

## **Terms & Conditions for Autologous Hematopoietic Stem Cell Transplantation (aHSCT)**

### **I. INTRODUCTORY PROVISIONS**

1. These General Terms and Conditions (hereinafter referred to as GTC) regulate relations between the Medical Center Prague, with its registered office at Praha 4, Modřany, Mezi vodami 205, Postal Code 143 00, IČ: 25032119, registered in the Commercial Register maintained by the Municipal Court in Prague, Section C, insert 116020 (hereinafter referred to as MCP or Provider) and Laboring parent (hereinafter referred to as "L-Parent") in the provision of services for the storage of hematopoietic stem cells from umbilical cord blood for autologous transplantation (hereinafter referred to as "aHSCT") on the basis of the Contract for the Provision of Hematopoietic Stem Cell Stem Cells for Autologous use.
2. These GTCs may be departed from in individual cases only on the basis of a written agreement between the Provider and the L-Parent. Oral statements made by the Provider or his employee towards the L-Parent, the Provider (MCP) does not bind to.
3. All contracts for the provision of the storage of hematopoietic stem cells for autologous transplantation concluded between the Provider and the L-Parent shall be made in writing, including any amendments or additions.
4. The L-Parent accepts and acknowledges the following GTC as binding for legal relations arising from the concluded contract for the storage of umbilical cord blood for autologous transplantation settled between the Provider and the L-Parent. Valid GTCs are published on the MCP website [www.kmenovsky.cz](http://www.kmenovsky.cz).

### **II. DEFINITION OF TERMS**

The following terms or abbreviations used in these GTC are defined as follows:

- Collection facility: a state or non-state health facility ("maternity hospital") with which the Provider has concluded a contract on the basis of which the facility will provide the L-Parent with a part of the performance agreed between the Provider and the L-Parent as the umbilical cord blood collection during delivery for the purpose of autologous use (transplantation),
- SÚKL: State Institute for Drug Control,
- autologous transplantation: therapeutic performance in which a patient's own haematopoietic stem cells are previously transplanted,



- aHSCT: hematopoietic stem cells derived from umbilical cord blood for storage and subsequent autologous transplantation,
- Archiving aHSCT: Long-term Storage aHSCT by Automated BioArchive® System According to Standard Operating Procedures in Liquid Nitrogen,
- Transplant Center: a medical facility different from the Provider that will perform an autologous aHSCT transplant in the future,
- aHSCT release: extract aHSCT from Archiving in Liquid Nitrogen BioArchive® based on an application to the authorized person in a way that allows the use of aHSCT for autologous transplantation,
- aHSCT distribution: transportation and delivery of the aHSCT to the transplantation center where it is to take place, subject to the conditions for the release and distribution of the aHSCT referred to in Article VI. in these GTC,
- disposal of aHSCT: liquidation of aHSCT as biological waste according to standard operating procedures based on decision of the responsible person of the Provider,
- Authorized person: owner of aHSCT or, at the time of minority, his/her legal representative, i.e. the person authorized to release aHSCT having ownership (disposition rights) for aHSCT.

### **III. CONTRACT, SUBJECT MATTER**

**1.** A written Contract for the provision of aHSCT storage services is concluded between the Provider and the L-Parent, the part of which is the GTC (hereinafter referred to as the Contract).

Provider's Services include:

- 1.1 Registration of the L-Parent, provision of information and instructions required in the informed consent process for the execution of the aHSCT,
- 1.2. provision of telephone service,
- 1.3 securing the collection of the aHSCT at the collection facility,
- 1.4 follow-up examination and processing of the withdrawn aHSCT so that it is in a condition for long-term archiving,
- 1.5 if the L-Parent is interested, on the basis of informed consent to the isolation and storage of the DNA sample from the umbilical cord blood for autologous use, also the storage of the DNA sample from the aHSCT,
- 1.6 Informing the L-Parent about the results of laboratory processing and aHSCT exams,
- 1.7 sending a confirmation (Certificate) to the L-Parent constructed by the MCP following the successful storage of the aHSCT and reimbursement of the 1st advance payment (remuneration) for the aHSCT collection services and aHSCT storage based on the pricelist,
- 1.8 Archiving aHSCT, i.e. long-term storage of aHSCT in a place and conditions that will allow the subsequent use of aHSCT for autologous transplantation. Storage is for 20 years, i.e. 240 months,
- 1.9 release long-term stored aHSCT at any time on the request of an authorized person (aHSCT owner) for autologous transplantation.

