

GENERAL TERMS AND CONDITIONS

(AT-10/2022)

Preamble

- (1) Vita 34 AG (hereinafter referred to as "**Vita 34 AG**") pursues the collection, processing, and storage of umbilical cord blood and umbilical cord tissue in order to preserve the stem cells contained in such blood and tissue.
- (2) Umbilical cord blood is the fetal blood from the placenta and the attached remaining umbilical cord that is collected immediately after the cord was cut. Umbilical cord tissue is collected after the cord was cut and cord blood taken by cutting the umbilical cord a second time close to the placenta. The full extent of future applications of umbilical cord blood and tissue cannot be foreseen yet.
- (3) Umbilical cord blood and tissue are processed, prepared, and stored at the GMP laboratory of Vita 34 AG (GMP = Good Manufacturing Practice pursuant to the EU GMP Directive for medicinal products for human and veterinary use). As required by law, Vita 34 owns the manufacturing license pursuant to art. 13 German Medicinal Products Act (AMG) to collect and store umbilical cord blood as well as the manufacturing license pursuant to art. 20b and 20c (AMG) to collect and store umbilical cord tissue. Vita 34 Gesellschaft für Zelltransplantate m.b.H. (hereinafter referred to as "Vita 34") as the contracting partner owns the certificate for the collection pursuant to the Austrian Tissue Safety Act (GSG).

§1 Contractual partners and subject matter of the contract

- (1) The contract on the collection and storage is concluded between Vita 34 Gesellschaft für Zelltransplantate m.b.H. and the legal representatives of the child or – in case of multiple births – the children (usually the custodian/s of the child as set forth in art. 158 sec. 1 Austrian Civil Code, hereinafter referred to as the "legal representatives" or "**contractual partners**"). Vita 34 Gesellschaft für Zelltransplantate m.b.H. as a subsidiary then assigns Vita 34 AG with the storage of the stem cell deposit.
- (2) However, the child or – in case of multiple births – the children (hereinafter, the term "**child**" shall also include the plural) as the owner/s shall have the sole power of disposal of the umbilical cord blood and tissue; its use by Vita 34 or third parties shall be excluded. The disposition of the umbilical cord blood and tissue shall comply with the requirements set forth under the applicable pharmaceutical laws. Until the child comes of age, its legal representatives shall represent the child. When attaining full age or before upon approval by the legal representatives, the child may enter into the rights and obligations arising from this contract instead of the contractual partner. The contractual partner shall agree to such change of contractual partner now already.
- (3) The subject matter of the contract comprises the collection and preparation of umbilical cord blood and, if applicable, cord tissue, the storage of the cord blood preparation and, if applicable, cord tissue as well as the services included in the selected type of contract (see the latest insert "**Products, services, and prices**," hereinafter referred to as "**appendix 1**"). With regard to umbilical cord blood, professional processing and preparation for transportation with the purpose of release to the prescribing doctor/other permissible user shall be another subject matter of the contract. The therapeutic application of the cord blood preparation and/or cord tissue preparation is not the subject matter of the contract.
- (4) Umbilical cord blood and, if applicable, tissue will be collected at a maternity institution that is partner of Vita 34. Otherwise, Vita 34 will be released from any and all obligations arising from this contract. Vita 34 will destroy the cord blood and/or cord tissue collected in the inadmissible manner. **The legal representatives shall agree to such destruction now already.** An up-to-date overview of the partner institutions is available online at <https://www.vita34.at/klinikfinder/>.
- (5) If the variant "**Option for public donation**" (**appendix 1**) is chosen, the anonymized data of the umbilical cord blood will be entered in a stem cell registry subject to the necessary suitability for donation. The legal representatives shall agree to HLA typing of the child's umbilical cord blood. If the assessment of the umbilical cord blood by Vita 34 has the

result that the criteria for registration in the stem cell registry are not fully complied with, the blood will be stored without being registered in a stem cell registry in accordance with the chosen type of contract. The variant "Option for public donation" is then regarded as not chosen.

- (6) If the option "**Preventive screening test**" is chosen, Vita 34 will analyze the DNA of the child's cord blood for the abnormalities and intolerances specified in **appendix 1**. Vita 34 will then forward the findings to the legal representatives.

