

Community Hospital of Indianapolis
Informed Consent Statement for Participation in a Clinical Research Study

**A Descriptive Study of the Feasibility of a Public Indiana Cord Blood Bank to Facilitate
Allogeneic Unrelated Donor Umbilical Cord Blood Transplantation and Research**

Protocol Number:

Principal Investigator: Mervin C Yoder, MD
GBT-Genesis Bank
1102 Indiana Avenue
Indianapolis, IN 46202

Introduction:

As a healthy pregnant woman over the age of 18, you are being asked to take part in this research study to evaluate banking of blood from your child's umbilical cord after delivery.

Before you can make an informed decision whether to participate or not, you should understand the possible risks and benefits associated with this study. This process is known as informed consent and means that you will:

- Receive detailed information about this research study,
- Be asked to read, sign, and date this informed consent once you understand the study and wish to participate. If you do not understand something about the study or if you have questions, ask for an explanation before you sign this form; and
- Be given a signed and dated copy of this form to keep.

A maximum of 40,000 participants will be enrolled in this study. Participants will be in the study at the time of delivery and will be asked to fill out a follow up post-card two (2) weeks after delivery.

Purpose of the Study:

The purpose of this study is to determine if an Indiana state-wide cord blood collection and banking program is feasible. This is being studied because the blood in the umbilical cord and placenta is unique as it contains a large number of blood and immune system forming cells. Seriously ill patients whose bodies cannot make healthy cells of their own can be helped by a donation of healthy blood and immune system forming cells from a matched cord blood unit. Cord blood donations give more patients hope of finding a match. Cord blood units which cannot for any reason be used for transplant will be used in ongoing research to improve the utilization of this valuable resource.

Study Procedures:

At the time of your delivery, once the umbilical cord is clamped and cut from your child, the blood from the umbilical vein will be drained into a sterile blood bag and shipped to the cord blood bank laboratory for processing of the umbilical cord blood stem cells. These cells will be tissue typed and frozen to await transplant into a recipient or used for research to enhance the use of cells isolated from cord blood.

To find out if the cord blood can be stored in the cell bank, a small amount of blood will be taken from you and tested for communicable diseases and possibly stored for future testing if tests become available for currently unknown diseases. All test results are confidential. Any test performed will be done for the safety of patients who may receive the cord blood. If blood tests indicate a potential communicable disease, we will inform your physician of any confirmed positive test results which may affect your health or your baby's health, who will in turn inform

you and advise you on an appropriate medical course of action. If you do not want to be told of these test results, you should not sign this consent form or take part in the study.

Additionally, two weeks after delivery, you are asked to fill out a form on the health of your child to be sent to the cord blood bank in a pre-paid envelope.

If the cord blood is not suitable for transplantation, it may be thrown away using standard hospital practices or it may be used in laboratory research. This may include research performed directly by the cord blood bank to better understand how to use cord blood, or it may be donated or sold to other laboratories developing cord blood programs or researching other applications for cord blood cells. The cord blood will not be cloned. Cord blood used in laboratory research will not be used for transplantation. If it is used for research, your identity and your baby's identity will not be revealed to anyone.

Risks of Participating in this Study:

After delivery, after an I.V. has already been started, a small amount of blood from you (2-3 tablespoons) will also be drawn to perform disease testing. Blood draws always have the risk of temporary discomfort from the needle stick, bruising, bleeding and rarely infection, however only experienced individuals will be performing these procedures.

Once you have agreed to become a donor, you will be asked to answer questions related to you and your family's health. These questions are used in the cord blood bank's evaluation of the cord blood donation to minimize risks to the patient. Loss of confidentiality is always a potential risk when taking part in a study where such information is collected; however no identifying information of any kind will be released to anyone outside of your physician, the PI, or the cord blood bank as a part of this study. For your protection, your records may be reviewed by the hospital Institutional Review Board (IRB) or its designees. Your confidentiality will be protected and your identity will not be revealed in any research report, publication or presentation.

Benefits:

While no direct benefits resulting from your participation in this study will take place for you, your donation may result in a lifesaving transplant for others in need or in future benefits from research on the use of cells from cord blood.

It is also possible that our tests will detect an infection or disease which would affect you or your baby and which might not have been otherwise detected. This early detection could result in earlier treatment and improved health care.

Compensation:

Participation in this study is voluntary and the participant may refuse or discontinue taking part at any time without jeopardizing the investigator's interest in the participant or the participant's care. No additional costs will result to the participant as a result of this study, and no payment will be received for participating.

Alternatives:

As an alternative to this study, you may elect to not participate. You may also elect to privately bank your child's umbilical cord blood for your own family's potential use. There are several banks across the United States who provide this service for a fee. The Parent's Guide to Cord Blood Banking (www.parentsguidetocordblood.com), a not for profit site, lists these banks. The Indiana Cord Blood Bank web site (www.indianacordblood.org) has information on the pros and cons of private vs. public banking, and information on how to privately bank your cord blood in Indiana.

