

**Upstate University Hospital- Community Campus**

**CONSENT TO DONATE TO THE UPSTATE CORD BLOOD BANK**

Nicholas Greco PhD, Executive Director, Upstate Cord Blood Bank

Address: 4910 Broad Rd, Syracuse, NY 13215  
Phone Number: 315-492-2645, 315-492-2600, 855-492-2600  
Fax Numbers: 315-492-2601 or 2611  
E-mail: grecon@upstate.edu

Please carefully review this document. The purpose of this consent form is to provide you with information to help you decide whether you wish to participate in the Upstate Cord Blood Bank Program. Your decision is completely voluntary and will not affect your medical care if you choose not to participate.

**INFORMATION ABOUT THE UPSTATE CORD BLOOD BANK PROGRAM**

After the birth of a baby, cord blood remains in the umbilical cord and placenta. This cord blood is a rich source of stem cells that can be used in the treatment of more than 70 diseases, including certain cancers, inherited disease, and immune system diseases. The cells help build new, healthy cells and replace cells that have been damaged. Typically, the umbilical cord and placenta along with the blood they contain are thrown away as medical waste. Instead of discarding the umbilical cord blood, you can donate it to a public cord blood bank.

Cord blood benefits people locally and around the world who are waiting for life-saving treatments. The most common use is for blood cancers or congenital genetic defects. There is on-going research showing benefits of cord blood use in degenerative diseases. One of the many benefits of cord blood is that the person receiving the cord blood transplant does not require an exact “tissue match.”

Cord blood is in high demand because it is used in lifesaving treatments for children and adults. Each year, thousands of people who could benefit from a cord blood transplant die waiting for treatment. There is an especially great need for cord blood donations from ethnic and racial minorities.

The primary purpose of the Upstate Cord Blood Bank (CBB) is to provide a treatment option for patients who need a bone marrow transplant, using cord blood instead of bone marrow. Cord blood cells can be useful for these patients because they are capable of developing into new bone marrow.

We are asking you to donate your child’s cord blood to the Upstate Cord Blood Bank (CBB).

With your permission, the cord blood can be placed into long-term storage at the CBB for future use.

## **HOW IS CORD BLOOD COLLECTED?**

After a baby is delivered, the umbilical cord is cut and clamped. Medical personnel extract blood from the umbilical vein into a sterile collection bag. The process takes five to ten minutes and yields about three to five ounces of cord blood. No blood is taken from the baby. Collecting cord blood is painless for both the mother and baby and does not interfere with labor or delivery of the baby. The cord blood will be delivered to the Upstate Cord Blood Bank for processing, testing, and storage.

## **WHAT OTHER PROCEDURES ARE NEEDED TO DONATE CORD BLOOD?**

The cord blood you donate needs to be screened to make sure it is safe to use to treat patients who need it. For this reason we will test your blood for transmissible infectious diseases, we will review your and your baby's medical record, and ask you to complete some questionnaires. We will also test the cord blood to check that it contains enough cells to be used as a treatment and the cord blood will be analyzed for tissue typing.

The medical record review, done by Program staff, helps us learn about possible complications of pregnancy and your baby's health that might affect the cord blood cells. Some of the questions asked help us determine which patients are most likely to benefit from the cord blood because their ethnic background is similar to your own. Some questions relate to family or inherited diseases that might affect the blood. Other questions are asked routinely of volunteers who donate blood or tissue and help determine if there are any infectious diseases that might infect the blood. In the event the biological father is unknown the cord blood cannot be collected. Program staff will ask these questions in a brief, private interview.

If possible, we will draw your blood sample (about 3 tablespoons of blood is needed) at the same time as other samples your doctor requests for your routine delivery care. Your blood will be tested for several infections that could be passed from you to the cord blood, including: human immunodeficiency virus (the virus that causes AIDS), hepatitis B and C viruses, human T-lymphotropic virus and syphilis.

We will report the results of these tests that may have possible implications for you or your baby's health. Test results will be reported to your physician or midwife in about 2-3 weeks. In addition, positive test results will be reported to the New York State Department of Health, as required by law. You will be counseled by your doctor about the meaning of these results. If you would rather not be informed of such test results, you will not be eligible to participate in the Program.

After all the above tests are completed, if the cord blood is acceptable for banking we will contact your child's pediatrician to obtain the mandatory New York State Department of Health newborn screening test results specifically for the disorders of sickle cell anemia and thalassemia.

Between 6 and 12 months after your baby's birth, Cord Blood Bank staff may contact you with a short form to follow up on your baby's health to ensure no problems have been found which may affect the suitability of the cord blood for future transplant to a patient.

