Collection Partner of the Cord For Life® 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. *CONFIDENTIALITY*

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. *REIMBURSEMENT AND COSTS*

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. *ALTERNATIVE TO PARTICIPATION*

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 dhudspeth@lifeforcecryobanks.com or Denise Clifton *(Director of Quality Assurance)* at dclifton@lifeforcecryobanks.com.

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 dhudspeth@lifeforcecryobanks.com.

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

X. *SUBJECT'S STATEMENT OF CONSENT*

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 *Date*

____
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.

Counseling Healthcare Professional *Date*

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 short form addendum for documentation.

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DONATION INFORMED CONSENT AND RELEASE - HOSPITAL/BIRTHING CENTER

I, the undersigned, desire the collection of my unborn baby's cord blood for donation. I have elected to utilize the services of Lifeforce Cryobanks to achieve the desired donation. For the donation to occur it is necessary to collect and save the blood from the placenta and umbilical cord after the birth of my baby, rather than discard the blood as medical waste. The collected cord blood will be shipped to Lifeforce Cryobanks for processing and placement into storage.

My physician, physician's designee, midwife or a Lifeforce Cryobanks trained and collection specialist will perform the collection of the cord blood after the delivery of my baby, while the delivery of the placenta occurs. He/she will use methods provided by Lifeforce Cryobanks in their standard operational procedures. Medical conditions may arise which preclude the collection of the cord blood and will be decided at the sole discretion of the attending physician.

I understand that the donation of cord blood includes medical procedures and that there can be no guarantee or assurance of success of the results of the service. I further, on behalf of myself and my unborn baby, our respective heirs, successors and assigns, hereby release and forever hold harmless the Hospital / Birthing Center, and its affiliates, successors, assigns, officers, directors, employees and agents from any and all actions, causes of action, claims, debts, demands, liabilities, covenants, controversies, omissions and damages and any and all other claims of every kind, nature, and description whatsoever, both in law and equity, which may arise relating to the collection of the cord blood on behalf of me and my unborn baby.

I approve the sharing of any/all testing results with other medical or research facilities that are in partnership with Lifeforce Cryobanks and whose standards and policies follow all confidentiality measures as required by the Health Insurance Portability and Accountability Act of 1996 (*HIPAA*).

PHYSICIAN - DONATED SAMPLE

My patient desires the collection of her unborn baby's cord blood for donation to Lifeforce Cryobanks. For the donation to occur, it is necessary to collect and save the blood from the placenta and umbilical cord after the birth of my patient's baby, rather than discard the blood as medical waste. The cord blood obtained will be shipped to Lifeforce Cryobanks for processing and placement into storage.

Myself or a Lifeforce Cryobanks trained and approved collection specialist will perform the collection of the cord blood after the birth of her baby, while the delivery of the placenta occurs. The collection will use the methods provided by Lifeforce Cryobanks in their standard operational procedures. The collection period will be brief and Lifeforce Cryobanks will provide the protocols and collection equipment in the kit. Every effort will be used to acquire as much cord blood as is feasible and will minimize the risk of fungal, bacterial or maternal blood contamination.

The health and welfare of my patient and her baby are the primary concern and responsibility and accordingly I reserve the right to forgo the collection of the cord blood if my best medical judgment indicates this to be necessary.

I understand that the donation of cord blood includes medical procedures and that there can be no guarantee or assurance of success of the results of the service. I, on behalf of myself, my heirs and successors and assigns hereby release and forever discharge Lifeforce Cryobanks and its affiliates, successors, assigns, officers, directors, employees and agents from any and all actions, causes of actions, demands, debts, claims liabilities, covenants and damages and any and all other claims of every kind, nature and description whatever, both in law and equity, which may arise relating to my performing the collection of the cord blood.

Lifeforce Cryobanks, on behalf of itself, its affiliates, assigns, officers, directors, employees and agents releases and forever discharges me and each of my heirs, successors and assigns from any and all actions, causes of actions, demands, debts, claims, liabilities, covenants and damages and any and all other claims of every kind, nature and description whatever, both in law and equity, which may arise relating to my performing the collection of the cord blood.

My patient,______________________________, releases me and each of my heirs, successors, and assigns from any and all actions, causes of action, claims, debts, demands, liabilities, covenants, controversies, omissions and damages and any and all other claims of every kind, nature and description whatsoever, both in law and equity, which may arise relating to my performing the collection of the cord blood.

In addition, I understand that the donation of cord blood is a voluntary program, and as such, I will ***not*** receive reimbursement from Lifeforce Cryobanks for my services in the collection of the cord blood unit. I hereby agree to perform the cord blood collection for my patient on behalf of Lifeforce Cryobanks as outlined herein.

