

BIOSCIENCE INSTITUTE S.p.A., with its registered office at via Rovereta, 42 – 47891 Falciano -Repubblica di San Marino – (hereinafter Bioscience Institute) represented by Mucci Giuseppe, in the capacity of Sole Director – Economic Operator Code 20021 Public Register of Companies number: 3794

Mother's details

Surname		First name		Place of birth	
Prov.	Date of birth	Citizenship	Tax code (Codice Fiscale)		
Residential address		Postcode	City	Prov.	
Telephone		Mobile	Email		

Father's details

Surname		First name		Place of birth	
Prov.	Date of birth	Citizenship	Tax code (Codice Fiscale)		
Residential address		Postcode	City	Prov.	
Telephone		Mobile	Email		

(Mother and Father hereinafter, jointly: PARENTS)

(Bioscience Institute and the parents, jointly: the PARTIES)

1. RECITALS

By this instrument (hereinafter CONTRACT), the undersigned PARENTS, on their own behalf and on behalf of their son/daughter (hereinafter: UNBORN CHILD), over whom they declare that they exercise parental responsibility, entrust BIOSCIENCE INSTITUTE S.p.A. (hereinafter: LAB) with the task of processing and storing by freezing the stem cells obtained from the blood and/or tissue of the umbilical cord collected at the time of birth (hereinafter: SAMPLE), in accordance with the provisions contained in this CONTRACT. This CONTRACT becomes binding between LAB and the PARENTS from the date of receipt of the collection kit by the PARENTS and, on the terms provided for in this CONTRACT, with respect to the UNBORN CHILD upon reaching the age of majority.

By signing this CONTRACT, the undersigned PARENTS agree to have the SAMPLE processed and stored at LAB's laboratory for autologous use and declare that they accept the following:

1.2 This CONTRACT must be signed by at least one of the PARENTS. If it is signed by only one of the PARENTS, regardless of any agreement or lack of agreement between them, LAB shall act on the basis of the instructions given by the signing PARENT. In such case, the term PARENTS shall be used in this CONTRACT to refer also to the sole signing parent.

1.3 The PARENTS are aware and informed that the therapeutic use of stem cells isolated from umbilical cord blood is such that it may bring benefits to the unborn child in the treatment of certain diseases, although therapeutic success is not guaranteed. They are also aware that at present there is no clinical evidence relating to a possible therapeutic use of the mesenchymal stem cells isolated from cord tissue, other than in an experimental setting, nor regarding the maintenance of their cell viability over time.

1.4 The recitals form a substantive part of this CONTRACT.

1.4 Glossary: CD34+ = cells that express on their surface the CD34 antigen, used as a marker for the identification and quantification of haematopoietic stem and progenitor cells; Haematopoietic stem cells = stem cells present in peripheral blood, bone marrow and umbilical cord blood; CNT = National Transplant Centre (Centro Nazionale Trapianti); Full blood count = blood test for the determination of the formed elements; GMP = Good Manufacturing Practice; HBsAg = Hepatitis B surface antigen; Anti-HBc = Hepatitis B virus anti-core antibodies; HCV = Hepatitis C virus; HIV = Human immunodeficiency virus; HLA = Human Leukocyte Antigens; HTLV = T-cell lymphotropic virus; ISO = International Organization for Standardization; TPHA = Test for syphilis; Heterologous transplant = transplant in which donor and recipient are two different individuals;

Autologous transplant = transplant in which donor and recipient are the same person; WBC = White Blood Cells, or leucocytes.

2. SUBJECT MATTER, DURATION AND EFFECT

2.1 The subject matter of this CONTRACT is the processing of the umbilical cord blood (if requested, of the cord tissue) and the cryopreservation of the stem cells at the laboratories having their registered and operational office in Località Falciano, via Rovereta 42 - Repubblica di San Marino, which are the exclusive property of LAB, for autologous use according to the instructions that will be given by the PARENTS or, on reaching the age of majority, by the UNBORN CHILD.

2.2 This CONTRACT shall have a minimum duration of 20 (twenty) years and may be extended, from year to year, starting from the twenty-first year, through continuation of the storage service and payment of the related annual fee, without prejudice to the provisions of arts. 10.1 and 16.1 concerning the exercise of rights over the SAMPLE and the person who bears the cost of the service.

