Information sheet for cord blood donation
Public Cord Blood Bank Switzerland

Dear expecting mother, dear parents

You will soon give birth and you are considering donating your child’s cord blood. This information sheet will tell you all you should know about the collection process for cord blood and storage of your child’s cord blood in a public cord blood bank (CBB).

Introduction

The blood that remains in the child’s umbilical cord and placenta after birth is known to contain a relatively large amount of potentially life-saving cells called blood stem cells. Blood stem cells from cord blood can be used for transplants to treat blood cancer (such as leukemia), other severe blood diseases or rare immunologic disorders. With a blood stem cell transplant, the patient’s diseased blood and immune system is replaced by healthy new blood stem cells.

Blood stem cells from cord blood can be used as an alternative source to bone marrow or peripheral blood stem cells for transplantation. Cord blood stem cells can be stored for years without losing their potential to develop into the different blood cell types. Cord blood storage in a public cord blood bank makes the donated blood stem cells available for the treatment of all patients requiring blood stem cell transplantation worldwide.

Blood stem cells from cord blood have some advantages:

- The collection process is safe and risk-free for mother and child
- Cord blood can be easily collected, frozen and stored for a practically unlimited length of time (cryoconservation)
- Cord blood is rapidly available for transplantation
- The necessity of compatibility (HLA-matching) between donor and recipient is less stringent than for blood stem cell transplantations with bone marrow or peripheral blood stem cells

However, the quantity of blood stem cells in a cord blood unit (CBU) is limited; therefore cord blood is preferably used for children as the quantity of it may not be sufficient for a transplant in an adult.

Cord blood donation is voluntary, anonymous and non-remunerated.

In the following you will find detailed written information on donating cord blood. If you are considering a donation, you will have the opportunity to ask any questions you may have regarding the collection process, the storage and the use of your donated cord blood stem cells before giving birth.
Requirements for donation

A medical evaluation is required before donation in order to ascertain the health of mother and child, and to assess donor eligibility and thus to protect the recipient from transmissible diseases.

This entails:

- Filling in a medical questionnaire on the state of health and medical history of the mother and father. The questionnaire also includes questions on known diseases or disorders in the family, which could be transferred to the recipient via the cord blood. The medical questionnaire should be filled in before the onset of active labour. A cord blood collection can only be performed if all the eligibility criteria are met.
- Signing an informed consent form before cord blood donation.
- Excluding transmissible viral or bacterial infections. For instance, it is mandatory to test for HI-Virus, Hepatitis-B- and -C-Virus and Syphilis (Screening-Tests).

However, in the initial period of an infection, an infectious disease may not be detectable and could be transmitted to the recipient of the cord blood stem cells. It is therefore of the utmost importance to mention any risk situation and fill in the medical questionnaire truthfully.

Should the screening tests reveal any abnormal results, you would be informed immediately. Of course you have the right to view all the test results.

Apart from the usual screening tests mentioned above, samples of the maternal donor’s blood and of the child’s cord blood are stored for later analysis, which may be necessary in the context of transplantation.

All data collected in context with a cord blood donation are pseudonymised and are solely available to qualified staff, which is bound to medical confidentiality. “Pseudonymised” means that the name will be replaced by a pseudonym (generally a multi-digit letter or numeric code) to make it impossible to determine the identity of the person concerned.

How is cord blood collected?

The cord blood stem cells are collected from the residual blood which remains in the placenta and the umbilical cord after delivery of the child and clamping. A minimum amount of cord blood is necessary for further processing and banking. Unfortunately this amount is not always reached.

The cord blood collection is performed by qualified staff under sterile conditions to minimise the risk of contamination and infection of the unit and in order to ensure the highest possible quality and safety of the future transplant product. The procedure is absolutely safe, pain- and risk-free for both mother and child.
It is important that there is no alteration of the usual management of labour and delivery. The cord blood donation does not interfere with the birth process, cord clamping and the immediate aftercare of mother and child. The care for mother and child always has priority over a cord blood collection.

Even if you fulfilled the donation criteria before delivery, the obstetrician in charge can decide that cord blood collection is not advisable or not possible in critical medical situations (i.e. premature delivery).

