

DEC 15 2009

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UNIVERSITY OF WASHINGTON MEDICAL CENTER
Evergreen Healthcare
Overlake Hospital Medical Center
Yakima Valley Memorial Hospital
Puget Sound Blood Center Cord Blood Program

CONSENT FORM

Cord Blood Banking for Transplantation

INVESTIGATORS:

Thomas Price, MD	Medical Director	Cord Blood Program	(206) 292-6571
JoAnna Reems Ph.D. (Principal Investigator)	Scientific Director	Cord Blood Program	(206) 398-5917
Bonnie Gong, MD	Co-Investigator, Childbirth Center	Evergreen Healthcare	(425) 889-3888
Ann Kolwitz, MD	Co-Investigator, Childbirth Center	Overlake Hospital Medical Center	(425) 454-3366
Roger Rowles, MD	Co-Investigator, Childbirth Center	Yakima Valley Memorial Hospital	(509) 453-7109

24-HOUR PHONE:

Western Washington

Douglas Mora, Cord Blood Program Hospital Services Supervisor

Joanna Moss, Cord Blood Donation Coordinator

Debra Grady, RN, Cord Blood Donation Coordinator

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Office: (206) 292-1896

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Maria Hernandez, OB Technician

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RESEARCHER'S STATEMENT

We are asking you to be in a research study. The purpose of this consent form is to give you the information that you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.' We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The primary purpose of this project is to collect and store umbilical cord blood for potential inclusion in the National Cord Blood Inventory (NCBI). The NCBI is a federally supported program to assist in the collection of cord blood to be made available to patients through the federally authorized C.W. Bill Young Cell Transplantation Program. This study will help evaluate the safety of methods used to prepare cord blood cells for transplantation, and to determine how effective cord blood cell transplantation may be in treating disorders such as blood cancers.

Blood cells produced by a baby before birth circulate through the baby's body, umbilical cord and placenta. When the baby is born, the umbilical cord is cut, separating the baby from the placenta and umbilical cord, and the baby is given to the parent. The placenta is delivered several minutes later and is sometimes thrown away. The blood of newborns contains a special type of cell known as a *stem* cell. After birth, these stem cells in the baby's body leave the blood and eventually become a permanent part of the bone marrow. They then produce new blood cells throughout the life of an individual. The stem cells that remain in the umbilical cord and placenta can be collected and used to replace the blood cells of a person who needs a bone marrow transplant and cannot find a matched bone marrow donor.

The Puget Sound Blood Center has developed a program to collect umbilical cord blood and to screen, process, store, and evaluate the suitability of these cells for transplantation. The Puget Sound Blood Center also conducts research related to the transplantation of cord blood stem cells. Although there have been over 1,000 cord blood transplants around the world, this is still a new area of investigation. The Food and Drug Administration has identified cord blood as a biological drug and regulates it as a HCT/P (Human Cells, Tissues and Cellular and Tissue Based Product). The Cord Blood Program currently follows recommended standards from the AABB, Advancing Transfusion and Cellular Therapies Worldwide.

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STUDY PROCEDURES

Collection Procedure And Potential Use Of The Cord Blood Sample

After your baby is delivered and the cord is clamped and cut, the remaining cord blood can be collected, tested and stored for transplantation. The cord blood will be collected by a trained person, while waiting for the placenta to be delivered. It will be processed and may be stored indefinitely. It is estimated that approximately 10% of all collected cord blood units may actually be transplanted. If tests show that the cord blood is not suitable for transplantation or storage, it may be discarded. Cord blood or cord blood components that cannot be transplanted may also be used for research to improve current methods for processing cord blood or for other research. If we provide cells to other researchers, it will be with the understanding that the cells will not become part of a commercial product. You will not be eligible to receive compensation from results of the research.

There is no guarantee that your cord blood will be collected or stored. There are many reasons that could prevent collection, such as staff unavailability, birth complications, or other events making donation inappropriate. Cord blood may not be stored if the amount of cord blood collected is too small, the cord blood is infected, or there are problems in the processing or freezing of the cord blood. You will not have any rights or claims to the cord blood, and you might not be told what is done with it. However, if you would like that information, you may contact us at the address on the front of this consent form.

Screening Of The Mother

We will need to interview you privately about your and your family's medical history, including questions about your pregnancy, health, and past medical problems in your family and in your baby's father's family. 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. The information that we collect in this screening interview is confidential and will only be used to find out if the cord blood can be stored in the cord blood bank. If your baby's cord blood is used for research, it will not be labeled in any way that will allow the users to identify you or your baby. You may refuse to answer questions asked in the screening process. Lack of information may cause the cord blood to be unbankable. This interview takes approximately fifteen minutes.

