

**Cord Blood Program
Puget Sound Blood Center
921 Terry Avenue
Seattle, WA 98104**

(206) 292-1896

**Swedish Medical Center
747 Broadway
Seattle, WA 98122**

(206) 386-6000

**CONSENT FORM FOR COLLECTION AND STORAGE
OF HUMAN BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES**

**Cord Blood Banking for Transplantation
IR#2922**

INVESTIGATORS:

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Jo Anna Reems Ph.D.	Scientific Director	Cord Blood Program	(206) 398-5917

24-HOUR PHONE:

**Douglas Mora, Cord Blood Hospital Services Supervisor
Joanna Moss, Cord Blood Donation Coordinator
Debra Grady, RN, Cord Blood Donation Coordinator
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Puget Sound Blood Center
Office: (206) 292-1896
1-800-DONATE-1, Ext. 1896
24-hour Cell Phone: (206) 388-9185**

This is a type of research study. Research studies include only people who choose to take part. Please take your time to make your decision to participate. Discuss it with your friends and family.

This particular research in humans is designed by the Puget Sound Blood Center.

This consent form may contain words that you do not understand. Please ask the study doctor or study staff any questions that you have. The following is a summary of the information you were given when this study was discussed with you.

PURPOSE, POTENTIAL FOR BENEFIT

Why is this study being done?

The purpose of this study is to establish a “repository”, which is a storage bank of medical information. You are being asked to consider providing about 45 mL of your blood, which is about 3 tablespoons, and allowing researchers to collect 40 mL to 100 mL, which is about 3 to 7 tablespoons, or more of cord blood from the umbilical cord after your baby is born. You are also being asked for access to your and your baby’s medical records regarding your delivery and the birth of your baby. Blood collected from this study will be tested for the following transmissible diseases: Chagas, hepatitis, cytomegalovirus (CMV), HTLV I and II, HIV (the virus that causes AIDS), West Nile Virus, and syphilis. You will be asked questions about your medical history, similar to questions asked when you donate blood for regular blood donations. If the cord blood you provide is selected for transplantation we may contact you to see if there are any changes to your baby’s health that could have an effect on the transplant. Cord blood may be selected for transplant up to 10 years in the future. Therefore, it is possible that the Puget Sound Blood Center may contact you 10 years from the time you provide the cord blood to ask questions about your child’s health.

The primary purpose of this repository 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. However, because the criteria for use of cord blood in transplants are so specific, only 1/3 of all cord blood donations collected for this repository can be used in transplants. If the cord blood cannot be used for transplantation we will use the cord blood for quality improvement purposes to test our storage systems, or for other research with your permission.

If cord blood cannot be used in transplantation you also have the option of allowing the blood collected for this repository to be used for other research and future research carried out by researchers in the Puget Sound Blood Center itself, or by researchers outside the Puget Sound Blood Center. You do not have to agree to allow the blood collected for this repository to be used for other research and future research. At the end of this consent form you can choose whether or not you want to participate in other research/future research. The other research/future research is explained in more detail later in this consent form.

The goals of this repository are to collect and bank stem cells from umbilical cord blood for transplantation. Stem cells are the parent cells of blood and immune cells. These stem cells can be used as an alternative to bone marrow in the treatment of blood and immune disorders. This repository is designed to 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.

Please note that some families prefer to store cord blood exclusively for their own use. This is called ‘private banking’ or ‘family banking’, and is not a service routinely provided by the Puget Sound Blood Center. If you would like information about private banking, please use the contact information above. If you choose to privately bank cord blood, you will not be able to participate in this research program.

How many people will take part in the study?

If you agree to participate, you will be one of approximately 45,000 subjects who will be participating in this research. Approximately 100 people will participate locally in a month.

Are there benefits to participating in this study?

If you agree to take part in this study, it is unknown if there will be direct benefit to you. The research that will be done with the cord blood probably will not help you. Information from the research may be valuable in treating different kinds of cancer, blood disorders, and leukemias. If you agree, other research that may be done with the cord blood may determine how stem cells in cord blood develop, or used to understand how stem cells may be used to treat specific diseases in the future.

There is a chance that the cord blood stored for this repository might be available to your family, if it is successfully stored and has not been used already. However, this cannot be guaranteed.

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.

TREATMENT / PROCEDURES

What is involved in the study?

If you agree to be in this study, we will be collecting biological specimens which include blood samples from you, and umbilical cord blood.

