatigued
  - If the anemia is significant enough, you may require a blood transfusion

The <u>less common</u> risks:

- Infection at aspiration (needle stick) sites
- Pain or numbness in a leg
- The aspiration needle breaking
- Fracture of the pelvic bone at the aspiration site
- Prolonged pain
- Local hematoma
- Retroperitoneal hemorrhage
- Death

There is a possibility of not collecting a sufficient number of stem cells to safely undergo an autologous stem cell transplant. My doctor will discuss with me the options to consider if this occurs.

Other risks discussed today, specific to my medical history:

_____

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_____

Risks Associated with Blood Tests:

The risks of blood tests may include pain from the needle stick, bruising, bleeding, fainting and/or infection at the needle stick site.

Reproductive Risks:

Anesthesia can cause adverse reactions in pregnant women and in unborn babies. I should not become pregnant while donating bone marrow or undergoing a stem cell transplant. If I am a female of child-bearing potential, I will have a pregnancy test within seven (7) days of the bone marrow harvest. If I have any questions about the reproductive issues or about preventing pregnancy, I will discuss them with my doctor.

Other Risks:

There is a possibility that a rare or previously unknown side effect may occur. It is not possible to measure the chances of such occurrences or their severity. My doctor may, at any time, without my consent, decide to stop my participation in this process if I develop a serious medical condition that would make it dangerous for me to continue taking part in the donation process.

F. BENEFITS OF BONE MARROW HARVEST PROCEDURE

My donated bone marrow will be infused as part of my autologous stem cell transplant procedure. It is hoped that through the autologous stem cell transplant procedure, I will receive benefit for my disease, either leading to cure or a prolonged remission from my disease, as discussed with my doctor.

G. REFUSAL TO DONATE/OTHER OPTIONS

I may choose to donate peripheral blood stem cells instead of bone marrow harvest, if my doctor believes that stem cells collected from peripheral blood will benefit my condition. I may also decline to participate as a donor of bone marrow or blood stem cells. I understand that without obtaining stem cells either by a bone marrow harvest or from peripheral blood by a process of apheresis, I will not be able to undergo an autologous stem cell transplant. The potential other consequences of my refusal, as discussed with my doctor, include

_____

_____

_____

H. CONSENT FOR ANESTHESIA OR SEDATION

1. When local anesthesia and/or sedation is used by the physician on page one, Section A1:

I consent to the administration of such ***local anesthetics*** as may be considered necessary by the physician in charge of my care. I understand that the risks of local anesthesia include: local discomfort, swelling, bruising, allergic reactions to medications, and seizures.

I consent to the administration of ***sedative medications*** by or under the direction of the physician named in Item A1 or the physician in charge of my sedation care. I acknowledge that I have been informed of the nature of the planned sedation and that I understand the risks of sedation to include: allergic reactions to medications, changes in breathing, changes in blood pressure and heart function, nausea and vomiting, aspiration of stomach contents and/or excitement. I understand that recall of the procedure is possible.

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2. When regional anesthesia, general anesthesia, or monitored anesthesia care is provided by the personnel in the **Department of Anesthesiology:**

I consent to care provided by the physicians of the Department of Anesthesiology. I acknowledge that the anesthesia may actually be administered by a physician in training (resident) or nurse anesthetist under the direction of the anesthesiologist who is assigned to care for me. The anesthetic technique may be a general anesthetic ("being put to sleep") and/or a nerve block. I understand that the risks of anesthesia include: sore throat and hoarseness, nausea and vomiting, aspiration of stomach contents, muscle soreness, injury to the eyes, injury to the gums or lips, damage to the teeth or dental work, allergic reactions to medications, recall of procedure, changes in breathing, changes in blood pressure and heart function, nerve injury, cardiac arrest, brain damage, paralysis, or death.

Additional information regarding the various forms of anesthesia and pain control, risks, and options is available from the anesthesiologist directing your care.

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I. PATIENT OR LEGAL REPRESENTATIVE SIGNATURE:

By signing below I state that I am 18 years of age or older, or otherwise authorized to consent. I have read or have had explained to me the contents of this form and I agree to receive the care, treatment or services listed on this consent. I have had a chance to ask questions and all of my questions have been answered.

SIGNATURE OF PATIENT OR LEGAL REPRESENTATIVE | PRINTED NAME | **DATE** | **TIME**

IF SIGNED BY PERSON OTHER THAN THE ADULT PATIENT DUE TO PATIENT'S INCAPACITY, CHECK RELATIONSHIP TO THE PATIENT:

☐ 1. Agent Named in Advance Directive ☐ 4. Adult Child ☐ 7. Other Blood Relative
☐ 2. Guardian ☐ 5. Parent ☐ 8. Other* _____
☐ 3. Husband/Wife ☐ 6. Adult Brother/Sister

FOR MINOR PATIENTS:

☐ 1. Parents ☐ 2. Guardian or Legal Custodian ☐ 3. Authorized person for child in out-of-home placement

*** Requires review and appointment by Ethics Consult Service. See Medical Center Policy 024, Informed Consent.**

J. PHYSICIAN STATEMENT/SIGNATURE & WITNESS SIGNATURE:

I have explained the procedure(s) stated on this form, including the possible risks, complications, alternative treatments (including non-treatment) and anticipated results to the patient and/or his/her representative. The patient and/or their representative has communicated to me that they understand the contents of this form.

SIGNATURE OF PHYSICIAN OR DESIGNEE OBTAINING CONSENT | PRINTED NAME | PIC # | **DATE** | **TIME**

SIGNATURE OF WITNESS (OPTIONAL) | PRINTED NAME | **DATE** | **TIME**
REQUIRED FOR TELEPHONE CONSENTS

K. INTERPRETER ATTESTATION:

Interpretation has been provided by:

SIGNATURE OF INTERPRETER/CYRACOM ID # | PRINTED NAME | **DATE** | **TIME**