

# Information booklet

*- to the expectant parents*

Information booklet contains the following documents:

- Welcome letter (page 2)
- Illustrated instruction of collection (page 6)
- Content of the Cellaviva Box (page 8)
- Consent – to the collection of stem cells (page 10)
- Health declaration – for the future mother (page 13)
- Agreement – for collection and storage of stem cells (page 19)

## *Hello and welcome to Cellaviva!*

*In front of you, you now have a fully equipped Cellaviva Box for the collection of stem cells from the umbilical cord tissue and umbilical cord blood. When the day has come for your child to be born, please bring the box with you to the maternity ward at the hospital, even if you are unsure if the birth has actually started.*

*Together with this information booklet, we have included a leaflet addressed to your midwife at your maternal health service. Bring it to your midwife on your next visit, ask her to write in your journal that you want to collect stem cells. This way, the personnel at the maternity ward at the hospital will be able read in the journal that you have arranged to cryopreserve your newborn's stem cells.*

*If you have **not** chosen the option where the Cellaviva staff helps with the collection, we kindly ask you to contact the maternity ward where you plan to give birth and tell them you wish to collect your child's stem cells and would be very grateful for their help with the procedure. Help from the medical staff is always preferable.*

*Instructions for collection are included and Cellaviva staff is available around the clock for any questions you might have. It is an easy procedure to collect cord blood for healthcare professionals who are already used to taking blood samples. The umbilical cord tissue can also be collected by the accompanying parent as it only requires the person to cut a piece of umbilical cord. If you do choose to do the collection yourself, please carefully read the instructions in advance.*

*Cellaviva has a special hotline telephone number that health professionals and parents can call night and day, before and during childbirth, see the back of this booklet for the number.*

*The Cellaviva Box contains all of the required equipment for collecting stem cells from two stem cell sources from the umbilical cord. Whether you choose, or if it is only possible to collect one of the Samples, the birth mother's blood samples is always a requirement for saving stem cells from the umbilical cord tissue and/or umbilical cord blood.*

*Please carefully read this information booklet, well in advance of the birth. In connection with your order of the Cellaviva Box, a digital document is also sent to you, we ask you to sign this as soon as possible. The documents that you sign digitally are also in this **Information booklet**, which is your copy.*

*The digital document is called the Return Booklet and contains the following parts:*

- *Consent - for the collection of stem cells from the umbilical cord (page 10)*
- *Health declaration - for the expectant mother (page 13)*
- *Agreement - for the collection and storage of stem cells from the umbilical cord (page 19)*

*It is important that you as expectant parents understand that the collection of stem cells should be seen as an opportunity, since neither Cellaviva nor the maternity ward can guarantee that the collection of stem cells will be successful. Despite time, experience and relevant equipment, it is not always possible to perform a successful collection of cord blood.*

*Umbilical cord tissue is much easier to collect, and the collection is almost always successful. The cells in the umbilical cord tissue are then grown in order to later isolate the stem cells. Note that in this process, successful cultivation cannot be guaranteed as biological material is never completely predictable. If any or both stem cell sources do not achieve the quality requirements, and you as parents wish to stop and cancel the freezing process, you do not pay for the service.*

*The collection procedure may not under any circumstances compromise the safety of the mother, child or other person in the maternity ward. The hospital staff have Cellavivas full confidence.*

*If you have any questions, please contact Cellaviva by e-mail: [kundtjanst@cellaviva.se](mailto:kundtjanst@cellaviva.se) or by phone +46 8 735 20 10.*

***For urgent issues call the Cellaviva hotline: +46 70-286 14 20.***

*For medical emergencies call 112!*

*Cellaviva wishes you the best of luck!*

## HOW IT WORKS

### 1 THE CELLAVIVA BOX

You have received the fully equipped box for the collection of stem cells from umbilical cord tissue and umbilical cord blood. Please carefully read through this information booklet. Fill-in and sign the digital document you received by e-mail, containing; health declaration, consent form and formal agreement. You will find your copy of the documents from page 10 of this *Information Booklet*.

Provide *Information till barnmorska* to your midwife at the maternal health service. Ask them to enter that you wish to collect stem cells in connection with childbirth, into your medical journal.

Please do not break the seal to the Cellaviva Box before you are in the maternity ward to give birth.



### 2 DURING CHILDBIRTH

Take the Cellaviva Box with you to the maternity ward. Please notify the admitting team that you will bring your Cellaviva Box for the collection of umbilical cord tissue and umbilical cord blood, when you call to tell them that you are on the way to the clinic. Then, before you arrive at the maternity ward, the staff knows that you intend to collect stem cells and they can consequently plan and prepare for it.



### 3 BIRTH MOTHER'S BLOOD SAMPLE

A blood sample is taken from the birth mother in conjunction with the delivery. The sample is taken to Sample for any infectious diseases and is a legal requirement. The umbilical cord tissue may only be processed when the birth mother's blood sample is provided in the Cellaviva Box or is sent to Cellaviva in advance.



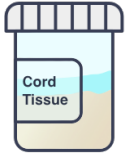
### 4 COLLECTION OF UMBILICAL CORD BLOOD

As soon as your child is born and the umbilical cord is cut, the collection of the umbilical cord blood is performed using the equipment provided in the Cellaviva Box. It is best to do the collection when the placenta is still in the uterus but after the umbilical cord is cut. The collection process takes about 3-5 minutes and is completely risk- and pain-free.

Cellaviva makes no official recommendation on the timing of cutting the umbilical cord. You decide this as a parent in consultation with your midwife.



## HOW IT WORKS



- 5 COLLECTION OF UMBILICAL CORD TISSUE**  
Umbilical cord tissue is collected after the umbilical cord is cut and after umbilical cord blood is collected. The umbilical cord is wiped dry and then the responsible person cuts a piece of at least 15-20 cm from the cord.