The material will be collected as follows:

Blood will be drawn from you with the start of your IV, with another sample draw, or a separate draw if necessary. We will need about 45 mL, or 3 tablespoons, of your blood to test for transmissible diseases using the same tests required for all regular 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. Some of your blood (about 2 mL, or less than a ½ teaspoon) may also be frozen and stored for transmissible disease testing later on, 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 we find that your baby's cord blood cannot be used for transplantation and you do not agree to allow the cord blood to be used for other/future research, your blood sample (along with your baby's cord blood) will be destroyed.

Cord blood will be collected by a trained person, while waiting for the placenta to be delivered. If initial tests indicate that it may be useable for a stem cell transplant, it will be processed by removing other types of cells and adding preservatives to the stem cells. It may then be stored indefinitely. It is estimated that approximately 1 out of 3 collected cord blood units may be useful for transplantation.

The specimens will be sent to the Puget Sound Blood Center and stored there. A custodian of the specimens, called the "Repository Manager" will oversee the receipt and storage of the specimens.

There will be no medicines to take and no treatments provided as part of this specimen collection.

If you agree to participate in this repository, you are agreeing to allow blood collected for this repository to be used for transplantation purposes or, if the blood cannot be used for transplantation, quality improvement purposes specific to this repository. Specimens will be used for the following research purposes at the Puget Sound Blood Center as part of this repository:

- Cord blood stem cell transplantation
- Ongoing quality control projects to determine how long cord blood can be safely stored
- Training in the processing and thawing of cord blood
- Research to determine other uses of cord blood.

Your specimens may be shared with transplant physicians for any of the reasons listed above without making your identity known. Your specimens may be shared with:

- The National Marrow Donor Program, an organization that facilitates stem cell transplants
- The Fred Hutchinson Cancer Research Center
- Saneron/University of South Florida
- Other Researchers working in cooperation with the National Cord Blood Inventory (NCBI)

If the cord blood can not be used for the above purposes, and you allow us to use it for other/future research by agreeing to other/future research at the end of this consent form, the blood will be used for the following research purposes at the Puget Sound Blood Center as well as by researchers outside the Puget Sound Blood Center:

- To determine if cord blood stem cells are able to develop into other types of cells (such as the cells that make up the nervous system, organs, and other tissues)
- To determine if cord blood is able to treat disorders other than cancer and leukemia
- To determine how long cord blood can be stored and still be useful
- Future research to determine other uses of cord blood. Due to the nature of such research being conducted in the future, it is difficult to define this future research. It may not be possible to identify all of the ways in which the specimens will be used.

For other/future research your specimens may be shared with:

Investigators within the Puget Sound Blood Center as well as with other investigators with research projects outside of the Puget Sound Blood Center. These cells will not become part of a commercial product. Please note that specimens provided to researchers for other/future research will not include any identifying information so the specimens cannot be linked back to you or your child.

There is no guarantee that your baby's 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 might not have access to the cord blood, and you may not know if it is used for research. This is also the case whether or not you agree to allow specimens to be used for other/future research. However, if you would like to know what is done with your specimens, you may contact us.

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 and are most often completed prior to the collection of the cord blood. However, it may be possible to complete the screening up to two days after the cord blood is collected. 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.

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 baby's cord blood may be stored for testing of infectious diseases, such as 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.

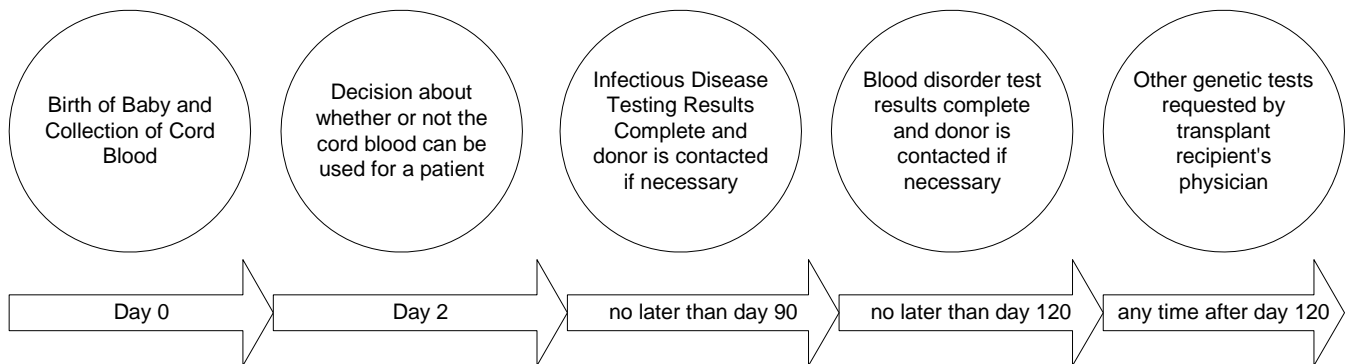
If your baby's cord blood is identified as a possible match for a transplant, a saved sample may also be tested for metabolic and/or genetic diseases, some of which could affect or be passed through blood cells. Examples of such diseases are Gaucher's disease, a lack of the enzyme which helps eliminate dead cells from the body, and adrenoleukodystrophy (ALD), a lack of the insulation which covers nerve fibers. 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.