Storage of the cord blood unit

Once collected, the cord blood is transported to the public cord blood bank for processing and freezing. The processing in the stem cell laboratory comprises isolating the blood stem cells from the cord blood, the labeling of the cord blood unit, HLA-typing, performing the screening tests for infectious diseases and the required quality parameters. If the cord blood unit fulfills all the quality requirements, it is then frozen and stored at a temperature of minus 150°C. The cord blood unit is then registered in the Swiss Transfusion SRC database and is available for patients worldwide.

The collection, processing and storage of cord blood units for public banking are performed according to the international quality standards of FACT-NetCord (International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release). In Switzerland, these standards are only implemented in a limited number of maternity units which is why cord blood collections for public banking are only possible in these clinics (see list below).

Should the cord blood you donated not fulfill the quality requirements and therefore not be suitable for clinical use, it will either be discarded, or, in certain centers - with your consent - it can alternatively be used for quality control tests in the cord blood bank, or for scientific research projects.

By voluntarily donating your child's cord blood, you will transfer the ownership of the donated cord blood unit to the public cord blood bank.

Costs

You will bear no costs for the collection and storage of the donated cord blood.

Genetic tests

After transplantation, the recipient undergoes genetic testing in order to monitor the function of the transplanted blood stem cells, or - on the other hand - to follow the initial disease. In very rare cases these tests could produce results which may be relevant for the donor. You will be informed, if the cord blood bank is apprised of any such results.
Duty to supply information post donation

Certain illnesses or infectious diseases, as yet unknown at the time of donation, can pose a risk for the recipient of a cord blood unit.

Any health problems occurring in the perinatal period or later in your or your child’s life could affect the quality of the unit and the safety of the future recipient. The cord blood bank must be informed of any such health issues. Please also notify the cord blood bank if you notice having answered a question on the medical questionnaire incorrectly.

List of clinics in Switzerland where cord blood donation for public banking is possible:

- Kantonsspital Aarau
- University Hospital Basel
- University Hospital Bern
- University Hospital Geneva
- At the following 6 maternity clinics in Tessin:
  - Ospedale Regionale - Civico, Lugano
  - Ospedale Regionale - Beata Vergine, Mendrisio
  - Ospedale Regionale Bellinzona e Valli - San Giovanni, Bellinzona
  - Ospedale Regionale - La Carità, Locarno
  - Clinica Sant’Anna, Sorengo
  - Clinica Santa Chiara, Locarno

If you are considering a cord blood donation, these hospitals can provide further information.

The two Swiss public cord blood banks are located at the University hospitals of Basel and Geneva.

Link
https://www.blutspende.ch/de/blutstammzellspende/blutstammzellsender_werden/wenn_es_zur_spende_kommt/wie_spende_ich_blutstammzellen/nabelschnurblutspende
Medical Questionnaire
Public Cord Blood Bank Switzerland

You have just read the information sheet for cord blood donation and you would like to donate your child's cord blood. We thank you for answering the following questions with the greatest sincerity by marking with a cross in the check box required. By doing so you will contribute to your own security and to the security of the recipient of your child's cord blood.

A. CHILD’S MOTHER’S INFORMATION

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<tr>
<th>Name</th>
<th>First Name</th>
<th>Date of Birth</th>
<th>Street</th>
<th>ZIP / City</th>
<th>Phone / E-Mail</th>
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B. PARENTS’ ETHNIC INFORMATION

Which ethnic group do you belong to? Please fill in according to the enclosed list.

Child……………………………………………………………………………

Child’s mother…………………………………………………………………..

Child’s father……………………………………………………………………

C. HEALTH QUESTIONNAIRE

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<td>1. a) Were you and/or the child's father adopted at early childhood?</td>
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<td></td>
<td>b) Did conception result from fertilization using either donor sperm, donor ovum or surrogacy?</td>
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<td>2.</td>
<td>During the past 4 weeks have you been ill, received medical care, or had a temperature of more than 38°C (or 100°F)?</td>
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<td>3. a) During the past 4 weeks, have you taken any medicines (tablets, injections, suppositories)?</td>
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<td>If so, please specify ………………………………………………………………………………...</td>
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<td></td>
<td>b) Have you taken Roaccutan® (acne) or Propecia® (baldness) during the past 4 weeks?</td>
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<td></td>
<td>c) During the past 3 years, have you taken Neotigason® / Soriatane (treatment of psoriasis)?</td>
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<td>4. a) Did you ever receive an immunotherapy (plasma, cells or serum of human or animal origin)?</td>
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<td>b) Have you been vaccinated against Rabies, Hepatitis B or Tetanus during the last 12 months?</td>
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<td>c) Have you had another vaccination during the last 4 weeks? Please specify? When?</td>
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5. Have you ever had any of the health problems or disorders mentioned below?