2.3 This CONTRACT becomes binding and takes effect between LAB and the PARENTS from the date of receipt of the collection kit by the PARENTS. Two copies of this CONTRACT, duly signed by the PARENTS, must be returned to LAB strictly before the birth.

3. COLLECTION

3.1 It is the sole responsibility of the PARENTS to carry out all the procedures necessary to obtain the issue, by the medical directorate of the facility where the birth will take place, of the clearance for the export of the cord blood.

3.2 The collection of the SAMPLE is the sole responsibility of the PARENTS, who shall verify its feasibility and agree on it with the healthcare staff, in accordance with LAB's Collection Instructions, enclosed in the dedicated Kit.

3.3 It is the obligation of the PARENTS to ensure that the healthcare staff responsible for the collection have carefully read the Collection Instructions, have understood their contents and have checked that everything necessary is available.

3.4 LAB shall in no case be liable for the actions of the healthcare staff chosen by the PARENTS for the collection of the SAMPLE.

4. REFUND

4.1 The PARTIES agree that the PARENTS are not required to pay the balance for the services requested if the collection of the cord blood and/or tissue has not taken place or if the processing of the

SAMPLE was limited to the assessment of the CD34+ cell count and of viability, but the SAMPLE was not frozen (see art. 8.1). In such case this CONTRACT shall cease to have any effect between the PARTIES, save for the obligation of confidentiality referred to in art. 21.

4.2 In the event of a positive result in one of the tests referred to in point 5.1, performed within the time limits provided for therein, the amount paid on receipt of the kit shall be refunded.

5. PROCEDURES FOR STORAGE

5.1 During the 30 (thirty) days preceding the expected date of birth, the following tests must be performed on the mother's blood and serum - anti HIV 1 - 2, - HBsAg, - anti-HBc (IgG-IgM), - anti HCV, - TPHA, - anti HTLV 1 - 2. The results of the above tests (bearing the date of sampling) must be sent to LAB together with the kit, in the dedicated TEST RESULTS ENVELOPE. If the results of the above tests are not yet available or the tests have not been performed, LAB must be informed; in any case, the tests must be carried out no later than 7 (seven) days after the birth.

5.2 In compliance with Directive 2006/17/EC (Annex II, point 2.5, letter b), it is mandatory to observe the quarantine period by repeating the TESTS on maternal blood 180 days (6 months) after the birth and sending those results to LAB. The blood tests must bear the validation signature and the date of sampling and must contain the results of the tests referred to in point 5.1.

5.3 In the event of a positive and/or doubtful result of one or more tests performed on the mother's serum and blood, whether before or after the birth, further investigations may be requested.

5.4 In the event of failure to comply with the provisions of points 5.2 and 5.3, LAB shall notify the PARENTS using the latest contact details available, inviting them to fulfil the required obligations within 30 (thirty) days of receipt of the notice. If that period expires to no avail, LAB shall no longer be required to continue storing the SAMPLE and shall be authorised to proceed with its disposal in accordance with the provisions of this CONTRACT, while in any event retaining the right to payment of the balance for the services, or to retain that balance if already paid.

Should the notice be undeliverable owing to inaccuracy, deactivation or failure to update the contact details, LAB shall not be required to search for different or additional contact details and the procedure provided for in arts. 10.2 and 10.3 shall apply.

6. PREPARATION FOR TRANSPORT

6.1 Once the SAMPLE has been collected, it is the obligation of the PARENTS to ensure that the adhesive label has been completed with all the required data and applied to the collection bag of the cord blood sample and to the container of the cord tissue sample, if collected.

It is the obligation of the PARENTS to ensure that the shipping KIT clearly and correctly shows the address of the Sender and that of the Recipient on the waybill. LAB is released from liability in respect of any errors in the preparation for transport.

7. TRANSPORT

7.1 Once the birth has taken place, the PARENTS are required to contact LAB at the contact details indicated in art. 20.3 of the contract so that it may activate DHL for the ordinary procedure provided for the pick-up and shipment of the SAMPLE; the PARENTS are also required to follow all the procedures provided for the transport of cord blood and to check that the SAMPLE is placed in the container supplied by LAB for transport.

