Clinic
Consent to Participate in a Research Study

Study Title: The Cord Blood Center and Hospital Volunteer Umbilical Cord Blood Program

Principal Investigator: MD, Department Director, Obstetrics and Gynecology, Hospital, , Phone:

Sponsor: Cord Blood Center, , Phone:

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

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1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

You are being asked to donate your child's cord blood and participate in The Cord Blood Center and Hospital Volunteer Umbilical Cord Blood Program carried out in collaboration with the ' Cord Blood Center. Some donated cord blood units will also be included in the National Cord Blood Inventory (NCBI) of the federally-sponsored C.W. Bill Young Cell Transplantation Program. The goal of the C. W. Bill Young Cell Transplantation Program is to provide an additional 150,000 cord blood units for public use and establish a system that allows transplant physicians access to adult volunteer donors and cord blood units. The creation of this national umbilical cord program significantly improves access for patients in need of transplants to treat blood diseases, metabolic and other rare disorders.

The following information is 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.

Why Is This Study Being Done?

The main purpose of the Program is to provide a new treatment option for patients who need a bone marrow transplant, using cells from placental and umbilical cord blood ("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 various diseases, for example, for patients with certain types of 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. 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.

How Many People Will Take Part In The Study?

About 2,500 people will take part in this study at Fairview Hospital each year. This is a multi center study including two different Clinic hospitals and approximately 5,400 people will take part at the Clinic. The Cord Blood Center participates in the federally-sponsored C.W. Bill Young Cell Transplantation Program and approximately 18,000 people will participate nationwide on an annual basis.

What Is Involved In The Study?

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

- keep the cord blood to use for transplantation for anyone who might need it, or for research or quality control purposes
- review your current hospital medical record and your baby's hospital medical record before discharge
- 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 infectious and genetic markers, and agree for your and your infant's physicians to receive the test results
- keep a sample of the cord blood and your blood for possible future testing for infectious and genetic diseases that might be passed on to a patient who receives the cord blood transplant which is a standard practice in cord blood donations.

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

If possible, we will draw your blood sample at the same time as other specimens that your doctor requests during your routine pre or 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. The cord blood will also be tested for some common inherited (genetic) diseases of the blood cells.

As part of this study, a sample of your blood is being tested for the presence of HIV (Human Immunodeficiency Virus) and certain other communicable diseases. HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome). If your blood tests are positive and you live in the state of Ohio, the results of that test(s), if positive, and demographic information about you will be reported to the Ohio Department of Health, as required by law. In addition, this information will be available on the hospital's laboratory reporting system. The results may influence your insurability and/or employability regarding your health status.

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 and Thalassemia or Cooley's anemia). 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 you or your baby's health to your current OB/GYN or midwife and as required by the state. 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.
- West Nile Virus: a test for the virus, an infection that is spread by mosquitoes.
- Syphilis Serology: a test for recent or past infection with syphilis.
- Test results will be reported to your physician(s) within 2-3 weeks ONLY if they are abnormal. 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 or may be discarded.
- The results of screening for hemoglobin abnormalities that we perform cannot be reported since the test is performed only for purposes of donor screening and not as official genetic disease testing. Official testing for hemoglobin abnormalities also is done through State Laboratories with these results reported to your physician(s).

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, the physician listed on your chart may be informed of these findings. If you would rather not be informed, you will not be eligible to participate in the Program.

Once collected, the cord blood unit and blood sample become the property of the Cord Blood Center. The Cord Blood Center has no policy or plan to share any commercial value with you. If the cord blood unit does not meet the Cord Blood public banking standards, then the Cord Blood Center will make the determination of alternative use, including research. The program is completely voluntary (Section 8). If the collected cord blood unit does meet public bank storage standards, the banked unit will be catalogued anonymously to protect patient privacy (Section 5). The banked unit is stored at Cord Blood Center (, ,) via cryo-preservation in liquid nitrogen.

How Long Will You Be In The Study?