______________________________ ______________ ______________________________ ______________
Signature of Expectant Mother (*Required*) Date Signature of Physician/Midwife ((*Required*) Date

______________________________ ______________________________
Print Full Name of Expectant Mother Print Name (Physician/Midwife)

IMPORTANT: THIS PAGE IS **REQUIRED** TO BE SIGNED BY YOU AND YOUR PHYSICIAN/MIDWIFE IN ORDER TO RECEIVE A LIFEFORCE CRYOBANKS CORD BLOOD DONATION COLLECTION KIT. TO AVOID ANY DELAYS IN YOUR PAPERWORK REVIEW, PLEASE ENSURE THAT ALL REQUIRED SIGNATURES ARE PRESENT PRIOR TO SUBMITTING YOUR FORMS.

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INFORMED CONSENT FOR THE INFECTIOUS DISEASE TESTING

HUMAN IMMUNODEFICIENCY VIRUS AND TRANSMISSION:

Human Immunodeficiency Virus (HIV) is a virus which can be transmitted from individuals through body fluids, primarily blood and semen. The spread is not through air or food or by casual social contact. It is passed on when the blood or body fluids of an infected person mix with your own. Sexual transmission is mainly the result of the transfer of and exposure to infected semen. Women as well as men can transmit the virus sexually. The HIV virus has also been detected in vaginal secretions, tears, and saliva, but exposure to saliva has not been proven to transmit the infection. Intravenous drug users and persons receiving blood transfusions can be exposed to the virus through infected blood or body products. A baby may become infected during pregnancy, delivery, or when breast feeding if its mother has the disease. A person may carry the virus for months before testing positive and may carry the virus for months or years before the symptoms appear. An HIV positive person can still spread the disease even though he or she may appear healthy.

When HIV enters the blood stream it invades and destroys cells in the body's infection and cancer fighting system and reduces the body's ability to fight infections. The HIV virus leads to the depletion of the immune system to a point that infections which one wouldn't normally get (opportunistic infections) start developing, at which point the patient has AIDS. The HIV virus is not what kills a person with AIDS, it is the opportunistic infections which cause death.

BEHAVIORS THAT INCREASE YOUR RISK OF BEING EXPOSED TO HIV:

Recent blood, plasma, or blood product transfusion, intravenous drug use, especially with sharing of needles or syringes, or having sexual contact with someone who: has tested positive for HIV infection, is at risk of infection through sexual practices, IV drug use, or recent blood transfusion, uses illicit intravenous drugs, received blood transfusions, plasma, or clotting factor before 1985 or within the last twelve months, has more than one sexual partner, especially ones who could be at risk of HIV infection, or is a man who has had sexual relations with another man.

THE HIV TEST AND VOLUNTARY TESTING

The HIV tests are blood tests for the presence of the HIV virus and antibodies to the HIV virus. A positive test result means that you have been exposed to the virus, and either have made antibodies or are infected. It may not mean that you have AIDS now or that you will become sick with AIDS in the future. A negative test means that you are probably not infected with the virus. It takes about 12 days to detect the virus from time of infection to time of detection.

Taking the HIV test is voluntary, and results are confidential by law. Results can only be given to people you allow, and a release form must be signed prior to releasing this information. The law requires Lifeforce Cryobanks to report any positive HIV test result to the County Health Department.

CONSENT ***(REQUIRED)***

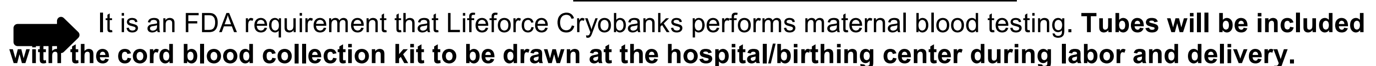
I have read the above information and have had my questions about the HIV test answered. I agree to take the HIV test. I allow the test results to be made available to Lifeforce Cryobanks and to my private physician, **Dr.**_________________________.

Printed Full Name of Expectant Mother's:____ Date: ____________________

Expectant Mother's Signature (full name as printed above): ____

PHYSICIAN'S ORDER FOR BLOOD TESTING ***(REQUIRED)***

Rx Patient Name**:** ___________________________________



It is an FDA requirement that Lifeforce Cryobanks performs maternal blood testing. **Tubes will be included with the cord blood collection kit to be drawn at the hospital/birthing center during labor and delivery.**

ORDER: Maternal Blood Draw for:

HIV-1 and HIV-2 (antibody to the AIDS virus)
HEPATITIS B (HBsAg & HBcAb)
HTLV-I and HTLV-II
CMV,
WNV

HCV/HIV NAT (Hepatitis C and AIDS virus by Nucleic Acid Test)
HEPATITIS C VIRUS (Anti-HCV)
SYPHILIS,
ABO Rh
CHAGAS DISEASE

Printed Name of Physician or Midwife:____Date: _______________________

Signature of Physician or Midwife: ____

IMPORTANT: THIS PAGE IS **REQUIRED** TO BE SIGNED BY YOU AND YOUR PHYSICIAN/MIDWIFE IN ORDER TO RECEIVE A LIFEFORCE CRYOBANKS CORD BLOOD DONATION COLLECTION KIT. TO AVOID ANY DELAYS IN YOUR PAPERWORK REVIEW, PLEASE ENSURE THAT ALL REQUIRED SIGNATURES ARE PRESENT PRIOR TO SUBMITTING YOUR FORMS.

