

NEW YORK BLOOD CENTER - NATIONAL CORD BLOOD PROGRAM

xxxxxxxxxxxxx HOSPITAL

Consent Form for Clinical Investigation

Project title: Cord Blood Program

Principal Investigator: xxxxxxxxxxxxx

Subject: _____ **Research Project No.** xxxxxxxxxx

A. Introduction:

You are being asked to participate in the New York Blood Center's National Cord Blood Program (the "Program") carried out in collaboration with xxxxxxxxxxxxx Hospital (the "Medical Center"). The Program may also list some donated cord blood units with the National Cord Blood Inventory (NCBI) of the federally-sponsored C.W. Bill Young Cell Transplantation Program.

The following information is provided 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 of your participation. 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 whether you want to participate and at any time during your participation in the Program. You will be told of any new findings that may influence your decision to continue to participate.

B. Purpose of the Program:

The main purpose of the Program is to provide a new treatment option for patients who need a stem cell transplant, by using the cells in placental and umbilical cord blood instead of those in bone marrow. Another purpose is to learn how to improve the clinical results of cord blood transplantation. Your participation in this Program is entirely voluntary.

Blood cells remaining in the placenta and umbilical cord after the baby is born are useful for patients because they are capable of developing into healthy new bone marrow. Bone marrow replacement can be a life saving procedure for patients with various diseases, for example, certain types of leukemia and other blood or immune diseases.

The cord blood remaining in the placenta 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 and its attached umbilical cord, before they were discarded. The collection did not affect the delivery or the care of you or your baby. With your permission, the Program will freeze and place this cord blood into long-term storage for future use for any appropriate patient who requires a new bone marrow system. More than 50,000 mothers have donated cord blood to the Program so far and we expect to receive another 30,000 donations over the next three to four years.

C. Description of the Program:

To participate in the Program, you must agree to let Program staff:

- a) evaluate the cord blood collection as described below, and if all results are acceptable, freeze and store the cord blood so that it can be used for transplantation for any patient who might need it (see also page 3),
- b) review your current hospital medical record and your baby's hospital medical record before discharge,

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- c) ask you questions about your pregnancy, medical and social history,
- d) draw four tubes of blood (about two tablespoons) from you,
- e) test the cord blood and your blood sample for certain infections and send the test results to your and your infant's physicians,
- f) test the cord blood and your blood sample for certain genetic markers (see page 3),
- g) keep a sample of cord blood and of your blood for possible future testing for infectious and genetic diseases that could be transmitted to a patient who receives the cord blood as a transplant.

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. Answers to some questions help us determine which patients are most likely to benefit from the cord blood transplant because their ethnic background is similar to your own. Other questions relate to family or inherited diseases that might affect the cord blood. Some questions are used routinely in all volunteers who donate blood or tissue to help determine whether they have been exposed to any infectious diseases that might be present in the blood. The Program staff will ask these questions in a brief, private interview.

If possible, we will obtain your blood sample at the same time as other specimens that your doctor requests during your routine medical care. This way no extra needle stick is 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. These infectious disease tests (listed below) are mandated by law whenever blood or tissue is offered for donation.

Test name	Explanation
HBsAg:	an indicator of hepatitis B virus infection. Hepatitis B virus infects the liver and causes hepatitis, jaundice and liver disease.
Anti-HCV and Nucleic Acid Test (NAT) for the virus:	antibody to hepatitis C virus (HCV) and test for hepatitis C virus, a virus that infects the liver and causes hepatitis, jaundice and liver disease.
Anti-HIV 1 and 2 and Nucleic Acid Test (NAT) for the virus:	antibody to human immunodeficiency viruses (HIV) and test for HIV, markers of infection with the AIDS viruses.
Anti-HTLV 1 and 2:	antibody to human T-lymphotrophic viruses. These viruses can cause a rare form of leukemia or weakness and paralysis of arms and legs.
Nucleic Acid Test (NAT) for the West Nile Virus:	a test for the virus. WNV infection is spread by mosquitoes.
Antibody to Chagas' Disease:	a test for infection with the parasite that causes Chagas' disease (T. cruzi). The parasite spreads by bugs and is common in South and Central America.
Syphilis Serology:	a test for recent or past infection with syphilis.

We will report the results of these tests to the physician(s) of your choice within 3-4 weeks. Your physician will discuss with you the meaning of these results. If you would rather not be informed of such test results, you would not be eligible to participate in the Program.

If **any** of the test results indicate that we cannot use the cord blood for transplantation, we may use it for medical research or laboratory quality studies, or we may discard it, according to the FDA recommendations.

