

RISK FACTORS FOR INFECTIOUS DISEASES				Mother	Father	
Relevant to both parents						
8	Which countries were the baby's parents born in?			_____	_____	
9	Has either parent lived or travelled outside Europe in the last 5 years?			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	Country	Dates (mm/yyyy)	Duration			M/F/both
	Did you require additional vaccines? If yes, for which diseases?					
	Did either of you contract a tropical disease (e.g. malaria, dengue fever, leishmaniasis etc.) during a trip?					
	Details (date and type)					
10	Do you or your partner have a history of any of the following: multiple tattoos, needle-stick injuries, IV drug abuse or have been at risk of sexually transmitted diseases?			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
11	Have you ever been refused as a blood donor? Indicate reason and date:			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
12	Have you ever had a blood transfusion, transfusion of other blood products, an organ transplant, tissue or cells from a human donor, or a xenograft (graft taken from another species)? Have you received hormones of human or animal origin? Indicate type and date:			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13	Have you spent 3 months or more in the UK between 1980 and 1996?			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTIONS RELATED TO GENETIC DISEASE				Mother	Father
Relevant to both parents					
14	Have you, your partner or your children ever suffered from any inherited condition e.g. thalassaemia, sickle cell, platelet or bleeding disorders or other genetic, metabolic, mitochondrial or autoimmune disease? Please indicate disease and genetic details if known e.g. type and carrier status.			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
15	Have any other relatives suffered from any of the diseases mentioned in Q14? Please provide details of the disease(s) and the relationship of each person to your baby.			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
16	Have you, your partner or children undergone genetic testing? What were the results?			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
17	Have you or your partner ever suffered from any form of cancer? Details _____ When was treatment completed? (mm/yyyy) _____			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

QUESTIONS ON THE USE OF MEDICINES		Answer
Relevant to the mother		
18	Have you taken antibiotics or medication for virus or fungal infections during the pregnancy? Please list (name, dates, reason)	<input type="checkbox"/> Yes <input type="checkbox"/> No
19	Have you taken any other medication (excluding vitamin and iron supplements) during the pregnancy? Please list (name, dates, reason)	<input type="checkbox"/> Yes <input type="checkbox"/> No
20	Have you received any vaccinations during the pregnancy? Please list (name, date)	<input type="checkbox"/> Yes <input type="checkbox"/> No

QUESTIONS ON THE USE OF MEDICINES		Answer
Relevant to the <u>mother</u>		
21	Are your routine vaccinations as required by the relevant national program up to date? If not, please specify what is missing: _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No

FINAL HEALTH QUESTIONS		Mother	Father
Relevant to both parents			
22	Do you or the baby's father suffer from a chronic disease not covered in the previous questions? Details: _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

Additional Notes

I confirm that the medical history above is accurate and as complete as possible.

If there is any change in the responses given on this Questionnaire before the birth, and/or if the baby develops any pathology that may compromise the future use of the cells, I must inform FamiCord Group.

INFORMED CONSENT

A. Purpose and nature of procurement

Collection: The medical team assisting the delivery will collect a blood sample from me, the mother, my child's cord blood (CB) and, where applicable, umbilical cord tissue (CT) and placental tissue (PT), using the kit previously provided by FamiCord Suisse. Collection of CB, CT and PT is a painless procedure both for me and for the baby and occurs after clamping of the cord.

Cord Blood: The CB collected at the time of the birth will be processed, frozen and stored at a temperature below -150°C in containers with liquid nitrogen (cryopreserved) for potential medical use by my child (autologous) or a suitably matched family member (directed allogenic). The cells may only be used for an approved therapy, within an authorized clinical trial or under hospital exemption. Reference samples will be stored for future testing.

Cord Tissue: According to the service package chosen, the CT will either be:

1. Stored and cryopreserved in fragments as a starting material. These will require further processing at a future date to isolate and culture mesenchymal stem cells before they can be used in EU as a medical product (regulated in the European Union as Advanced Therapy Medicinal Products (ATMPs) or in Switzerland as Transplant Product (TP).

OR

2. Mesenchymal stem cells will be directly isolated and cultured from the fresh CT and stored instead of the fragments, as an intermediate product, in preparation for use in Europe as ATMP, or in Switzerland as TP.

Placental Tissue: Chorionic villi from the placenta will be cryopreserved and stored in fragments as a starting material which will require further processing at a future date to isolate and culture mesenchymal stem cells before they can be used in EU as ATMP or in Switzerland as TP.

B. Quality Control and Testing

Maternal Blood Sample: A sample of blood from the mother will be used to test for infectious diseases including HIV, hepatitis B, hepatitis C, HTLV, CMV, syphilis, toxoplasmosis and others as required, and samples may be kept frozen for future testing. These are required by law. The results will be made available to you.