If yes, please specify on page 5, under E Child’s mother Child’s father

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<td>b) breathing, lungs</td>
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<td>c) stomach/intestines</td>
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<td>d) urinary tract, kidneys, genital</td>
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<td>e) neurological</td>
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<td>f) immune system</td>
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<td>g) infections</td>
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<td>h) malignant blood disease, please specify (s. question 17)</td>
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<td>i) cancer, please specify (s. question 17)</td>
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<td>j) other, (e.g., diabetes) please specify</td>
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11. During the past 6 months have you undergone:
- tattooing?  □
- a gastro-, colonoscopy? □
- acupuncture? □
- electric epilation? □
- permanent make-up? □
- body piercing? □
- injury by a blood-contaminated product/device? □
If so, when?
………………………………………………………………………………………………
Sterile instruments □
- yes □
- no □

12. a) Have you ever had jaundice (hepatitis) or a positive test for hepatitis?
□
□

b) Has anyone who lives in the same domicile as you, or your sexual partner, had jaundice (hepatitis) during the last 12 months?
□
□

13. Have you been exposed to one of the following risk situations?

a) Change of sexual partner in the past 4 months or sexual intercourse (with or without protection) with several partners in the last 12 months
□
□

b) During the past 12 months, stay of at least 6 months in countries where AIDS is epidemic
□
□

c) Had your partner sexual intercourse with men since 1977?
□
□

d) Sexual intercourse for money since 1977
□
□

e) Intravenous drug abuse at present or in the past
□
□

f) Positive test for HIV, syphilis, or jaundice (hepatitis B and C)
□
□

14. During the past 12 months, have you had sexual intercourse with partners exposed to one of the risk situations mentioned under 13 or who received blood transusions in countries where AIDS is epidemic?
□
□

15. During the past 12 months, have you shown evidence of or been treated for Chlamydia, genital herpes, syphilis or any other sexually transmitted disease?
□
□

16. Before 01.01.1986, did you receive hormone injections as treatment of sterility?
□
□

17. Is there in the family a history of the following diseases? If yes, please specify degree of relationship.

a) Red Blood Cell disease (e.g. thalassemia, sickle cell disease etc.)
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

b) White Blood Cell disease
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

c) Platelet disease (e.g. essential thrombocytosis, thrombocytopenia etc.)
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

d) Metabolic/storage disease (e.g. Tay-Sachs, Fabry’s, Gaucher, Niemann-Pick, diabetes etc.)
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

e) Immunodeficiencies
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

f) Acquired/inherited autoimmune system disorders (e.g. Lupus, M. Basedow, etc.)
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

g) Malignant blood disorders (e.g. leukemia, multiple myeloma, myelodysplastic syndrome, etc.)
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

h) Other cancers including multiple tumours
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □

i) Inherited bleeding disorders (e.g. hemophilia, von Willebrand disease, etc.)
- Child’s father □
- Child’s mother □
- sibling □
- grandparents □
I confirm the accuracy of my personal data and that I filled out the questionnaire truthfully.

**Mother:**
Name:……………………………………… First name:…………………………… Date of birth:…………………………
Date:……………………………………… Signature:……………………………………………………………………………

**Father (facultative):**
Name:……………………………………… First name:…………………………… Date of birth:…………………………
Date:……………………………………… Signature:……………………………………………………………………………
Verification of the medical questionnaire by medical personnel

D. TO BE FILLED OUT BY THE MATERNITY CLINIC

Remarks to section C "Health Questionnaire":

Question …… : ……………………………………………………………………………………………………………………………

Question …… : ……………………………………………………………………………………………………………………………

Question …… : ……………………………………………………………………………………………………………………………

Questionnaire controlled by maternity clinic: Date: …………………………………………………. Visa: ……………………………

