

Medical History Sheet

Answering these questions conscientiously, completely and, if possible, unsupervised (no later than 48 hours before delivery) is absolutely necessary for the subsequent release of the donated cord blood.

**If you have any further questions, please do not hesitate to contact us at:
+49 (0)351 250966 0.**

Any questions answered with ☒ Yes require additional clarification to be given regarding the type of disease, onset, duration and medication used. Please also use the "Comments" field on page 3 for this purpose.

MOTHER'S CASE HISTORY

Please check the appropriate box! You can provide confidential information to the doctor in person.

1. Within the past 4 weeks , have you - had an infection (e.g. a cold, diarrhea)? If yes: What? _____ When? _____ with a fever ☐ No, ☐ Yes - taken medication or received injections? If yes: Please specify _____ - had any contact to persons suffering from infectious diseases (e.g. rubella, measles, mumps)?	☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes
2. Have you received a rabies vaccination in the past 12 months , or have you received a hepatitis B vaccination or live vaccine (e.g. for yellow fever, typhoid fever, varicella, measles, mumps, rubella, cholera) in the past 4 weeks ? If yes: Please specify _____	☐ No ☐ Yes
3. Have you had acupuncture that was not performed in aseptic conditions with single-use needles or a tattoo or other cosmetic procedures involving injury to the skin or mucous membranes (e.g. ear or body piercings, transdermal implants, cutting, branding, permanent makeup) in the past 4 months ?	☐ No ☐ Yes
4. Have you had any contact with persons suffering from jaundice/hepatitis or tuberculosis, e.g. among the members of your household, in the past 4 months ?	☐ No ☐ Yes
5. Have you had any exposure to another person's blood in the past 4 months , e.g. through an open wound, through mucous membranes (also eyes) or due to an injury with an instrument (e.g. injection needle)?	☐ No ☐ Yes
6. Have you ever been diagnosed with HIV, hepatitis A/B/C/D/E, AIDS or HTLV 1/2?	☐ No ☐ Yes
7. Have you belonged to a group of people who are particularly at risk of contracting HIV/hepatitis in the past 4 months ¹ , or have you had sexual contact with a person belonging to this group in the past 4 months ? Have you taken an HIV pre-exposure prophylaxis (PrEP) medicine in the past 4 months ?	☐ No ☐ Yes ☐ No ☐ Yes
8. Are you currently in prison or were you released from prison at any time within the past 4 months ?	☐ No ☐ Yes
9. In the last 4 months , have you had intimate contact with a person who lives in an endemic area/high-prevalence country for HBV, HCV or HIV or has entered the country from such a region?	☐ No ☐ Yes
10. Have you received any blood, blood products or serums of animal origin in the past 12 months ?	☐ No ☐ Yes
11. Have you ever received a transplant of human origin (e.g. stem cell donation, egg donation, sperm donation), of animal origin (e.g. xenograft) or live-cell therapy of animal origin?	☐ No ☐ Yes
12. Have you had surgical, endoscopic or catheterization procedures (exception: single-use catheters) or accidents in the past 4 months ? If yes: Please specify the type and date	☐ No ☐ Yes
13. Have you had any minor surgery or tooth extractions in the past week ? If yes: Please specify	☐ No ☐ Yes

1 A person with sexual behavior that carries a significantly increased risk of transmission of serious blood-borne infectious diseases within the past 4 months. This includes: Sexual intercourse with more than two persons in total, sexual intercourse with one new person, if anal intercourse has been practiced, sexual intercourse with more than one person in total, if anal intercourse has been practiced, sex work or use of sex work, sexual intercourse with a person infected with HBV, HCV or HIV, sexual intercourse with a person who lives in an endemic area/high-prevalence country for HBV, HCV or HIV or has entered the country from such a region.