Positive results may limit the storage and/or future use of the cord blood or stem cells. In addition, they may indicate that you are suffering from an infection that you were previously unaware of. Any positive results should be shared with your doctor, who can guide you on any necessary follow-up for you or your baby.

Cord Blood: Tests will be carried out on the CB to assess the quality of the sample including, but not limited to, total cell count, total cell viability, mononuclear cell and CD34+ cell counts, cell viability, and sterility testing with identification of the contaminating organism, if present, and antibiotic sensitivity.

Cord Tissue and Placental Tissue: CT and PT samples will also be tested for bacterial contamination. Excess tissue remaining after processing will either be discarded and destroyed or it may be used for internal quality control or in-process validation prior to destruction. In both cases, under full preservation of anonymity and without influence on the quality of the service.

C. Destruction of Biological Materials

Famicord is hereby authorised to destroy biological materials (CB, CT and/or PT) when they cannot be stored, handled and processed as intended.

D. Personal Data Protection

In compliance with the General Data Protection Regulation („GDPR“) dated 25 May 2018 and the new Swiss Federal Data Protection Act dated 01 September 2023 („nFADP“) currently in force, FamiCord Suisse undertakes to adopt the appropriate measures to protect the confidentiality of the information resulting from the tests, ensuring the safety of the facilities and equipment, control of access to information, as well as strengthening the duty of confidentiality and ethical training of all professionals involved.

For legal and technical reasons related to the full traceability of the collected and preserved samples, the laboratory will have to record and store the personal data in the agreement, as well as the procurement date and location, for a time equal to the duration of the signed agreement. The data and information may be processed for the purposes of fulfilment and execution of the contract, by Famicord, as well as by third parties, including international parties.

The data subject may exercise the rights of access and amendment to the processing of their data in writing by contacting kundendienst@famicord.ch

You can find further information about your rights and data processing at FamiCord in the Attachment 'Personal Data Processing Policy' of your service contract.

E. Medical Confidentiality

Any medical information relating to the parents or the Child, will be treated with confidentiality to protect identities and privacy. This information may only be communicated to third parties after formal written consent from the parents (or the child once over the age of 18) or by law enforcement.

F. Consequences and Risks

I accept that

1. There is no guarantee that the collection will be successful or that the material obtained will be sufficient to yield an adequate number of stem cells or tissue fragments necessary for producing ATMP or TP.
2. The medical team may refuse to collect the biological samples if they determine that the conditions at the time of delivery are unsafe or unsuitable. They cannot be held responsible when the collection cannot be performed.
3. Delayed cord clamping is associated with a reduced volume of CB that can be collected for storage which may limit future application.
4. For CB, CT and PT there is always a risk of microbiological contamination of the samples at the time of collection which may limit future application.
5. Famicord Suisse S.A. may contact me at any time

G. Therapeutic purpose and potential benefits

I acknowledge that

1. There is no guarantee that therapy with cells from umbilical cord blood, umbilical cord tissue or placenta tissue will work, or that the cells are compatible with any member of the family (except for the baby) or that the cell transplant is successful. The therapeutic result of a stem cell therapy or transplant depends on many factors beyond the availability of stem cells, such as the patient's condition, the type of illness, the compatibility between donor and recipient, etc.

2. Other sources of stem cells exist including bone marrow, peripheral blood and cord blood from public banks, which have been successfully used in the treatment of some diseases treatable with CB stored for family use.

3. The cord blood may be used for approved therapy, within an authorized clinical trial or under hospital exemption. Currently, stem cells from CT or PT may only be used in an authorized clinical trial or under hospital exemption. This may change in future as stem cell treatments develop.

H. Consent

I declare that

1. I, the mother, hereby give my consent on behalf of myself and my unborn child for FamiCord Suisse S.A. and its associated laboratory to receive, process, analyze, cryopreserve, and store my child's cord blood (CB), and, if applicable, cord tissue (CT) and placental tissue (PT), for potential future medical use, as well as my maternal blood.
2. I have been duly informed about the whole procurement process, including the need for my informed consent, and about the cryopreservation of stem cells from my child's umbilical cord blood, umbilical cord tissue and placenta tissue and that I can revoke this consent freely at any time until the birth of my child.
3. I agree to notify FCS in case of diagnosis of a serious infection (HIV, hepatitis, etc.) or hereditary and/or neoplastic disease (cancer) diagnosed in the child and/or in close family members.
4. I hereby authorize Famicord Suisse S.A. to destroy biological materials (CB, CT and/or PT) when they cannot be stored, handled and processed as intended.
5. I have read and understood, and I agree with the information provided.

Date _____ Mother's Signature _____	
Date _____ Father's Signature _____	
Signature and Identification (sticker Stamp) of attending physician (if applicable)	
Stamp or Sticker	Attending Physician, Name and Signature