§2 Obligations of Vita 34

- (1) Vita 34 assumes the following duties in connection with the collection of cord blood and cord tissue and the storage of the cord blood preparation in compliance with the licenses as governed by the regulations under pharmaceutical law:
 1. the overall responsibility for the collection of umbilical cord blood;
 2. the delivery of the collection kit to the specified shipping address;
 3. the instruction of the chosen maternity institution or attending physician or freelance midwife that collaborates with Vita 34 (hereinafter referred to as the "**person collecting the cord blood**") to abstain from collecting the cord blood in their sole discretion, if required from the medical point of view to protect mother and child;
 4. the transport of the umbilical cord blood from the maternity institution to the facilities of Vita 34;
 5. the testing of the umbilical cord blood upon delivery for its suitability for preparation;
 6. a) the preparation, cryo-preservation, and storage of the umbilical cord blood preparation;
 - b) the issuance of the certificate of storage;
 - c) the quality control of the umbilical cord blood preparation as stipulated by law in Germany;
 7. the professional processing and preparation for transport with the purpose of release to the prescribing doctor and/or other permissible user after repeated testing of the cord blood preparation; transportation to the applying institution free of charge within Austria, unless the costs are born by third parties (e.g., health insurance);
 8. providing the services as included in the chosen type of contract (**appendix 1**); clauses 1 to 6 and clause 8 shall apply to the storage of umbilical cord tissue accordingly.

The obligations under art. 2 and 4 to 8 above shall be performed by Vita 34 AG in accordance with art. 3 of the Preamble.

- (2) If the tests pursuant to art. 2 sec. 1 clause 5 have the result that the preparation of the umbilical cord blood and/or tissue is impossible or not justifiable, Vita 34 shall inform the legal representatives in this regard and destroy the umbilical cord blood and/or tissue.
- (3) The legal representatives are aware that the field of application of umbilical cord blood cells is still under research and development. At present, the stored umbilical cord blood cells are used for hematopoietic reconstitution of bone marrow after high-dose chemotherapy or radiation, provided that the specifications of the umbilical cord blood preparation required for this purpose are met according to the current state of scientific knowledge. If the quality check shows that storage is possible but that the specifications for hematopoietic use are not met, the cord blood is nevertheless stored in order to be able to use it for therapeutic purposes in the future, possibly as specifications change with the further development of the state of scientific and technical knowledge.

The legal representatives therefore consent to the storage of the cord blood preparation even in the event that the currently applicable specifications are not complied with.

- (4) Vita 34 may use reliable subcontractors to fulfil its obligations. That does not require approval by the legal representatives.

§3 Obligations of the mother/legal representatives, consent

- (1) The contractual partners or – as specified individually – the mother shall:
1. Return the following forms provided by Vita 34 – fully and truthfully completed and signed – to Vita 34:
 - 1) Medical history form until the birth;
 - 2) Copy of the maternity card until the birth;
 - 3) Educational letter and declaration of consent until the birth as specified for selected type of contract;
 - 4) Follow-up medical history form 14 days after the birth at the latest;
 - 5) Consent form regarding tissue typing pursuant to Genetic Diagnosis Act if the variant “Option for public donation” (appendix 1) is chosen;
 - 6) Consent form for preventive screening test pursuant to Genetic Diagnosis Act if the option “Preventive screening test” is chosen.
 2. Choose only a maternity institution collaborating with Vita 34, indicate the desired collection of umbilical cord blood and, if applicable, tissue again to the physician/midwife as well as hand the collection kit provided by Vita 34 and the signed original deed of release pursuant to art. 8 sec. 3 over to the person collecting the umbilical cord blood and, if applicable, tissue right before the birth. If the contractual partner intends to change the maternity institution after the contract on the collection and storage was concluded with Vita 34, he/ she shall inform Vita 34 of such intent in writing. Art. 1 sec. (4), art. 6 sec. (5) clause 3, and art. 6 sec. (6) shall apply;
 3. Promptly notify Vita 34 of the child’s name in writing after the birth;
 4. Promptly notify Vita 34 of blood-borne infectious diseases of mother or child occurring within twelve months after the birth (e.g., hepatitis B, hepatitis C, or HIV).
- (2) The contractual partners shall agree to umbilical cord blood and, if applicable, tissue being collected after the cord of the child was cut.
- (3) The mother shall agree that a blood sample is taken from her to do the necessary serological tests for infectious diseases (including HIV) at the time of the birth (\pm 48 h) and that retain samples are stored for 30 years in accordance with the applicable legal stipulations in order to enable at least two repetitions of the laboratory tests required for the release.
- (4) The contractual partners shall agree that the physician/midwife/clinic submits the findings/data obtained during the pregnancy/birth to Vita 34. That shall apply as well to findings obtained after transplantation of the umbilical cord blood or cord tissue cells. The contractual partners shall release the medical personnel from their obligation to confidentiality in this respect. The contractual partners shall agree that Vita 34 may submit findings obtained by Vita 34 (except the results of the preventive screening tests) as well as copies of medical documents to the attending physician at the clinic in order to comply with the statutory obligations to report.
- (5) If the contract option “Preventive screening test” is chosen, the contractual partners shall agree that the child’s umbilical cord blood is subjected to molecular-genetic diagnostic tests (preventive screening) in accordance with the given parameters. Such consent may be revoked at any time with effect for the future. The contractual partners shall be entitled not to acknowledge the test results or parts thereof and to have them destroyed. The contractual partners shall agree to the storage of the sample material for verification purposes; that sample will be destroyed after ten years. The contractual partners furthermore agree that the laboratory forwards the results of the analysis to Vita 34 in a confidential manner.