The cord blood and your sample of blood also will be tested to identify genetic tissue markers called

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HLA (Human Leukocyte Antigens) which are needed for matching with future patient's tissue type.

Your baby's cord blood will also be tested for common inherited (genetic) diseases of the blood cells causing hemoglobin abnormalities, such as sickle cell disease. However, the Program will not report these results to you as these tests are being performed only for donor screening and not as official disease testing. Official testing for hemoglobin abnormalities is done through State Laboratories, and those results are reported to your physician(s).

In addition, the Program will store samples of the cord blood and of your blood 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 donated is selected for a transplant, certain additional tests may be done by the transplant physicians (e.g. screening for the same disease that the patient has). Also a disease derived from the cord blood might be identified in the patient after the transplant. We will make every effort to inform you if such additional testing or follow up of the patient identifies a disease or infection that may be important for your child's health.

Between 6 and 12 months after your baby's birth, the Program staff may attempt to follow up with you by telephone or by sending you a short form to inquire about your baby's health to make sure that no problems exist that might affect the ability to use the cord blood for a transplant. Program staff may also contact you to check on your baby's health if the cord blood is selected for a transplant. It is very important that you also contact the Program if any problems regarding your health and your baby's health arise, that may also affect the cord blood, such as leukemia or other diseases of the blood cells. You can contact the Medical Director of the National Cord Blood Program, Dr. Andromachi Scaradavou, at (718) 705-5207 or another senior Program Staff Member at (718) 752-4751.

D. Potential Risks and Discomforts:

There are no significant risks related to participating in the Program. The amount of blood drawn from you is small and not enough to affect your health. Taking blood from you has a small risk of slight pain and bruising, light headedness, possible fainting and, rarely, infection. The blood taken from the placenta is not needed after your baby is born and after the cord is cut. Some of the questions that we will ask you are of a personal nature and may cause you to feel embarrassed. It is also possible that some information obtained by participating in the Program, such as test results, may have negative psychological or financial effects or may affect your ability to get health insurance.

You may ask to review the questions before deciding whether to participate.

E. 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 and get treatment earlier. An indirect benefit of participating is that you will help us give patients with life-threatening diseases 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 stem cell transplantation. If the cord blood you donated to the Program has not already been used by another patient and if it is still available at that time, it can be made available to your family at no cost. However, the treating physician must determine whether the stored cord blood would be appropriate for use in that situation. (We can identify your child's cord blood 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). If your donated cord blood is not available, we will make every effort to provide you with another, suitable unit.

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F. Alternatives to Participation:

You have been informed that there are private Banks that will collect and store cord blood to be kept exclusively for your family. If you choose to use one of these private Banks, you will need to contact them directly. You may not participate in the Program if you wish to keep the cord blood for use only by you or a member of your family. In that case, the Program will not perform any of the procedures or tests outlined above.

If you do not want to participate in the Program and do not want to store the cord blood privately, you must decide whether the Program can use the collected cord blood for research purposes (without any information linking it to you or your baby) or should discard it.

G. Confidentiality:

Program staff will attach the identification number assigned to your baby's cord blood to your hospital record and to your baby's hospital record, as a reference link between you and your cord blood donation. These links could help us trace and contact you for routine follow-up or in the unlikely event that we must inform you of an unusual, unforeseen infection or a genetic disease that could be important for your baby's health.

The Program will keep the Medical Questionnaire and this Consent Form that have your identity and your baby's identity, at the New York Blood Center. To protect your privacy, we will keep all information that contains your personal identifiers confidential and in a secure location, with access allowed only to authorized Program staff. We will also store all other information we collect about you and all test results in a secure electronic database and allow access only to authorized personnel.

We may, however, share certain information about you and your baby's cord blood, with government agencies that oversee the Program (US Food and Drug Administration, Office of Human Research Protection (OHRP) or the New York State Department of Health or accrediting agencies) and representatives from **xxxxxxx Hospital** and the Institutional Review Board, in accordance with applicable laws and regulations. However, we will not identify you or your, unless (as mentioned above) we need to contact you for some reason related to your baby's health or for public health reasons. We will also transfer information on cord blood units that become part of the National Cord Blood Inventory (NCBI) to the C.W. Bill Young Cell Transplantation Program's Cord Blood Coordinating Center. We will not transfer any identifying information that would allow linkage to you or your infant. We will not identify you or your baby in any publications.

If you agree to participate in this Program, and sign this consent form, you are giving us permission to collect, use and share your information as described in this consent. This permission is called authorization.