Delivery Institution (please tick appropriate):
Basel: ☐ Bern: ☐ Geneva: ☐ Tessin: ☐ Aarau: ☐

After having reviewed the Medical Questionnaire and the future mother’s medical records, I hereby certify that there are no physical signs to suggest present or past HIGH RISK BEHAVIOUR for transmissible infectious diseases (HIV, HTLV, hepatitis B or C and sexually transmitted diseases) at the moment and that all responses to the Medical Questionnaire are accurate to the best of my knowledge. According to the answers I confirm that this donor is able to donate her child’s cord blood at birth to the Public Cord Blood Bank Switzerland. In the event of new health information that may arise and which might affect this donation I assure to provide such information to the Public Cord Blood Bank Switzerland.

Name of Physician: …………………………………………… First Name: ………………………………………………………………………

Date: ………………………………………………….. Signature of Physician: ……………………………………………………………

E. TO BE FILLED OUT BY THE CORD BLOOD BANK OR THE BLOOD TRANSFUSION SERVICE

Questionnaire controlled and approved by:
☐ Cord Blood Bank ☐ Blood Transfusion Service

Name: ………………………………………………….. First Name: ………………………………………………………………………

Date: ………………………………………………….. Signature: ………………………………………………………………………

F. TO BE FILLED OUT BY THE CORD BLOOD BANK

Cord Blood Bank (please tick appropriate):
Basel: ☐ Geneva: ☐

Criteria to donate Cord Blood are fulfilled:
☐ Yes ☐ No

Name: ………………………………………………….. First Name: ………………………………………………………………………

Date: ………………………………………………….. Signature: ………………………………………………………………………
Informed consent for maternal cord blood donors

I am willing to voluntarily donate my child’s cord blood for storage in the Public Cord Blood Bank (CBB). The blood stem cells collected from this cord blood may be used to treat a patient in Switzerland or any other country worldwide, who is in need of a blood stem cell transplantation.

I specifically confirm the following points:

- I have received the information about public cord blood donation
- I have read the Information sheet for cord blood donation - Public Cord Blood Bank, Switzerland and understood the content
- I had the possibility to ask questions and have had all my questions answered to my complete satisfaction. I had enough time to make my decision
- I was informed about the necessary examinations before donation (especially the tests for transmissible infectious diseases such as HIV, hepatitis and syphilis)
- I was instructed on my right to view all the test results
- I am conscious of the fact that the requirements mentioned in the information sheet (e.g. donor eligibility, communicating any changes to my health) must be respected
- I agree to provide the maternity hospital with information on any relevant changes to my health which could affect my eligibility to donate
- I commit to informing the maternity hospital immediately if I myself, a close contact person or my child should fall ill in the next few days or soon after the birth
- I also confirm that I will inform the Cord Blood Bank and/or the maternity hospital if any health issues should arise later in my life or in the life of my child, that might impact on the quality and safety of the stored cord blood unit (CBU) or that could potentially affect the recipient
- I allow the maternity hospital and my child’s paediatrician to provide health information now and in future concerning myself or my child, that might impact on the quality and safety of the stored cord blood unit or that could potentially affect the recipient
- I am aware that - up until the birth of my child - I have the right to withdraw my consent to donate my child’s cord blood
- I agree to donate my child’s blood stem cells without remuneration
- I accept that by voluntarily donating my child’s cord blood I am transferring the ownership of the donated cord blood unit to the Cord Blood Bank
- I agree that a cord blood sample be taken for HLA-typing. This sample and the corresponding data (in pseudonymised form) shall be sent to external laboratories, which can also be situated in foreign countries, for HLA-testing and storage.
- I agree that my personal data (in pseudonymised form) and my HLA results are registered in the Swiss Transfusion SRC database. My data may be submitted to international registries for blood stem cell donors in the context of a donor search for patients worldwide
- I permit Swiss Transfusion SRC and authorised laboratories to make use of my samples and HLA data to analyse HLA variability in the population and the distribution of the various HLA combinations. I am aware that my data will be used only in pseudonymised form and that these analyses carry no risks for me or my child
- I know that my blood and the blood of my child will be tested with molecular biological techniques to prevent the transmission of a disease to the recipient
- I know that - should the donated cord blood be transplanted - certain blood samples will be stored at long term in order to answer any questions in context with this specific transplantation that should arise later and that could be relevant for the recipient
I know that, following the transplantation, genetic tests will be performed on the recipient to monitor the function of the transplanted blood stem cells or to follow the initial disease. In rare cases these tests could produce results which may be relevant for me or my child. The CBB will inform me if appraised of any such results.

