

CONSENT TO DONATE CORD BLOOD

xxxx Hospital

A. Introduction:

You are being asked to participate in The New York Blood Center's National Cord Blood Program ("Program") carried out in collaboration with XXXX Hospital. The following information is being given to you to explain the purpose of the program, what you will be asked to do as a participant, and the potential risks and benefits. It will also explain that you do not have to participate in this program to receive medical care. You are encouraged to ask questions before deciding if you want to participate, or at any time during the program. You will be told of any new findings that may influence your decision to continue to participate.

B. Purpose of Program:

The main purpose of the Program is to provide a new treatment option for patients who need a bone marrow transplant but who have no donors to provide marrow, using cells in placental and umbilical cord blood instead of bone marrow. Another purpose is to learn how to improve cord blood transplants for these patients. Blood cells remaining in the placenta and umbilical cord (the afterbirth) after the baby is born can be useful for these patients because they are capable of developing into new bone marrow. Bone marrow replacement can be a life saving procedure for patients with certain leukemias and other blood or immune diseases who depend on tissue from a donor to cure their underlying disease.

The "cord blood" remaining in the afterbirth is normally discarded after delivery. You qualify for participation in the Program because you have just delivered a baby and the blood from your child's afterbirth was saved, rather than discarded. The collection took place after your baby was born, from the delivered placenta before it was discarded. The collection did not affect the delivery or the care of you or your baby in any way. With your permission, this cord blood can be placed into long-term storage for future use for any appropriate patient who requires a new bone marrow system. More than 25,000 women have donated cord blood to the Program so far. We expect to receive another 40,000 – 50,000 donations over the next four to five years.

C. Description of the Program:

For you to participate, you must agree to let the Program:

- a) keep the cord blood for anyone who might need it,
- b) review your hospital medical record and your baby's hospital medical record,
- c) ask you some questions about your pregnancy, medical and social history,
- d) draw two tubes of blood (the amount equal to about one tablespoon) from you,
- e) collect a saliva sample from your baby and
- f) test the blood and saliva for certain infections and genetic markers.
- g) keep a sample of the cord blood and your blood for possible future testing for infectious and genetic diseases that might be transmissible to a recipient.

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

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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. Program staff will ask these questions in a brief, private interview.

Program staff or staff in the newborn nursery will obtain the saliva from your baby by gently wiping a cotton-tipped swab around his/her gums. The saliva will be tested for a virus (Cytomegalovirus) that is uncommon in newborn babies but, if present, can cause significant disease in a transplant patient. If possible, we will draw your blood sample at the same time as other specimens that your doctor requests during your routine post-delivery care. This way no extra needle stick would be necessary. Your blood and your baby's cord blood will be tested for several infections that could be passed from you to the cord blood. The blood also will be tested to identify inherited cell or tissue markers called HLA (Human Leukocyte Antigens) that are needed for matching with future patient's tissue type. Your baby's cord blood will also be tested for the common inherited (genetic) diseases of the blood cells.

The infectious disease tests mandated by law whenever blood or tissue is offered for donation are human immunodeficiency virus (the cause of AIDS), hepatitis B and C viruses, human T-lymphotropic virus and syphilis. The genetic diseases that will be tested for are hemoglobin abnormalities (such as sickle cell disease). Specimens will also be stored for future testing in case other tests become appropriate.

We will report the results of any of these tests that may have possible implications for your or your baby's health to the physician(s) of your choice. The results of the following specific infectious disease tests will be reported:

HBsAg:	an indicator of hepatitis B virus infection, a virus that infects the liver and causes hepatitis, jaundice and liver disease.
Anti-HCV:	antibody to hepatitis C virus, an indication of infection with another virus that infects the liver and causes hepatitis, jaundice and liver disease.
Anti-HIV 1 and 2:	antibody to human immunodeficiency viruses (HIV), a marker of infection with the AIDS viruses.
Anti-HTLV 1 and 2:	antibody to human T-lymphotropic viruses, a marker of viruses that can cause a rare form of leukemia or paralysis.
Syphilis Serology:	a test for recent or past infection with syphilis.
Cytomegalovirus:	a positive test of your baby's saliva indicates infection with Cytomegalovirus, a virus that can cause hearing loss and, if it occurred in <u>early</u> pregnancy, can cause brain damage.

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The results of the following specific genetic disease tests will be reported:

Hemoglobin Abnormalities: a test to detect sickle cell disease, sickle cell trait and other inherited abnormalities of hemoglobin in red blood cells. Sickle cell disease, for example, is relatively common in people who have African ancestry. People with sickle cell "trait" carry only one copy of the sickle cell gene and are not affected by the disease. Even though New York State already tests all infants for sickle cell disease, the program will repeat the test.

Test results will be reported to your physician(s) within 3 weeks. Your physician will counsel you 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. If test results indicate that the cord blood should not be used for transplantation, it may be used for research, validation or quality control, or may be discarded.