H. Costs and Reimbursements:

There will be no cost to you for any blood test. The Program will not pay you for the cord blood donation. Participation in the Program is voluntary. There is no penalty and you will not lose any of your benefits should you decide not to participate. Choosing not to participate or withdrawing from this research Program will not affect your medical care at the Medical Center in any way.

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I. Participation:

If you choose not to participate in the Program or to leave the Program, this decision will have no impact on your medical care, your relations with the Medical Center, your physicians, or other personnel. In addition, you will not lose any benefits to which you are entitled. If you decide to participate, you are free to discontinue participation at any time without affecting the quality or availability of your medical care. You are aware that your participation in this Program is completely voluntary. Your doctor has the right to take you out of the Program at any time without regard to your consent if he or she feels it is in your best interest to do so. In this situation, you will be asked to cooperate in having whatever laboratory tests and examinations your doctor thinks are necessary for evaluation of your health. We will keep you informed of any significant new information which may affect your decision or willingness to participate in this Program.

J. Possible Transfer of Cord Blood Units:

If, in the future, the New York Blood Center is no longer willing or able to manage the Program, we may transfer those cord blood units that are part of the National Cord Blood Inventory (NCBI) and the C.W. Bill Young Cell Transplantation Program and all associated information to another organization to store and manage. Such transfer, however, would include a guarantee of your and your baby's confidentiality.

The Policy of XXXXXXXXXXXX Hospital (if needed):

In accordance with Federal regulations, we are obliged to inform you about the Medical Center's policy in the event an injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research 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 such 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 (the Institutional Review Office of the Medical Center).

K. Questions:

- If you have any questions regarding your rights as a participant in the Program or concerning a research related injury, please call (xxx) xxx-xxxx to speak with a representative from the Institutional Review Board of the XXXXXXXX Hospital.
- If you have any questions regarding the Program or wish to inform us of a potential problem that might affect the suitability of the cord blood for transplantation, you may call the Medical Director of the National Cord Blood Program, Dr. Andromachi Scaradavou, at (718) 705-5207 or another senior Program Staff Member at (718) 752-4751.
- You may also contact XXXXXXXXXXXX (Principal Investigator at the Medical Center) or his associates. XXXXXXXXXXXX is located at (Hospital, address, telephone number)

L. We will give you a copy of this form to keep.

Patient's Initials _____

01/2010

Protocol # XXXXXXXXXXXX

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By signing this form, you freely and voluntarily consent to participate in the Program described above. You are giving this consent based on the verbal and written information provided to you and the understanding that you are medically and physically qualified to participate in this Program. You are free to ask questions at any time. By consenting to participate in this Program, you are responsible for carrying out instructions and you must relate to your doctors, nurses, or to Program personnel any information that may be pertinent to the Program such as any side effects of a treatment or procedure. Please inform the Program Staff if you are either reluctant at all to continue or decide to withdraw from the Program.

Please report any reluctance you may have to continue in the Program to any of the telephone numbers listed above. Any new information regarding the Program and any treatment it involves which may affect your willingness to continue your participation in the Program will be related to you in an appropriate way. The Program could be terminated at any time for safety reasons or lack of benefit. If you decide to withdraw from the Program, please contact any of the telephone numbers above.

Mother's Statement:

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 voluntarily agree to participate and to donate the cord blood to the Program and to be included in the National Cord Blood Inventory (NCBI) of the federally-sponsored C.W. Bill Young Cell Transplantation Program for transplantation to any patient who might need it or to be used for medical research purposes or laboratory quality studies. I understand that I can withdraw consent at any time without penalty, provided that the cord blood still remains in the Program. By signing this consent form, I understand that I have not waived any of the legal rights that I would otherwise have.

I am also giving permission to collect, use and share my health information, as described in this consent.

I agree to participate and to donate the cord blood to the Program for any patient who might need it.

_____	_____
(Mother's Name)	(Date)
_____	_____
(Signature of Mother)	(Date)
_____	_____
(Signature of Program Staff Member)	(Date)
_____	_____
(Signature of Person Performing Translation, if applicable)	(Date)

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I do not wish to participate in the Program, but the cord blood may be used for other research purposes without any links to me or my baby's identity.

_____ (Mother's Signature) _____ (Date)

Mother agrees to donate for Research. Place ID label here.↓ and send this **signed Research Consent** to NYBC.



Mother declines participation. Place ID label here .I. and send this **unsigned Consent** to NYBC.



This consent form is only valid if it carries the IRB approval stamp with current dates.