14. Do you currently have an open wound, an abscess or a skin infection? If yes: Please specify _____	☐ No ☐ Yes															
15. Are you suffering from an addiction to alcohol or legal or illegal drugs, or have you suffered from such an addiction in the past?	☐ No ☐ Yes															
16. Have you been abroad in the past 6 months ? If yes: Please specify where and when? _____	☐ No ☐ Yes															
17. Were you born or raised in a malaria-endemic area, or have you ever spent time in one for more than 6 months ? If yes: Where and when was your last stay? _____	☐ No ☐ Yes															
18. Have you been to a malaria-endemic area in the past 6 months ? If yes: Where? _____ Were you given medication? If yes, which? _____	☐ No ☐ Yes															
19. Was a Zika virus infection detected during your pregnancy? During the pregnancy, did you travel to or spend any time in an endemic high-risk area for Zika virus transmission? During this pregnancy, have you had sexual contact with a person who has been diagnosed with a Zika virus infection in the 6 months prior to your sexual contact or who has been in a Zika virus endemic area in the 6 months prior to your sexual contact?	☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes															
20. Have you been diagnosed with a West Nile virus infection in the past 4 weeks ?	☐ No ☐ Yes															
21. Have you, the child's father or any of your (or his) relatives contracted Transmissible Spongiform Encephalopathies (TSE), e.g. Creutzfeldt-Jakob disease, any variant of Creutzfeldt-Jakob disease, or been suspected of contracting TSE?	☐ No ☐ Yes															
22. Do you now have or have you ever had cancer, tumors, cardiovascular diseases, high blood pressure (treated with medication), allergies, rheumatic fever, tuberculosis, salmonella infections as a chronic carrier (such as typhoid or paratyphoid fever), Lyme disease, toxoplasmosis, Q fever, tropical diseases (such as malaria, typhus fever and other rickettsiosis conditions, babesiosis, trypanosomiasis, leishmaniasis, tularemia, leprosy, brucellosis, relapsing fever, melioidosis, etc.), sexually transmissible diseases (such as gonorrhea, syphilis, chancroid, lymphogranuloma venereum, etc.)? If yes: Please specify the type and date	☐ No ☐ Yes															
23. Do you now have or have you ever had any illnesses of the blood, lymph nodes, nerves (e.g. seizures), kidneys, thyroid gland, lungs/bronchial tubes, bones (e.g. osteomyelitis), liver, gastrointestinal tract, urogenital tract, or central nervous system? If yes: Please specify the type and date	☐ No ☐ Yes															
24. Have you been diagnosed with any autoimmune or metabolic disorder, such as diabetes? If yes: What and since when? _____ Do you require medication? ☐ No ☐ Yes, please specify _____	☐ No ☐ Yes															
25. Did you experience any severe complications during pregnancy or is there any indication of malformations, chromosomal disorders or severe illnesses of the unborn child?	☐ No ☐ Yes															
26. Did you have any acute infections during pregnancy or do you have any now? If yes: Please specify the type and date _____	☐ No ☐ Yes															
27. Did you have or do you now have hepatitis during your pregnancy? If yes: Please specify the type and date _____	☐ No ☐ Yes															
28. In the past 12 months , have you had: <table border="0" style="width: 100%;"> <tr> <td>☐ Thromboses</td> <td>☐ Impaired blood flow</td> <td>☐ NO abnormalities</td> </tr> <tr> <td>☐ Swelling of the lymph nodes</td> <td>☐ Heart symptoms</td> <td>☐ Gastrointestinal disorders</td> </tr> <tr> <td>☐ Skin changes</td> <td>☐ Fever</td> <td>☐ Coagulation disorders</td> </tr> <tr> <td>☐ Seizures/fainting spells</td> <td>☐ Weight loss</td> <td>☐ Unusual bleeding</td> </tr> <tr> <td>☐ Cough</td> <td>☐ Night sweats</td> <td>☐ Kidney/bladder inflammation</td> </tr> </table>		☐ Thromboses	☐ Impaired blood flow	☐ NO abnormalities	☐ Swelling of the lymph nodes	☐ Heart symptoms	☐ Gastrointestinal disorders	☐ Skin changes	☐ Fever	☐ Coagulation disorders	☐ Seizures/fainting spells	☐ Weight loss	☐ Unusual bleeding	☐ Cough	☐ Night sweats	☐ Kidney/bladder inflammation
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Please provide details of all questions answered with ☒ yes (indicating the type, onset, medication administered, if applicable): _____ _____ _____																

MEDICAL HISTORY OF THE FAMILY (from the child's perspective)

We need information from the family history of the pregnant woman and the biological father. Please note that the relationships given below are from the **child's point of view**, i.e. the mother is you, siblings refer to the newborn's siblings, etc.