**2.** The Provider's obligations within the framework of the Services:



- 2.1 to ensure the consumables needed for the collection and transport of aHSCT within the framework of the collection facility and the contracted transport service,
- 2.2. ensure the collection of aHSCT at the collection facility,
- 2.3 ensure the transport of the taken aHSCT from the collection facility to the storage location,
- 2.4 ensure legally required examinations of aHSCT for bacterial contamination with the possibility of execution at contractual health facilities,
- 2.5 to provide a qualitative assessment of the withdrawn aHSCT, e.g. examination of viability and number of stem cells in aHSCT,
- 2.6 ensure that the L-Parent is informed of the collection results, processing and examinations within 5 weeks of receiving the aHSCT,
- 2.7 ensure the processing and freezing of the aHSCT in a way that allows long-term storage and subsequent storage of aHSCT properties so that it can be used for autologous transplantation,
- 2.8 ensure the handling of aHSCTs and the subsequent storage of aHSCT in accordance with generally accepted medical practices and generally binding legislation,
- 2.9 ensure that aHSCT is released in accordance with this Contract to the owner of aHSCT or their legal representative; the person authorized by them,
- 2.10 comply with the requirements of applicable legal regulations and regulatory institutions during the term of the Contract - the State Institute for Drug Control (SÚKL),
- 2.11 fulfill the subject of the Contract with the maximum possible professional care.

### **3. The Provider has the right:**

- 3.1 for the payment of the price for the services, the amount, the method of payment and the due date are set out in Article V. of the Contract and the Provider's price list valid on the date of conclusion of the Contract, which is an integral part thereof,
- 3.2. refusal to provide the aHSCT storage service on the basis of positive microbiological results and/or in case of low cell viability. In these cases, when aHSCT cannot be processed in accordance with the quality requirements of the product, it is entitled to shred such aHSCT, informing the L-Parent of the shredding.

### **4. Authorized person - aHSCT owner has the following rights:**

- 4.1 request the release of the stored aHSCT in accordance with the GBC,
- 4.2 decide at any time about shredding the stored aHSCT, shredding Contract expires,
- 4.3 to request from the Provider or its contractual health facilities information related to the fulfillment of the Contract.

## **IV. PAYMENT TERMS**

1. The Parties agree that the L-Parent is obliged to reimburse the Provider for the services rendered in the manner, amount and deadlines specified in Article V of the Contract.

2. If the aHSCT taken under Article II. point 1.1. of the Contract, the Provider concludes that it is not possible to store aHSCT for a long time and it is not possible to fulfill the Contract in the part of Art. II par.1.2; b) of the Contract shall not be reimbursed and the amount of the one-time remuneration pursuant to Article V, par. 1 (a) of the Contract shall be amended as follows:

- a) if aHSCT cannot be stored for reasons on the L-Parent's side, these are: a serious infectious disease (Syphilis, HIV), which the L-Parent had to know about or was informed of during pregnancy or check-ups, listed in the MCP pricelist.
- b) if aHSCT cannot be stored for reasons on the Provider's side, no claim for remuneration arises. The L-Parent does not pay the reward. In such a case, the Provider shall return to the L-Parent the financial compensation paid so far, no later than 30 days after the date of the occurrence and/or collection of the aHSCT.
- c) if low cell viability (below 80%) is detected or low number, aHSCT will not be further processed if a qualitative assessment of hematopoietic stem cells from the withdrawn aHSCT is made. If, at the time of aHSCT collection, the umbilical cord suddenly and quickly collapses and the collection is negligible or does not take place, the Provider will discard the aHSCT and inform the L-Parent about this, and return the payment due to 30 days from the disposal of aHSCT.

3. In the event of the L-Parent's withdrawal from the Contract pursuant to Article VII, item 2, the Parent undertakes to pay the Provider an advance payment of CZK 4,900. If this financial settlement was paid by the L-Parent before receiving the Certificate, the Provider does not return the advance payment.

