UNIQUE IDENTIFICATION CODE MOTHER

Leuven Cord Blood Bank
Herestraat 49 3000 Leuven
Tel 32-16-34.68.94 Fax 32-16-34.68.83
e-mail : leuvencord@uzleuven.be
www.uzleuven.be/Navelstrengbloedbank

BARCODE / COLLECTION NUMBER

CONSENT FORM FOR VOLUNTARY DONATION OF UMBILICAL CORD BLOOD

I hereby declare that I voluntarily wish to donate the cord blood that will be collected from my child after birth. This cord blood will be processed and stored in the public cord blood bank. It may be used for any patient who is potentially eligible for stem cell transplantation. I have read the information brochure on cord blood (NS-00ALG1-015) and have had the opportunity to ask all my questions. I understand that there are no charges associated with this donation, and that collecting the cord blood has no adverse effects on me or my baby. No blood samples will be taken from the baby.

1. I **consent** to the collection of cord blood. I also agree to the preservation of the placenta membranes and their use for transplantation after processing.
2. I agree to the collection of **blood samples** from myself at the time of delivery.
3. I agree to answer questions on my medical history and that of my immediate family in order to determine whether the cord blood can be safely used for transplantation. I allow the medical staff to check my medical file and the file of my baby if necessary.
4. I declare that I have completed the questionnaire carefully and truthfully to the best of my knowledge. I understand that I may **possibly** be contacted in the future to provide **additional information** or a **verification blood sample** of myself (in case of e.g. a technical problem with the initial blood sample processing).
5. A year after the delivery, I agree to return a **questionnaire** to the Leuven Cord Blood Bank (Leuvense Navelstrengbloedbank – LNBB), filled out by a paediatrician or general practitioner**, concerning my baby's health**. This health certificate of my baby will contribute to the safe use of cord blood for transplanting.
6. I consent to all necessary **analyses** on my blood and cord blood to verify the cord blood quality, including tests for hepatitis, syphilis, CMV, HTLV, HIV and, if necessary, on genetic material. I am aware that cord blood reference samples and samples of my blood will be stored (frozen) for any subsequent additional quality checks. I allow the LNBB to send the results of those tests to the medical doctor of my choice*.
7. I authorise the stem cell bank to compile a donor file with the **necessary data**. This information will be treated confidentially. (*Act of 8 December 1992 on the protection of privacy in relation to the processing of personal data. Consolidated version, as last amended by the Act of 11 December 1998, B.S. (Belgian Government), 3 February 1999*).
8. I consent to the **coded archiving** of all relevant information on the umbilical cord in the register controlled by the LNBB of Leuven University Hospitals, and to the sharing of these coded data with other registers or transplantation centres.
9. I know that the cord blood will be discarded if it does not comply with the stringent storage requirements or if the laboratory is unable to process it safely.
10. I am aware that I have the **right** at any moment to refuse the donation of umbilical cord blood.
11. I understand that we (me, the child and the father) **cannot raise any claim** on this cord blood.
12. **I do / do not * consent to the use of the cord blood for scientific research**, instead of discarding it, if for some reason it would be not fit for use by the cord blood bank. * *please mark the appropriate mention*

DONOR INFORMATION			
Name and first name of the baby's **MOTHER**:		Date of birth **mother:**	Place of birth **mother:**
Name and first name of the baby's **FATHER**:			
Name and first name of the **BABY**:			
Street + number			
Postal code + municipality			
Telephone/Mobile phone		Telephone work:	
E-mail address			
Please tick ☐ to whom abnormal test results should be sent * **Gynaecologist ☐ / GP ☐ / Child's Pediatrician ☐**			
Name:		Postal code + municipality:	

Signed in	**Date**	**Signature MOTHER**
.....	.....	.....