§4 Payment

- (1) Vita 34 shall receive a fee for the preparation of the umbilical cord blood and, if applicable, the umbilical cord tissue of a child in accordance with Appendix 1 (hereinafter “Contract Fee”) as well as a fee for the annual storage of the umbilical cord blood or umbilical cord tissue after the expiry of the storage period (hereinafter “Annual Storage Fee”) in accordance with the selected contract variant (appendix 1).

- (2) Upon conclusion of the contract, the contract fee will be invoiced per child, whereas the storage costs included therein can be paid in advance as stipulated in the selected contract variant (appendix 1). The annual storage fee is due in advance on the child’s birthday. The customer shall agree that an electronic invoice will be sent to the e-mail address provided by him/her. Changes to the e-mail address for the invoice must be communicated immediately.
- (3) If the contract fee or the annual storage fee is not paid within three months after the due date despite a request for payment/reminder, Vita 34 shall be entitled to terminate the contract and to destroy the cord blood or cord tissue preparation by giving two months’ notice. The legal representatives now already agree to the destruction.
- (4) Price discounts and other benefits granted by Vita 34 cannot be combined with each other, do not apply to the fee for logistics and collection package and are not granted retroactively.

§5 Price adjustment annual fee

The annual fee is subject to price adjustment as follows:

- (1) The price shall not be adjusted for the first two years from the storage of the umbilical cord blood or tissue.
- (2) If the consumer price index for Germany officially determined by the Federal Statistical Office (Bundesamt fuer Statistik) has changed when compared to the CPI published in the month of December of the year the contract was concluded, Vita 34 reserves the right to reduce or increase the agreed annual storage fee by the same percentage after the first 2 years of storage (as of year 3 of storage). Further adjustments are permitted respectively after another year of storage has expired. The beneficiary may also request the corresponding adjustment of the agreed annual storage fee. In case the annual storage fee is paid in advance as specified for the selected type of contract (appendix 1), Vita 34 shall be entitled to adjust the annual storage fee for the first time after the expiration of the period the down payment was made for. Further adjustments are permitted respectively after another year of storage has expired.
- (3) The contractual partner shall be notified of such exercise of the right to price adjustment at the latest four weeks after the respectively relevant time of adjustment. If the beneficiary exercises the right of statutory termination after having received such notification pursuant to art. 6 sec. 2, the adjustment of the annual storage fee shall not take effect.
- (4) If the annual storage fee is increased by more than 5 percent compared to the annual storage fee as agreed, then the beneficiary shall be entitled to extraordinary notice of cancellation.
- (5) If the consumer price index for Germany determined by the Federal Statistical Office (Bundesamt fuer Statistik) is not continued during the contract period and is replaced by another index, then such index shall be used to solve the problem of value assessment accordingly. The contractual partners shall undertake in such a case to agree another, economically appropriate indexation clause.
- (6) Irrespective of the stipulations given in sec. 2, 3, 4, and 5 above, Vita 34 shall be entitled in case of an increase in the applicable VAT and be obligated in case of the reduction of the applicable VAT to adjust the prices of contractually agreed services rendered as of the time of the respective statutory change accordingly with effect for the future. The contractual partner shall not have the right to cancel the contract in case of such price adjustment.

§6 Contract period/cancellation/termination

- (1) The contract is concluded for an unlimited term. That applies also if the annual storage fee is paid in advance as specified for the selected type of contract (appendix 1).
- (2) The contractual partners may cancel the contract in text form without stating any reasons with effect of the child’s next birthday, though at the earliest for the child’s 2nd birthday. That shall not affect the right of extraordinary cancellation for cause.
- (3) Regular cancellation by Vita 34 shall be excluded. That shall not affect the right of extraordinary cancellation for cause of Vita 34 (e.g., default of payment pursuant to art. 4, breach of duties as stipulated in art. 3).
- (4) If the contract is cancelled by the legal representatives, the claim of Vita 34 for payment of the full contract fee and the annual storage fee shall persist. That shall not apply if the contract is cancelled for cause, in which case the payment will be reimbursed on a pro rata basis.