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DONOR INFORMATION AND HEALTH HISTORY

MOTHER'S LAST NAME	FIRST NAME	M.I.	LAST 4 SS# DIGITS
BEST CONTACT PHONE:	EMAIL		MOTHER'S DOB:
ADDRESS	CITY	STATE	ZIPCODE

FATHER'S LAST NAME	FIRST NAME	M.I.	LAST 4 SS# DIGITS(OPTIONAL)
BEST CONTACT PHONE:	EMAIL		FATHERS DOB:
ADDRESS	CITY	STATE	ZIP CODE

BABY'S DUE DATE:

DELIVERY PHYSICIAN'S NAME			PHONE
CLINIC NAME			
DELIVERY HOSPITAL NAME			PHONE
HOSPITAL ADDRESS	CITY	STATE	ZIP CODE

BABY'S RACE AND ETHNICITY INFORMATION

Since certain HLA Types may be more common in each ethic group; the information below will help in selecting a cord blood unit for transplant.

Baby's Ethnicity: Response is required, please check one. ☐ **Hispanic or Latino** ☐ **Not Hispanic or Latino**

Baby's Race: Response is required. Of which group(s) is your baby a member? (Select all that apply.)

American Indian or Alaska Native

	Alaska Native or Aleut (ALANAM)
	North American Indian (AMIND)
	American Indian South or Central American (AMIND)
	Caribbean Indian (AMIND)

Black or African American

	African (AFB)
	African American (AAFA)
	Black Caribbean (CARB)
	Black South or Central American (SCAMB)

Asian

	Chinese (NCHI)
	Filipino (Philipino) (FILI)
	Japanese (JAPI)
	Korean (KORI)
	South Asian (SCSEAI)
	Vietnamese (SCSEAI)
	Other Southeast Asian (SCSEAI)

Native Hawaiian or Other Pacific Islander

	Guamanian (OPI)
	Hawaiian (HAWI)
	Samoan (OPI)
	Other Pacific Islander (OPI)

White

	Eastern European (CAU)
	Mediterranean (CAU)
	Middle Eastern (MENAFC)
	North Coast of Africa (MENAFC)
	North American (CAU)

	Northern European (CAU)
	Western European (CAU)
	White Caribbean (CAU)
	White South or Central American (CAU)
	Other White (CAU)

Please read the following Health Questionnaire ***carefully***. You may contact Lifeforce Cryobanks, if you need help understanding any of the questions, please call Lifeforce Cryobanks: 1-800-869-8608 outside of the Orlando area, or 407-834-8333 in the Orlando area.

Completion of all the requested information on the health questionnaire is required before a cord blood unit can be eligible for transplant. This is the only opportunity the cord blood center has to gather this important information from you. ***An incomplete questionnaire will result in disqualification.*** The questionnaire should be filled out privately by the expectant mother, only or in a private interview by an approved screener. Your answers to these questions are confidential. Please refer to Lifeforce Cryobanks Notice of Privacy Practices included in this packet.

If after being accepted into this program or after your baby's cord blood is collected you learn of a reason which would exclude you from donating or feel that it should not be transfused to a patient, please call Lifeforce Cryobanks. You will not be penalized from withdrawing from the program, at any time.

My signature below confirms that the information provided on Pages 1-7 of Form, B.1-1 is true and accurate to the best of my knowledge.

EXPECTANT MOTHER SIGNATURE:____**DATE**:________________

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Collection Partner of the Cord for Life Foundation

