

General Terms and Conditions of Peripheral Blood Mononuclear Cells (PBMCs) derivation

I. INTRODUCTORY PROVISIONS

- 1.** These General Terms and Conditions (hereinafter referred to as GTC) regulate the relations between Medical Center Prague, with its registered office at Praha 4, Modřany, Mezi vodami 205, Postal Code 143 00, IČ: 25032119, listed in the Commercial Register maintained by the Municipal Court in Prague, Section C, insert 116020 (hereafter referred to as MCP or the Provider) and the Client (hereinafter referred to as the Client) in providing the services of procuring, investigating, processing, dismissing, storing and distributing peripheral blood-derived mononuclear cells for autologous use (hereinafter referred to as PBMCs) on the basis of the contract for the provision of investigation, processing, release, storage and distribution of peripheral blood mononuclear cells for autologous use (hereinafter referred to as the Contract).
- 2.** The establishment of oral agreements shall be excluded and, in the event that any contracting party considers any action of the other party to constitute an oral agreement, such action shall be deemed legally unenforceable.
- 3.** All contracts for the provision of the service of procuring, investigating, processing, dismissing, storing and distributing peripheral blood mononuclear cells for autologous use between the Provider and the Client shall be made in writing, including any amendments or additions. The exchange of simple e-mail messages will not be considered as a written form for this purpose.
- 4.** The Client accepts and acknowledges the following GTC as binding for legal relations arising from the concluded Contract on provision of services for the procurement, investigation, processing, release, storage and distribution of peripheral blood mononuclear cells for autologous use concluded between the Provider and the Client. Valid GTCs are published on the MCP website www.kmenovsky.cz.

II. DEFINITION OF TERMS

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

- PBMCs: mononuclear cells derived from the peripheral blood of the Client for archiving (storage) and subsequent autologous use,
- SÚKL: State Institute for Drug Control,
- autologous transplantation: therapeutic performance, in which the transfer of patient's own hematopoietic stem cells, that were taken previously, occurs,
- mobilization: application of a substance intended for the mobilization of peripheral stem cells,

- obtaining PBMCs: separation of blood components in order to separate mononuclear cells by established operating procedures through a dedicated and approved instrument in the Provider's sampling room,
- PBMCs archiving: long-term storage of PBMCs in liquid nitrogen and/or liquid nitrogen vapours according to standard operating procedures,
- transplant centre: a medical facility different from the Provider that will in the future carry out autologous PBMCs transplantation,
- manufacturer: a manufacturer holding a license to manufacture a corresponding type of advanced therapy medicinal product, within the scope of the authorization of manufacturing evaluated medicinal products,
- Issuance of PBMCs: removal of PBMCs from archiving on the basis of Client's request for compliance with the conditions for issuance and distribution of PBMCs in a manner that allows the usage of PBMCs for direct use by the recipient, respectively for manufacturing advanced therapy medicinal product,
- release: release of PBMCs by the responsible MCP for distribution and subsequent use for transplantation or for the manufacture of advanced therapy medicinal product,
- PBMCs distribution: transport and delivery of PBMCs to the transplantation centre for autologous PBMCs transplantation or to the manufacturer where the advanced therapy medicinal product is to be produced.

III. CONTRACT, SUBJECT MATTER

1. A written Contract is concluded between the Provider and the Client for providing services for the procurement, investigation, processing, release, storage and distribution of peripheral blood mononuclear cells for autologous use, of which Appendix No. 1 and these GTC form an integral part.
2. The Provider's services include the activities specified in Appendix No. 1 to the Contract.
3. The Provider is obliged to provide the material, equipment and means within all activities specified in Appendix No. 1 to the Contract as a service.
4. The Provider has the right for payment of the services price - remuneration and storage, the amount of which, the method of payment and the due date are set out in Appendix No. 1 and the Price List, which form an integral part of the Contract.
5. The Provider has the right to refuse to provide the PBMCs Subscription Service based on the positive results of microbiological and serological examinations found within the Medical Examination Services as defined in Appendix No. 1 to the Contract.
6. The Provider has the right to refuse to provide the PBMCs Storage Service in the event of insufficient PBMCs or low cell viability. In such cases, he is entitled to discard such PBMCs,

informs the Client of the disposal, the amount of remuneration is stipulated in Article IV, paragraph 2.1 of these GTC.

