

**Rhode Island Blood Center
Women & Infants Hospital of Rhode Island
Community Blood Services**

Title: INFORMED CONSENT FOR UMBILICAL CORD BLOOD DONATION

A. Nature, Duration, and Purpose of Study:

The Rhode Island Blood Center (RIBC) at 405 Promenade Street, Providence, RI 02908, is determining if a RI public umbilical cord blood bank is possible. RIBC is asking you to give us your baby's umbilical cord blood (UCB) after your baby's birth. If you give the UCB, RIBC plans to send it to Community Blood Services (CBS), 970 Linwood Avenue West, Paramus, NJ 07653. The CBS works with the National Marrow Donor Program to help understand the effects of UCB transplants. Stem cells found in UCB may help people with blood cancer and other diseases. You will have your baby under the normal care of your physician. This research study does not affect your care your physician provides to you. Please read this form, ask questions, and sign the form if you wish to give the UCB.

B. Conduct of Study:

The process for donating your baby's UCB is much the same as donating blood, in that you will not be given information about the status of the blood donation except if the donation will be used for a transplant.

Your physician, midwife or a RIBC collections specialist will obtain the UCB for the study. Collecting UCB is not part of routine clinical care. The UCB may be collected before or after the placenta is out. The UCB collection usually takes about 10-20 minutes.

Laboratory testing will be done on your blood, your baby's blood and the UCB unit. Four 6ml tubes (slightly less than one ounce) of blood will be drawn from you which will take about 10 minutes. The blood test includes Hepatitis, Human Immunodeficiency Virus (HIV) & West Nile Virus. You will be informed of any abnormal test results and we will report positive results (e.g. HIV and Syphilis) to Rhode Island Department of Health (RI DOH) per state law, who may contact you.

As part of routine newborn care your baby will have a Metabolic Screen blood test done in the hospital. This includes testing for inherited diseases including sickle cell anemia as well as a hemoglobin test. You agree to allow the results of your baby's blood test to be sent from the RI DOH to the RIBC.

The UCB sample will be tested by the RIBC to see if it meets the initial criteria for being included, such as the minimum volume and number of blood cells (cell count). If it meets the requirements, the RIBC will send the UCB to CBS, along with your demographic information, Delivery Information form, and the Family Medical History

Questionnaire & the Maternal Risk Questionnaire that you will complete. In certain circumstances: including; contamination; low volume, or positive test results your UCB sample may be prevented from going into storage. If this happens you will not be notified. The UCB sample may be used for research or discarded

The CBS will perform additional tests on the UCB for infectious diseases and repeat the cell count. They will also perform tissue typing on the UCB to match the stem cells to a potential patient. Abnormal test results for infectious diseases will be sent to the RIBC with only a number identifying it. The CBS will notify you of any abnormal test results.

If the UCB does not meet the criteria the UCB may be used for research without identifying personal information linked to the unit, or discarded. If your UCB unit is selected for Transplant, you will be contacted prior to releasing the UCB by the CBS to learn of any changes in your health information. At no time will you be able to transfer the UCB to a private donor bank.

You and your baby's medical record may be reviewed for information and test results up until you leave the hospital. If the physician or midwife delivering your baby feels that collecting the UCB would add any additional risk to your care, or you deliver before the baby reaches 36 weeks, the UCB will not be collected.

All final decisions regarding the UCB unit will be made by Dr Carolyn Young at the RIBC or the Medical Director at CBS.

Participation in the National Cord Blood Inventory: The National Cord Blood Inventory (NCBI) is part of the Stem Cell Therapeutic and Research Act of 2005, Public Law 109-129. This law states that 150,000 new units of high-quality cord blood will be collected and made available for public use. These cord blood units must meet specific criteria and will be available through the C.W. Bill Young Cell Transplantation Program (Program) to treat patients who need a transplant. The New Jersey Cord Blood Bank has been awarded a contract to collect and store umbilical cord blood units for the NCBI. Fees will not be charged to the donor mother or donor baby for the collection and storage of the cord blood units for the NCBI.