7.2 LAB shall not be liable for damage, loss, late delivery or any other event connected with the transport of the SAMPLE attributable to the appointed courier. The cost of transport is included in the price referred to in art. 9.3 of this CONTRACT.

If the birth takes place on a Saturday, the pick-up of the collected cord blood will be carried out on the Monday.

If the birth takes place close to public holidays and the DHL service is not available, LAB shall use, at no additional cost to the PARENTS, an ALTERNATIVE courier able to guarantee delivery in time for the freezing of the SAMPLE; unless the PARENTS intend to make the delivery personally.

7.3 To carry out the transport, LAB uses a courier of proven reliability. The provisions of the preceding art. 7.2 remain unaffected. Where the PARENTS consider it appropriate to use a trusted courier of their own, they may do so, at their own expense and under their own responsibility, managing the logistics themselves, provided that they give prior notice to LAB and the sample arrives at the laboratories in time to be frozen.

8. SERVICES OF LAB

8.1 Processing. The SAMPLE received by LAB will be processed using procedures compliant with the applicable legislation and with the quality and safety standards adopted by the laboratory and applicable to the service. LAB freezes cord blood samples with a quantity of CD34+ cells greater than 100,000. For samples with a quantity below this threshold, the provisions of art. 23 apply.

8.2 The PARENTS expressly authorise LAB to carry out on the SAMPLE the analyses and tests necessary to verify the suitability of the SAMPLE and the correct performance of the processing and storage procedures provided for in this CONTRACT. Following the processing and storage of the SAMPLE, LAB will issue to the PARENTS, in the manner and within the terms provided for in art. 9.1, a certificate attesting the analyses carried out, the outcome of the processing and the completed storage of the SAMPLE of the UNBORN CHILD, provided that the payments relating to the services requested have been duly made. On reaching the age of majority, the related documentation will be issued to the UNBORN CHILD, at his or her request, in accordance with art. 10.1. The PARENTS or, on reaching the age of majority, the UNBORN CHILD may visit LAB's laboratories by prior appointment agreed with the Technical Directorate.

8.3 LAB shall store the SAMPLE in dedicated cryobiological containers designed to hold other biological samples in separate compartments. LAB is authorised to transfer the SAMPLE, where necessary, to another laboratory or other suitable place, guaranteeing a quality level of processing and storage at least equal to the previous one. LAB shall give notice thereof using the latest contact details available, without prejudice to the obligation to update provided for in art. 22.4.

8.4 Subject to and without prejudice to the provisions of art. 9.4 and art. 10, LAB undertakes to return the SAMPLE in accordance with the instructions and within the times that will be agreed with the PARENTS or, on reaching the age of majority, with the UNBORN CHILD, guaranteeing that such return takes place in compliance with the quality procedures laid down by the applicable reference standards. LAB declares that it complies with the GMP (Good Manufacturing Practice) standard in accordance with European Directives 2001/83/EC, 2003/94/EC and 2006/86/EC.

8.5 In the event of return of the SAMPLE for therapeutic purposes, LAB shall reimburse any expenses incurred by the PARENTS or, on reaching the age of majority, by the UNBORN CHILD for the stem cell transplant up to a maximum amount of €20,000.00 (twenty thousand). The reimbursement is made against documentation of the expenses actually incurred for the transplant.

9. PRICE

9.1 Prices and methods of payment:

Enrolment fee for the service (mandatory)	€200.00 (two hundred)
payment is made cash on delivery to the courier	

SERVICES REQUESTED (one box must be ticked)	
☐ A freezing of cord blood	€2,000.00 (two thousand)
☐ B freezing of cord tissue only	€600.00 (six hundred)
☐ C freezing of blood + tissue	€2,400.00 (two thousand four hundred)
payment is made once freezing has taken place, by: Rid/bank transfer	

annual fee (mandatory)	€50.00 (fifty)
payment is made from the second year of cryopreservation onwards, by: Rid	

The invoice for the balance of the services requested is issued only if the freezing has been successful, and is sent by email. In the case of service C, if freezing was possible only for the cord blood or only for the cord tissue, the amount of the invoice will be equal to that indicated at point A or point B respectively.