Family origin of parents and grandparents (e.g. Germany, Turkey):

Mother _____ Grandfather _____ Grandmother _____
 Father _____ Grandfather _____ Grandmother _____

1. In the child's immediate family (e.g. mother, father, sibling), have there been or are there now any malignant tumors, leukemias or myeloproliferative diseases? If yes: Please specify who and the type of condition:	☐ No ☐ Yes
2. In the extended family of the pregnant woman or the biological father (e.g., including the grandparents of the child), are there any genetic diseases that may affect the lymphatic or blood forming system (e.g. spherocytosis, Diamond-Blackfan anemia, thalassemia, sickle cell anemia, elliptocytosis, Fanconi anemia, SCID, leukodystrophies, chronic granulomatous disease, hypoglobulinemia, DiGeorge, Wiskott-Aldrich, Nezelof syndrome, ADA, PNP deficiency, Glanzmann, Alport, congenital thrombocytopenia, platelet storage disease, Tay-Sachs, ataxia teleangiectasia, other miscellaneous teleangiectases, Fillipo, Gaucher, Hurler, Hunter), autoimmune diseases, muscular dystrophy, multiple sclerosis or severe hereditary skin diseases (e.g. neurofibromatosis, congenital extreme photo damage)? If yes: Please specify who and the type of condition:	☐ No ☐ Yes
3. Are there any known chromosomal disorders or other severe hereditary illnesses in the child's family? If yes: Please specify who and the type of condition:	☐ No ☐ Yes

FINALLY, PLEASE DOUBLE-CHECK:

- Have all questions been answered?
- Has a brief explanation been provided for all questions that were answered with "Yes"?
- Have you provided all the information to the best of your knowledge and belief?
- Is the personal information complete (name, date of birth, address, phone number)?
- Has the informed consent form been signed?
- Does all medical and personal information provided in this questionnaire relate to the time of birth?
- I understand that providing incomplete or false information may cause severe harm to the health of the recipient of the donation or to myself.

Date

Mother's signature

If required, name of the interpreter or translator

Confirmation from the doctor responsible for the cord blood collection

From a medical perspective and in accordance with production instructions (ID 290 „Allogeneic cord blood collection“), there are no grounds for exclusion of the cord blood donation. The eligibility of the donor and suitability of the mother at the time of donation are hereby confirmed.

Date

Name

(Block letters or stamp)

Signature

of the responsible doctor

Remarks:

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Informed Consent Form for Cord Blood Donation

	Mother	Father (if he also has custodial rights and power of representation)
Last name, first name:		
Date of birth:		
Address: (street, postcode, city)		
Phone number:		
Email (requested):		

I hereby declare my consent to the planned collection and donation of my child's umbilical cord blood to DKMS Stem Cell Bank gGmbH.

- I confirm that I was informed about cord blood donation according to the information sheet that was handed out to me and that I had the opportunity to ask questions, which were answered to my satisfaction.
- I hereby confirm that the information provided on the mother, father and child is correct, and I undertake to inform DKMS Stem Cell Bank gGmbH of any change of address. If DKMS Stem Cell Bank gGmbH has reason to believe that my address data is incorrect, I consent to an inquiry at the resident's registration office.
- On behalf of my child, I transfer the ownership of the cord blood to DKMS Stem Cell Bank gGmbH so that it can use it in accordance with the purposes described.
- I agree that the respective commissioned testing laboratory may test the cord blood and the blood samples taken for infection markers, such as indirect or direct detection of viruses (e.g. HIV, hepatitis, CMV), microorganisms (e.g. the bacteria that cause syphilis) and hemoglobinopathies (congenital diseases of the red blood pigment) as well as other biological factors (e.g. HLA characteristics), in order to include the cord blood donation in the donor database of DKMS Stem Cell Bank gGmbH. I also agree to the storage of retained samples for possible retesting and to the collection of new samples if necessary.
- I have been assured that the cord blood donation will not be used after the confidential withdrawal procedure. I can submit my withdrawal in writing (Enderstr. 94/Haus C, 01277 Dresden, Germany; office@dkms-stemcellbank.de) to DKMS Stem Cell Bank gGmbH.