(5) The contract shall be terminated automatically, without a notice of cancellation being required, if

1. Urgent medical reasons in accordance with the stipulated regulations prevent the storage of the umbilical cord blood or tissue before the collection. Vita 34 shall notify the legal representatives of such in writing;
2. The person collecting the umbilical cord blood or tissue refuses to execute the assignment of collecting the umbilical cord blood and/or tissue or refrains from the collection at his/her own discretion (art. 2 sec. (1) para 3) or other reasons prevent the collection of umbilical cord blood or tissue;
3. The collection of the umbilical cord blood or tissue took place in an institution that is not a partner of Vita 34;
4. The tests upon receipt of the umbilical cord blood and tissue pursuant to art. 2 sec. (1) para 5 show that the preparation and storage are impossible or not justifiable pursuant to art. 2 sec. (2).
5. The reasons of termination as stated in para 1 to 4 shall apply to the storage of umbilical cord blood and tissue only if the preparation of both products (umbilical cord blood or umbilical cord tissue) is impossible according to the quality requirements. Otherwise, the storage of the umbilical cord blood or tissue will be continued. In that case, the amount of the contract fee for storage is based on the contract fee for the storage of umbilical cord blood less the deposit paid, plus the annual storage fee if applicable, depending on the selected contract variant (**appendix 1**). Differences to payments already made will be refunded to the account designated by the contractual partner.

(6) If the contract is terminated pursuant to art. (5) sec. 1 to 4, Vita 34 shall be paid shall only the down payment of the selected contract variant (**appendix 1**). That shall not apply to the case according to sec. (5), para 5 above (storage of umbilical cord blood and tissue), for which the stipulations specified therein shall apply.

(7) If umbilical cord blood and tissue are stored, the termination of the storage of the umbilical cord blood or of the umbilical cord tissue is possible. The amount of the annual storage fee for the remaining storage is then equal to the annual storage fee for the storage of umbilical cord blood. The contract fee or already paid annual storage fees for umbilical cord blood and tissue will not be refunded retroactively.

(8) If a contract that includes the optional preventive screening test pursuant to art. 3 sec. (5) is terminated, an additional fee at the amount as specified in **appendix 1** shall be paid to Vita 34 for each child for the provided findings of the preventive screening tests. That shall apply also to multiple births.

(9) If the contract is terminated pursuant to sec. (2), (3), (5), para 1, 2, 4, and 5 and/or sec. (7) above, **the legal representatives shall agree that Vita 34 destroys the stored umbilical cord blood and/or tissue**, unless the beneficiary disposes otherwise of the umbilical cord blood and/ or tissue within eight weeks after the contract has ended pursuant to art. 48 AMG. If the contract ends pursuant to sec. (5) para 3 above, the stored umbilical cord blood and/or tissue will be destroyed immediately as stipulated in art 1 sec. (4).

(10) Apart from the above stipulations, the contract shall terminate and thus the obligation to pay the annual storage fees, if Vita 34 submits the stored umbilical cord blood and/or tissue to the attending physician/other permissible user upon his/her request. For the storage of umbilical cord blood and tissue, sec. (7) para 2 shall apply accordingly.

§7 Assignment of claims

- (1) The legal representatives shall agree that Vita 34 may assign all outstanding monetary claims against them in whole or in parts and disclose the data required for the assertion and enforcement of such claims (name and address of the contractual partner, amount, due date, invoice number of the assigned claims), as well as submit the required documents. Such information and documents will be treated as strictly confidential and not be misused.
- (2) Further regulations are stipulated in the data privacy statement of Vita 34.

§8 Liability of Vita 34/waiver of claims against the clinic

- (1) Vita 34 shall be liable – apart from material default (breach of contractual obligation the fulfilment of which facilitates the proper implementation of the contract in the first place and the compliance with which

the contractual partner usually trusts in and may trust in) or in case of injury to life, body, or health – only for intent and culpable negligence.

(2) Vita 34 shall not furnish any guarantee whatsoever for current or possible future applications of the umbilical cord blood or tissue preparation, which are not the subject matter of the contract in accordance with art. 1.

(3) On their own behalf and in the name of the child, the legal representatives shall waive any claims against the maternity clinic and the person collecting the umbilical cord blood and/or tissue and the maternal blood, unless such claims are based on deliberate intention or culpable negligence. That shall not apply to damages resulting from injury to life, body, or health or from the serious violation of a contractual obligation. For the purpose of this exemption from liability, the legal representatives shall submit the signed original deed of release to the maternity clinic or the person collecting the umbilical cord blood and/or tissue. This deed shall not affect any claims of the child against Vita 34 due to culpable conduct of the maternity clinic or the person collecting the umbilical cord blood and/or tissue.