## **V. DURATION OF THE CONTRACT, TERMINATION OF THE CONTRACT**

1. The contract is concluded for 240 months from the date of aHSCT archiving. If any of the following occurs, the contract will expire:

1.1. by issuing aHSCT for distribution to the Transplantation Center upon the request of an authorized person to release aHSCT for autologous transplantation,

1.2. by ensuring the distribution under the conditions for the issue and distribution of the aHSCT described in Article VI. GTC, upon request of an authorized person for the release of aHSCT for the purpose of autologous transplantation,

1.3. by the decision to eliminate the responsible person of the Provider, based on:

1.3.1 termination of archiving, the termination of archiving shall be based on the request of the authorized person and at the same time the conditions for the issue and distribution of aHSCT pursuant to Article VI. GTC,

1.3.2 termination of archiving at the request of the authorized person and subsequent communication of the authorized person or a person approved by, or a designated transplant center that is not interested in the distribution of aHSCT

1.3.3 termination of archiving, if the subject of the Contract is frustrated from the professional point of view, i.e. aHSCT is not objectively suitable for autologous use,

1.3.4 the facts referred to in Article III (3) (3.2) of these GTC.

1.4. by the expiration of 20 years (240 months) from the date of Archiving of the aHSCT, unless the prolongation of storage pursuant to paragraph 2 of this GTC is agreed upon on the request of the authorized person,

1.5. termination of any of the Contracting Parties, the Contracting Parties agreeing to a period of notice of 3 months. The notice period begins on the first day of the month immediately following the month in which the notice was delivered to the other party.

2. If the aHSCT is not released for autologous transplantation within 240 months, the Contract will expire upon expiry of this period; however, it is possible, on the basis of an application by the authorized person stating the required time and after acceptance of this request by the Provider, to extend the duration of the Contract. The validity of this Contract is prolonged by the acceptance if the person entitled undertakes to pay, for an extended storage period, the contractual storage price according to the MCP pricelist valid at the time of the request for renewal and published on [www.kmenovky.cz](http://www.kmenovky.cz).

3. If termination of the Contract is authorized by the L-Parent or aHSCT Owner, the Parent or aHSCT Owner is obliged to pay the storage fee for the period of the notice period, if the notice period exceeds the 1<sup>st</sup> of January of the relevant calendar year; the calendar year in which the period of notice was given.

4. In the event that the Contract is not terminated by handing over for distribution or distributing the aHSCT to the respective Transplantation Center, but the Contract is otherwise terminated, the aHSCT will be discarded upon termination of the Contract.

5. In the event of the L-Parent's delay or their legal successor with payment of a fee or of storage longer than 3 months, the Provider is entitled for an immediate termination of the Contract. The contract expires on the day of delivery of the immediate notice to the other party, the L-Parent or the legal successor is obliged to pay the Provider all due obligations, incl. contractual penalties within 7 days from the date of delivery of the immediate notice. If the L-Parent fails to do so, the Provider shall be entitled to shred the aHSCT without further notice; this does not cease the Provider's entitlement to pay remuneration or for storage.

## VI. CONDITIONS AND DISTRIBUTION OF aHSCT

1. The release of the aHSCT is done by the owner (Authorized person) of the aHSCT, or in case of minors the legal guardian. The responsible employee of the Provider shall assess whether the person mentioned in the application is an authorized person - the owner of the aHSCT stored sample provider. In the application, the person entitled will state: for what purpose the aHSCT is being requested, if they are aware of the requirements of the Transplant Center for the aHSCT, they will include these requirements: identify the transplantation center, department and physician - contact person for autologous transplantation. They may also authorize the Transplant Center to take all necessary steps to ensure the distribution of aHSCT from the MCP and the subsequent takeover of aHSCT for autologous use by the Transplantation Center.

2. Upon receipt of the request and verification of the Applicant's person according to the Provider's records, upon proving that the Applicant is the owner of aHSCT (or their legal representative), the Provider shall contact the Transplantation Center without delay through the contact person specified in the application.