Informed consent according to data protection regulations

- With regard to the registration of the cord blood donation, I agree that DKMS Stem Cell Bank gGmbH:
 - may store personal data to identify me and my child (including name, address, date of birth) as well as medical data on our health and genetic data obtained from the above-mentioned laboratory tests in order to include my child's cord blood donation in the donor database of DKMS Stem Cell Bank gGmbH, to verify donor eligibility and to update the donor profile accordingly;
 - may transmit search-relevant data (e.g. age, sex, HLA characteristics) exclusively in pseudonymized form to national and international donor registries for the purpose of finding the right donor;
 - may use my contact details (incl. email, phone number) to contact me if our cord blood donation should become an option for a specific patient.
- In addition, I agree that the clinical staff may share information with DKMS Stem Cell Bank gGmbH about my medical treatment, the medical treatment of my child and the birth. To this end, I release the clinic personnel from medical confidentiality.
- I understand that I can withdraw this consent, without giving reasons, until transfer has made to a patient, by submitting my withdrawal to DKMS Stem Cell Bank gGmbH (Enderstr. 94/Haus C, 01277 Dresden, Germany; office@dkms-stemcellbank.de). In the event of withdrawal, my data will be deleted, unless there are statutory deadlines to the contrary.
- I have noted the additional explanations on the separate "Data protection information sheet."

Please make an individual decision regarding the following: If the donation does not meet the quality criteria for use for a patient, I agree that the cord blood donation

☐ **Yes** ☐ **No** May be used for **quality assurance at DKMS Stem Cell Bank gGmbH** (see Section 7.1 of the information sheet).

☐ **Yes** ☐ **No** May be used for **worldwide scientific research** (see Section 7.2 of the information sheet).

Date, location	_____	Date, location	_____
Name	_____	Signature	_____
	(Block letters or doctor's stamp)		(Mother)
Signature	_____	Signature	_____
	(Doctor providing information in the collection clinic)		(Father if he also has custodial rights and power of representation)

(If required, name of the interpreter or translator)

write: for DKMS
pink: to be retained by patient
blue: to be retained by the hospital

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Data Protection Information Sheet

DKMS Stem Cell Bank gGmbH is aware of its special responsibility to protect your personal data and ensure compliance with data protection and data security regulations. We want to provide you with transparent information about the way we process your personal data in order to comply with our legal obligations.

Processing of your data

When you provide your consent to donate cord blood, we collect your name, the name and sex of your child, your dates of birth, your family background, your contact details including your phone number and email address, some medical details and transplant-related data concerning you and your child, including but not limited to, your HLA tissue type. The personal data collected will be retained and processed by DKMS Stem Cell Bank gGmbH in order to store your cord blood, to register the available donation in the donor database of DKMS Stem Cell Bank gGmbH and to organize the subsequent transfer of your cord specimen to a patient. To the extent possible, your data will be processed under a pseudonym, i.e. a code comprising numbers and/or letters will be used to designate your cord blood donation.

Additional data protection information

- The collection clinic and DKMS Stem Cell Bank gGmbH are joint controllers for data processing during the collection process and have established corresponding data protection agreements in this regard. The controller for further data processing after successful cord blood donation is DKMS Stem Cell Bank gGmbH, Enderstr. 94, Haus C, 01277 Dresden, Phone: +49(0)351 2509660, office@dkms-stemcellbank.de.
- The Data Protection Officer of DKMS Stem Cell Bank gGmbH can be contacted at datenschutz@dkms-stemcellbank.de for questions or concerns regarding joint or individual processing activities.
- The purpose of processing the personal, medical and genetic data concerning you and your child during registration and storage of the cord blood donation is to compare the donor data with potential transplant recipients around the world, to enable DKMS Stem Cell Bank gGmbH to contact you regarding the transfer of your cord blood donation to a recipient, to verify donor eligibility and to update the donor profile accordingly. Your and your child's data will be processed on the basis of your consent in accordance with Article 6 (1) Sentence 1 lit. a) and Article 9 (2) Sentence lit. a) of the General Data Protection Regulation (GDPR).
- Another purpose of the processing of your data is to carry out scientific evaluations with pseudonymized data in the context of the unused donation and stem cell transplant in accordance with Article 6 (1) Sentence 1 lit. f), Article 9 (2) lit. j) of the GDPR for research in accordance with Article 89 of the GDPR in conjunction with Section 27 of the German Federal Data Protection Act (BDSG).
- For registration, your data will be processed by service providers commissioned by DKMS Stem Cell Bank gGmbH (e.g. document processors). Your additional blood sample will be sent to testing laboratories commissioned for analysis, and any residual sample will be stored there. Additional retained samples will be stored at DKMS Stem Cell Bank gGmbH. Disclosure of your data to third parties may be necessary in order to:
 - a) ensure that your data is up to date so that we can contact you in the event of a transplant transfer (registry office).
 - b) transfer your data to companies that acquire the rights, interest and title from us in the event of a merger, acquisition or reorganization.
 - c) cooperate with law enforcement agencies and/or regulatory authorities.
 - d) fulfill legal obligations or comply with court orders.

