

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT

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

About the Study:

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. The blood in the umbilical cord and placenta is unique because 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. Discarded tissue such as the placenta and umbilical cord are ready sources of valuable stem cells that are not found in your baby's cord blood, For this reason, you are also being asked to donate discarded tissue such as the placenta and umbilical cord after delivery.

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.

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. The placenta and umbilical cord may be placed into containers and shipped along with the cord blood so that the stem cells inside the tissues can be isolated.

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.

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.

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:

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.

Further Information:

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. If you cannot reach the researcher during regular business hours (e.g. 8:00AM – 5:00PM), please call the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

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 the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

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 Midwest Cord Blood Bank web site (www.midwestcordblood.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.

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.

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.

Financial Interest Disclosure

One or more individuals involved in this research might benefit financially from this study. The Institutional Review Board (an ethics committee which helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

Making Your Choice:

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No." No matter what you decide to do, it will not affect your care.

- 1. My blood may be drawn and tested for communicable and genetic disease.

Yes

No

- 2. My child's umbilical cord blood may be collected, processed and stored for potential transplant or for use in research to further study the use of cord blood cells.

Yes

No

Please sign your name here after you circle your answers.

Your Signature

Date

Signature of Person Obtaining Consent

Date

IRB Approval Date: August 17, 2011

Expiration Date: January 17, 2012