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QUESTIONNAIRE for CORD BLOOD DONATION

If positive answer, NO collecting / processing

Questions concerning the WHOLE FAMILY — !!! if positive answer, NO collecting / processing!!! To your knowledge, are there in your family (you, the father and grandparents of your child, brothers and sisters, uncles and aunts, cousins, nephews and nieces) any known cases of:	NO	YES
1. **Creutzfeld-Jacob disease**, **early dementia** (<65 yrs) or another nervous system disorder caused by a virus or an unknown origin? (**NOTE:** the "classic" senile dementia is not an exclusion criteria! In that case: answer "no")	☐	☐
Questions only for the MOTHER/ FATHER/ CHILD — !!! if positive answer, NO collecting / processing!!!	NO	YES
2. Did you need a **fertility treatment** such as egg donation and/or sperm donation (where the egg and/or sperm is from an **unknown** donor)? Was a surrogate mother involved in this pregnancy?	☐	☐
3. Are you and the father of the child **blood relatives** (up to cousins' level)?	☐	☐
4. Did you or your partner suffer from a **contagious disease** (such as hepatitis B or C, AIDS, HTLV or syphilis) during the past 12 months?	☐	☐
5. Do you and/or your sex partner belong to a group with **increased risk** of contamination by the **AIDS** virus (HIV) such as prostitutes, intravenous drug users, multiple or homosexual / bisexual partners? Have you had a **new sexual partner** during the past 12 months?	☐	☐
6. Were any **chromosomal anomalies** detected with your child during the pregnancy?	☐	☐
7. Have you or your partner ever undergone a medical procedure that exposed you to **animal** cells or organs (e.g. transplant)?	☐	☐
Questions only for the MOTHER — !!! if positive answer, NO collecting / processing!!!	NO	YES
8. Are you currently **pregnant with multiple children** (e.g. twins)?	☐	☐
9. Have you received a **transfusion** with blood, plasma or platelets during the past 12 months?	☐	☐
10. Have you received an **organ transplant**? A dura mater (brain) graft?	☐	☐
11. Are you suffering from an **autoimmune disorder** requiring a systemic immunosuppressive/ immunomodulating therapy during the past 12 months (oral, intravenous, sub cutaneous or intra muscular), **Systemic Lupus Erythematodes** or **Sjögren's syndrome?**	☐	☐
12. Were you ever diagnosed with **malaria, babesiosis, leprosy, Leishmaniasis, West Nile virus infection**, or **Chagas disease**?	☐	☐
13. Did you experience an accidental **needle prick** or contact with someone else's **blood/body fluids** to open wounds or mucous membranes during the past 12 months?	☐	☐
14. Between 1980 and 1996, were you in the **United Kingdom** for three months (cumulative) or more? Have you ever been treated with **growth hormones**? Have you ever used **bovine insulin** since 1980? (such as Rapitard MC, Ultralente MC, Lente MC, Iletin)	☐	☐
15. Were you ever diagnosed with a malignant disease (**cancer**)?	☐	☐
16. Did you have an active **tuberculosis** or **toxoplasma** infection during your pregnancy?	☐	☐
17. Have you ever been exposed to **heavy metals** (lead, mercury, zinc,…) **poisoning**?	☐	☐

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QUESTIONNAIRE for CORD BLOOD DONATION

Vragen enkel voor de MOEDER	**!!! bij positief antwoord, GEEN collectie / verwerking !!!**	
	NEEN	JA
18. Were you diagnosed with a Zika virus infection during your pregnancy or 4 weeks prior to the onset of your pregnancy?	☐	☐
19. Have you travelled to / lived in a ***risk area**** for Zika virus infection during your pregnancy or 4 weeks prior to the onset of your pregnancy?	☐	☐
20. Have you had any sexual contact with a man: a) Who has been diagnosed with a Zika virus infection in the 15 months prior to the delivery? b) Who has travelled to/lived in a ***risk area**** for Zika virus infection in the 15 months prior to the delivery?	a. ☐ b. ☐	a. ☐ b.☐

(*) Risk area for zika virus infection

According to the US Center for Disease Control (CDC) the risk areas at this moment are: South America, Central America, The Caribbean, Africa, Asia and The Pacific Islands. The information about the risk areas on the 'CDC ZIKA information website' (https://wwwnc.cdc.gov/travel/page/zika-information) is always up to date.