7. The Client has the right to request the issuance and distribution of stored PBMCs in accordance with these GTC.

8. The Client has the right to decide at any time about the disposal of the stored PBMCs, thus the Contract expires.

9. The Client has the right to request information related to the fulfilment of the Contract from the Provider or its contractual medical facilities.

IV. PAYMENT TERMS

1. The Parties agree that the Client is obliged to pay the Provider fees for service in the amount and time limits set forth in Appendix No. 1, which forms an integral part of the Contract.

2. If after the examination of the taken PBMCs, the Provider concludes that it is not possible to store the PBMCs for a long time, the Provider shall immediately notify the Client and dispose of the PBMCs. In which case the storage, specified in Appendix No. 1 of the Contract, shall not be paid. Further, the amount of the one-off remuneration for "PBMCs withdrawal" services specified subsequently in Appendix No. 1 to the Contract is amended as follows:

2.1 in case of unsuccessful withdrawal or insufficient amount of PBMCs withdrawn or low cell viability, the Provider's contractual remuneration is CZK 5,000,

2.2 if the PBMCs cannot be stored for reasons lying on the Provider's side, no entitlement to remuneration arises. The client does not pay the fee.

V. DURATION OF THE CONTRACT, TERMINATION OF THE CONTRACT

1. The Contract is concluded for a definite period of time, not exceeding 120 months from the date of archiving of PBMCs.

The contract will expire if any of the following occurs:

1.1 by issuing the PBMCs for distribution under the conditions for the issue and distribution of PBMCs described in Article VI. upon the Client's request to issue the PBMCs for the purpose of autologous use,

1.2 a decision for disposal by the responsible person of the Provider, based on:

1.2.1 termination of archiving, the termination of archiving will be based on the Client's request, and at the same time the conditions for issuing and distributing PBMCs pursuant to Art. VI. of these GTC,

1.2.2 termination of archiving at the request of the Client or a person authorized by him/her that there is no interest in distribution of the PBMCs,

1.2.3. Termination of archiving, if from a professional point of view the subject of the Contract is frustrated, i.e. PBMCs is not objectively suitable for autologous use,

1.2.4 the facts referred to in Article III, points 4 and 6 of these GTC,

1.3 by the expiration of a period of 10 years (120 months) from the date of archiving of PBMCs, unless an extension of storage pursuant to par. 2 of this GTC article.

1.4 termination without giving any reason to any of the Contracting Parties, in which case the Contracting Parties agreed on 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 PBMCs is not issued for autologous use within 120 months of storage, the Contract shall expire upon ending of this period; however, it is possible, at the request of the Client, specifying the required time and after accepting this request by the MCP, to extend the duration of the Contract. The validity of this Contract is extended by this acceptance, if the Client 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, published at www.kmenovky.cz.

3. Upon termination of the Contract by the Client, the Client is obliged to pay the storage fee also for the time of the notice period. If the notice period exceeds 1st of January of the relevant calendar year, the Client is obliged to pay the entire storage year for the relevant calendar year in which the notice period was executed.

4. In the event that the Contract is not terminated by releasing for distribution or securing the distribution of PBMCs, but the Contract ceases to exist by other means, the PBMCs will be discarded upon the termination of the Contract.

5. In the event of the Client's delay in payment, of the fee or storage sum, longer than 3 months, the Provider is entitled to immediately terminate the Contract. The contract expires on the day of delivery of the immediate notice to the other contracting party, the Client or his legal successor is obliged to pay to the Provider all due obligations, incl. contractual penalties within 3 days from the date of delivery of the immediate notice. Otherwise, the Provider shall be entitled to discard the PBMCs without further notice. This disposal does not affect the Provider's entitlement for fee or storage remuneration.

