

# Collection Partner of the Cord For Life<sup>®</sup> Foundation 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 Lifeforce Cryobanks – 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.

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:

- Disease Treatment
- Regenerative Medicine

In addition, researchers may 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. 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 the Lifeforce Cryobanks scientific board, executive and quality management.

#### III. POSSIBLE RISKS AND BENEFITS

There are no physical risks to your or 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. Lifeforce Cryobanks – Cord for Life Program has several 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. <u>CONFIDENTIALITY</u>

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

### V. <u>REIMBURSEMENT AND COSTS</u>

You will not be paid for donating your baby's cord blood for medical research. It will not cost you anything to donate your baby's cord blood for medical research.

### 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

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destroyed if it has not already been used. This will not affect your relationship with Lifeforce Cryobanks – Cord for Life Program. To withdraw your unit forward a notarized letter to Lifeforce Cryobanks Client Services Department.

## VII. <u>ALTERNATIVE TO PARTICIPATION</u>

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

## VIII. QUESTIONS OR CONCERNS

If you have questions, concerns, or complaints about donating your baby's cord blood for medical research contact Donald Hudspeth (Director of Laboratory Operations) at <u>dhudspeth@lifeforcecryobanks.com</u> or Denise Clifton (Director of Quality Assurance ) at <u>dclifton@lifeforcecryobanks.com</u>.

If you have questions or concerns about your rights as a research subject or about potential risks and injuries, please contact *Donald Hudspeth* (*Director of Laboratory Operations*) at <u>dhudspeth@lifeforcecryobanks.com</u>.

### IX. DONOR ADVOCACY

If you have additional concerns and desire information from an impartial source, Lifeforce Cryobank's suggests visiting the following websites:

NMDP-Be the Match<sup>®</sup> Program: Parents' Guide to Cord Blood: Save the Cord Foundation: https://bethematch.org/Support-the-Cause/Donate-cord-blood/ http://parentsguidecordblood.org/ http://www.savethecordfoundation.org/

Date

### X. <u>SUBJECT'S STATEMENT OF CONSENT</u>

I have read both pages of 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.

Donor Advocacy information was provided to me by Lifeforce Cryobank's.

Mother's Signature

Mother's Printed Name

Certification of Counseling Healthcare Professional

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

Date

Counseling Healthcare Professional

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	