Your participation in the study will last between 6 and 12 months after your baby's birth. Program staff will send you a short form or call to follow up on the baby's health to make sure no problems have been found that might affect the suitability of using the cord blood for a future transplant to a patient. Program staff may also contact you to check on your baby's health if the cord blood is selected for a transplant. You should also contact the Program ( ) if any problems arise that you think we should be informed of regarding your health and that of your baby. If a health problem for you or your baby develops that renders the cord blood unsuitable for a future transplant to a patient, this cord blood will be discarded. Any medical treatment you or your baby may require will remain the responsibility of your medical providers.

2. RISKS AND DISCOMFORTS

What Are The Risks Of The Study?

The risks related to participating in the Program are generally considered minimal. The blood taken from the umbilical cord is not needed after your baby is born. 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 pain from the needle being inserted through the skin into a vein in your arm, bruising, light-headedness, possible fainting and, rarely, infection. Some of the questions you will be asked about are of a personal nature and may cause you embarrassment or stress. You may ask to see the questions before deciding whether or not to participate. The collection procedure will not interfere with routine obstetrical practice. Additionally, negative information, such as positive infectious disease results may impact future insurability of the donor and infant. The saved cord blood and your blood sample will be used for HLA and genetic testing. This is called "tissue typing". When a person needs a stem cell transplant their blood is 'tissue typed' and this is used to seek a match in the records of the Cord Blood Program.

Gina Language:

A new federal law, called the Genetic Information Nondiscrimination Act (GINA), effective May 21, 2010, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on genetic information. This law generally will protect you in the following ways: (1) Health insurance companies and group health plans may not request your genetic information that we get from this research and may not use your genetic information when making decisions regarding your eligibility or premiums; and (2) Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting terms of your employment. This new federal law does not apply to companies that sell life insurance, disability insurance, or long-term care insurance and does not protect you against discrimination based on an already diagnosed genetic condition or disease.

Blood Draw:

The risks of drawing blood from a vein includes discomfort at the site of the needle stick, possible bruising and swelling around the site of the needle stick, rarely an infection, and uncommonly feeling faint from the procedure.

Questionnaire/Survey Research:

There are minimal physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. This Questionnaire will take approximately 15 minutes to complete.

3. BENEFITS

Are There Benefits To Taking Part In The Study?

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, distributed for research purposes, or discarded, 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.

4. ALTERNATIVES
What Other Options Are There?

You have been informed there are several private enterprises that will collect, process and store your baby's cord blood for a fee to be kept exclusively for your family to use. If you choose to use one of these private enterprises, you will need to contact them directly. Instead of donating your baby's cord blood to the Hospital Volunteer Umbilical Cord Blood Program in affiliation with Cleveland Cord Blood Center 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. Participation in the Program is voluntary and you may withdraw at any time 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 reasonably be expected to affect your willingness to participate will be provided to you before you consent. You are free to withdraw your consent without any change to your medical care at Fairview Hospital. Please report any decision to withdraw to program staff. If the donated unit does not meet public banking minimum standards (such as, not enough cells) the unit may also be used for research (clinical or commercial via donation or sale to recover collection costs), quality control and/or training purposes. The rate at which donated units do not have enough cells occurs the majority of the time. If the cord blood unit is not collected for private or public banking the cord blood unit is routinely discarded as medical waste.

5. PRIVACY AND CONFIDENTIALITY

Your research information may be disclosed to Cord Blood Center, the research study Sponsor and its agents, the Clinic research review staff, the U.S. Food and Drug Administration, and other outside collaborators or laboratories that are participating in this study, including the Health Resources and Services Administration (HRSA), the C.W. Bill Young Cell Transplantation Program, Accrediting Organizations, and the National Institutes of Health (NIH). The Clinic also may use and disclose this information for treatment and payment reasons. The Clinic must comply with legal requirements that mandate disclosure in unusual situations. Otherwise, the information recorded about you as part of this research will be maintained in a confidential manner. It is possible that information disclosed about you outside the Clinic could be re-disclosed and no longer protected by federal privacy laws.