- 6 PREPARATION AND TRANSPORT**  
In the Cellaviva Box there is a *Collection Report* where information such as the time and date of the birth must be filled in. When the collection is complete, the midwife from the maternity ward or the Cellaviva staff fills in the report and places it in the box. Then, as parents or childbirth staff, you call Cellaviva's hotline number to order a courier who picks up the box at the hospital. If Cellaviva's staff are present, this step is handled by us.

*All samples should always be stored at room temperature.*



- 7 AT THE LABORATORY**  
When the box is delivered to the laboratory, the laboratory staff takes care of the collected samples. The box is checked, the cells are counted, analyzed, cultured and isolated. The stem cells are then frozen in liquid nitrogen. The temperature in the freezers is  $-196^{\circ}\text{C}$ . It is so cold that all activity in the cells stops completely and "time stops".



- 8 FUTURE**  
Your child's stem cells are stored at Cellaviva (Biobank no. 932) and are available to the family. All indications suggest that stem cells can be stored for a lifetime.

The stem cells can only be requested by the owner. When the child reaches the age of 18, ownership of the stem cells passes from the mother to the child.

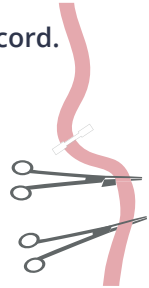
## INSTRUCTION FOR COLLECTING CORD BLOOD

The collection starts immediately after the clamping of the cord.

1

Collect the blood when the placenta is still in the uterus. Keep in mind that the blood bag must be kept lower than the insertion site.

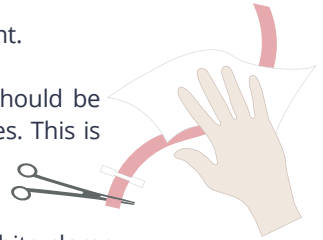
Place two hemostats as usual on the umbilical cord, as close to the baby as possible, and also a white umbilical cord clamp a bit above the hemostats against the placenta. This for possible blood gas testing or blood type testing.



2

Clean the umbilical cord with the supplied disinfectant.

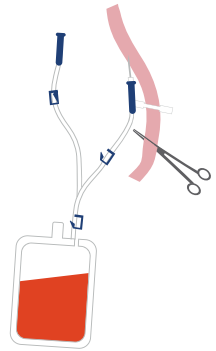
Then wipe with a sterile pad. The insertion point should be dried thoroughly with the supplied disinfectant wipes. This is done to prevent bacterial contamination.



3

Open the white clamp closest to the bag and the white clamp of the needle to be used. Remove the protective cap from the needle. Keep in mind that the blood bag must be placed / kept lower than the insertion site to utilize the natural effects of gravity. Insert needle close to the hemostat, ie far down the umbilical cord, to enable as much blood as possible to be collected.

If the needle or vein is clogged, a new insertion can be made closer placenta. Move the hemostat closer towards the placenta. A new area, above the hemostat, is disinfected, see step 2. Close the clamp belonging to the used needle and make a new insertion with the blood bag reserve needle, remember to open clamp. Proceed as described above.



4

When the blood bag is filled, knead it so that the anticoagulant contained in the bag is mixed-in with the blood. Continue the collection of umbilical cord blood until the umbilical cord is completely drained of blood. When the collection is complete, close the 2 white clamps closest to the needles. Open the small bag by cracking the tube on the thick part closest to the bag. Let the anticoagulant drain into the blood bag and squeeze any residue in the tubing into the blood bag using the white clip.

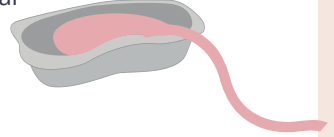
Close remaining clamps as close as possible to the blood bag. Attach an unused white umbilical cord clip about 5 cm from the blood bag.



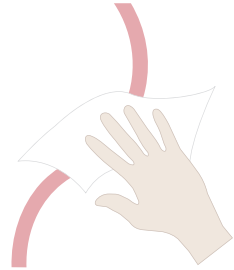
## INSTRUCTION FOR THE COLLECTION OF UMBILICAL CORD TISSUE

The collection begins as soon as possible after the placenta has been expelled.

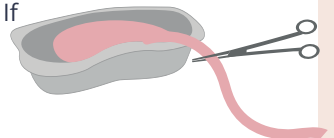
- 1 Remove any clamps or hemostats from the umbilical cord.



- 2 In order to remove bacteria, wipe dry the umbilical cord with dry sterile compresses, then injector wipes. Wipe thoroughly.

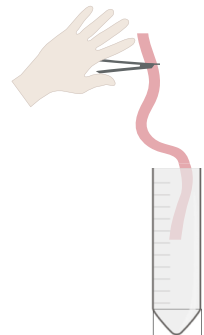


- 3 Take the included scissors. Hold the umbilical cord end and cut about 15-20 cm of the umbilical cord. If possible, choose segment without insertion points.



- 4 Using the tweezers, insert the cut umbilical cord into the tissue collection container.

Fill with the provided NaCl solution so that the umbilical cord is covered with liquid and then tighten the cover firmly.



**NOTE!** All samples should always be stored at room temperature.

**Detailed instructions are available in the Cellaviva Box.**

# Equipment in the Cellaviva Box

1. Sterile cloth
2. Purple top blood tubes
3. Cannulas
4. Sterile gloves
5. Disinfectant wipes (4 pcs)
6. Sterile gauze
7. Disinfectant
8. Sterile blood bag for collection of umbilical cord blood
9. Sterile scissors
10. Sterile plastic tweezers
11. Tissue collection tube, sterile centrifuge tube with lid
12. Sodium chloride solution
13. Absorbent collection cloth
14. Temperature regulating gel packs (2 pcs)
15. Temperature logger
16. Orange-colored Biohazard label
17. Small bag with adhesive tape strip (A5)
18. Large bag with adhesive tape strip (A4)
19. Adhesive label for blood bag

## Documents:

1. *Illustrated instructions for the collection of stem cells*
2. *Collection report*



# Referral Program



Are you ready to share the benefits of family saving with your family and friends? With your referral, both the family referring and the family using referral are offered one year of free storage of the stem cells.