The cryopreservation certificate is sent by email using a two-factor authentication system within 60 days following payment of the aforesaid invoice.

The prices include transport costs (except where the courier is chosen independently by the PARENTS) and taxes. The annual cryopreservation fee is adjusted in line with ISTAT indexation.

The invoice for the fee is sent annually by email to the address of the

person named on the invoice.

9.2 In the event of a twin birth, a discount of 50% is applied to the services (9.1.A) of freezing, characterisation and molecular biology for the cord blood SAMPLE of the second unborn child.

For any payment of the services in instalments, LAB's administrative office must be contacted at least 15 days before the expected date of birth. Such methods of payment are subject to authorisation.

9.3 Services included in the price:

The enrolment fee includes shipment of the collection kit; The service described under letter A of point 9.1 includes:

transport of the sample from the place of collection to the laboratory (see art. 7.2), processing of the blood and extraction of stem cells, laboratory tests for cryopreservation purposes, certification of the outcome of the processing, freezing of the stem cells in bag and overbag, biological cryopreservation for the first year; in the event of return of the SAMPLE for therapeutic use:

- > reimbursement of HLA typing on the SAMPLE and on the recipient
- > transport and supply of the container for transport (in nitrogen)
- > reimbursement of any transplant expenses incurred, up to €20,000.00 (twenty thousand);

The service described under letter B of point 9.1 includes:

freezing of the cord tissue and cryopreservation;

The annual fee referred to in point 9.1 covers the costs of the annual biological cryopreservation of the SAMPLE obtained from the cord blood and/or tissue and runs from the second year, for the entire duration of the CONTRACT.

9.4 In cases of return of the SAMPLE for therapeutic use, LAB provides the PARENTS or, on reaching the age of majority, the UNBORN CHILD, on free loan for use, with the packaging system (Dry Shipper) and the technical organisation to allow the safe transport of the SAMPLE itself in accordance with international regulations. The return may be requested from LAB by ordinary post or email, by the PARENTS or, on reaching the age of majority, by the UNBORN CHILD.

10. RIGHTS OVER THE SAMPLE

10.1 All rights over the SAMPLE are conferred on the UNBORN CHILD. Until the age of majority is reached, such rights are exercised by the PARENTS and/or by the guardians or curators in the event of guardianship or curatorship. LAB is authorised to assume, in the absence of specific written notice, that the legal representatives of the unborn child are the PARENTS; LAB is not required to carry out any kind of verification in this respect.

Throughout the period of validity of this CONTRACT, any event concerning the legal representation of the UNBORN CHILD must be promptly notified to LAB in writing.

On reaching the age of majority, all rights over the SAMPLE shall be exercised exclusively by the UNBORN CHILD, except in cases of judgments of incapacity.

10.2 In cases where this CONTRACT provides for the cessation of storage or the disposal of the SAMPLE, if it is not possible to contact the PARENTS or, on reaching the age of majority, the UNBORN CHILD, owing to inaccuracy, deactivation or failure to update the contact data, LAB shall make the attempts at communication using the latest contact details available. Once a period of 90 (ninety) days has elapsed from the last documented attempt at communication without it having been possible to establish contact, LAB shall be authorised to proceed with the disposal of the SAMPLE even in the absence of a specific written authorisation or confirmation from the PARENTS or the UNBORN CHILD.

10.3 Signature of this CONTRACT constitutes express acceptance and prior authorisation for LAB to proceed with the disposal of the SAMPLE in the circumstances and in the manner indicated above, without the need to obtain a subsequent written authorisation.

11. WARRANTIES OF THE PARENTS

11.1 The PARENTS expressly declare that they have assessed with a competent doctor every aspect relating to the collection, transport, freezing and storage of the SAMPLE; that they have carefully examined this CONTRACT and accept without reservation all the provisions contained herein; that they are aware that the collection, transport, freezing and storage of the SAMPLE derive from a conscious expression of their will.

12. EXCLUSION OF LIABILITY

12.1 LAB shall not be liable for the actions of the healthcare staff appointed by the PARENTS for the collection of the SAMPLE.