HEALTH QUESTIONNAIRE

MOTHER'S LAST 4 SS# DIGITS:_____________________ **MOTHER'S DOB:** ____________________________

CORD BLOOD MATERNAL QUESTIONS Please *read carefully* and *answer each* of the following questions *individually* "Y" for "YES" or "N" for "NO". Please provide details including dates, where requested, for all "Y" responses (except for #38 and #73)			
1	Have you ever donated or attempted to donate cord blood using your current or a different name to Cryobanks International or Lifeforce Cryobanks? Details: ______________________	Y ☐	N ☐
2	Have you, for any reason, been deferred or refused as a blood or cord blood donor, or been told not to donate blood or cord blood? ***If yes***, why?______________________	Y ☐	N ☐
3	Have you taken any of the following medications (check all that apply): **a. ☐ Insulin from cows (bovine or beef insulin) since 1980?** **b. ☐ Growth hormone from human pituitary glands ever?** **c. ☐ Rabies vaccination in the past 12 months.**	Y ☐	N ☐
4	**In the past 8 weeks,** have you had any shots or vaccinations? ***If yes***, details:______________________	Y ☐	N ☐
5	**In the past 12 weeks**, have you had contact with someone who has received the smallpox vaccine?(Examples of contact include physical intimacy, touching the vaccination site, touching the bandages or covering the vaccination site, or handling bedding or clothing that had been in contact with an unbandaged vaccination site) Details:______________________	Y ☐	N ☐
6	**In the past 4 months,** have you experienced **TWO (2)** or more of the following: a fever (>100.5ºF or 38.6ºC), headache, muscle weakness, skin rash on trunk of the body, swollen lymph glands? **If yes**, which symptoms and when? Details::______________________	Y ☐	N ☐
7	Have you ever had any type of cancer, including leukemia? ***If yes,*** details::______________________	Y ☐	N ☐
8	**In the past 5 years,** have you had a bleeding problem, such as hemophilia or other clotting factor deficiencies, and received human-derived clotting factor concentrates? ***If yes,*** details:______________________	Y ☐	N ☐
9	During your pregnancy, have you been diagnosed with West Nile Virus or had a positive test for West Nile Virus?	Y ☐	N ☐
10	Have you ever had a past diagnosis of clinical, symptomatic viral hepatitis after age 11? ***If yes,*** details, with dates:	Y ☐	N ☐
11	Have you ever had a parasitic blood disease such as Leishmaniasis, Chagas disease or Babesiosis or any positive test for Chagas or T. cruzi, including screening tests?	Y ☐	N ☐
12	Have you ever been diagnosed with Creutzfeldt-Jakob Disease (CJD), dementia, and degenerative or demyelinating disease of the central nervous system, or other neurological disease where the cause is unknown?	Y ☐	N ☐
13	Have any of your blood relatives ever been diagnosed with Creutzfeldt-Jakob Disease (CJD), or have you been told that your family has an increased risk for CJD?	Y ☐	N ☐
14	Have you received a dura mater (brain covering) graft?	Y ☐	N ☐
15	Have you ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an **animal**? Details: ______________________	Y ☐	N ☐
16	Have you ever lived with or had sexual contact with anyone who had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an **animal**? ***If yes,*** details:______________________	Y ☐	N ☐
17	**In the past 3 years**, have you had malaria? ***If yes,*** details:______________________	Y ☐	N ☐
18	**In the past 3 years**, have you been outside the United States or Canada? Where:______________________ When:______________________ How Long:	Y ☐	N ☐
19	**In the past 12 months**, have you had a blood transfusion? Details: ______________________	Y ☐	N ☐
20	**In the past 12 months**, have you had a transplant or tissue graft from someone other than yourself, such as organ, bone marrow, stem cell, cornea, bone, skin or other tissue?	Y ☐	N ☐
21	**In the past 12 months**, have you had a tattoo or piercing (ear, skin or body)? *If yes*, please indicate type and answer question **22**. ***If no***, skip to question **23** **Type: ☐ Tattoo ☐ Piercing,** details:______________________	Y ☐	N ☐
	22. ***If yes***, were shared or non-sterile instruments, needles, or inks used for the tattoo or piercing?	Y ☐	N ☐

HEALTH QUESTIONNAIRE

MOTHER'S LAST 4 SS# DIGITS:_____________________ **MOTHER'S DOB:** ____________________________

#	Question	Y	N
23	**In the past 12 months,** have you had an accidental needle stick or have you come into contact with someone else's blood through an open wound (for example, a cut or sore), non-intact skin, or mucous membrane (for example, into your eye, mouth, etc)? Details:	Y ☐	N ☐
24	**In the past 12 months**, have you had or been treated for a sexually transmitted disease, including syphilis? ***If yes,*** details with dates:________________	Y ☐	N ☐
25	**In the past 12 months** have you given money, drugs, or other payment to anyone to have sex with you?	Y ☐	N ☐
26	**In the past 12 months** have you had sex with anyone who has taken money, drugs, or other payment in exchange for sex in the **past 5 years**?	Y ☐	N ☐
27	**In the past 12 months,** have you had sexual contact or lived with a person who has active or chronic viral hepatitis B or Hepatitis C?	Y ☐	N ☐
28	**In the past 12 months**, have you had sex, even once, with anyone who has used a needle to take drugs, steroids, or anything else not prescribed by a doctor in the **past 5 years**?	Y ☐	N ☐
29	**In the past 12 months,** have you had sex with a male who has had sex with another male, even once, in the **past 5 years**?	Y ☐	N ☐
30	**In the past 12 months**, have you had sex, even once, with anyone who has taken human-derived clotting factors for a bleeding problem in the **past 5 years**?	Y ☐	N ☐
31	**In the past 12 months**, have you had sex, even once, with anyone who has HIV/AIDS or had a positive test for the AIDS virus?	Y ☐	N ☐
32	**In the past 12 months,** have you been in juvenile detention, lockup, jail or prison for more than 72 ***continuous*** hours?	Y ☐	N ☐
33	**In the past 5 years** have you received money, drugs, or other payment for sex?	Y ☐	N ☐
34	**In the past 5 years,** have you used a needle, even once, to take drugs, steroids or anything else not prescribed for you by a doctor?	Y ☐	N ☐
35	Do you have AIDS or have you ever tested positive for HIV (including screening tests)?	Y ☐	N ☐
36	**Do you have any of the following**:		
	A) Unexplained night sweats?	Y ☐	N ☐
	B) Unexplained blue or purple spots on or under the skin or mucous membranes?	Y ☐	N ☐
	C) Unexplained weight loss?	Y ☐	N ☐
	D) Unexplained persistent diarrhea?	Y ☐	N ☐
	E) Unexplained cough or shortness of breath?	Y ☐	N ☐
	F) Unexplained temperature higher than 100.5ºF (38.6ºC) for more than 10 days?	Y ☐	N ☐
	G) Unexplained persistent white spots or sores in the mouth?	Y ☐	N ☐
	H) Lumps in your neck, armpits, or groin lasting longer than one month?	Y ☐	N ☐
	I) Any infection during your pregnancy?	Y ☐	N ☐
37	Have you ever tested positive for HTLV-Human T-cell Lymphotropic Virus (including screening tests) or had unexplained paraparesis (partial paralysis affecting the lower limbs)?	Y ☐	N ☐