If you have any questions, please contact Cellaviva's customer service on 08 - 735 20 10 or e-mail: [kundtjanst@cellaviva.se](mailto:kundtjanst@cellaviva.se).

Please visit our website [www.cellaviva.se](http://www.cellaviva.se)

## Consent

*- for the collection of stem cells*

This consent, ID 45-04-04, is drawn up in two originals, of which the expectant mother will retain the original in the *Information Booklet* (page 10, ID 40-04-03) while a digital version, sent to you by email, of Consent ID 45-04-04, Health Declaration ID 44-04-04 and Agreement ID 31-04-04 are completed and signed in good time before childbirth, preferably as soon as possible.

## Consent to collection

With this consent, you, the expectant mother, agree that umbilical tissue and/or cord blood is collected from the umbilical cord after your baby is born and the umbilical cord has been cut. The stem cells are consequently transported to the laboratory for analysis, cultivation, isolation, freezing and then storage in Cellaviva's biobank, with registration number 932 from the Inspectorate for Health and Care Services, IVO. The actual storage of the stem cells is regulated according to a separate agreement, **Agreement for the collection and storage of stem cells from the umbilical cord**.

Cellaviva makes no official recommendation regarding the timing of when the umbilical cord is cut, but urges the parents to discuss the preferred time for cutting in consultation with their midwife before the birth. It is possible to collect and save stem cells from the umbilical cord blood, even if one chooses to wait with clamping, but the amount of umbilical cord blood that can be collected decreases with time. When the umbilical cord is cut it is advised to collect the blood as soon as possible, preferably when the placenta is still inside the uterus, but it is also possible to collect umbilical cord blood after the placenta has come out. Umbilical cord tissue is collected by cutting off a piece of umbilical cord and is to be performed after the umbilical cord blood has been collected and the placenta has come out.

## Risks and discomfort

There is no additional risk for your child or you when collecting stem cells from the umbilical cord. The placenta and umbilical cord do not provide any function for your child or you after the umbilical cord is cut. The procedure must not under any circumstances jeopardize the safety of the mother, child or other person at the maternity ward. You should be aware that it is not always possible to perform a successful collection, despite time, experience and relevant equipment.

## Confidentiality

The collected umbilical cord tissue and/or umbilical cord blood, also called the "Sample" is stored inaccessible to unauthorized persons at the Cellaviva premises. The personal data belonging to the Sample are recorded in a special register for biobank/tissue establishments and are handled in agreement with the Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council). The personal data collected may be used by Cellaviva as a basis for administration of Cellavivas' and mother's commitments, analyzes of the venture and development functions. Personal data as well as information about health and diseases related to the mother and the child may, for the stated purposes included in the agreement (medical treatment, transfer and research) be shared with healthcare providers, tissue establishments, analytical laboratories, biobanks or researchers in accordance with the National Board of Health and Welfare's regulations SOSFS 2009: 30.

**I approve:**

- *That the umbilical cord tissue and/or cord blood (the "Sample") from the umbilical cord is collected in connection with the childbirth.*
- *That the blood sample collected from the mother is to be analyzed for infectious diseases. Blood samples are taken to exclude blood infection caused by HIV, hepatitis or syphilis. In the event of a positive response, Cellaviva has an obligation to notify the maternity ward, which in turn informs the hospital and the mother.*
- *That the Sample collected is analyzed for a number of quality parameters.*
- *That Cellaviva sends Samples for analysis to a contracted subcontractor within the EU and that the necessary personal data is processed with confidentiality by any third party.*
- *That the collected Sample is frozen and stored in Cellaviva's biobank, no. 932.*
- *That the maternity staff have my and Cellaviva's full confidence to determine when and if the collection of umbilical cord blood is possible, given the mother's and the child's health.*
- *That Cellaviva handles my and the child's personal information according to Data protection regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council).*

**I declare:**

- *That I understand that the procedure is completely voluntary and can be interrupted at any time without any explanation. If I consent to the Sample being collected, I have the right to change my decision, and to withdraw my consent, according to the Swedish Biobank Act.*

**The undersigned has read the written information regarding the collection of stem cells.**

Place and date: \_\_\_\_\_

Signature: \_\_\_\_\_

Print name: \_\_\_\_\_

Personal/ID number: \_\_\_\_\_ - \_\_\_\_\_

# Health declaration

## *- for the expectant mother*

This Health Declaration, ID 44-04-04, is drawn up in two originals, of which the expectant mother will retain the original in the **Information Booklet** (page 13, ID 40-04-03) while a digital version, sent to you by email, of Consent ID 45-04-04, Health Declaration ID 44-04-04 and Agreement ID 31-04-04 are to be completed and signed well in advance of childbirth, preferably as soon as possible

The following questions are asked to the expectant mother to reduce the risk of infection or disease being transmitted via donated biological material to the recipient. The health declaration is designed according to the tissue law (the National Board of Health and Welfare's regulations SOSFS 2009: 30).

In cases where there are doubts about the long-term storage of the collected stem cells, Cellaviva will get in touch with the person who filled out the health declaration. The health declaration and its contents are treated as confidential information and saved by Cellaviva only to ensure traceability in case of any future treatment with the collected Sample.

If you do not know if you have a disease, answer No.

For questions regarding the health declaration, you are welcome to contact Cellaviva by phone: +46 8 735 20 10 or our customer service on e-mail: [kundtjanst@cellaviva.se](mailto:kundtjanst@cellaviva.se)

# Health declaration Cellaviva

Have you or have you had any of the following illnesses?	Yes	No
HIV 1 or 2		
HTLV-1 virus infection		
Hepatitis B (a form of jaundice)		
Hepatitis C (a form of jaundice)		
Syphilis		
Gonorrhoea		
Chlamydia		
Genital Herpes		
Tuberculosis		
Parasitic Disease		
Fungal Disease (single genital infections, answer No)		
Trypanosoma cruzi (Chagas' disease, occurs in Central and South America)		
Creutzfeld-Jacob Syndrome		
Malaria		
CMV infection		
Toxoplasmosis		
Epstein Barr virus infection		
West Nile virus infection		
Diabetes type 1		
Diabetes type 2		
Blood disease or bleeding problems		
Babesia (tick-borne disease transmitted by dogs, rare in Sweden)		

If you answered yes to any of the above diseases; please provide details and specify the year.