In addition, a sample of the cord blood and your blood will be stored for future testing if more sensitive tests for the above infectious diseases become available or other infectious or genetic diseases are identified that require testing. If the cord blood that you donate is selected for a transplant, certain additional tests may be done by the Transplant Center to screen for the same genetic disease the patient has. Also a disease derived from the cord blood might be identified in the patient after the transplant. If such testing or follow up of the patient identifies a disease or infection that may be of importance to your child's health, you will be informed of these findings. If you would rather not be informed, you will not be eligible to participate in the Program.

D. Potential Benefits:

The only possible direct benefit to you or your baby from participating in the Program is that you might learn of an infection or a genetic disease that might benefit from 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 and help us learn more about how to improve cord blood transplantation.

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 family member. Whether or not this cord blood would be appropriate to use would be up to the physicians who take care of your child or family member. If available and appropriate to use, the blood will be provided. (Your child's blood can be found easily by testing a fresh blood specimen for his or her HLA type to find the matching blood in storage that was collected on his or her birth date) However, we cannot guarantee that the blood would still be available or that it would be appropriate to use or would be effective.

E. Potential Risks and Discomforts:

There are no significant risks from participating in the Program. The amount of blood drawn from you is minimal and not enough to affect your health. Taking blood from you has a minimal risk of slight pain and bruising, light-headedness, possible fainting or, rarely, infection. The blood taken

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from the cord is not needed after your baby is born and after the cord is cut. Some of the questions that you will be asked about are of a personal nature and may cause you embarrassment. You may ask to see the questions before deciding to participate.

F. Alternatives to Participation:

Instead of donating your baby's cord blood to the New York Blood Center's National Cord Blood Program for any patient to use, you may decide not to participate in the Program. If you do not want to participate, none of the Program procedures or tests outlined above will be done. Any cord blood already collected will be discarded or may be used anonymously (without any linkage to you or your baby) strictly for research purposes.

G. Costs and Reimbursements:

There will be no cost to you for any blood test nor will you be paid for the cord blood donation.

H. Voluntary Participation:

Participation in the Program is voluntary and you may withdraw at anytime without penalty. You will not lose any benefits to which you are otherwise entitled should you decide not to participate or to withdraw. Significant new findings that have been learned during the course of the Program that might be reasonably expected to affect your willingness to participate will be provided to you before you consent. Choosing not to participate or withdrawing from this research Program will not affect your medical care at xxxx Hospital in any way. Please report any decision to withdraw to program staff.

I. Compensation for Injury Related to the Program:

In accordance with Federal Regulations, we are obliged to inform you about xxxx and New York Blood Center policy in the event that a physical injury occurs. If, as a result of your participation, you experience a physical injury from known or unknown risks of the procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available. No monetary compensation, however, is available and you will be responsible for the costs of medical treatment, either, directly or through your medical insurance and/or other forms of medical coverage. Further information can be obtained by calling (xxx) xxx-xxxx.

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J. Confidentiality.

All information collected from you in connection with the Program will be kept confidential and in locked files. The information may be reviewed by government agencies (US Food and Drug Administration or the New York State Department of Health) in accordance with applicable laws and regulations. However, neither you nor your baby will be identified as a participant in such review, unless (as mentioned above) you need to be contacted for some reason related to your baby's health or for public health reasons. Neither you nor your baby will be identified in any publications.

To protect your privacy, your identity and your baby's identity will be kept only temporarily in New York Blood Center records (until after results of the infectious and genetic disease test results are reported). The identification number assigned to your baby's cord blood, however, will be attached to your hospital record and to your baby's hospital record as a permanent link between you and your cord blood donation. This link would help us to trace you through your Hospital record in the unlikely event that this is absolutely necessary for public health reasons such as an unusual, unforeseen infection that might be important to you or your baby, or if a genetic disease is identified that may be passed on to a patient.

K. Contacts for Questions and Access to Consent Form:

If you have any questions regarding the program, you may call Dr. Cladd E. Stevens at (212-570-3167). If you have any questions regarding injury related to participation in the program you may also call Dr. Stevens. For questions regarding your rights as a participant in the program, you may call the Office of the Institutional Review Board (the committee that oversees this program at xxxx Hospital) at (xxx) xxx-xxxx. A copy of the consent will be given to you.

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L. Participant's Consent:

I have read the above information about the National Cord Blood Program and have had all of the risks and benefits discussed with me and have had all my questions answered to my satisfaction. I have been assured that a member of the program staff will answer any future questions that may arise.

I voluntarily agree to participate and to donate the cord blood to the Program for anyone who might need it. I understand that I can withdraw consent at any time without penalty. By signing this consent form, I understand that I have not waived any of the legal rights that I would otherwise have.

_____	_____	_____
(Mother's Printed Name)	(Mother's Signature)	(Date)
_____	_____	
(Signature of Person Obtaining Consent)	(Date)	

Note: If mother does not consent, cord blood should be discarded or used for research. If the cord blood is used for research, no identifiers will be retained and the blood will be used anonymously, at no liability to the mother.

If the cord blood is to be discarded, place ID label here and send this unsigned consent to NYBC.

If the cord blood can be used for research, place ID label here and send this unsigned consent to NYBC.