#	Question	Y	N
38	***Do you understand*** that if you have the AIDS virus, ***you can give it to someone else*** even though you may feel well and have a negative AIDS test?	Y ☐	N ☐

Collection Partner of the Cord for Life Foundation

HEALTH QUESTIONNAIRE

MOTHER'S LAST 4 SS# DIGITS:_____________________ **MOTHER'S DOB:** ______________________________

FOR USE WITH QUESTIONS #39 – 42 – COUNTRIES DEFINED AS EUROPE

	ALBANIA ____Travel ____Resident Date(s): Total Time:		GREECE ____Travel ____Resident Date(s): Total Time:		ROMANIA ____Travel ____Resident Date(s): Total Time:
	AUSTRIA ____Travel ____Resident Date(s): Total Time:		HUNGARY ____Travel ____Resident Date(s): Total Time:		SLOVAK REPUBLIC ____Travel ____Resident Date(s): Total Time:
	BELGIUM ____Travel ____Resident Date(s): Total Time:		IRELAND (REPUBLIC OF) ____Travel____Resident Date(s): Total Time:		SLOVENIA ____Travel ____Resident Date(s): Total Time:
	BOSNIA-HERZEGOVINA ____Travel ____Resident Date(s): Total Time:		ITALY ____Travel ____Resident Date(s): Total Time:		SPAIN ____Travel ____Resident Date(s): Total Time:
	BULGARIA ____Travel ____Resident Date(s): Total Time:		LIECHTENSTEIN ____Travel ____Resident Date(s): Total Time:		SWEDEN ____Travel ____Resident Date(s): Total Time:
	CROATIA ____Travel ____Resident Date(s): Total Time:		LUXEMBOURG ____Travel ____Resident Date(s): Total Time:		SWITZERLAND ____Travel ____Resident Date(s): Total Time:
	CZECH REPUBLIC ____Travel ____Resident Date(s): Total Time:		MACEDONIA ____Travel ____Resident Date(s): Total Time:		UNITED KINGDOM (UK) includes England, Northern Ireland, Scotland, Wales, Isle of Man, Channel Islands Gibraltar & Falkland Islands ____Travel______Resident Date(s): Total Time
	DEMARK ____Travel ____Resident Date(s): Total Time:		NETHERLANDS (HOLLAND) ____Travel ____Resident Date(s): Total Time:		
	FINLAND ____Travel ____Resident Date(s): Total Time:		NORWAY ____Travel ____Resident Date(s): Total Time:		YUGOSLAVIA (FEDERAL REPBULIC OF)_____Travel ____Resident Date(s): Total Time:
	FRANCE ____Travel ____Resident Date(s): Total Time:		POLAND ____Travel ____Resident Date(s): Total Time:		KOSOVO, MONTENEGRO, SERBIA_____Travel ____Resident Date(s): Total Time:
	GERMANY ____Travel ____Resident Date(s): Total Time:		PORTUGAL ____Travel ____Resident Date(s): Total Time:		

#	Question	Y	N
39	**Since 1980**, have you ever lived in or traveled to Europe? (*refer to chart above*) ***If no,*** skip to question **43.** a) Use the chart above and place a check in all the appropriate box(es) above to identify the country(ies), reason, date(s) and total time that apply. b) Answer questions **40** through **42**.	Y ☐	N ☐
	40. **From 1980 through 1996,** did you spend time that adds up to 3 months or more in the United Kingdom (*refer to chart above*)?	Y ☐	N ☐
	41. Since 1980, have you received a transfusion of blood or blood components while in the UK or France?	Y ☐	N ☐
	42. **Since 1980**, have you spent time that **adds up to 5 years or more** in Europe (*refer to chart above*), including time spent in the UK between 1980 and 1996?	Y ☐	N ☐
43	**From 1980 through 1996**, were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?	Y ☐	N ☐
44	**From 1980 through 1990,** did you spend a **total of 6 months or more** associated with a military base in any of the following countries: United Kingdom, Belgium, Netherlands or Germany?	Y ☐	N ☐
45	**From 1980 through 1996,** did you spend a **total of 6 months or more** associated with a military base in any of the following countries: Spain, Portugal, Turkey, Italy or Greece?	Y ☐	N ☐