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Have you ever suffered from any serious illness? If yes, what?

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Are you vaccinated against Hepatitis B (common for overseas trips to certain countries)?

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# Health declaration Cellaviva

Questions regarding the risk of transmission of infection	Yes	No
Have you ever been denied to donate blood? If yes, please specify why on page 17.		
Have you received a dura mater transplant?		
Have you received human pituitary gland growth hormone?		
Have you or anyone in your family had Creutzfeldt-Jakob Syndrome, or variant of Creutzfeldt-Jakob Syndrome?		
Do you have any degenerative neurological disease of known or unknown origin? E.g. ALS, or dementia.		
Have you lived in another country over a longer period? If yes, which country and year?		
Have you been abroad during the last month before the birth? If yes, please specify country / countries:		
Have you had unprotected sex with a person from one of the following countries / areas? Japan, the Caribbean, Australia, New Guinea, South America, Iran or Africa (south of Sahara)?		
Have you used a needle to inject medication, steroids or drugs that are not prescribed by a doctor or had unprotected sex with a person who has?		
Have you tested positive for HIV or AIDS or had unprotected sex with a person with HIV?		
Have you been involved in any accident requiring hospitalization?		
Is the child you are carrying conceived with a donated egg?		

# Health declaration Cellaviva

<b>Have you within the last 12 months before birth giving:</b>	<i>Yes</i>	<i>No</i>
Received blood, plasma or other blood products other than your own?		
Got a tattoo, body piercing, acupuncture, accidental needle sticks or been in contact with another person's blood?		
Had close contact with a person with hepatitis?		
Received hepatitis B immunoglobulin (post exposure prophylaxis)?		
Been vaccinated or have taken any other injection? If yes, please specify.		
Had an active infection during your pregnancy with any of the following diseases: HIV 1 and 2, hepatitis B, hepatitis C, syphilis, gonorrhea, chlamydia, genital herpes, the HTLV-1 virus infection, malaria, CMV infection, Toxoplasma, Epstein Barr virus infection, including mononucleosis, West Nile virus infection, or Trypanosoma cruzi? If yes, please specify.		
Consumed drugs in any form other than vitamins and iron supplements in the past four weeks prior to birth giving? If yes, please specify what medicines, how long and the reason why?		
Have you taken the blood coagulation factor against bleeding disorder such as hemophilia or had unprotected sex with someone who has?		



# Health declaration Cellaviva

If you answered yes to any of the questions on the previous pages, please provide details and specify the year, country, disease, infection etc if applicable.

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By signing below, I hereby acknowledge that I have read and fully understand the information regarding infections, diseases and the risk of transmitting such infections and diseases through biological material to the recipient.

I testify that the information I have given is truthful.

**Place and Date:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Name in print:** \_\_\_\_\_

## *Scandinavia's largest biobank for family saving of stem cells*

Cellaviva is Sweden's first stem cell bank for family saving of stem cells. We are the only stem cell bank who has received permission from the Inspectorate for Health and Care Services (IVO) according to the tissue law and the Health and Medical Care Act.

Since the first life-saving transplant with stem cells from umbilical cord was made in 1988, more than 50,000 people have been treated with their own or well-matched stem cells, for life-threatening diseases such as leukemia, immunodeficiency and cancer.

Your child's stem cells have 100% matching to themselves. Using their own cells for medical treatment poses minimal risk of complications and there is no risk of transmissible diseases from the donor. Siblings have a 25% chance of being a perfect match for each other. In addition, immature stem cells extracted from the umbilical cord are more adaptable than other stem cells, so in many cases a partial match is sufficient. This means that the chance that the stem cells can be used within the family increases to over 75%



## Agreement

*- for the collection and storage of stem cells  
from the umbilical cord*

This Agreement, ID 31-04-04, is signed between the expectant mother and Cellaviva and applies from the date of childbirth.

Agreement, ID 31-04-04, is drawn up in two originals, of which the future mother will keep the original in the **Information Booklet** (page 19, ID 40-04-03) while a digital version, sent to you by email, of Consent ID 45-04-04, Health Declaration ID 44-04-04 and Agreement ID 31-04-04 is completed and signed in good time before delivery, preferably as soon as possible.

The Mother's personal and contact details are treated confidentially by Cellaviva.

## 1. Applicability, scope etc.

- 1.1 This agreement (the "Agreement") applies between Cellaviva, which is a trade name owned by of NextCell Pharma AB, org. 556965-8361, ("Cellaviva"), and the woman giving birth ("Mother"), who has ordered storage of stem cells from umbilical cord tissue and/or cord blood ("Sample", or "Samples") in Cellavivas Biobank (the "Service"). The Agreement is only signed with the Mother for the reason that the umbilical cord from which the Sample is taken belongs to the woman giving birth. Mothers personal and contact details are stated in point 19.
- 1.2 The Service offers expectant parents the opportunity to collect and store their newborn child's ("Child") stem cells from the umbilical cord for potential future medical treatments. The Sample is collected with medical equipment approved and provided by Cellaviva. The Sample is collected, as agreed by staff at the maternity wards, by personnel sent by Cellaviva or by an appointed trained person. Umbilical cord tissue collection is considered to be possible to be carried out by the Mother herself or any accompanying person after carefully reading the instructions. The Sample is then transported to the Cellaviva laboratory or to Cellaviva's subcontractor's laboratory, where it is registered, analyzed, frozen and stored in Cellavivas Biobank. Samples that require further processing before freezing are manufactured according to GMP with manufacturing approval by the Medical Products Agency or equivalent authority abroad. Cellaviva is a tissue establishment approved by the Inspectorate for Health and Care ("IVO") and whose biobank has registration number 932. IVO is the supervisory authority and conducts inspections of the stem cell bank.
- 1.3 Cellaviva is responsible for the storage of the Sample. The Sample can only be released, transferred and / or destroyed under the terms and conditions specified in this Agreement.
- 1.4 The Mother enters the Agreement with Cellaviva by approving the contract terms with her signature, as per paragraph 19. The Agreement shall be considered to commence when the Mother has signed the Agreement. Through the signature, the Mother accepts the contract terms in the Agreement.
- 1.5 The Mother is responsible for ensuring that the contact information provided in the Agreement (point 19) is correct and undertakes to notify Cellaviva if any information changes. Changes are notified to Cellaviva in writing.
- 1.6 These contract terms, as well as instructions, policies and other information about the Service, are available on Cellaviva's website, [www.cellaviva.se](http://www.cellaviva.se) and are sent on demand via [kundtjanst@cellaviva.se](mailto:kundtjanst@cellaviva.se).