Medical Records Review:

The Cord Blood Program will gather 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. We may request a copy of the routine Washington state newborn screening tests. The Cord Blood Program will obtain specific details about your baby's delivery, such as the date and time of delivery and the person performing the cord blood collection. Because the cord blood is frozen, the Blood Center may retrieve information about your baby in the future. This information will be used to determine if the cord blood is suitable for use in transplantation.

If your baby's cord blood is matched for transplant, we may attempt to contact you or your baby's pediatrician in order to ask about any changes in your baby's health that might affect transplantation. This could be up to ten years or more from your baby's date of birth. If we are unable to contact you, the intended transplant recipient may choose not to use the cord blood, in which case the cord blood would be kept in the bank for possible use by someone else. If we do contact you, you may decide to limit or refuse any further contact from the Cord Blood Program.



Storage of Specimens

The samples collected will need to be identified so that they can be linked to your medical information; however, if you agree to other/future research, your identity will not be released to researchers who request samples for their studies from the repository.

The cord blood and your maternal blood samples will be stored in security protected collections belonging to and managed by the Puget Sound Blood Center. Under rare circumstances, it may be necessary to transfer the cord blood and associated information to another organization to store and manage. Any such transfer will include guarantee of confidentiality. The following security measures will be used to protect the cord blood, maternal samples, and medical information:

- All cord blood units are assigned a unique identifying number. This number is provided to the transplant physician or researcher, but none of your identifying information will be given.
- Cord blood and maternal samples are stored in locked freezers in restricted areas of the Puget Sound Blood Center.
- Information provided to transplant physicians and researchers is kept in a separate database from your identifying information.
- The Repository Manager is responsible for ensuring that records are kept in accordance with established policies and procedures, which are based on current regulations.

Representatives from regulatory groups, such as the AABB, (Advancing Transfusion and Cellular Therapy Worldwide), the Food and Drug Administration (FDA), and the National Marrow Donor Program (NMDP), will have access to Cord Blood Program records as part of routine inspections.

How long will I be in the study?

If the cord blood is successfully stored for transplant use, it may remain in the freezer for 10 years or more. At any time during storage, you may be contacted for additional information. An attempt will be made to contact you prior to sending out the cord blood for transplant. If the cord blood is designated for research use because it is unable to be used for transplantation, it is unlikely that you will need to be contacted further.

Risks

What are the risks of the study?

There are no known risks or discomforts to you or your baby during the cord blood collection procedure.

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.

The major risk of your participation is the possible risk of loss of confidentiality of private medical information.

In addition, since DNA can be extracted from these tissues, potentially harmful information could be gained (for example, paternity). If we utilize your DNA, you should realize that every person's DNA is unique; therefore, it may be possible some day that someone could find out who you are just from knowing your DNA sequence.

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 negative emotions in response to these results, including uncertainty and frustration, and your personal and professional relationships could change significantly. If any infectious disease tests are confirmed positive, we will follow Puget Sound Blood Center procedures to notify you. The Seattle/King County Public Health Service is given information about persons with positive test results for syphilis and HIV as required by law. In the case of confirmed positive HIV results, the Puget Sound Blood Center will provide you with in person, post-test counseling about the test results. If we cannot contact you for this, the Public Health Service may assist us. The Puget Sound Blood Center will provide contact information for follow-up care.

Each cord blood unit that is useable for transplantation is tested for blood disorders, such as sickle-cell anemia and thalassemia. If you are notified that test results on your baby's cord blood 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. There are risks associated with a loss of confidentiality of your health information and genetic testing results. Information about genetic test results may affect your or your child's employment, insurance, or family relationships.