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- If a previously unknown tissue characteristic (allele) is identified during the analysis of the samples, the DKMS Life Science Lab gGmbH laboratory will publish this allele under its name, country of collection and year of collection with the responsible institutions (European Nucleotide Archive (ENA), IPD-IMGT/HLA Database). The publication will not include any identifying information on the origin of the allele.
- All search-relevant data for the procurement of a cord blood donation (e.g. age, sex, HLA characteristics) are pseudonymized and shared with international organizations via the German National Bone Marrow Donor Registry (ZKRD) in Ulm for the purpose of finding a donor. The institutions making the request (other donor registries, transplant hospitals, etc.) that process your search-relevant data in the context of an active procurement may also be located in countries that potentially have a lower level of data protection than the European Union (EU) or the European Economic Area, e.g. the USA. As a result, there is a risk that government agencies or private institutions may access your data for surveillance purposes. In addition, you may be entitled to fewer or less enforceable remedies there than under European data protection law. The EU standard contractual clauses have been agreed with the vast majority of international donor registries in order to establish a level of data protection that is adequate for the EU pursuant to Article 46 (2) lit. c) of the GDPR. Regarding the few other international donor registries that do not provide an adequate level of data protection, we ask for your consent in accordance with Article 49 (1) lit. a) of the GDPR for the transmission of your search-relevant data. As a security measure, your data will be encrypted with a pseudonym (without mentioning your name) before transmission in order to exclude the risk of your person being identified by unauthorized third parties as far as possible.
- Your cord blood donation will be made available for worldwide foreign donor search for a limited period of time, i.e. until the expiry date of the cord blood donation, to enable your donation to be requested and used for a patient. After the expiry date, it may be used for quality assurance and/or scientific research, subject to your consent. Otherwise, the sample will be destroyed and the reference to your person will be deleted, unless there are longer statutory retention requirements (e.g. in case a donation to a patient was performed).
- You have the following rights under the GDPR with regard to your personal data: to access (Article 15 of the GDPR), rectification (Article 16 of the GDPR), erasure (Article 17 of the GDPR), blocking, i.e. restriction of processing (Article 18 of the GDPR) and data portability (Article 20 of the GDPR). With regard to data processing for the purpose of carrying out scientific evaluations according to Article 89 of the GDPR and Section 27 of the BDSG, you have the right to object in accordance with Article 21 of the GDPR.
- Your consent is voluntary. You may withdraw your consent to DKMS Stem Cell Bank gGmbH at any time and without giving any reasons. The withdrawal does not affect the lawfulness of the processing carried out up to this point. In this case, your data will be deleted and the sample will be destroyed, unless there are other statutory retention requirements.
- If you have a complaint concerning our handling of your personal data, you can contact our Data Protection Officer at datenschutz@dkms-stemcellbank.de or by mail to DKMS Stem Cell Bank gGmbH, Data Protection Officer, Enderstr. 94, Haus C, 01277 Dresden, Germany, and we will look into the matter.
- You have the right to lodge a complaint with a supervisory authority in accordance with Article 77 of the GDPR, particularly with the authority responsible for your place of residence or the data protection authority responsible for DKMS Stem Cell Bank gGmbH (Saxon Data Protection Regulator, <http://www.saechsdsb.de/n-kontakt>).