C. Possible Benefits:

No benefit except for helping others, unless you find after giving UCB that you need it, then your child or a blood relative may get the UCB if the UCB has not been used by someone else.

D. Potential Risk and Discomforts:

There is no risk to the baby. Drawing blood from you may cause bruising, infection, fainting, pain, or discomfort. We use all usual ways to prevent these events.

E. Alternatives:

You can choose not to donate your baby's UCB or to bank with another company. If you decline to donate your baby's UCB, you will still receive standard medical care. You can cancel your consent at any time before UCB unit release. Contact Barbara Riter at (401) 453-7677 for more information on your rights.

F. Payments:

You will not be paid to participate in this study or for costs associated with transportation. The CBS, RIBC, and your obstetrician will not charge you or your insurance company any fees to participate in this study. You are still responsible for payment associated with your regular care provided by your physician and hospital care for your visits, birth, and baby's care.

G. Understanding of Consent:

1. I have been told about this study and its procedures. I have had a chance to ask questions. My questions were answered to my satisfaction.
2. I authorize my confidential, protected health care information to be shared with individuals, persons and groups associated with this study. My confidential health care information will be used only as necessary to participate in this study. Except when required by law, I will not be identified in study records disclosed outside the Rhode Island Blood Center (RIBC), Community Blood Services (CBS), or Women and Infants Hospital, by name, social security number, address, telephone number, or any other direct personal identifier. The key to the alphanumeric code will be kept in a locked file in an office at CBS.
3. I authorize as part of this study that Dr. Young and her team report infectious, genetic disease, and hemoglobinopathy test results. Information may be released to an official of the United States Food and Drug Administration, the United States Department of Health and Human Services, the United States Inspector General, the United States Office of Civil Rights, and the Women and Infants Hospital and its Institutional Review Boards, and when required by law.
4. I authorize the retention of my personal health information indefinitely.
5. Any information from the study will be used to determine whether it is possible for RIBC to develop an umbilical cord blood bank in Rhode Island.
6. I will be told of any changes to the risk or benefits of this study.
7. I do not have to take part in this study. I do not have to authorize use of my confidential, protected health information. My authorization to share my protected, personal health information will not expire.

8. I am free to stop taking part in the study at any time. My baby and I will still receive the best care possible. I will contact Dr. Carolyn Young in writing to let her know if I withdraw my consent. Her mailing address is Rhode Island Blood Center, 405 Promenade Street, Providence, RI 02908. However, the information which has already been collected about me or my baby by the researchers may need to be kept by the researchers for auditing purposes.

9. In the event that injury occurs as a result of this research, I am requested to notify the Principal Investigator, Dr. Carolyn Young at 401- 453- 8393, and treatment will be provided at Women and Infants Hospital, or at another appropriate health care institution, at no cost to me beyond that which third party payers will cover. Further information in regards to this may be obtained from Barbara Riter, Manager, Research Administration, whose telephone number is 401-453-7677.

10. If I have questions about this study, I may call Dr. Carolyn Young at RIBC at 401-453-8393, Dr. Roger Mrowiec at CBS at 201-251-3964 or the Medical Director at CBS at 201-251-3739, or Carolyn Kohn, Donor Advocate, at 302-765-2875. If I have questions about my rights as a research subject, I may call Barbara Riter, Manager, Research Administration at 401-453-7677.

11. My permission to allow the investigator and research staff to review my personal information will not end.

Signature: _____ Date: _____ Time: _____ AM/PM

Name (please print): _____

Name of Translator (if used): _____

Translator's signature: _____

If not for self: relationship to patient: _____

Person who explained study: _____ Date: _____

Donor Identification Number _____

Inquire about our study by mail, phone 401-248-5768, or website at www.ribc.org any time before active labor.

Hospital policy states that the signed original consent form is to be included in the subject's medical record. One copy of the original signed consent form is to be given to the subject. One copy of the signed original consent form should be retained in the investigator's files. One copy of the signed original consent form will be sent to CBS.