If you agree to other/future research, please note that since we do not yet know the exact questions that will be studied by scientists in the future, we cannot tell you what specific information they will be looking at or what that might mean to 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

What other options are there?

You may choose not to provide maternal blood and cord blood to this repository. This will not alter your care or your relationship to any of your physicians. If you decide now that your cord blood can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your cord blood. Then the cord blood will no longer be used for research.

You may choose to bank your cord blood for your family's exclusive use with a company that provides such a service for a fee. If you choose to privately bank the 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.

Confidentiality

Every effort will be made to keep your and your baby's personal information confidential, but we cannot guarantee absolute confidentiality. Your and your baby's personal information may be disclosed for purposes related to the study, or if required or allowed by law, and there is a possible risk of inadvertent disclosure of personal information. However, in order to protect the confidentiality of your and your baby's personal information:

- The identifying numbers and links with donor information are kept in electronically secured databases.
- Paper copies and files are kept in locking file cabinets in restricted areas of the Puget Sound Blood Center, or stored in a secure off-site archive facility.
- Access to records is restricted to Puget Sound Blood Center staff working with the Cord Blood Program.
- The medical information you contribute to the storage bank will not be released to any insurance company, potential employer, government agent or agency, family member, or friend.
- A certificate of confidentiality has been obtained from the federal government. This certificate will allow the researchers to protect your private information in cases where law enforcement officials may request it, such as with a subpoena.

By law, you have certain rights related to your health information. These include the right to know who may be able to get the information and why they may be able to get it. If you agree to participate in this study and you sign this consent form, you are also agreeing that the research team may share your information with any or all of the following:

- the sponsor: National Marrow Donor Program
- Puget Sound Blood Center
- doctors and other healthcare providers taking part in this study
- the U.S. Food and Drug Administration (FDA)
- the U.S. Department of Health and Human Services (DHHS) agencies, including the Health Resources and Services Administration (HRSA) and the C. W. Bill Young Cell Transplantation Program
- Government agencies that must receive reports about certain diseases
- Swedish Medical Center and entities within Swedish Health Services
- Swedish Medical Center IRB

- The National Marrow Donor Program and other transplant facilitation organizations
- The AABB), Advancing Transfusion and Cellular Therapy Worldwide, an organization that inspects and accredits cord blood programs

The results of the research study may also be presented at meetings or in publications, but your identity **will not** be disclosed in those presentations or publications.

You do not have to agree to allow these groups to look at your information, but if you do not, you may not be allowed to participate in this study.

If you give your permission to give your information to a person or business, the information may no longer be protected by federal or state privacy laws. There is a risk that your information will be released to others without your permission.

You may revoke (“take back”) your agreement to participate in this study and authorization to use your health information for this research study by contacting the Principal Investigator, Dr. Jo Anna Reems, in writing. After contacting Dr. Jo Anna Reems, any unused cord blood and associated samples will be destroyed. The cord blood can not be returned to you or forwarded to any other individual or facility. However, any data that has been obtained from testing your biological material until that point, or information that has been collected about you before you revoke, may still be used for purposes of the study. Unless revoked in writing, your agreement and authorization to use your health information for this research and to keep adding information about you to the registry will continue. There are no plans to stop using the registry, so researchers may keep using the information about you that has been included in the registry indefinitely.

What are the costs?

Taking part in this study will not lead to added costs to you or your insurance company. The Puget Sound Blood Center will assume financial responsibility for all costs associated with this research.

Is there compensation for injury?

If you are hurt or become sick as a result of this study, you will receive medical care. The charges for such care will be billed to you and/or your insurance company. You should be aware that your insurance company may or may not pay for such charges. There are no plans to pay you or your family for loss of income, pain and suffering or other consequences of any such injury or death. However, you do not give up your rights, if any, which otherwise may be available to you by law.

Will I be paid for participating?

No payment will be made directly to you for taking part in this study.

Specimens may also be used in an attempt to develop products to be sold, and there are no plans to share the profits or losses in the development and sale of those products with you. The cord blood and your samples will not become part of a commercial product.

Who is paying for this study?

Funding for this study comes from the Puget Sound Blood Center's operating budget.

What are my rights as a research subject?

Taking part in this study is voluntary, and you may choose not to take part. If you do want to be part of this study, but later change your mind, you may leave the study at any time. Your decision to leave the study will not change your future medical care here.