### **HOW WILL YOUR INFORMATION BE KEPT PRIVATE?**

The Data Form and Consent Form have your identity and your baby's identity encoded in a barcode system that will be maintained at the Upstate Cord Blood Bank. The identification number assigned to your baby's cord blood also will be attached to your hospital record and to your baby's hospital record as an additional link between you and your cord blood donation. To protect your privacy, your identity and all information collected from you in connection with the Program will be kept confidential and in locked files at the Upstate Cord Blood Bank. No information about you or your baby will be given to anyone not identified in this consent form, unless required by law, or unless you request that information be given to others.

### **ARE THERE ANY RISKS OR DISCOMFORTS?**

No blood is taken from your baby. Collecting cord blood is painless for both the mother and baby and does not interfere with labor or delivery of the baby. Taking blood from you has a minimal risk of pain from the needle being inserted through the skin into a vein in your arm and bruising, light-headedness, possible fainting and, rarely, infection.

There is a potential risk to your privacy and confidentiality as information about you and your baby will be used; however, we feel this is a very minimal risk due to the protections in place as part of the CBB Program. It is also possible that we may find out something about you or your baby's health that was not known. These results will be communicated to your or your baby's primary care doctor.

### **ARE THERE ANY BENEFITS TO YOU OR YOUR BABY?**

The only possible direct benefit to you or your baby from participating in the Program is you might learn of an infection that might benefit from early treatment. An indirect benefit of participating is that you will help us give patients who require new bone marrow a chance for a healthy life.

There is a very remote possibility that, in the future, your child or another family member may develop a disease requiring bone marrow transplantation. If the cord blood donated to the Program has not already been used by another patient and is still available at that time, it might be of use for your own child or a family member.

### **WHAT OTHER OPTIONS ARE THERE?**

There are private companies or family banks that will collect, process, and store your baby's cord blood exclusively for your family to use. If you choose to use one of these family banks, you will need to contact them directly and there is a fee for collection and storage. The Upstate Cord Blood Bank will also offer a Family Bank option.

## **VOLUNTARY PARTICIPATION AND PROGRAM WITHDRAWAL**

Donating cord blood is entirely your choice. You may choose to participate in the Cord Blood Bank donation program or you may choose not to participate. Your choice will not affect the care you receive. If you agree to donate cord blood and change your mind, any blood or tissue obtained for the donation program, which has not already been used, will be destroyed.

### **ARE THERE ANY COSTS FOR DONATING CORD BLOOD?**

There is no cost to you or your child's insurance carrier to donate cord blood to the Upstate Cord Blood Bank's Public Bank.

### **WHERE CAN YOU GET MORE INFORMATION?**

If you have any questions about the Upstate Cord Blood Bank Program, please contact Dr. Nicholas Greco or other CBB personnel at (315) 492-2645 or FAX 315-492-2601 or 2611.

### **OPTIONAL RESEARCH DONATION**

In addition to using cord blood to treat patients, cord blood can be used to help doctors and scientists learn more about caring for and treating people with cancer and other diseases, such as heart disease and stroke. We know that some of the donated cord blood units will not meet the strict criteria for use in patient care and therefore we are requesting your permission to use any collected cord blood which cannot be donated to another person to be used for research purposes. We may also use this cord blood for quality control and/or staff training purposes, or it may be discarded.

You will not receive any payments for allowing your cord blood to be used for research studies, even if it is used to help develop commercial products or tests someday.

If you agree to allow your cord blood to be used for research, the cord blood will be sent to researchers within 48 hours of collection or it will be frozen and stored at the Upstate Cord Blood Bank to be sent to researchers in the future, or used for internal quality control and/or staff training purposes. The stored specimens may be kept indefinitely or until they are used up. Only cord blood which cannot be donated to another person will be used for research and training purposes.

Any research done on the cord blood must also be reviewed by the researcher's Institutional Review Board (a group of people who review the research to protect patient rights), before the unit is released. The only information that will be provided to researchers is that the sample was collected within 48 hours/or was frozen and that it is not known to be infectious. We will not release your or your baby's name or identity. No results from research tests will be provided to you or your or your baby's doctor or added to your or your baby's medical record. The CBB may charge researchers a fee for the cord blood, to recover collection costs.

We do not foresee any risks or benefits to you or your baby if your cord blood is used for research purposes. If you decide you no longer want your cord blood used, you can call the CBB

at: 315-492-2600 or 855-492-2600 and request it be discarded. However, if it has already been sent to a researcher or used for training, we will not be able to get it back.

The choice to allow your cord blood to be used for research, quality control and/or staff training purposes if it does not meet the criteria for use in patient care, is completely up to you. No matter what you decide to do, your decision will not affect your participation in the Cord Blood Bank Program or your medical care. You will be asked to make your choice about a research donation at the end of this form.

