



ALLOGENEIC INFORMED CONSENT TO PARTICIPATE IN THE ELIE KATZ UMBILICAL CORD BLOOD PROGRAM

You are being asked to contribute your newborn child's umbilical cord blood to the Elie Katz Umbilical Cord Blood Program at Community Blood Services, 970 Linwood Avenue West, Paramus, NJ 07653. This public bank will provide the stem cells collected from your baby's umbilical cord blood to be used to treat patients with leukemia, rare genetic diseases, immune deficiencies, strong anemia's, bone marrow failure and other disorders.

This informed consent form provides details about the Elie Katz Umbilical Cord Blood Program. Once you have had a chance to read this form, you will have the opportunity to ask any questions you may have. You will then be asked to sign the form if you wish to participate. You will also be given a copy of the form for your records.

Purpose of the Elie Katz Umbilical Cord Blood Program

Certain blood cells found in a baby's umbilical cord can be used to replace the bone marrow for patients in need of a bone marrow transplant. The Elie Katz Umbilical Cord Blood Program was created to collect the blood cells from the umbilical cord and bank them for use in bone marrow transplantations. If the collected blood, for any reason, does not meet qualifications for storage, it may also be used for laboratory research purposes. Possible research involves methods to improve the storage and use of umbilical cord blood for transplantation. All research samples are anonymous, and all identifying information is removed.

By volunteering to contribute your child's umbilical cord blood, you are agreeing to the following:

1. You will allow the blood from the umbilical cord taken after your baby's delivery to be tested and stored for later transplantation or research. If our tests show that the umbilical cord blood is suitable for transplantation, it will be stored until it has been identified as possible match for a person who needs a bone marrow transplant or until it is no longer suitable for storage. If the umbilical cord blood is not suitable for transplantation, it may be used for laboratory research and/or discarded. **The stem cells in your baby's umbilical cord blood will not be cloned.**
2. You will allow a sample of the umbilical cord blood to be tested for infectious diseases such as hepatitis, cytomegalovirus (CMV), HTLV (a virus associated with lymphomas) and HIV (the virus that causes AIDS). You will allow

additional samples of the cord blood to be tested for some genetic diseases that can be passed through blood cells, like Gaucher's Disease and Adrenoleukodystrophy (ALD). These samples may be tested if the cord blood is selected to be used for transplant.

All test results are confidential. Any tests performed are done for the safety of patients who may receive the umbilical cord blood. We will attempt to inform you of any positive test results that may affect your health or your baby's health. If you do not want to be told of these test results, you should not sign this consent form, or take part in this program.

3. You will allow a sample of the umbilical cord blood to be tissue typed (HLA typing). Tissue typing of the blood cells is done by analyzing the cell's DNA. The tissue typing is needed in order to match the cord blood stem cells to the patient's blood cells.
4. You will be asked to give approximately 30 ml (about 2 to 3 tablespoons) of your blood for tests at the time of delivery. The blood will be taken from your arm by a qualified person and tested for viruses and bacteria such as Hepatitis, CMV, HTLV, HIV and syphilis. The tests are performed to determine if the umbilical cord blood can be stored in the umbilical cord blood bank. Some of the blood will be stored for future testing if tests become available for known or currently unknown diseases.

All test results are confidential. Any tests performed will be done for the safety of patients who may receive the umbilical cord blood. We will attempt to inform you of any positive test results that may affect your health or your baby's health. If you do not want to be told of these test results, you should not sign this consent form, or take part in this program.

The law in New Jersey requires that we give the names of persons who test positive for certain diseases, including HIV and syphilis, to public or state health agencies. These agencies may contact you if you have a positive test results.

5. You will be asked to answer questions during the medical history interview. You will be asked for information about your pregnancy, medications you are taking, and any medical problems that you, your family, the baby's father, or the baby's father's family have had. There are also questions about your current and past lifestyle, including sexual history and drug use. These questions are similar to questions asked when a person donates blood. You may decline to answer these questions. If you decline your baby's umbilical cord blood will not be collected for storage in the umbilical cord blood bank. The information is confidential and will only be used to find out if the umbilical cord blood can be stored in the umbilical cord blood bank.
6. You will allow your and your baby's medical charts to be reviewed by Elie Katz Umbilical Cord Blood Program representatives, specifically for

pregnancy and delivery information and hospital test results up to the time of your discharge from the hospital.