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Samples of your blood, about 3 tablespoons, will be collected near the time of your baby's birth and if the unit qualifies for banking or for a research program, tested for transmissible diseases using the same tests required for all blood donations. The blood will be taken from your arm by a qualified person and tested for Chagas disease, a blood parasite, and viruses such as hepatitis, cytomegalovirus (CMV), HTLV I and II, HIV (the virus that causes AIDS), West Nile Virus, and syphilis. The tests will be used to find out if the cord blood can be safely stored in the cord blood bank. Your demographic information and test results will be entered into the Puget Sound Blood Center's donor database so that notification will be performed if any test results require it. Only authorized personnel at the Puget Sound Blood Center have access to this information. Some of the blood may also be frozen and stored for future testing, in the event that better tests become available.

A sample of your blood may be tissue typed, if necessary. Tissue typing (a DNA test) gives a "fingerprint" of the blood cell. This may help us tell if some of your blood is mixed in with the baby's cord blood.

If any tests are confirmed positive, we will follow Puget Sound Blood Center procedures to notify you. Washington State law requires that blood and tissue banks report the name of anyone with confirmed positive test results for HIV to the public health department. The purpose of this reporting is to monitor the level of HIV infection in the state population. Local health departments must convert names to an identifier code and destroy names on paper and in computer files within 90 days. The local health department will send the code and other information about you to the Washington State Department of Health. Penalties for violation of the confidentiality laws are severe. In the case of confirmed positive HIV results, the Puget Sound Blood Center will provide you with in person, post-test counseling. If we cannot contact you for this, the Public Health Service may assist us. If you have a false positive test, it is possible that your name may be falsely reported.

The Washington State Public Health Service becomes aware of all people with positive test results for syphilis because they perform the confirmatory testing. We are also required to inform the county health department of confirmed positive results for certain hepatitis tests.

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Testing Of The Cord Blood

Samples of the cord blood cells may be tissue typed. This "fingerprint" will be needed to match the cord blood cells to a recipient patient's blood cells.

A sample of the cord blood may be stored for future testing for infectious diseases, such as Chagas disease, hepatitis, cytomegalovirus (CMV), HTLV I and II, West Nile Virus, and HIV (the virus that causes AIDS). These tests are done only if the cord blood is selected to be used in a transplant. All blood test results are confidential. We will make every reasonable effort to inform you of any confirmed positive test results, which may affect your health or your baby's health.

If your baby's cord blood is identified as a possible match for a transplant, a saved sample may also be tested for metabolic and/or genetic diseases, some of which could affect or be passed through blood cells, like Gaucher's disease and adrenoleukodystrophy (ALD). These tests are performed to protect the person who will eventually receive the cord blood.

If a licensed test confirms the presence of this type of disorder, the Cord Blood Program will try to notify you of the test results and recommend that you contact your primary care physician for an explanation of how this disorder may affect your baby's health. If requested, we will assist your physician with referrals to resources for genetic counseling.

RISKS, STRESS, OR DISCOMFORT

Drawing blood from your arm for the blood tests may cause bruising, fainting, pain and, in very rare circumstances, infection. All normal precautions will be taken to prevent these side effects.

In the rare event that you have a positive blood test result (such as for HIV testing) and that result became known, you could be treated unfairly by others. You could experience extreme and negative emotions, including stress, fear, guilt, anger and depression, and your personal and professional relationships could change significantly.

If you are notified that your baby's test results are confirmed positive, indicating that they have an increased risk of disease, you could experience fear, anxiety, or depression. You may feel guilt related to the possibility of having passed on this risk or disease to your child. You or your child may experience increased cost of insurance, cancellation of insurance policies, and/or the inability to purchase insurance sometime in the future.

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When applying for a new policy, you or your child could be asked about medical conditions of which you are aware. Insurance companies may be able to obtain genetic information about you or your child if you have released this information to your doctor.

In the rare event that your baby's cord blood was transplanted and confidentiality was somehow broken, a transplant patient could try to contact you.

At any time, you may contact the Cord Blood Program with questions about the study, its risks and other options available to you. The appropriate phone numbers are included on the front page of this consent form.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You can choose not to have your cord blood collected. There are also companies that collect, process and store cord blood specifically for exclusive family use. If you wish to ensure that your baby's cord blood is collected and is available to be used for members of your family, you should contact one of these companies. Please understand that if you do choose to privately store your baby's cord blood, you will not be able to participate in this program. It may be possible to participate in other research projects using cord blood through other programs. If you choose to participate in another research project using the cord blood, you might not be able to donate your cord blood to the Puget Sound Blood Center. You may contact the University of Washington IRB office to inquire about other research options.