### **CONFIDENTIALITY OF RECORDS AND AUTHORIZATION TO USE/SHARE PROTECTED HEALTH INFORMATION:**

If you agree to participate in the Upstate Cord Blood Bank (CBB) program, identifiable health information about you and your baby will be used and shared with others involved in this program. For you to be in this program we need your permission to collect and share this information.

When you sign this consent form at the end, it means you have read this section and authorize the use and/or sharing of your and your baby's protected health information as explained below. Your signature also means you have received a copy of Upstate's Notice of Privacy Practices.

Individually identifiable health information under the federal privacy law is considered to be any information from your and your baby's medical record, or obtained from this program, that can be associated with you or your baby, and relates to your and your baby's past, present, or future physical or mental health or condition. This is referred to as protected health information.

#### ***Why is it necessary to use/share your and your baby's protected health information with others?***

The main reason to use and share your and your baby's health information is to conduct this donation program as described in this consent form. Your and your baby's information may also be shared with people and organizations that make sure this program is being done correctly, and to report unexpected or bad side effects you or your baby's may have.

#### ***What protected health information about you and your baby will be used or shared with others?***

We may use and share the results of tests, questionnaires, and interviews. We may also use and share information from your and your baby's medical records. We will only collect information that is needed for the program.

#### ***Who will be authorized to use and/or share your and your baby's protected health information?***

CBB Staff of Upstate Medical University participating in the program will use your and your baby's protected health information for this Program. The CBB staff will determine if your and your baby's protected health information will be used or shared with others outside of Upstate Medical University for purposes directly related to the conduct of the program.

***With whom would the protected health information be shared?***

Your and your baby's protected health information may be shared with:

- The Upstate Cord Blood Bank;
- The New York State Department of Health;
- Federal agencies that supervise the way this program is conducted, such as the Department of Health and Human Services' Office for Human Research Protections, the Food and Drug Administration (FDA), or other governmental offices as required by law.

All reasonable efforts will be used to protect the confidentiality of your and your baby's protected health information. However, not all individuals or groups have to comply with the Federal privacy law. Therefore, once your and your baby's protected health information is disclosed (leaves Upstate Medical University), the Federal privacy law may not protect it.

***For how long will your and your baby's protected health information be used or shared with others?***

There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for the program purposes continues to be used and analyzed for many years and it is not possible to determine when this will be complete.

***Can you withdraw your authorization to collect/use/share your and your baby's protected health information?***

You always have the right to withdraw your permission for us to use and share your health information, by putting your request in writing to Dr. Nicholas Greco, CBB director (address on page 1). This means that no further private health information will be collected. Once authorization is revoked, you may no longer participate in this program, but standard medical care and any other benefits to which you and your baby are entitled will not be affected.

**CONSENT TO PARTICIPATE IN THE UPSTATE CORD BLOOD BANK & AUTHORIZATION TO USE AND SHARE PERSONAL HEALTH INFORMATION**

By volunteering to participate in this program, you must agree to allow us to do the following:

- store the cord blood to use for transplantation or infusion into anyone who might need it,
- review your hospital medical record and your baby's hospital medical record before you leave the hospital,
- ask you some questions about your pregnancy, medical, and social history,
- draw five tubes of blood (the amount equal to about three tablespoons) from you,
- test the blood for certain infections, and agree for your and your infant's physicians to receive the test results,
- store a sample of the cord blood and your blood for possible future testing for infectious that might be passed on to a patient who receives the cord blood in a transplant

PLEASE INITIAL YOUR CHOICE ABOUT THE OPTIONAL RESEARCH DONATION

\_\_\_ I agree that if the cord blood unit is not acceptable for patient use, that the blood can be used for research or training purposes.

\_\_\_ I DO NOT agree that if cord blood unit is not acceptable for patient use, that the blood can be used for research or training purposes.

I hereby give my consent to donate my child's cord blood to the Upstate Cord Blood bank and agree that my and my child's personal health information can be collected, used and shared by the Program staff for the purposes described in this form. I will receive a signed copy of this consent & authorization form.

\_\_\_\_\_  
Printed name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

First Last Name: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

**Statement of Person Conducting Informed Consent Discussion**

I have discussed the above points with the participant. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this program.

\_\_\_\_\_  
Printed name of person obtaining consent

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

SUNY Upstate IRB Approved  
Expiration Date: September 24, 2017

HPC, Cord Blood Bar Code

An empty rectangular box with a black border, intended for entering the HPC, Cord Blood Bar Code.

Maternal Hospital Label

An empty rectangular box with a black border, intended for entering the Maternal Hospital Label.