

CORD BLOOD BANK OF ARKANSAS (CBBA)
Collection Partner of Lifeforce Cryobanks

Informed Consent for Cord Blood Medical Research

I. INVITATION AND PURPOSE

You are invited to donate your baby's cord blood for medical research if it cannot be used as a transplant product. You are being invited because you have already agreed to donate your baby's cord blood to the Cord Blood Bank of Arkansas – Cord for Life Program for patients in need of a transplant. There are many reasons that cord blood may not meet the requirements for transplant. Cord blood not meeting these requirements can be used for medical research.

Cord Blood Bank of Arkansas in conjunction with Lifeforce Cryobanks - Cord for Life Program provides investigators cord blood units to use in medical research. Although the exact studies for which cord blood units may be used is not known at this time, the following are types of studies in which these units may be included.

Studies to investigate:

- Disease-specific Treatments
- Regenerative Medicine

Researchers may only conduct research studies with cord blood units that have had all identifiers removed. In these studies, there will be no way for the unit to be linked to you. CBBA/Lifeforce Cryobanks – Cord for Life Program may allow researchers to use these anonymous cord blood units for many other kinds of studies. These studies are not limited to the types of studies listed above, or related to transplantation in general.

II. PROCEDURES

If you agree to donate your baby's cord blood unit for medical research, nothing additional is required from you. After the cord blood is collected it will be tested to see if it meets all the requirements for transplant. If, and only if, it does not meet the requirements for transplant, the cord blood may be used for medical research.

All research studies using cord blood must first be approved by either the CBBA IRB or the Lifeforce Cryobanks scientific board, executive and quality management.

III. POSSIBLE RISKS AND BENEFITS

There are **no physical risks to you or your baby** by donating the cord blood to be used in medical research. The decision to use the cord blood for medical research is only made after the cord blood is collected and it does not meet the requirements for transplant.

There is a very small risk that an unauthorized person could find out which cord blood unit is your baby's. CBBA and Lifeforce Cryobanks – Cord for Life Program have procedures in place to keep your data private. No identifiable information about you will be given to the researchers, nor will it be published or presented at scientific meetings.

You or your baby will not be helped by donating your baby's cord blood for medical research. However, this research may help future patients who need a transplant or other therapeutic medical treatment.

IV. CONFIDENTIALITY

CBBA/Lifeforce Cryobanks – Cord for Life Program follows all HIPPA regulations and will not intentionally tell anyone that you donated your baby's cord blood for medical research.

CBBA/Lifeforce Cryobanks – Cord For Life Program will try hard to make sure no one outside the CBBA/Lifeforce Cryobanks – Cord For Life Program will know which cord blood unit is yours.

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V. REIMBURSEMENT AND COSTS

You will not be paid for donating your baby's cord blood for medical research. You will not be charged by CBBA/Lifeforce Cryobanks or any participating registry for any expenses resulting from the donation of the cord blood.

It is important for you to verify that your physician will not charge you for collection of the cord blood. Physician charges to you are not reimbursable by CBBA or Lifeforce Cryobanks.

Your insurance company will not be charged for anything associated with the study. You will not be charged for any aspect of participating in this research study.

VI. VOLUNTARY PARTICIPATION IN AND WITHDRAWAL

It is up to you if you want to donate your baby's cord blood for medical research. If you choose not to, your unit will be discarded as medical waste.

If you decide to donate your baby's cord blood for medical research you may change your mind at any time in the future. If you decide you don't want your baby's cord blood used for medical research, your baby's cord blood will be destroyed if it has not already been used. This will not affect your relationship with CBBA. To withdraw your unit, you will need to send a notarized letter to CBBA.

VII. ALTERNATIVE TO PARTICIPATION

You may choose not to donate your baby's cord blood for medical research. If you choose not to our unit will be discarded as medical waste.

VIII. QUESTIONS OR CONCERNS

If you have questions, concerns, or complaints about donation your baby's cord blood for medical research contact CBBA at 1-855-854-2222.

If you have questions or concerns about your rights as a research subject or about potential risks and injuries, please contact CBBA's Medical Director, Dr. Michele Fox or Quality Management at 1-855-854-2222.

IX. SUBJECT'S STATEMENT OF CONSENT

I have read this consent form and I have been given the opportunity to ask questions. I voluntarily agree to donate my baby's cord blood for medical research studies, if it cannot be used for transplantation, as defined in this consent form.

Mother's Signature

Date

Mother's Printed Name

Witness Signature

Date

Witness Printed Name

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Use of an Interpreter: Complete if the subject is not fluent in English and an interpreter was used to obtain consent.

Print name of interpreter: _____ Date: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the subject in _____ (state language) by an individual proficient in English and _____ (state language). See the attached addendum for documentation.

[TO BE COMPLETED BY CBBA STAFF - ONLY]

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with this research study have been explained to the above individual and that any questions about this information have been answered.

Counseling Healthcare Professional

Date