Additional information on data protection is available on the website <https://www.dkms-stemcellbank.de/datenschutz/>.

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Information Sheet for Cord Blood Donation

1 What is cord blood?

During pregnancy, the umbilical cord provides your baby with everything it needs for healthy development. For this purpose, the cord blood flows back and forth between the bodies of the mother and the child. This provides the baby with nutrients and protection against infection, for example.

After the birth and once the baby's umbilical cord has been cut, the umbilical cord is no longer needed. Mother and child are now separated from each other. But that does not mean that the cord blood has become useless. As it contains stem cells, among other things, it can be donated to benefit other people. Otherwise it is discarded.

2 What can cord blood be used for?

Stem cell transplants are a promising treatment for patients with malignant, hereditary or acquired diseases of the blood-forming system, such as leukemia, thalassemia or aplastic anemia, and enzyme defects. These cells can be collected from the bone marrow or circulating blood of voluntary donors after stimulation with growth factors. An equivalent option is the transplant of stem cells from cord blood.

3 Pre-requisites for cord blood donation

Cord blood donation is considered a blood donation that is subject to legal requirements (e.g. the German Medicinal Products Act, the German Transfusion Act and the guidelines issued by German Medical Association). This means that some formalities are needed prior to donation. In addition to this information sheet, you will receive a case history sheet containing questions on your medical history, an informed consent form and a data protection information sheet. The case history sheet and informed consent form must be completed and signed by you.

4 Why do we need personal data?

The name and address of the mother and, if applicable, the father, are needed to inform the mother or the parents about whether the donated cord blood is processed or discarded. A phone number must be provided so that contact can be made quickly in case of queries, in particular to ask about the child's current health status when there is a specific request on behalf of a patient. The information is also compared to the patient number used in the hospital to ensure that the mother can be uniquely identified.

There are regional differences in tissue characteristics and their combinations, and there is a higher likelihood that these characteristics match within the same ethnic group. Often, donor registries or cord blood banks are inactive or hardly active in regions where people with rare tissue characteristics come from. The family background therefore makes the search for suitable donors faster and more targeted.

5 Collection of cord blood

Cord blood can only be collected within the donation times defined at the clinic. If delivery occurs outside of this period and thus while collection is suspended, it will not be possible to collect cord blood.

On the day of delivery, some blood (approx. 33 ml) is collected from you for routine examinations. After the birth of your baby, the umbilical cord is clamped first and then cut, and the baby is cared for. The blood contained in the umbilical cord (60 ml on average) is now extracted and collected in a sterile bag. This does not constitute any disadvantage or danger to you or your baby at any time.

The cord blood is then transported to DKMS Stem Cell Bank gGmbH (hereinafter referred to as DKMS SCB), where it is processed. The stem cells are then stored in nitrogen tanks at 180 °C, even for longer periods if necessary.

At the same time, tests are carried out on the mother's blood and the cord blood. It is examined for example for infectious diseases, such as syphilis, hepatitis B/C, CMV, HIV, HTLV, and hemoglobinopathies. The tissue characteristics are also determined. The personal data concerning you and your child are entered in the DKMS SCB database, where they are linked with the cord blood donation and stored for an indefinite period of time. If the results of all examinations are satisfactory, your donation will be made available to transplant centers around the world via national and international stem cell registries. Patients who may receive your donation suffer from diseases of the blood-forming system, for example, and are treated with blood stem cell transplants. Transplant centers and patients are not provided with any data that identify you or your child. The donation is labeled using a unique pseudonym (number and/or letter code).

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6 Reporting of abnormal findings or infections

Testing your blood samples and cord blood in the laboratory can yield significant findings relating to your health. Due to the associated transmission risk, you will always be notified if any infections with pathogens are detected for which notification is mandatory under the German Infection Protection Act (*IfSG*). There is also a legal obligation to report certain infections to the competent authority. For infections that must be reported by name (Sec. 7 (1) of the *IfSG*), the report is made including your name, sex, date of birth, address and other contact details. In case of infections that do not have to be reported by name (Sec. 7 (3) of the *IfSG*), the report is made including your sex, month and year of birth, the first three numbers of your postcode and, in case of HIV infections, also a pseudonym of your name.