3. In agreement with the Transplantation Center and the authorized person, the method of distribution of the aHSCT sample through the holder of the authorization of distribution activity in the area of Human Tissues and Cells granted to SÚKL shall be ensured as follows:

a) the authorized person entrusts the Provider by ensuring the distribution, which he/she will do through their contractual partner, whom is the holder of the distribution license issued by SÚKL,

b) the Authorized Person shall, either by themselves or through their chosen Transplantation Center, elect a Distributor according to the List of Holders of Distribution Authorizations in the Area of Human Tissues and Cells issued by SÚKL, of their choice.

4. The Provider declares and warrants, for the entire duration of the provision of umbilical cord blood storage services for autologous use, the enclosed a contract with a contractual partner who has the relevant license to distribute SÚKL pursuant to Act No. 296/2008 Coll. of Human Tissues and Cells intended for human use, (hereinafter referred to as the "contractual partner"), and is able through this contractual partner to ensure without delay the distribution of the aHSCT according to the requirements of the authorized person and the Transplant Center.

5. In the event that the Authorized Person decides to use the Provider to ensure distribution through the Provider's contractual partner, the Provider shall promptly ensure the release of the aHSCT and handover to the contractor for distribution.

6. The Provider shall ensure that the aHSCT is handled in accordance with the requirements of the Transplantation Center and the Human Tissues and Cells Act when issued and distributed. If appropriate, distribution of the aHSCT sample will be done in conjunction with and with the assistance of the Provider's staff.



7. The Provider shall charge the distribution fee to the Beneficiary in the amount charged to the Distribution Services by the contractual partner (re-invoicing) if the Provider runs the distribution.

8. From receiving of the aHSCT by an authorized person and/or a person approved to do so, the Provider bears no responsibility for the condition and usability of the aHSCT if it was handled in violation of the GTC or Act No. 296/2008 Coll. human tissues and cells for human use.

9. From the date of issue of these GTC, Meditrans s.r .o. Prague 4, Vazovova 3/3228, Postal Code 143 00, IČ: 438 74 681, the amount of the contractual fee is governed by the terms of the contract for the provision of medical transport services - distribution of tissues and cells.

## **VII. IMPOSSIBILITY OF FULFILLMENT, WITHDRAWAL FROM THE CONTRACT**

1. The contracting parties agree that the contract shall terminate without any further due to the impossibility of achievement if the following facts occur:

1.1. the L-Parent shall not provide the necessary synergies before the planned labor term according to Article II, point 2, paragraph 2.1-2.3 of the contract,

1.2. birth occurs prematurely or outside the collection facility,

1.3 birth takes place in a medical facility that is not a contracting facility contractually agreed by the Provider,

1.4 if the Provider becomes aware before the commencement of delivery that the L-Parental or fetal health status does not allow fulfillment of this Contract.

1.5 if the delivery process does not allow the aHSCT to be taken by the attending physician.

The L-Parent is entitled, after receiving the aHSCT collection certificate, to withdraw from the Contract without giving a reason, in writing, within 10 days of receiving the Certificate. In such case, the Provider does not return the Parent's advance payment of 4,900 CZK.

Failure to provide services by the Provider, shall not be considered a delay and shall not give right to claim for damages, provided that the Provider was temporarily or permanently prevented from fulfilling its obligations under the Contract by an unforeseeable and unbeatable obstacle independent of its will. Such an obstacle is, in particular, a natural disaster, war, fire, explosion, labor dispute, etc. The affected party undertakes to inform the other party in writing immediately of the reasons and duration of such an obstacle.

## VIII. PROTECTION OF PERSONAL DATA

In accordance with Section Act No. 110/2019 Coll., On Personal Data Processing, as amended, we are obliged to inform you of the reason and extent to which personal data will be processed, who will process your personal data and how, and to whom your personal data may be disclosed. This information is given in Appendix no. 1 to these General Terms and Conditions (GTC).