The Data Form and Consent Form that have your identity and your baby's identity will be kept at the Cord Blood Center. The identification number assigned to your baby's cord blood will also be attached to your hospital record and your baby's hospital record as an additional link between you and your cord blood donation. These links would help us to trace and contact you to follow up on you or your baby's health or in the unlikely event that this is absolutely necessary for public health reasons such as an 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 or be important to you or your infant's health.

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 Cord Blood Center. In addition, your identity will be retained in a Program computerized database that has ONLY HIPPA approved

linkage to the internet or any outside computer. Only authorized Program staff will have access to the locked files and the Program database. The information may be reviewed by government agencies. 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.

You have been told that no information about you or your baby will be given to anyone not identified in this consent, unless required by law, or unless you request that information be given to others. Neither your name nor your baby's name or any identifying information will be included in any published reports or papers. If the umbilical cord blood is used, your name as the volunteer donor, as well as the recipient's name will not be revealed. Information collected in this program may be reported in a confidential format to government agencies including the National Institutes of Health, The Food and Drug Administration, and the Ohio Department of Health. Information on cord blood units that become part of the Cord Blood Center will be transferred to the C.W. Bill Young Cell Transplantation Program's Cord Blood Coordinating Center. The information transferred, however, will not include identifying information that would allow linkage to you or your infant.

If, in the future, ' Cord Blood Center is no longer willing or able to manage its Cord Blood Program, 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 may be transferred to another organization to store and manage. Such transfer, however, will include a guarantee of confidentiality.

If you agree to participate in this Program, we will obtain information from you by interview as well as information from your and your baby's medical records. We will only collect information that is needed for the Program. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. This authorization will not expire, unless you withdraw your permission in writing. Even if you withdraw your permission, your personal information that was collected prior to your withdrawal of permission will still be used; however no new information will be collected. If you withdraw your permission to use any blood or tissue obtained for the Study, the Principal Investigator, the Clinic Hospital, and ' Cord Blood Center will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing _____ ____, Department Director, Obstetrics and Gynecology, Hospital, . If you do so, any information previously disclosed cannot be withdrawn. The Clinic will not use or disclose the information collected in this study for another research purpose without your written permission unless the Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects.

By signing this informed consent form, you are authorizing such access to your medical records. If you choose not to sign this consent form, you will not be permitted to participate in this research study.

6. RESEARCH RELATED INJURIES

What Happens If An Injury Occurs?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at .

7. COSTS

What Are The Costs?

There will be no charge to you or your insurance company for the cord blood collection, processing and any associated studies involved with this program. You will not be paid for taking part in this program. All obstetric care costs associated with the labor, delivery, and recovery process will be billed in the usual way. You or your insurance provider will be responsible for the routine tests and services related to your medical care. These routine tests and services would normally be performed even if you don't participate in the study. Cord Blood Center will pay for the study drug/device/procedure and extra study specific tests that are not routine and only being performed because you are participating in this study. The Clinic will not pay for the costs of procedures, tests, visits and hospitalizations in connection with this study. There are no plans to provide financial compensation to you in the event the results from this research lead to the development of new products.

8. VOLUNTARY PARTICIPATION

What Are Your Rights As A Participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

9. QUESTIONS

Whom Do You Call With Questions Or Problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact at or the Cord Blood Center at or info@ . If you have questions about your rights as a research subject, you should contact the Institutional Review Board at ( ) .

Tissue types may be more similar within ethnic groups; please indicate all that apply:

Mother of Baby Ethnicity

- ☐ *American Indian/Alaskan Native*
- ☐ *African-American/Black*
- ☐ *Asian*
- ☐ *Caucasian (non-Hispanic)*
- ☐ *Hispanic*
- ☐ *Native Hawaiian/Pacific Islander*

Father of Baby Ethnicity

- ☐ *American Indian/Alaskan Native*
- ☐ *African-American/Black*
- ☐ *Asian*
- ☐ *Caucasian (non-Hispanic)*
- ☐ *Hispanic*
- ☐ *Native Hawaiian/Pacific Islander*

Disclosing ethnicity is optional

10. SIGNATURE

Statement of Participant

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 anyone who might need it or to be used for research or quality control purposes. 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. I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

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