As regards the transport of the SAMPLE to the LABORATORY, the provisions of art. 7 apply.

12.2 LAB shall not be required to perform any service of a medical nature, medical consultancy or other function other than those described in this CONTRACT.

12.3 LAB does not guarantee that the SAMPLE collected will be sufficient for the purposes of processing and storage or for future use for any purpose.

12.4 LAB does not guarantee the current or future therapeutic or other value of the SAMPLE.

12.5 LAB shall not be liable for any interruptions or alterations of the cryopreservation process due to factors or circumstances not attributable to it. LAB adopts control procedures and systems aimed at maintaining the characteristics of the SAMPLE and at the safety of the cryopreservation process, in compliance with the applicable legislation in force and the relevant technical and quality standards.

12.6 The PARENTS accept without any reservation the exclusions of liability of LAB contained in points 12.1 to 12.5.

13. COMPENSATION FOR DAMAGE

13.1 LAB shall be liable only in the event of wilful misconduct or gross negligence. In such case the compensable damage is limited exclusively to the total amount paid under this CONTRACT. Further damage of any kind will not be compensated.

14. WITHDRAWAL

14.1 The PARENTS may withdraw from this CONTRACT by returning the kit to LAB no later than 10 (ten) days from the date of receipt, accompanied by a withdrawal request stating the bank details for the refund of the amount paid.

In the event of a validly exercised withdrawal, LAB shall return the sum paid by the Parents on receipt of the kit, less the costs of the initial shipment of the latter.

15. TERMINATION OF THE CONTRACT

15.1 The CONTRACT may be terminated by mutual agreement of the PARTIES.

15.2 The CONTRACT may be terminated by LAB in the event of total or partial non-payment of the price or in the event of non-payment of an annual cryopreservation fee, once 10 (ten) working days have elapsed from receipt of the notice to perform sent by LAB by registered letter with return receipt to the latest contact details communicated by the PARENTS or, on reaching the age of majority, by the UNBORN CHILD, or appearing in its own records.

If that period expires to no avail, LAB may proceed with the termination of the CONTRACT, notifying the PARENTS or, on reaching the age of majority, the UNBORN CHILD thereof. LAB shall continue to store the SAMPLE for a further 30 (thirty) days from receipt of the notice of termination.

If that period expires to no avail, without the sums due having been settled and the continuation of the contractual relationship having been agreed with LAB, LAB shall no longer be required to continue storing the SAMPLE and may proceed with its disposal. Should the notice to perform or the notice of termination be undeliverable owing to inaccuracy, deactivation or failure to update the contact details, LAB shall not be required to search for different or additional contact details and the procedure provided for in arts. 10.2 and 10.3 shall apply.

16. OBLIGATIONS

16.1 The financial obligations incurred by the PARENTS remain their responsibility. On reaching the age of majority, the UNBORN CHILD directly exercises the rights over the SAMPLE in accordance with art.

10.1. The continuation of the storage service may be paid for by the PARENTS or by the UNBORN CHILD, in the manner agreed with LAB. The person who pays the annual fee shall be the person named on the related invoice. Payment of the fee by a person other than the UNBORN CHILD does not confer on the payer any right over the SAMPLE or any power to dispose of it.

17. GOVERNING LAW, JURISDICTION

17.1 This CONTRACT is governed exclusively by the legislation in force in the State of San Marino. The competent judicial authority, in the event of a dispute, is exclusively that of the Republic of San Marino. The parties expressly waive the right to raise objections regarding jurisdiction as identified above and undertake to give effect to the judgments handed down by the Judicial Authority of San Marino concerning this CONTRACT.

18. UNDERSTANDINGS

18.1 All the understandings reached between LAB, the PARENTS and the UNBORN CHILD are incorporated in this CONTRACT. Any other

prior understandings are superseded by this CONTRACT. Any future understandings must be drawn up in writing and signed by the parties.

19. PRESERVATION OF THE CONTRACT

19.1 Any provision of this CONTRACT that is void or unenforceable shall be amended in order to make it enforceable.
The remaining provisions shall retain full validity and effect.