QUESTIONNAIRE for CORD BLOOD DONATION

If positive answer, DO COLLECT but specify

Questions concerning the MOTHER and IMMEDIATE FAMILY (if positive answer, DO COLLECT but specify) *To your knowledge, are there in the first degree family (you, your child's father, brothers and/or sisters) any known cases of:*		
	NO	YES
21. **Hereditary hematologic disorders/bleeding tendencies** (e.g. thalassaemia, sickle-cell anaemia, Fanconi anaemia,), **immune system disorders** or **storage diseases** (e.g., mucopolysaccharidosis ...)? If so, who is concerned by the disease? ..... Since when? ..... From which disease?	☐	☐
22. Other **hereditary diseases** or **chromosomal anomalies**? (e.g. Cystic fibrosis (= mucoviscidosis)? If so, who is concerned by the disease? ..... Since when?..... From which disease?.....	☐	☐
Questions concerning the MOTHER only (if positive answer, DO COLLECT but specify)		
	NO	YES
23. Have you had any problems during your pregnancy? If so, which?	☐	☐
24. Was your baby diagnosed with any abnormalities? If so, which?	☐	☐
25. Have you been taking any medication during the first trimester of your pregnancy? If so, which?	☐	☐

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Questions concerning the MOTHER only (if positive answer, DO COLLECT but specify)	NO	YES
26. Have you been taking any medication during the remainder of your pregnancy? If so, which?	☐	☐
27. Have you travelled outside Belgium during the past six months? If so, where and when?	☐	☐
28. Have you travelled outside Europe during the past three years? If so, where and when?	☐	☐
29. Have you been on an adventurous trip (sleeping in huts or tents) in Central /South America during the past 5 years?	☐	☐
30. Are you originally from a country with a risk of malaria, or have you been living in any such country for >5 years?	☐	☐
31. Have you been in any malaria risk areas during the past 3 years?	☐	☐
32. Have you experienced any inexplicable fever within 6 months after returning from your trip? If so, which country and when?	☐	☐
33. Have you received any live vaccine during the past 8 weeks? *Note: Boosterix and the flu vaccine are not live vaccines.* If so, which vaccine?	☐	☐
34. Did you get any tattoos ☐, acupuncture☐, earlobe perforation ☐ or piercing☐ during the past 12 months? If so, was it performed by a qualified practitioner taking hygienic and aseptic precautions and using sterile disposable material?	☐ ☐	☐ ☐
35. Do you know that HIV/AIDS may even be contagious if the person feels good and has a negative HIV serology??	☐	☐
36. Have you ever donated cord blood before?	☐	☐
37. Have you ever been refused for cord blood donation? If so why?	☐	☐
38. Did you have any contact during the past 12 weeks with a person who had recently received a smallpox vaccine?	☐	☐
39. Did you suffer from two or more of the following symptoms during the past 4 months: fever (> 38°C) □, headache □, muscle weakness □, skin rash □ or swollen glands □ ?	☐	☐
40. Did you experience any blood clotting problems (e.g. haemophilia) during the past 5 years and received human-derived clotting factor?	☐	☐
41. Are you originally from an African malaria/HIV risk area* or have you been living in any such area for over a year?	☐	☐
42. Were you in custody for more than 72 hours during the past 12 months? (imprisonment/pre-trial detention)	☐	☐

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Questions concerning the MOTHER only (if positive answer, DO COLLECT but specify)	NO	YES
43. Have you ever had any sexual contact with a partner who:		
a. might have been exposed to live animal cells (e.g. transplants)	a. □	a. □
b. had hepatitis B, C or HIV	b. □	b. □
c. was taking clotting factors	c. □	c. □
d. was originally from an African malaria/HIV risk area* or had been living in any such area for over a year?	d. □	d. □
44. Did you ever suffer from:		
a. unaccountable night sweats?	a. □	a. □
b. unaccountable blue skin lesions suggesting Kaposi's sarcoma?	b. □	b. □
c. unaccountable weight loss?	c. □	c. □
d. unaccountable diarrhea?	d. □	d. □
e. unaccountable coughing or shortness of breath?	e. □	e. □
f. unaccountable fever (> 38°C) for more than 10 days?	f. □	f. □
g. unaccountable lesions in the mouth?	g. □	g. □
h. unaccountable swollen glands for more than a month?	h. □	h. □
45. Have you ever had a transfusion during a trip in the United Kingdom, France or African malaria/HIV risk area? *(= Benin, Cameroon, Central African Republic, Chad, Congo, Guinea, Gabon, Kenya, Niger, Nigeria, Senegal, Togo, Zambia)*	□	□

Geographical origins of the child's parents (to be completed by the parents)

Fill in the **native land** of the parents and grandparents of the child.