(4) If the umbilical cord blood or umbilical cord tissue or the stem cell preparation made of umbilical cord blood or tissue is negligently destroyed or otherwise made unusable due to negligence, the liability of Vita 34 AG shall be limited to the compensation of the additional cost of a possible autologous donation (e.g., cell separation, bone marrow) or allogeneic donation (e.g., cell separation, bone marrow) of stem cells. Further liability claims shall not be applicable. Vita 34 is in particular not liable for possibly missed therapeutic chances.

§9 Data privacy

(1) Vita 34 shall be authorized to store the personal data of the child and the legal representatives that are necessary to implement the contract and to pass them on to contractual partners where required to implement the contract. Vita 34 shall treat such data as confidential and commit its contractual partners to confidentiality.

(2) Vita 34 shall be authorized to pass the data, which are necessary to apply the umbilical cord blood for therapeutic purposes, onto the physician/other permissible user upon request.

(3) Within the scope of public donation, Vita 34 will pass on only the data of the preparation, however, no personal data (apart from the date of birth), to the stem cell registry or to the applying physician in case of release for application.

(4) Further regulations are stipulated in the data privacy statement of Vita 34.

§10 Final provisions

(1) The parties shall notify each other promptly in writing of changes of address or name. The legal representatives shall furthermore notify Vita 34 promptly of changes in the representation relationships. The legal representatives shall inform the child at the latest when it comes of age about the content of the contract and in particular about the child's rights of ownership.

(2) Modifications and amendments of this contract shall be made in writing to be effective. That does also apply to the cancellation or modification of this written form requirement. The requirement of the written form shall not apply to agreements made orally between the parties directly after the contract was concluded.

(3) If a provision of this contract is or becomes invalid or infeasible, that shall not affect the validity of the remaining provisions. The contractual parties shall undertake to replace the invalid or infeasible provision by such a valid and feasible provision that comes closest to the originally intended economic purpose of the invalid or infeasible provision. The same shall apply to gaps in the contract.

(4) The laws of Germany shall apply.

(5) In case of doubt, the German version of the present General Terms and Conditions shall have priority.

INFORMATION ON THE RIGHT OF WITHDRAWAL

Right of withdrawal

You are entitled to withdraw from this contract without stating any reasons within fourteen days.

The period of withdrawal is fourteen days from the date on which the contract is concluded.

To exercise the right of withdrawal, you need to submit an explicit declaration (sent e.g. by mail, fax, or e-mail) of your decision to withdraw from this contract to:

Vita 34 Gesellschaft für Zelltransplantate m.b.H.
Hartäckerstrasse 28, 1190 Wien
Phone: +43 (0)153394-43
E-mail: kundenservice@vita34.at

You may use the enclosed sample form of withdrawal, which is not compulsory though.

To comply with the period of withdrawal, it shall be sufficient to send the declaration of withdrawal prior to the expiry of this period.

Consequences of withdrawal

If you withdraw from the contract, we shall reimburse any payment made by you, including the cost of delivery (except for the additional cost arising from your choice of another than the low priced standard type of delivery), promptly and at the latest within fourteen days after we received the declaration of withdrawal. We will use the same means of payment that you used for the initial transaction, unless otherwise expressly agreed. We will in no event charge extra costs for such reimbursement.

You have to return the goods (the collection kit) promptly and in any case at the latest within fourteen days after you informed Vita 34 about the withdrawal to **Vita 34 Gesellschaft für Zelltransplantate m.b.H., Hartäckerstrasse 28, 1190 Wien**. This period shall be regarded as complied with, when you send the goods prior to the expiry of this period.

You will bear the direct charges for the return.

You need to pay for a possible depreciation of the goods only, if such depreciation is the result of you handling the goods in a way that is not required to check the quality, properties, and functionality of the goods.

If you requested that the services start during the period of withdrawal, you will have to pay an adequate amount corresponding to the portion of the services already rendered at the date on which you informed us about your decision to withdraw from the contract compared to the total scope of services provided for in the contract.

End of information on right of withdrawal

Withdrawal

(Please fill in only if you want to withdraw from the contract!)

I/we herewith withdraw from the contract I/we concluded regarding the purchase of the following goods/the provision of the following services:

Order date* _____

Name/address of consumer/s

Title* First name* Last name*

Street and house number*

Postal code and place*

Country

Your e-mail address for prompt confirmation of the withdrawal

E-mail*

Date of withdrawal* _____

Signature* _____

All fields marked with an asterisk (*) are required fields.