Collection Partner of the Cord for Life Foundation

HEALTH QUESTIONNAIRE

MOTHER'S LAST 4 SS# DIGITS:______________________ **MOTHER'S DOB:** ______________________________

FOR USE WITH QUESTIONS 46-48: AFRICAN COUNTRIES		
BENIN _____Travel _____Resident Date(s): Total Time:	EQUATORIAL GUINEA _____Travel _____Resident Date(s): Total Time:	SENEGAL _____Travel _____Resident Date(s): Total Time:
CAMEROON _____Travel _____Resident Date(s): Total Time:	GABON _____Travel _____Resident Date(s): Total Time:	TOGO _____Travel _____Resident Date(s): Total Time:
CENTRAL AFRICAN REPUBLIC _____Travel _____Resident Date(s): Total Time:	KENYA _____Travel _____Resident Date(s): Total Time:	ZAMBIA _____Travel _____Resident Date(s): Total Time:
CHAD _____Travel _____Resident Date(s): Total Time:	NIGER _____Travel _____Resident Date(s): Total Time:	
CONGO _____Travel _____Resident Date(s): Total Time:	NIGERIA _____Travel _____Resident Date(s): Total Time:	

#	Question	Y	N
46	**Since 1977**, were you born in, have you lived in, or have you traveled to any African country listed above? ***If yes***, answer question **47.** ***If no,*** skip to question **48.** a) Use the chart above and place a check in all the appropriate box(es) above to identify the country(ies), reason, date(s) and total time that apply.	Y ☐	N ☐
	47. While in one of the African countries listed above, did you receive a blood transfusion or any other medical treatment with a product made from blood?	Y ☐	N ☐
48	Have you had sexual contact with anyone who was born in or lived in any African country listed above **since 1977**?	Y ☐	N ☐
49	Were you and/or the baby's father adopted at early childhood?	Y ☐	N ☐
	If yes, is a family medical history available for you and/or the baby's father?	Y ☐	N ☐
50	Are you and the baby's father related, except by marriage? (e.g. first cousins)	Y ☐	N ☐
51	Did this pregnancy use either a donor egg or donor sperm?	Y ☐	N ☐
	If yes, is a family medical history questionnaire available for the egg or sperm donor? (please attach copy) Name of the Clinic: ____________________	Y ☐	N ☐
52	Have you ever had an abnormal result from a prenatal test (e.g. amniocentesis, blood test, ultrasound)? If yes, answer the following questions. If no, skip to question 53.	Y ☐	N ☐
	A) Which test was abnormal? ____________________		
	B) What was the abnormal test result? ____________________		
	C) Was a diagnosis made? Specify diagnosis:____________________		
53	Have you had any children who died within the first 10 years of life?	Y ☐	N ☐
	If yes, what was the cause? ____________________		
54	Have you ever had a stillborn child?	Y ☐	N ☐
	If yes, what was the cause? ____________________		

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Collection Partner of the Cord for Life Foundation

HEALTH QUESTIONNAIRE

MOTHER'S LAST 4 SS# DIGITS:_____________________ **MOTHER'S DOB: _____________________________**

FAMILY MEDICAL HISTORY

For the following questions please use the following codes to describe the relationship between the baby and a family member with a disease:

Family Relationship Codes: BM Baby's Mother; BF Baby's Father; BGP Baby's Grandparent; BS Baby's sibling; BMS Baby's Mother Sibling; BFS Baby's Father's Sibling

(Parents' sibling (BMS and BFS) refer to the baby's aunts and uncles by blood, and does *not* include aunts and uncles who are in-laws of the parents.)

55	Cancer or Leukemia? Y ☐ N ☐				
	If yes, please specify all that apply in **59A-J**. ***If no,*** skip to question **56.**	**BM**	**BF**	**BS**	
	A) Brain or other nervous system cancer	☐	☐	☐	**IMMEDIATE FAMILY ONLY**
	B) Bone or joint cancer	☐	☐	☐	
	C) Kidney (including renal pelvic) cancer	☐	☐	☐	
	D) Thyroid Cancer	☐	☐	☐	
	E) Hodgkin's Lymphoma	☐	☐	☐	
	F) Non-Hodgkin's Lymphoma	☐	☐	☐	
	G) Acute or chronic myelogenous/myeloid leukemia	☐	☐	☐	
	H) Acute or chronic lymphocytic/lymphoblastic leukemia	☐	☐	☐	
	I) Skin Cancer	☐	☐	☐	
	J) Other cancer/leukemia Specify Type:______________________ Specify Type:______________________	☐	☐	☐	

Answer Questions **56-60** for any Blood Disorders or Diseases. ***If yes,*** please specify as applicable.