## 2. Mother's commitments

- 2.1 The Mother is responsible for
- a) bringing the Cellaviva Box to the clinic when it is time to give birth (the Cellaviva Box is ordered at [www.cellaviva.se](http://www.cellaviva.se)).
  - b) signing the digital Agreement received before childbirth.
  - c) providing Cellaviva with all requested information and documentation regarding the birth and medical conditions (Health Declaration according to Social Board's regulations SOSFS 2009: 30).
  - d) informing both their midwife at the maternal health service and the maternity ward at the hospital about their desire to collect the Sample(s).
  - e) The Mother and any accompanying person must appoint in advance who is responsible for the collection of the Samples. This person should familiarize themselves with the instructions for collecting umbilical cord tissue and after completing the collection fill in the collection report.
- 2.2 The Mother agrees that Cellaviva may store the Sample in Cellavivas Biobank.
- 2.3 The Mother agrees to take responsibility to inform the child's guardian of all information according to section 6.1 regarding the future possibilities of treating diseases using stem cells.

## 3. Cellaviva's commitments

- 3.1 The Mother may at any time revoke her consent for storage under point 2.2. Cellaviva shall, upon revocation of consent, destroy the Sample free of charge. A revocation must be made in writing to Cellaviva. The Sample is destroyed as soon as possible and always within thirty (30) days from the day Cellaviva received the written request. The Mother receives a written confirmation when the Sample has been destroyed.
- 3.2 The collection must not expose the mother or child to any risks. Cellaviva is not responsible for the medical care in connection with the childbirth or the medical postures that the donor/childbirth staff consider for a decision to collect or refrain from collecting the Sample.
- 3.3 If Cellaviva's quality requirements for the Sample are met, the Agreement shall be completed, and the Sample will be frozen.
- 3.4 If Cellaviva's quality requirements for the Sample are not met, the following applies: In the event of major deviations, the Sample is disqualified, and the Mother is notified. In case of minor deviations, the Sample is frozen and Cellaviva contacts the Mother. The contact takes place orally or in writing and shall include information about the deviation and its significance for the Sample's usability. The Mother then has the right to either complete or cancel the Agreement. If the Mother decides to cancel the Agreement, the Mother shall within seven (7) days from the contact day, inform Cellaviva of the cancellation.

Upon cancellation, Cellaviva will destroy the Sample as soon as possible and always within thirty (30) days from the day the cancellation notice is received. If the Mother does not provide notice of termination within the specified deadline, Cellaviva shall complete the Agreement and keep the Sample.

3.5 Cellaviva holds all the necessary permits to conduct its business and offer the Service. Cellaviva is responsible for ensuring that Cellaviva's subcontractors hold all necessary permits to perform sub-parts of the Service for which the subcontractor is engaged. In order for Cellaviva to ensure that all handling including storage of the Samples is in accordance with applicable laws, ordinances, regulations and permits. The handling, including storage of the Sample, must be characterized by high quality and safety, and may only take place in adapted premises and with equipment intended for the purpose. All handling of the Sample should be documented and archived and made traceable in an appropriate manner. Examples of, but not limited to, deviations from the Agreement are:

- The Collection report has not been signed by the person who carried out collection.
- Collection is done with other equipment than the Cellaviva Box.
- The Sample is damaged in transport due to incorrect packing.

3.6 If the collected Sample deviates from the Agreement, Cellaviva reserves the right to determine whether the Sample is suitable for freezing or if it is to be destroyed. In cases where the Sample, despite deviations, is considered suitable for freezing, we will contact the Mother according to section 3.4. Information about the deviation may include deficiencies in both quality and traceability. Cellaviva's ambition is to let the Mother make a informed decision regarding the destruction or storage of a deviating Sample.

#### **4. Ownership etc.**

4.1 Ownership of the Sample lies exclusively with the Mother until the day the Child reaches the age of majority (18 years), whereby the right of ownership changes to the Child and the Agreement with the Mother ceases. Cellaviva only allows the Sample owner to sign the Agreement.

4.2 The information in section 4.1 shall be provided in writing to the Mother and Child's official address (see paragraph 16) in connection with the termination of the Agreement. The Mother and the Child should be informed about the ownership of the Sample and that the Child can sign an agreement for continued storage. A new agreement on storage according to the then current price list, is obtained in writing with a special form provided by Cellaviva.

- 4.3 According to a decision by IVO (2014-11-19, no. 28933/2013), Cellaviva shall inform the Child when he or she has reached the age of majority, regarding the right to revoke or extend the consent to storage which the Mother has provided pursuant to section 2.2.
- 4.4 The information according to items 4.1 and 4.3 shall be submitted in writing to the Mother and the Child's address as registered in the Swedish Population Registry (see paragraph 16), at the Child's 18th birthday. The Child must be informed about the ownership of the Sample and about the possibility of signing a new agreement and consent. The consent is obtained in writing using a special form provided by Cellaviva. If the Child withdraws consent, the Child may request that the Sample be either destroyed or moved according to item 7.
- 4.5 The Mother agrees to share details of her personal health and other important information that the Mother provided to Cellaviva at the signing of the Agreement and in connection with the collection of the Sample, may be disclosed to the owner of the Sample, at the request of movement/relocation of the Sample as in paragraph 4.3. The consent for the aforementioned purpose also exists if the Mother dies.
- 4.6 If the Mother dies before the Child has reached the age of 18, the ownership of the Sample shall be transferred to the Child, and the Agreement ceases according to section 4.1.