VI. PBMCs ISSUANCE AND DISTRIBUTION CONDITIONS

1. The Client shall request the issuance of their PBMCs in writing. The Provider's responsible person shall assess whether the specified person is the Client and thus the owner of the stored PBMCs sample. In the application, the Client identifies a transplantation center or a modern therapy medicinal product manufacturer.

2. Upon receiving the request and verification by the Provider's records that the Client is the applicant, the Provider shall immediately contact the transplantation centre or the manufacturer

of the advanced therapy medicinal products, through the contact person specified in the application.

3. Upon agreement with the transplantation centre or the manufacturer of the advanced therapy medicinal product and with the Client, the manner of distribution of the PBMCs sample through the authorized distribution activity holder in the area of human tissues and cells granted to SÚKL. This shall be ensured as follows:

- a) The Client entrusts the Provider by facilitating the distribution through its contractual partner, whom is the holder of a distribution license issued by SÚKL,
- b) The Client shall, either by him/herself or through an authorized transplant centre or a manufacturer of advanced therapy medicinal products for autologous use, choose a distributor according to the list of holders of distribution authorized in the area of human tissues and cells issued by SÚKL, at their discretion.

4. The Provider is responsible and declares that, during the entire period of provision of PBMCs storage services for autologous use, the Provider has concluded a contract with a contractual partner who has the relevant license to distribute SÚKL pursuant to Act No. 296/2008 Coll. of quality assurance and safety of human tissue and cells intended for human use, (hereinafter referred to as the Contractor), and through this Contractor is able to ensure without delay the distribution of PBMCs as required by the Client and the transplant centre or the advanced therapy medicines manufacturer.

5. In the event that the Client decides to use the Provider to ensure the distribution, the Client shall provide the service through its contractual partner, the Provider shall ensure the immediate release of the PBMCs and distribution to its Contractor.

6. The Provider shall ensure that the PBMCs is handled in accordance with the requirements of the Transplantation Centre/Advanced Therapy Manufacturer and the Human Tissues and Cells Act when issued and distributed.

7. The Provider shall charge the Client for remuneration for the distribution in the amount that will be charged by the Contractor for the distribution services if the distribution is provided by the Provider.

8. From the takeover of PBMCs by the Client and/or by a person authorized by the Client, the Provider shall not be liable for the state and usability of PBMCs if it has been handled in violation of the GTC or Act No. 296/2008 Coll. of the tissues and cells for human use.

9. From the date of issue of these GTC, the contractual partner of the Provider is Ambulance Meditrans s.r.o. Praha 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

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

1.1. the Client does not provide the necessary cooperation according to all the provisions of Article II of Appendix No. 1 of the Contract,

1.2. if the Provider becomes aware, during the provision of Medical Examination Services, that the Client's health status does not allow the realization of this Contract.

2. Failure to provide performance (Services) by the Provider shall not be deemed to be a delay and shall not give rise to a claim for compensation provided that it has been temporarily or permanently prevented from fulfilling their obligations under the Contract by an unforeseeable and unbeatable obstacle independent of the Provider's will. Such an obstacle is in particular; natural disaster, war, fire, explosion, labour dispute. The Party concerned undertakes to inform the other Party in writing immediately of the reasons and the expected duration of such an obstacle.

VIII. PROTECTION OF PERSONAL DATA OF REGISTERED CLIENTS

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

IX. FINAL PROVISIONS

1. By signing this Contract, the Provider is responsible and expressly declares to the Client that, in the event of termination of the Provider's activities, to operate a tissue establishment pursuant to Act no. No. 296/2008 Coll., on Quality Assurance and Safety of Human Tissues and Cells for Human Use and the alteration of certain related acts (Human Tissues and Cells Act), as amended, the Provider will secure the PBMCs specimen storage and documentation, traceability and the availability of stored tissues and cells for the purpose of the Client's use, in accordance with the mentioned 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 18th 2019

Appendix no. 1 of the General Business Terms and Conditions for Peripheral Blood Mononuclear Cells (PBMCs) derivation

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 PBMCs derivation 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 Center 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.