Indicate the **geographical region** where your **ancestors** were from / where do they originally come from?.

GEOGRAPHIC REGION	Mother	Father	GEOGRAPHIC REGION	Mother	Father
Scandinavia	□	□	Nothern Asia	□	□
Eastern Europe	□	□	Central Asia	□	□
Western Europe	□	□	Middle East	□	□
Southern Europe	□	□	Far East	□	□
North Africa	□	□	Southeast Asia	□	□
Central Africa	□	□	North America	□	□
Southern Africa	□	□	Central America	□	□
East Africa	□	□	South America	□	□
West Africa	□	□	Oceania	□	□

NATIVE LAND

Mother: .....

Grandmother mother's side: .....

Grandfather mother's side: .....

Father: .....

Grandmother father's side: .....

Grandfather father's side: .....

This information aims to improve the Cord Blood Bank management and inventory and has no influence whatsoever on the final decision on the cord blood sample's suitability for banking. Thanks in advance for completing this form.

I hereby declare that I have answered the questions asked to the best of my knowledge

Signed in	**Date**	**Signature MOTHER**
.....	.....	.....

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UMBILICAL CORD BLOOD COLLECTION FORM – ON THE DAY OF BIRTH

(To be completed by the gynecologist, midwife or nurse attending the collection)

If the answer to any of the questions below is 'NO' → 'DO NOT COLLECT cord blood!

		YES	NO
1.	Is the informed consent and the questionnaire signed and confirmed by the mother?	☐	☐
2.	Did the mother understand the information?	☐	☐
3.	Is the mother more than 18 years old?	☐	☐
4.	Gestational age more than 34 weeks?	☐	☐
5.	I declare that there was no rupture of membranes > 24 h before the collection.	☐	☐
6.	I declare that the mother presented without fever (> 38°C) < 24 hours before delivery.	☐	☐
7.	I declare no antibiotics were used <48h before birth started because of infection symptoms. (**GBS prophylaxis is ok!**)	☐	☐

Note: Do not collect in case of: (a) excessive bleeding or (b) transfusion

INFORMATION CONCERNING THE MOTHER Identification as described in procedure Patiëntidentificatie			
Name and first name		Date of birth	
Type of birth	**Vaginal – C-section**	Gestational age	
Abnormalities with the mother at birth: **YES – NO** If so, please describe: ……..		>2L IV fluids/24h (before maternal blood collection): **YES - NO**	
INFORMATION CONCERNING THE CHILD			
Name and first name		Date of birth	
Gender	**male – female**	Hour of birth	
Abnormalities with the baby at birth: **YES – NO** If so, please describe.: ……..			

I have completed the information above and cord blood was collected from the umbilical vein in accordance with the guidelines (NS-06LA1-009). I have also taken control sample tubes from the mother in accordance with the guidelines (NS-06LA1-009). Everything was **labelled** according to the procedure (NS-06LA1-009). The **questionnaire** was **checked** again with the mother. I confirm that her **identity** and that of the donor child were **certified** before the collection and his/her consent was obtained by **signing** the **informed consent** form. During my clinical examination of the mother, I have found **no anomalies suggesting the presence of infectious diseases** (no genital lesions, no needle prick injuries, no infected piercing, no glands, no oral deformities, no indication of Kaposi's sarcoma, no icterus or hepatosplenomegaly, no indication of recent smallpox vaccination).

Date	NAME/SEAL of collecting physician	SIGNATURE of physician
……	……	……

RESERVED FOR THE UMBILICAL CORD BLOOD BANK

- ❑ This medical history form is sufficient to store the cord blood
- ❑ The attending physician should be contacted for more information
- ❑ The cord blood must be discarded

Date: Signature:

Prof. Dr. T. Devos