Confidentiality of Records:

The law in Indiana requires that we give the names of persons who test positive for certain diseases to public or state health agencies of confirmed positive test results for certain diseases, including HIV and syphilis. These agencies may contact you if you have confirmed positive test results.

No information identifying you or your baby will be given to anyone unless required by law or unless you request that the information be given. All banked specimens will be labeled with a unique identification (ID) number and stored anonymously. The unique ID number will be linked to a file containing all test results and the follow up post card. Access to information linking you or your child to the unique identifier will be limited only to the study Director and key laboratory personnel authorized by the Director. All cord blood bank and laboratory personnel who have any access to confidential information must sign confidentiality statements protecting the identities and other medical and personal information obtained from you through participating in this project. The importance of patient confidentiality is emphasized to all cord blood bank employees at the time of their orientation to the project.

AUTHORIZATION

THIS SECTION DESCRIBES HOW PERSONAL HEALTH INFORMATION COLLECTED ABOUT YOU DURING THIS STUDY MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Federal law requires hospitals, researchers and health care providers to protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions.

The researchers and staff listed with Community Hospital Indianapolis participating in the research, will use your medical/health information for this research study and possibly for other research data analysis purposes not currently planned as part of this study.

Your personal health information will be collected and used to:

- *conduct the study and possibly other research data analysis*
- *monitor your health status*
- *determine research results*
- *develop new tests, procedures, and commercial products*

The health information that will be used includes, but is not limited to, your date of birth, gender, ethnicity, race, pregnancy test (if applicable), your medical history, the assessments you provide and the assessments that your study doctor provides regarding your dehydration. Any differences in how you feel and any medications you report may also be used. Again, this information will be reported using your initials and code numbers only. However, the information associated with your name may be reviewed at the site by the above entities to ensure quality data.

At the completion of the study, you will have the right to access your protected health information created during this research that relates to your treatment or payment, provided such information is not exempted under certain laws and regulations.

*The permission to share your personal health information for this study begins on the date that you sign this form and does not have an expiration date. After your personal health information has been shared or disclosed during this research it may be re-disclosed by others who are not subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and therefore your information may no longer be protected by the Act. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study doctor, **Dr. M. Yoder, 1102 Indiana Avenue, Indianapolis, IN 46202.** You may decide not to give permission for the release of your personal health information for this study. In that case, you would not be able to participate. This is because the study staff and study doctor would not be able to collect information needed to evaluate the study medication.*

Every effort will be made to keep your personal health information private, however, complete confidentiality cannot be guaranteed. By signing this consent form you authorize the release of your information to the individuals listed above.

I understand that this release also pertains to records whose confidentiality is protected by either Federal Regulations (42 CFR Part 2) or State Law (IC 16-39-2 or IC 16-41-8-1) concerning hospitalization or treatment, including but not limited to, information regarding alcohol abuse, substance abuse, communicable disease documentation, human immunodeficiency virus (HIV) or mental health treatment or counseling.

The Principle Investigator, Dr. M. Yoder, MD, his research staff, GBT-Genesis Bank, and other professional vendors may be compensated for their services.

Payment for the Treatment of Study Related Injuries:

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

Questions:

The Principal Investigator for this study is Dr. Mervin Yoder who can be reached at 317-274-4738. Participants may ask any questions they have about the study.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact Glen J. Bingle, MD, Chairman of the Institutional Review Board, at 317-355-4522.

Costs:

There is no cost to you for your participation in this study.

Your Rights as a Participant:

Your participation in this research study is voluntary. You may refuse to participate in, or withdraw from, this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You may be withdrawn from the trial without your consent if you do not follow your doctor's instructions, or if it is thought to be in your best interest. The sponsor and/or FDA may stop the

study at any time if it is in the best interest of the people who are participating, or if the study is stopped for administrative or regulatory reasons.

I have read the information provided above and voluntarily agree to participate in this research study. I understand that I will not lose any rights to which I am otherwise entitled.

By my signature I acknowledge receipt of a signed and dated copy of this informed consent statement.

(Print Patient name)

(Signature of Patient)

____/____/____
Date

(Print name of person obtaining consent)

(Signature of person obtaining consent)

____/____/____
Date

(Print name of witness (if required))

(Signature of witness)

____/____/____
Date

Physician's Statement:

I have offered an opportunity for further explanation regarding the nature and purpose, the potential benefits and possible risks associated with participation in this research study and have answered any questions that have been raised by the individual whose signature appears above.

Date: _____ Physician's Signature: _____

Signature of Person Obtaining Consent

Date