I was informed that SBSC is subject to the Swiss Federal Act on Data Protection and hence all my personal data will be treated confidentially. In Switzerland the policy of anonymity between unrelated donor and recipient is applied.

I know that all the data collected in context with this donation of cord blood will be pseudonymised and are only accessible to qualified staff, which is subject to medical confidentiality.

I herewith declare that I am willing to donate my child’s cord blood for storage in the public cord blood bank.

☐ Yes ☐ No

I consent to the use of my child’s blood stem cells, should they not be suitable to be banked for transplantation, for the following purposes:

- For research purposes (approved by an ethical committee)
  ☐ Yes ☐ No ☐ not applicable

- For quality controls in the Cord Blood Bank
  ☐ Yes ☐ No ☐ not applicable

Mother:

Last name: ........................................ First name: ........................................

Date: ........................................ Signature: ........................................

Father (optional):

Last name: ........................................ First name: ........................................

Date: ........................................ Signature: ........................................
# Zika Virus Infection Risk Assessment Questionnaire for Maternal Donors of Cord Blood

<table>
<thead>
<tr>
<th>Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
</tr>
<tr>
<td>Date of Collection</td>
<td></td>
</tr>
<tr>
<td>Collection Center</td>
<td>Basel [ ]</td>
</tr>
<tr>
<td></td>
<td>Geneva [ ]</td>
</tr>
<tr>
<td>Cord Blood Bank</td>
<td></td>
</tr>
</tbody>
</table>

**Purpose:** Gather information to evaluate possible Zika virus risks for use in determining eligibility.

**Instructions:** SBSC requires that the following questions be asked of all maternal donors of cord blood who donate on or after July 1st, 2016.

Questions – please enter comments below for an answer of “Not Asked / Not Answered / Unknown”.

1. During your pregnancy, have you had a medical diagnosis of Zika virus infection?
   - Yes [ ]
   - No [ ]
   - Not Asked/Not Answered [ ]

2. During your pregnancy, have you resided in or travelled to a **risk area*** for the Zika virus?
   - Yes [ ]
   - No [ ]
   - Not Asked/Not Answered [ ]

3. During your pregnancy, have you had sexual contact with a male who:
   - a. Was diagnosed with a Zika virus infection in the 6 months prior to the sexual contact?
      - Yes [ ]
      - No [ ]
      - Not Asked / Not Answered / Unknown [ ]
   - b. Traveled to or resided in a **risk area*** for the Zika virus in the 6 months prior to the sexual contact?
      - Yes [ ]
      - No [ ]
      - Not Asked / Not Answered / Unknown [ ]

**Risk Area:** Under the following link you will find the specific areas where Zika Virus transmission is ongoing.


The CDC (Center for Disease Control and Prevention) updates the site regularly for the most current information on risk countries. Alterations of the risk areas are to be expected.

Link to Zika risk areas within the US (NMDP):

https://network.bethematchclinical.org/Zika Risk Areas within the United States
Comments:

### Measures:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Assessment</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes  (to any of the above assessment questions)</td>
<td>Donor ineligible</td>
<td>No donation</td>
</tr>
<tr>
<td>No</td>
<td>Donor eligible</td>
<td>Donation accepted</td>
</tr>
<tr>
<td>Not answered / Unknown</td>
<td>Donor eligible under reserve*</td>
<td>Donation accepted under reserve*, test recommended</td>
</tr>
</tbody>
</table>

* Note on the Cord Blood Unit Data, information of the transplant centre by SBSC.

**NB: If a CBU is requested for delivery which was accepted for “donation under reserve”, a declaration of urgent medical need must be obtained from the transplant centre.**

**Decision:**
- [ ] no donation
- [ ] donation accepted
- [ ] donation accepted under reserve, test recommended

Completed by: ________________________________ Date: ________________________________