## **5. Release etc. of the Sample**

- 5.1 During the storage period, the Mother may dispose of the Sample as per the following:
- Medical treatment by a caregiver.
  - Movement to another tissue establishment.
  - Use the Sample for research and development work.
  - Destroy the Sample according to the terms of the Agreement (see point 3.1).

## **6. Release of the Sample for Medical Treatment**

- 6.1 The purpose of saving the Sample is to be able to use it for future treatments. However, Cellaviva cannot give any guarantees that the Sample will in fact be able to be used. Much depends on which treatment methods are used at that time, as well as the amount and quality of the cells saved.
- 6.2 In accordance with section 6.1, Cellaviva only releases the Sample for medical treatment under the condition that the medical treatment refers to the Child or a relative. The term "relatives" refers primarily to siblings, parents, children or cousins of the Child. The Mother's request to claim the Sample for such purpose shall be made in writing. The request shall include a report of
- a) the disease,
  - b) the responsible physician (caregiver), and
  - c) who the patient is.

- 6.3 Cellaviva only releases the Sample to a health care provider or tissue establishment according to the Act (2008: 286) on quality and safety standards when handling human tissues and cells. If the patient and the recipient are approved patients / recipients, Cellaviva is responsible for the Sample being available for collection free of charge at Cellaviva's premises no later than fourteen (14) days from receipt of written request for disclosure. Subsequently, a written confirmation is sent to the Mother. Cellaviva does not provide transport of the Sample to the recipient. In case of non-collection on deferred delivery date or cancellation later than seven (7) days prior to delivery date, the Mother will be charged 5000 SEK.
- 6.4 Cellaviva can also release parts of the Sample for medical use. The first release is free of charge, any other release is charged according to the current price list.
- 6.5 If the need for urgent release of the Sample is requested directly from the treating physician or caregiver, Cellaviva will release the Sample as soon as possible. Cellaviva is responsible for keeping the Sample available at Cellaviva's premises at no extra cost. The Agreement does not cover the transport of the Sample to the recipient. Urgent request for disclosure must be approved in writing by the Mother.
- 6.6 Cellaviva ensures on the Mother's behalf that a written receipt is collected from the recipient upon delivery of the Sample. The health care provider or tissue establishment assumes responsibility for the Sample by means of signing the receipt. Cellaviva's responsibility for the Sample ceases after the receipt has been obtained and the Sample has been handed out to the recipient. Cellaviva is not responsible for the medical treatment or other handling of the Sample after disclosure

## **7. Release of the Sample for storage at another location (transfer)**

- 7.1 The Mother's request for a transfer of the Sample shall be made in writing. Cellaviva only releases the Sample for storage to approved recipients. Approved recipients are Swedish tissue establishments, which are registered with IVO and thereby comparable foreign tissue establishments.
- 7.2 If the recipient is an approved recipient for transfer, of which the approval is communicated to the Mother in writing, Cellaviva is responsible for keeping the Sample free of charge at Cellaviva's premises for thirty (30) days from the day of approval. The Agreement does not cover the transport of the Sample to the recipient. In the event of non-collection on deferred delivery date or cancellation fourteen (14) days before the scheduled delivery date, the Mother will be charged 5000 SEK.
- 7.3 Cellaviva ensures on the Mother's behalf that a written receipt is collected from the recipient upon delivery of the Sample for the purpose of Sample relocation. The receiving biobank assumes responsibility for the Sample through the receipt. Cellaviva's responsibility for the Sample ceases completely after the receipt has been obtained and the Sample has been handed out to the recipient. Cellaviva is not responsible for any medical treatment or other handling of the Sample after release.



## **8. Release of the Sample for research activities and/or Cellaviva's research & development activities**

- 8.1 The Mother can request the Sample to be released for:
- Research or
  - Cellaviva's research & development activities.
- 8.2 Cellaviva's research & development activities aim to optimize the collection process and can result in improved opportunities for the saving of cells. Research refers to research that has been approved by a ethics committee according to the law (2003: 460) on ethical testing of research relating to people, or an equivalent body for research conducted in another country than Sweden. Requests for release of the Sample for research purposes shall be made in writing. The written document must state
- a) type/description of the research study,
  - b) who the principal investigator of the study is, and
  - c) whether the Sample should be destroyed after the research or returned to Cellaviva.
- 8.3 Cellaviva reserves the right to review the research study as well as ethics application and ethics approval. After examination, Cellaviva informs the applicant if the research is an approved research for the release of the Sample and the day from when the Sample is available for collection at Cellaviva's premises.
- 8.4 Upon release of the Sample, Cellaviva is responsible for securely coding of the Sample, which means that the receiving researcher cannot connect the Sample to the Mother or the Child. The Sample is made available for research against the receipt of the responsible recipient. Cellaviva ensures on the Mother's behalf that a written receipt is obtained from the recipient when submitting the Sample for the purpose of research. Receiving principal investigator assumes responsibility for the Sample through the receipt. Cellaviva is not responsible for the principal investigator's handling or any other use of the Sample after release. Cellaviva is also not responsible for any medical treatment in connection with the research. Cellaviva is, however, responsible for notifying the principal investigator whether the Sample is to be destroyed by them or returned to Cellaviva's biobank after the completion of the research study, in accordance with the Mother's wishes according to point 8.2.

## **9. Agreement duration and termination**

- 9.1 The Agreement runs until further notice, with no set-period, starting on the date the Child is born. The Agreement is considered to apply until the Child owns the Sample, which is from the age of 18 (see section 4.1). The initial agreement ends 18 years after the birth of the Child, when ownership is transferred to the Child.