BENEFITS OF THE STUDY

Aside from knowing that your donation might help the life of someone else, there will probably be little or no direct benefit to you or your baby from taking part in this study. It is possible that some of the screening tests performed on the cord blood may detect an infection or genetic disorder in you or your baby, which otherwise might not have been detected. For some conditions, this early detection could result in earlier treatment and improved health care.

Possible benefits to society as a result of this project are that a cord blood bank could provide a diverse source of stem cells for transplant that will help the many people who cannot find a suitable bone marrow donor match.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

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Data will be confidential and retained indefinitely. If you agree to participate, the Cord Blood Program will receive information related to your obstetric medical record and your baby's medical records. This will include specific pregnancy and delivery information up to the time of your discharge from the hospital. The collector will complete a form with specific details about your baby's delivery, such as the date and time of delivery and the person performing the collection. We may request a copy of the routine state newborn screening tests.

If your baby's cord blood is matched for transplant, we may attempt to contact you, your baby's other parent, or your baby's pediatrician in order to ask about any changes in your baby's health that might affect transplantation. Because cord blood can be stored for long periods, this may be in the next several years.

We will make every effort to protect your and your baby's confidentiality. When the cord blood is received at the Puget Sound Blood Center, it will be issued an identifying number. This will be used for all cord blood samples during testing and processing. Donor records that link your name with your number will be kept in a locking file cabinet and stored on a computer in restricted areas of the Puget Sound Blood Center.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

You will not be charged and there will be no charges to your insurance company for costs related to the Cord Blood Program. You will not be paid for your donation. The Puget Sound Blood Center will assume financial responsibility for all costs associated with this work. Costs related to care for you or your baby, as the result of disease testing results will be your responsibility.

As part of the ongoing scientific and research activities of the Puget Sound Blood Center, cord blood that cannot be banked may be preserved and used for research or development purposes. The Puget Sound Blood Center may provide these cells to other scientists interested in cord blood research. These samples will be provided only as anonymous samples. We may store your cord blood samples to use in future research. If we want to use them for a research purpose not described in this consent form, we will send our request to an Institutional Review Board. This board protects the rights and welfare of research subjects like you. The Board will determine if we need to contact you and ask your consent to do the research. If your baby's cord blood is used for research, your and your baby's identities will be completely unlinked from the cord blood unit and will be anonymous. The Puget Sound Blood Center is a non-profit entity and no direct profits will be derived from this.

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Your decision to donate your baby's cord blood is voluntary. At any time prior to the use of the cord blood, you may withdraw your consent. To withdraw, notify the Cord Blood Program Coordinator by calling 206-292-1896 or 1-800-366-2831 ext. 1896. You will continue to receive all obstetric care to which you are entitled, even if you decide not to donate cord blood. If you choose not to donate or choose to stop storage at any time, your decision will not affect your future relations with the UW Medical Center, the Puget Sound Blood Center, or your physicians. If, at any time, you feel that your baby's cord blood should not be used for transplant, or if you realize that you do not meet the screening criteria, please notify the Cord Blood Program immediately. Any information that you provide will be maintained confidentially. The number to call is included on the last page of this document.

COMPENSATION FOR INJURY

If you think you have an injury or illness related to this study, contact Dr. Jo Anna Reems at (206) 398-5917 right away. She will refer you for treatment. Your insurer will be billed for treatment if required. If your insurer refuses to pay, you may be billed directly.

No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form.

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Cord Blood Program
Puget Sound Blood Center
921 Terry Ave
Seattle, WA 98104
(206) 292-1896

University of Washington Medical Center
Evergreen Healthcare
Overlake Hospital Medical Center
Yakima Valley Memorial Hospital
Puget Sound Blood Center Cord Blood Program

Signature of Investigator or Designee

Printed Name of Investigator or Designee

Date

SUBJECT'S STATEMENT

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at 206-543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

I AGREE to allow use of my baby's cord blood for research purposes, if it cannot be stored for transplant. In this case, the cord blood will be stored and used anonymously.

I DO NOT AGREE to allow use of my baby's cord blood for research purposes.

Signature of Mother

Printed Name of Mother

Date

Mother's Date of Birth

cc: Mother
Mother's Obstetric Medical Record
Investigator's Files

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