If you agree to allow the samples of your cord blood to be stored for this repository or for other/future research studies, you are free to change your mind at any time. If you decide that you do not want your samples stored for this repository or for other/future research studies, you should contact Dr. Jo Anna Reems at 206-398-5917. After contacting Dr. Jo Anna Reems, any unused cord blood and maternal samples will be destroyed and not used for this repository or for other/future research studies. The sample cannot be returned to you or forwarded to any other individual or facility. However, any data that has been obtained from testing your specimens or information that has been collected about you until that point, will remain part of the research.

If it is still available, you may contact the Cord Blood Program to use the cord blood for your family. If the cord blood is designated for research use, because it could not be used in transplantation, it is unlikely that you will be able to access stored samples for information that may be medically helpful.

Whom do I call if I have questions or problems?

- For questions about study procedures, risks/side effects, and/or study costs, contact one of the coordinators for the study at 206-292-1896 or 800-366-2831 ext. 1896.
- To report a study-related injury, contact Dr. Jo Anna Reems at 206-398-5917.
- For questions about financial responsibility for study-related injury, contact the Swedish Research Center Director at (206) 215-3100.
- For questions about your rights as a research subject, contact the SMC Institutional Review Office (IRO) Manager. The IRO Manager administers the Institutional Review Board (a group of people who review this research to protect your rights and welfare) and may be contacted at (206) 215-2536.
- A patient advocate is available to respond to ethical questions. Reverend Cynthia Kirtland can be reached at 206-583-6463.

Where can I get more information?

Information about cord blood banking can be found at www.parentsguidecordblood.org, at Swedish Medical Center's James B. Douglas Health Education Center, or from your OB provider. You may also contact the Cord Blood Program to inquire about current publications or other informational resources.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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SUBJECT'S CONSENT AND AUTHORIZATION

I have read this consent form and agree to take part in this study. By signing this form I do not give up my rights, if any, which may be available to me by law. I authorize the use and disclosure of my health information as described in this consent form. My signature also indicates that I have been given a copy of this consent form.

Subject's (Baby's Mother) Signature: _____

Subject's Name (Printed): _____

Date: _____

For Cord Blood Program Use Only:

CERTIFICATE OF PERSON OBTAINING CONSENT:

I have provided an explanation of the above research study, and have encouraged the subject to ask questions and request additional information regarding the study and possible alternatives. A copy of this consent form has been given to the subject.

Signature of person obtaining consent: _____

Name (Printed): _____

Date: _____

CERTIFICATE OF INVESTIGATOR:

I certify that this subject has been properly consented and I understand that I am responsible for the conduct of this study:

Signature of investigator or designee: _____

Investigator Name (Printed): _____

Date: _____

Emergency phone number: 206-292-1896

Research site: Puget Sound Blood Center

cc: Subject, OB provider, and Investigator's File

Other/Future Research Use Of Materials
That Do Not Qualify For Use In Transplantation

If cord blood cannot be used in transplantation you also have the option of allowing the blood collected for this repository to be used for other future research carried out by researchers in the Puget Sound Blood Center itself, or by researchers outside the Puget Sound Blood Center. You do not have to agree to allow the blood collected for this repository to be used for other/future research.

If the cord blood can not be used in transplantation, and you allow us to use it for other/future research, the blood will be used for the following research purposes:

- To determine if cord blood stem cells are able to develop into other types of cells (such as the cells that make up the nervous system, organs, and other tissues)
- To determine if cord blood is able to treat disorders other than cancer and leukemia
- To determine how long cord blood can be stored and still be useful
- Future research to determine other uses of cord blood.

For other/future research your specimens may be shared with other research projects outside of the Puget Sound Blood Center. If we provide cells to other researchers, the cells will not become part of a commercial product. There are no plans for you to receive compensation from results of the research. Please note that specimens provided to other researchers will not include any identifying information so the specimens cannot be linked back to you or your child.

I AGREE that my baby's cord blood may be used for other research and/or future research purposes if it does not meet the minimum criteria for human transplantation. The research specimen will not be labeled in any way that will allow the users to identify me or my baby. I will not be notified if the cord blood unit is used for other research/future research nor will I receive results of any research.

Signature of Mother

Printed Name of Mother

Date

I DO NOT AGREE to allow use of my baby's cord blood for other research and/or future research purposes. If it does not meet the minimum criteria for storage in this repository, I wish to have the cord blood unit destroyed.

Signature of Mother

Printed Name of Mother

Date