- 9.2 The Mother can terminate the Agreement at any time under point 9.6. Cellaviva can only terminate the Agreement if payment for storage remains unpaid for at least twelve (12) consecutive months.
- 9.3 If payment for storage remains unpaid for six (6) months, Cellaviva shall notify the Mother in writing that the Agreement may be terminated after another six (6) months if the debt is not settled within the deadline (see paragraph 9.2). The notification must be made to the Mother's address in the Swedish Population Registry. If the Mother wishes to be contacted in another way or elsewhere, the Mother is responsible for informing Cellaviva of current contact information and the way of contact. The Mother must be notified in accordance with point 16. If the Mother does not contact Cellaviva within the deadline, Cellaviva is entitled to destroy the Sample.
- 9.4 If the Sample is still present in Cellaviva's repository at the end of the contract, the Child shall be notified by Cellaviva of the possibility of signing a new agreement for the storage of the Sample.
- 9.5 After 18 years, the Modern and the Child are informed of the termination of the Agreement in accordance with paragraph 4. If the Child has not made itself known to Cellaviva within six (6) months, Cellaviva reserves the right to re-notify the Child and Modern about the Child's ability to sign an agreement for storage at Cellaviva. The Child then receives a reconsideration period of six (6) months. If the Child does not contact Cellaviva within the deadline, Cellaviva is entitled, according to these terms and conditions, to destroy the Sample (in accordance with paragraphs 9.2 and 9.3).
- 9.6 The Agreement ceases with immediate effect if the Sample is destroyed, transferred or released for medical treatment. The Mother's request for destruction, transfer or release for medical treatment does not entitle the Mother any right to reduction or repayment of the fee already paid to Cellaviva.

## **10. Personal data and privacy**

- 10.1 As a tissue establishment, Cellaviva is liable under §21 of the Act (2008: 286) on quality and safety standards when handling human tissues and cells, to keep a register containing information on
- a)** its activities,
  - b)** donors and recipients of human tissues and cells, and
  - c)** analysis processing performed on human tissues and cells.

The purpose of the register and the collection of data is to: ensure the quality and traceability of human tissues and cells to prevent the transmission of diseases. Register may be maintained with automated processing. In the case of personal data, the register contains information only concerning

- a)** the identity of the donor and parents,
- b)** the donor's stated medical history,

- c) the outcome of examinations on the donor and on analysis processing of the human tissues and cells,
- d) the Child's identity, and
- e) the identity of the recipient.

The data in the registry must be kept 30 years after the introduction of the data or final use of the Sample. Cellaviva is the Data Protection Officer for the registry.

- 10.2 The Mother agrees that Cellaviva processes personal data provided by the Mother in connection with signing of the Agreement. Such personal data may e.g. include names, consents, personal identification number, mobile phone numbers, address details, e-mail address and IP address, with the purpose of providing the Mother services via the website that the Mother herself has chosen to buy, and received information from correspondence between the Mother and Cellaviva. Such personal data is processed in order for Cellaviva to be able to complete the Agreement and for administration purposes. The personal data may be used by Cellaviva as a basis for administration of the Mother's commitments, business analysis and development of services and products. Personal data as described above, as well as information on health and diseases related to the Mother and Child, may be disclosed to healthcare providers, tissue establishments, biobanks or research principals in accordance with the National Board of Health and Welfare's regulations SOSFS 2009: 30 for specified purposes in the Agreement (medical treatment, transfer and research). Personal data can also be provided to subcontractors in connection with handling, analyzing and freezing of the Sample.
- 10.3 Cellaviva is the Data Protection Officer for personal information that the Mother provides to Cellaviva. Cellaviva handles personal data in accordance with the Data Protection Regulation (European Parliament and Council Regulation (EU) 2016/679). Cellaviva has appointed a Data Protection Officer, which the Mother can contact for all questions concerning Cellaviva's processing of personal data. Contact information for the Data Protection Officer is available on request via [kundtjanst@cellaviva.se](mailto:kundtjanst@cellaviva.se).
- 10.4 The Mother can at any time turn to Cellaviva to correct any incorrect information and to, once a year, get information about which personal data is processed free of charge. The mother can request that personal data be deleted in connection with the termination of the Agreement, provided that applicable laws allow Cellaviva to delete the data.
- 10.5 Cellaviva undertakes not to disclose to third parties information about Mother or Child without prior approval or to use such information to a greater extent than is required for the performance of this Agreement. Cellaviva's commitment to confidentiality under this paragraph 10 does not apply to information that: (I) was already known to the receiving Party upon receipt; (II) is or has become publicly available or known without Cellaviva violating this privacy obligation; (III) the receiving party has duly obtained from a third party who is not

bound by the obligation of confidentiality in relation to the counterparty; (IV) The Inspectorate for Care and Care or other supervisory authority, or (V) it is incumbent on Cellaviva to make publicly available through court rulings, governmental decisions or otherwise as prescribed by law.

- 10.6 If the Child (or other person who owns the Sample) signs a new agreement for the storage of the Sample with Cellaviva according to clause 9.4, the Mother agrees that her personal data registered in Cellaviva's repository may continue to be processed by Cellaviva within the framework of the new agreement on storage.
- 10.7 Cellaviva is responsible for the observance of the provisions set forth herein and for its respective employees and consultants, and through confidentiality other appropriate measures shall ensure that the Agreement's secrecy is observed.
- 10.8 Cellaviva's confidentiality obligation under the Agreement applies during the contract period and also for a period of five (5) years after termination of the Agreement.
- 10.9 The Mother may at any time lodge complaints regarding Cellaviva's processing of personal data to the Swedish Data Protection Authority.

## **11. Fees and payment terms**

- 11.1 After the Sample has been approved for freezing according to Cellaviva's quality requirements, or approved for freezing by the Mother, regardless of the fact that the Sample has not achieved Cellaviva's quality requirements, the Mother is invoiced. The Mother must pay the fee according to, at the time, current price list. The amount constitutes Cellaviva's full compensation for handling the Sample. The invoice must be paid within thirty (30) days. In case of late payment, interest on late payment is charged according to the Interest Act (1975: 635).