7. You will allow for the review of your baby's blood test results that may have been conducted. Such tests look for diseases such as Sickle Cell Anemia, Phenylketonuria (PKU), and Galactosemia.
8. You will allow us to contact you to ask about any changes in your baby's health which might affect the cord blood's suitability for transplantation.

Possible Risks and Discomforts

Taking blood from your arm for any tests may cause bruising, infection, fainting, pain, or discomfort. All normal precautions will be taken to keep these side effects from happening.

Possible Benefits to You and Your Baby

There will probably be little or no direct benefit to you or your baby from contributing your baby's umbilical cord blood. However, it is possible that our tests will detect an infection that would affect you or your baby and which might not have otherwise been detected. This early detection could result in earlier treatment and improved health care.

If in the future your child or a blood relative needs a bone marrow transplant, and the umbilical cord blood banked is still available, we may be able to provide it to them. Keep in mind though, if the umbilical cord blood has already been given to another recipient for a transplant, it will not be available for your child or relative.

Another benefit to you and your family is the satisfaction of helping others.

Possible Benefits to Society

Currently, many patients who need a bone marrow transplant cannot find a donor. The umbilical cord blood bank will provide another source of donor stem cells, allowing more people the chance to receive a potentially life-saving transplant.

Financial Obligation

The Elie Katz Umbilical Cord Blood Program will not charge you or your insurance company any fees for participation in this program. You will not be paid for taking part in this program.

Privacy and Confidentiality

No information identifying you or your baby will be given to anyone without your permission unless required by law.

Collecting and Storing Your Child's Blood

There is no guarantee that your cord blood will be collected or stored. Reasons that this may happen include: blood may not be collected due to complications at the time of birth, the amount of blood collected may not meet minimum volume requirements, the umbilical cord blood could contain a contaminant that would preclude it from being stored. In addition, there is always the possibility that another unexpected problem may arise and result in the umbilical cord blood not being collected and stored.

Identification of Investigators

If you have any questions about the Elie Katz Umbilical Cord Blood Program, feel free to contact Dr. Roger Mrowiec, director of the program at (201) 251-3964 or the programs Medical Director, Dr. David Sharp at (201) 251-3739. If you have any questions concerning your participation in this program, you may also contact our Donor Advocate, Linda Todd, RN at (845) 783-7696.

Rights of Participants

At any time before the umbilical cord blood is released for transplantation, you may withdraw your consent and end your participation with the Elie Katz Umbilical Cord Blood Program without any penalty. If you have any questions about your rights as a participant in this program please contact Dr. Vincent A. DeBari at the St. Joseph's Regional Medical Center, Office of Research or Dr. Patrick Perrin, Chairman of the St. Joseph's Regional Medical Center Institutional Review Board at (973) 754- 2000.

***** We have noticed that very few doctors will charge the patient a fee for collection of umbilical cord blood. Most of the time, this fee is not paid for by your insurance agency. Please make sure you discuss this with your doctor. Most doctors will waive a fee because it is a donation to the community. Community Blood Services is not responsible for any fees charged to you by your doctor.*****



ALLOGENEIC INFORMED CONSENT FOR PARTICIPATION IN THE

ELIE KATZ UMBILICAL CORD BLOOD PROGRAM

Purpose

The purpose of this program is to collect and store umbilical cord blood. This blood may be used for treatment of persons with serious blood or immune system diseases. This blood may also be used for laboratory research on blood cells.

Signature of Donor/Mother:

I attest that I am at least 16 years of age. I have read and understand the information provided above. I have been given the opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of the information provided above. By signing this form, I willingly agree to participate in the Elie Katz Umbilical Cord Blood Program described in this form.

Name of Donor/Mother

Signature of Donor/Mother

Date

Signature of Person Obtaining Consent:

I have explained participation in the Elie Katz Umbilical Cord Blood Program to the donor/mother and answered all of her questions. I believe that she understands the information described in this document and freely consents to participate.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date