		BM	BF	BS	BGP	BMS	BFS
56	**Red Blood Cell** Y ☐ N ☐						
	If yes, please specify all that apply in **56A-D**. ***If no,*** skip to question **57**.	**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
	A) Diamond-Blackfan Syndrome	☐	☐	☐	☐	☐	☐
	B) Elliptocytosis	☐	☐	☐	☐	☐	☐
	C) G6PD or other red cell enzyme deficiency	☐	☐	☐	☐	☐	☐
	D) Spherocytosis	☐	☐	☐	☐	☐	☐
57	**White Blood Cell Disease?** Y ☐ N ☐						
	If yes, please specify all that apply in **57A-D**. ***If no,*** skip to question **58**.	**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
	A) Chronic Granulomatous Disease	☐	☐	☐	☐	☐	☐
	B). Kostmann Syndrome.	☐	☐	☐	☐	☐	☐
	C) Schwachman-Diamond Syndrome	☐	☐	☐	☐	☐	☐
	D) Leukocyte Adhesion Deficiency (LAD)	☐	☐	☐	☐	☐	☐
58	**Immune Deficiencies?** Y ☐ N ☐						
	If yes, please specify all that apply in **58A-H**. ***If no,*** skip to question **59**.	**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
	A) ADA or PNP Deficiency	☐	☐	☐	☐	☐	☐
	B) Combined Immunodeficiency Syndrome (CID), Common Variable Immunodeficiency Disease (CVID)	☐	☐	☐	☐	☐	☐
	C) DiGeorge Syndrome	☐	☐	☐	☐	☐	☐
	D) Hereditary Hemophagocytic Lymphohistiocytosis (HLH) including FEL	☐	☐	☐	☐	☐	☐
	E) Hypoglobulinemia	☐	☐	☐	☐	☐	☐
	F) Nezeloff Syndrome	☐	☐	☐	☐	☐	☐
	G) Severe Combined Immunodeficiency	☐	☐	☐	☐	☐	☐

H) Wiskott-Aldrich Syndrome	☐	☐	☐	☐	☐	☐

HEALTH QUESTIONNAIRE

MOTHER'S LAST 4 SS# DIGITS:____________________ **MOTHER'S DOB:** ___________________________

#	Question	Y	N	BM	BF	BS	BGP	BMS	BFS
59	**Platelet Disease?**	Y ☐	N ☐						
	If yes, *please specify all that apply in 59A-G. If no, skip to question 60.*			**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
	A) Amegakaryocytic Thrombocytopenia			☐	☐	☐	☐	☐	☐
	B) Glanzmann Thrombasthenia			☐	☐	☐	☐	☐	☐
	C) Hereditary Thrombocytopenia			☐	☐	☐	☐	☐	☐
	D) Platelet Storage Pool Disease			☐	☐	☐	☐	☐	☐
	E) Thrombocytopenia with absent radii (TAR)			☐	☐	☐	☐	☐	☐
	F) Ataxia-Telangiectasia			☐	☐	☐	☐	☐	☐
	G) Fanconi Anemia			☐	☐	☐	☐	☐	☐
60	**Any diagnosis of other platelet disease or disorder?** Specific Type: ____________________	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
Hemoglobin Problems				**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
61	Sickle cell disease, such as sickle-cell anemia or sickle thalassemia? Specify disease:____________________	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
62	Thalassemia, such as alpha thalassemia or beta-thalassemia?	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
63	**Metabolic/Storage Disease?**	Y ☐	N ☐						
	If yes, please specify all that apply in **63A-Q**. ***If no,*** skip to question **64.**			**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
	A) Hurler Syndrome (MPS I)			☐	☐	☐	☐	☐	☐
	B) Hurler-Scheie Syndrome (MPS I H-S)			☐	☐	☐	☐	☐	☐
	C) Hunter Syndrome (MPS II)			☐	☐	☐	☐	☐	☐
	D) Sanfilippo Syndrome (MPS III)			☐	☐	☐	☐	☐	☐
	E) Morquio Syndrome (MPS IV)			☐	☐	☐	☐	☐	☐
	F) Maroteaux-Lamy Syndrome (MPS VI)			☐	☐	☐	☐	☐	☐
	G) Sly Syndrome (MPS VII)			☐	☐	☐	☐	☐	☐
	H) I-cell disease			☐	☐	☐	☐	☐	☐
	I) Globoid Leukodystrophy (Krabbe Disease)			☐	☐	☐	☐	☐	☐
	J) Metachromatic Leukodystrophy (MLD)			☐	☐	☐	☐	☐	☐
	K) Adrenoleukodystrophy (ALD)			☐	☐	☐	☐	☐	☐
	L) Sandhoff Disease			☐	☐	☐	☐	☐	☐
	M) Tay-Sachs Disease			☐	☐	☐	☐	☐	☐
	N) Gaucher Disease			☐	☐	☐	☐	☐	☐
	0) Niemann Pick-Disease			☐	☐	☐	☐	☐	☐
	P) Porphyria			☐	☐	☐	☐	☐	☐
	Q) Other or unknown metabolic/storage disease, Details:			☐	☐	☐	☐	☐	☐