## IX. FINAL PROVISIONS

1. By signing this Contract, the Provider expressly declares and warrants to the L-Parent that, in the event of termination of the Provider's activities, to operate a tissue establishment pursuant to Act no. No. 298/2008 Coll., on quality assurance and safety of human tissues and cells for human use and on amendments to certain related acts (Act on Human Tissues and Cells), as amended, ensures preservation of aHSCT samples and documentation, traceability and the availability of stored tissues and cells for the purpose of their use, in accordance with the listed Act on Human Tissues and Cells.
2. The contractual relationship shall be governed by the laws of the Czech Republic and any disputes arising out of or in relation to it shall be entitled to be heard and decided by the competent courts in the Czech Republic.
3. Any written communication between the Parties shall take the form of a registered letter or electronically to contacts communicated by the Parties during the term of the Contract. Interested parties undertake to notify the other party in writing of the change of address, residence or change of other contact details. The day of delivery of documents sent under the Contract or in connection with the Contract, unless another day of delivery is proven, is understood to be the last day of the period in which the document for the addressee has been deposited with the postal operator, even if the addressee did not know of the deposit.

These General Business Terms and Conditions come into effect on June 18<sup>th</sup> 2019





## **Appendix no. 1 of the General Business Terms and Conditions for Autologous Hematopoietic Stem Cell Transplantation (aHSCT)**

### ***Information on processing of personal data***

*In accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46 / EC (General Regulation on the protection of personal data) and in accordance with Act No. 110/2019 Coll., on the Processing of Personal Data and Amendments to Certain Acts, as amended (hereinafter referred to as "GDPR"), we are obliged to inform you as the data subject (the "Client") about the way of processing your personal data at the Medical Center Prague (hereinafter referred to as the "Administrator").*

The Administrator and the Client have concluded a Contract for the provision of aHSCT storage services. Within this legal relationship, the Provider will process the client's personal data in accordance with Act No. 110/2019 Coll., On Personal Data Processing, as amended.

### ***Actualisation of the contractual relationship:***

This processing is necessary for the performance of the Contract to which the Client is a party. The processing of personal data of the client is carried out on the basis of the legal authorization of Article 6, section 1, GDPR.

**Under this authority, the Administrator is not required to demand the Client's consent to the processing of personal data.**

### ***Privacy Manager:***

Medical Centre Prague, with its registered office at Mezi Vodami 205/29, 143 00 Praha 4, IČ: 25032119, registered in the Public Register kept by the Municipal Court in Prague, Section C, File 116020.

### ***Scope of processed personal data:***

- name and surname,
- year of birth
- delivery (billing) address
- email address,
- phone number.



***Purpose of processing provided data:***

These data are processed for the purpose necessary to fulfil the terms of the Contract.

***The time length that personal information will be stored:***

The personal data will be stored by the administrator for 10 years. The period of deposit is set out in Section 5 (2) of Act No. 235/2004 Coll., On Value Added Tax, as amended.

***Personal data processors:***

- Medical Center Prague, Mezi Vodami 205/29, 143 00 Praha 4.
- Sales Representative in contractual relationship with Medical Center Prague, for order mediation.

***Your rights to the protection of your personal information:***

- According to Article 15 of the GDPR, the data subject has the right of access to personal data concerning him/her, pursuant to Article 16 GDPR, the right to require the administrator to correct inaccurate personal data concerning him, pursuant to Article 17 GDPR, the right to delete personal data, which concern him/her. The data subject has the right to prevent the controller from restricting the processing of personal data of the data subject in the cases listed in Article 18 of the GDPR.
- The data subject has the right to require the controller to inform him/her of the recipients of personal data under Article 19 of the GDPR. The administrator does not perform the processing of personal data in an automated way; the right for data portability under Article 20 GDPR is not applicable.
- Under Article 21 of the GDPR, the data subject has the right at any time to object to the processing of personal data concerning him/her in the case of processing necessary for the performance of the public interest task or the exercise of public authority under Article 6 (1) e) GDPR.
- It is not possible to request the deletion of personal data that the health service provider is obliged to collect under a legal obligation (obligation imposed by law).
- The data subject has the right to file a complaint with the Supervisory Authority, which is the Office for Personal Data Protection. Postal address: ÚOOÚ, Sochora 27, 170 00 Praha 7, e-mail address: posta@uouu.cz, data box: qkbaa2n.

The controller does not transmit or intend to transfer personal data to a third country or international organisations.