20. COMMUNICATIONS

20.1 All communications concerning this CONTRACT must be made using the contact details provided by the PARTIES and may be transmitted, according to the nature of the communication, by ordinary or registered post, email, telephone or other means suitable for documenting the attempt at contact.

For the purposes of communications to the PARENTS or, on reaching the age of majority, to the UNBORN CHILD, LAB shall use the latest contact details communicated and appearing in its own records. The PARENTS and, on reaching the age of majority, the UNBORN CHILD are required to notify LAB promptly of any change in their personal and contact data, in accordance with art. 22.4.

20.2 LAB shall not be required to search for contact details different from or additional to those communicated and appearing in its own records. Should communications be undeliverable owing to inaccuracy, deactivation or failure to update the contact details, the provisions of arts. 10.2 and 10.3 shall apply, where the relevant conditions are met.

20.3 Communications intended for LAB must be sent to the following contact details or to any different contact details subsequently communicated by LAB:

BIOSCIENCE INSTITUTE SPA, Strada Rovereta n.42 - 47891 Falciano (RSM) tel. 0549 909905 - info@bioinst.com

21. CONFIDENTIALITY

21.1 The Parties acknowledge that all information concerning this CONTRACT is confidential in nature.

LAB shall adopt all the measures necessary to keep such information confidential, except where the relevant legislation provides

otherwise.

22. DOMICILE AND RELEVANT INFORMATION

22.1 For the purposes of this CONTRACT, the PARENTS request that the invoice be issued using:

Mother's details ☐

Father's details ☐

22.2 The possibility of subsequently changing the person named on the invoice remains unaffected, in accordance with the provisions of this CONTRACT and subject to prior notice to LAB.

22.3 If no choice is made at point 22.1, the address indicated in the mother's details will be used for the purposes of issuing the invoice.

22.4 The PARENTS and, on reaching the age of majority, the UNBORN CHILD are under an obligation to inform LAB of any change in their personal and contact data and, where applicable, in the bank details provided for the debit of the fee.

22.5 In the event of a change in the person paying the annual fee or in the current account used for the related debit, a new SEPA mandate, signed by the new holder of the current account, must be provided to LAB.

The change of paying person does not entail any change in the ownership or exercise of the rights over the SAMPLE, which remain governed by arts. 10.1 and 16.1 of this CONTRACT.

23. AUTHORISATION

23.1 I authorise freezing and storage even if the sample contains fewer than 100,000 CD34+ cells:

YES ☐

NO ☐

23.2 Failure to indicate a choice at point 23.1 does not constitute authorisation to store the SAMPLE under the conditions indicated therein. LAB will contact the PARENTS to obtain the relevant instruction.

Date (dd/mm/yy)

Father's signature

Mother's signature

Bioscience Institute spa

 **BIOSCIENCE**
INSTITUTE SpA

The method of payment for the balance of the cryopreservation service must be specified.

Method of payment for the services requested (tick the box for the option chosen)

☐ Option A: PAYMENT BY BANK TRANSFER

The details for making the transfer will be shown directly on the invoice that will be sent to you.

☐ Option B: PAYMENT BY SDD (formerly RID)

For this type of payment, the SEPA CORE DIRECT DEBIT MANDATE (the SDD form is attached to this contract) must be completed and signed in order to authorise the debit to the current account.

This MANDATE must be returned in the original, together with this contract, by registered letter with return receipt to:

BIOSCIENCE INSTITUTE S.p.A.
S.da Rovereta, 42 - 47891 Falciano
Repubblica di San Marino

☐ Option C: PAYMENT BY CREDIT CARD

After the invoice has been sent by email, a link will be sent to you at the same address.

By clicking on this link you will be able to pay the invoice using your credit card.

Method of payment of the annual fee (mandatory)

For payment of the annual fee, the SEPA CORE DIRECT DEBIT MANDATE (the SDD form is attached to this contract) must be completed and signed in order to authorise the debit to the current account.

This MANDATE must be returned in the original, together with this contract, by registered letter with return receipt to:

BIOSCIENCE INSTITUTE S.p.A.
S.da Rovereta, 42 - 47891 Falciano
Repubblica di San Marino