#	Question	Y	N	BM	BF	BS	
Acquired Immune System Disorders				**BM**	**BF**	**BS**	**IMMEDIATE FAMILY ONLY**
64	**HIV/AIDS?**	Y ☐	N ☐	☐	☐	☐	
65	**Severe autoimmune disorder?**	Y ☐	N ☐	☐	☐	☐	
	If yes, please specify all that apply in questions **65A-D**. ***If no,*** skip to question **66.**			**BM**	**BF**	**BS**	
	A) Crohn's Disease or Ulcerative Colitis			☐	☐	☐	
	B) Lupus			☐	☐	☐	
	C) Multiple Sclerosis (MS)			☐	☐	☐	

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	D) Rheumatoid Arthritis			☐	☐	☐	
66	Any diagnosis of other or unknown immune system disorder?	**Y** ☐	**N** ☐	**BM**	**BF**	**BS**	
	Specify Disorder:____			☐	☐	☐	

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HEALTH QUESTIONNAIRE

MOTHER'S LAST 4 SS# DIGITS:______________________ **MOTHER'S DOB:** ______________________________

				BM	BF	BS	BGP	BMS	BFS
67	Required Chronic Blood Transfusions?	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
68	Been told you or your family member(s) have hemolytic anemia?	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
69	Had spleen removed to treat a blood disorder?	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
70	Had gallbladder removed before the age of 30?	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
71	Had Creutzfeldt-Jakob disease (CJD)?	Y ☐	N ☐	☐	☐	☐	☐	☐	☐
72	Other serious or life-threatening diseases affecting the family?	Y ☐	N ☐	BM	BF	BS	BGP	BMS	BFS
	If yes, list affected family member(s) and type of disease								
	Specify Type:________________________			☐	☐	☐	☐	☐	☐
	Specify Type:________________________			☐	☐	☐	☐	☐	☐
	Specify Type:________________________			☐	☐	☐	☐	☐	☐

73	In answering these questions, have you answered for both your family and the baby's father's family?	Y ☐	N ☐

Addendum A: STATE OF NEW YORK-ONLY For collections within the State of NY**,** the following questions must be answered.

1.	Any history of acute respiratory disease? ***If Yes***, please describe________________	**Y** ☐	**N** ☐
2.	Any active tuberculosis disease or history of tuberculosis therapy? ***If Yes***, please describe	**Y** ☐	**N** ☐
3.	Any history of drug or alcohol abuse? ***If Yes***, please describe________________	**Y** ☐	**N** ☐

Addendum B: Severe Acute Respiratory Syndrome (SARS)

Only **during time of person-to-person transmission of SARS, the following questions must be answered:**

1.	**In the past 28 days**, have you been ill with SARS or suspected SARS?	**Y** ☐	**N** ☐
2.	**In the past 14 days**, have you cared for, lived with, or had direct contact with body fluids of a person with SARS or suspected SARS?	**Y** ☐	**N** ☐
3.	**In the past 14 days,** have you traveled outside of the United States?	**Y** ☐	**N** ☐
4.	**In the past 14 days,** has someone you live with traveled to, traveled through, or resided in areas affected by SARS?	**Y** ☐	**N** ☐
5.	**In the past 14 days,** do you believe you have been exposed to SARS or to someone who has traveled to, traveled through, or resided in areas affected by SARS?	**Y** ☐	**N** ☐

TO BE COMPLETED BY LIFEFORCE CRYOBANKS: ☐ **N/A** Person-to-person transmission of SARS not occurring.
LC Employee Initials/Date(s): ______________________

INITIAL REVIEW ***TO BE COMPLETED BY LC AFFILIATE COLLECTION SPECIALIST, ONLY***

I have performed and reviewed the above responses and have determined this HQ ***initial*** *status to be (☑ one):*

☐	**Acceptable –** All LC HQ requirements met.	☐	**Follow Up** – Further follow up by LC required for final status determination.

Reviewed By: **Date(s):**

LC REVIEW ***TO BE COMPLETED BY*** **LIFEFORCE CRYOBANKS** ***ONLY***

CLIENT SERVICES REVIEW (☑ *one*) ☐ **N/A**				**LABORATORY REVIEW (☑ *one*)**			
☐	**HQ-OK**	☐	**Defer**	☐	**HQ-OK**	☐	**Defer**
☐	**Unusual Findings**	☐	**Ineligible**	☐	**Unusual Findings**	☐	**Ineligible**
☐	**Other:**			☐	**Other:**		
Reviewed By:		**Date(s):**		**Reviewed By:**		**Date(s):**	