A monthly / annual fee must be paid for the storage of the Sample. The fee for storage is stated in the, at the time, current price list. It is the sample owner who is responsible for payment for the Sample. Payment can be made by automatic transfer or by invoice, when choosing for an invoice, an invoice fee is added. The invoice must be paid within thirty (30) days. In case of late payment, interest on late payment is charged according to the Interest Act (1975: 635).

Cellaviva offers a installment-based payment system for the fee for handling the Sample, also via invoice or via automatic transfer. In case the Mother chooses to split the payment, we reserve the right to perform a credit report and evaluate whether the application is accepted.

## **12. Quality requirements for release**

- 12.1 In case the Sample, which initially met Cellaviva's quality requirements, is deemed to be useless after the contract period due to negligence caused by Cellaviva, the company will repay the entire cost to the Sample owner. The entire cost includes cost for handling of the Sample and accrued costs for storing of the Sample. By unusable is meant that the Sample does not meet the quality requirements. Cellaviva can however, not give any guarantees that the Sample actually can and will be used. This depends on which treatment methods are available at any given time, as well as the amount and quality of the cells saved.

## **13. Development and change of conditions**

- 13.1 New research and new legislation regarding stem cells may lead to methods are changing and improving. Cellaviva therefore reserves the right to change the provided Service. Product and service development may mean that the Agreement is affected. Such changes will be communicated to the concerned customers in writing, as well as via Cellaviva's website. At any time, the applicable customer terms and conditions for the Service under this Agreement can be obtained on demand via [kundtjanst@cellaviva.se](mailto:kundtjanst@cellaviva.se).
- 13.2 The owner of the Sample is entitled to terminate the Agreement for immediate cessation in the event that Cellaviva's proposed changes to the Service or the Agreement may be deemed to be materially detrimental to the Sample's owner and, in the event of such termination, is entitled to a refund to a maximum of half of the fee paid. In the event of such immediate cessation, the Sample owner shall within thirty (30) days request Cellaviva to release the Sample to another recipient/tissue establishment. Cellaviva only accepts tissue establishments and healthcare providers as recipients. If the Sample owner does not assign a recipient within the deadline, Cellaviva is entitled to destroy the Sample.

## **14. Force Majeure**

- 14.1 Cellaviva does not compensate for damage as a result of strike, fire, governmental practice, labor disputes, accidents, errors or delay of subcontractor, operation stop in public communication systems or other circumstances beyond Cellaviva's control and which Cellaviva reasonably does not expect and whose consequences Cellaviva could not reasonably avoid or overcome.

## **15. Liability Restrictions**

- 15.1 Cellaviva is not responsible for the medical treatment and potential benefit of the Sample in connection with such. Cellaviva is not responsible for ensuring that the Sample responds to the quality criteria that may be required for a specific medical treatment or other medical purposes. Cellaviva cannot guarantee that there are medical methods, equipment, techniques etc., for which the Sample can be used. Furthermore, Cellaviva is not responsible for any kind of personal injury or other consequences, which may be a result, directly or indirectly, by the use or misuse of the Sample.
- 15.2 Cellaviva's total liability under the Agreement is limited to repayment of the cost of handling the Sample and storage.

## **16. Notification**

- 16.1 The message shall be deemed to have been received by the recipient;
- if sent by e-mail, text message or equivalent with a receipt,
  - if sent by letter; three working days after the letter was posted
  - if sent by registered letter; two working days after delivery for mailing, or
  - if submitted with courier; at the handover.

## **17. Other**

- 17.1 Should any provision of the Agreement or part thereof be found to be invalid or contrary to applicable laws, ordinances, regulations or permits, such provision shall be adjusted to the extent required for it not to be regarded as invalid or contrary to applicable laws, regulations, regulations or permits. If the Mother and Cellaviva fail to agree on such adjustments to the Agreement, such adjustments shall be decided by the court in accordance with paragraph 18 of this Agreement.
- 17.2 The owner of the Sample may not assign the Agreement and rights and / or obligations as a result of the Agreement to another party.
- 17.3 Cellaviva has the right to hire a subcontractor for the performance of its obligations under the Agreement.

## **18. Dispute**

- 18.1 On the Agreement, Swedish law shall apply. Disputes arising out of the Agreement shall be settled by a public court with the Stockholm District Court as the first instance.
- 18.2 With the signing of the Agreement, the Mother approves that the Sample is handled in accordance with what is stipulated above in the Agreement and Cellaviva's routines as they are designed.

## 19. Signing of agreement

- 19.1 Agreement, ID 31-04-04, is drawn up in two originals, of which the expectant Mother retains the original in the Information Booklet (page 19, ID 40-04-03) while a digital version of Consent ID 45-04-04, Health declaration ID 44-04-04 and Agreement ID 31-04-04 are to be filled in and signed in good time before childbirth, preferably as soon as possible.
- 19.2 The Mother's personal and contact details are treated confidentially by Cellaviva.

The Mother's name: \_\_\_\_\_

Personal Identification Number: \_\_\_\_\_

Street Address: \_\_\_\_\_

Postal code: \_\_\_\_\_

City: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

- 19.3 I hereby certify that I have read and understood the terms of the Agreement regarding the collection and storage of stem cells from the umbilical cord, Cellaviva Agreement ID 31-04-04.

Place and date: \_\_\_\_\_

Signature: \_\_\_\_\_

Print name: \_\_\_\_\_

## **Information booklet**

*- to the expectant parents*

If you have questions regarding the documents in this information booklet or the collection of stem cells from the umbilical cord, please contact Cellaviva's customer service by phone +46 8 735 20 10 or e-mail: kundtjanst@cellaviva.se.

**For urgent issues call the Cellaviva Hotline:**

**+46 70-286 14 20.**

Please visit our website [www.cellaviva.se](http://www.cellaviva.se)