7 Use of your donation for research

It is possible that a cord blood donation does not meet the quality criteria and therefore cannot be used for a patient. Nevertheless, your donation is always valuable to DKMS SCB, because it can help in other ways. We therefore ask you to agree to the use of your donation for the following alternative purposes, if it cannot be stored at DKMS SCB.

- 7.1 *Quality assurance: internal validation and process development at DKMS SCB as well as training of new employees. This serves to maintain high quality standards and to optimize processes, if necessary.*
- 7.2 *Scientific research: scientific research to improve the effectiveness and safety of stem cell transplants. Such research projects may be carried out in cooperation with universities, research institutes and other research institutions, or independently by such organizations. The prerequisite for such use is that the projects have been reviewed by the responsible ethics committee and that the cord blood products are only used after re-pseudonymization.*

The use or release of a cord blood product for commercial purposes is excluded. At the end of the informed consent form, you have the option to make a personal decision regarding these points. If you do not agree to the use of your donation for research, the cord blood product which has been excluded from use for stem cell transplants will be destroyed.

8 Can the cord blood be used and stored for my newborn child?

For a number of years now, it has been possible to store cord blood for the newborn child. According to current developments in science, there are no generally valid areas of application for this type of cord blood, which is referred to as "autologous." However, it cannot be ruled out that possible applications will be developed in a few years' time, meaning the stored cells could possibly be used at a later date. In the case of private storage, the specimen primarily belongs to the child and, in exceptional cases, to the child's family. Without a medical indication, autologous storage is not possible at DKMS SCB.

9 Directed cord blood donation

The special case of directed donation is defined as cord blood donation for a sick sibling or another first-degree relative for whom an indication for a transplant exists or may arise due to an illness. In the case of a directed donation, the specimen is available exclusively to the sick person.

If you have any questions about the storage of cord blood for your own child or about directed cord blood donation, we will be happy to provide you with more information.

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10 What are the next steps?

If you decide to make a donation, please contact a DKMS SCB cooperation hospital. There, you will be provided with detailed information about the entire cord blood collection process and receive the necessary documents. The documents can also be downloaded from the DKMS SCB website (<https://www.dkms-stemcellbank.de/eltern/>).

The informed consent form you have signed and the case history sheet you have completed will be sent to DKMS SCB in Dresden (together with other documents and the cord blood), where it will be checked.

The decision regarding acceptance, further processing and storage of your cord blood donation as well as its transfer to a patient is determined by the persons responsible at DKMS SCB in compliance with the legal provisions governing medicinal products.

In the event of cryopreservation (storage) of your cord blood, retained samples will always be kept for possible serological follow-up testing for infectious diseases of you and your child.

A stem cell transplant carries the risks of transmitting infections and genetic diseases to the patient. Therefore, your donation will only be made available to transplant centers, and thus to patients all over the world, if the results of all examinations are satisfactory. Please inform DKMS SCB immediately if there are any reasons related to the donation at this or a later date that could affect the quality of the cord blood donation (e.g. infectious disease such as HIV, cancer, serious condition of the blood-forming system in you and/or your child, genetic diseases). We hereby assure you that all information will be treated confidentially and that the donation will not be used after the confidential withdrawal procedure.

If your cord blood donation is requested for a patient, DKMS SCB will call you to inquire about the history of your child's health. This is necessary in order to rule out diseases that are not yet detectable at the time of donation. The patient's treating hospital will only make a specific selection for cord blood donation after all the relevant information has been obtained.

Your decision to donate cord blood is voluntary, and the donation is made without payment. If you decide against collection, this will not result in any disadvantages to you. You will not incur any costs. You may withdraw your consent to donating cord blood to DKMS SCB at any time and without giving any reasons. In this case, your donation to DKMS SCB will be destroyed.

We hope this information has helped you increase your knowledge and understanding about umbilical cord blood donation. If you have any further questions, please contact us or one of the cooperating hospitals.

DKMS SCB staff will be happy to assist you:

Phone: +49 (0)351 250 966 0

Email: office@dkms-stemcellbank.de