Medicínské centrum Praha s.r.o.
Mezi Vodami 205
143 00 Prague 4
T: +420 270 003 562
E: info@mc-praha.cz
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General Terms and Conditions (GTC)

I. INTRODUCTORY PROVISIONS

1. These General Terms and Conditions of MNC-product A (hereinafter referred to as GTC) regulate the relations between Medicínské Centrum Praha s.r.o, with registered office in Prague 4, Modřany, Mezi Vodami 205, Postal Code 143 00, ID No: 25032119, registered in the Commercial Register maintained by the Municipal Court in Prague, Section C, Insert 116020 (hereinafter referred to as the Provider) and the Client (hereinafter referred to as the Client) in providing services of procurement, investigation, processing, storage, release and distribution of peripheral blood mononuclear cells of the mobilized Client for autologous use or for the production of advanced therapy medicinal product for autologous use (hereinafter referred to as MNC) under the Contract for the provision of services for the procurement, investigation, processing, storage, release and distribution of peripheral blood mononuclear cells of the mobilized Client for autologous use or for the production of advanced therapy medicinal product for autologous use (hereinafter referred to as the Contract).

2. These GTC are an integral part of the Contract.

II. DEFINITION OF TERMS

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

- **MNC**: mononuclear cells from the Client's peripheral blood **enriched with haematopoietic stem cells** for autologous use or for the production of advanced therapy medicinal product for autologous use
- **Haematopoietic stem cells:** immature blood cells found mainly in the bone marrow that have the ability to mature into mature red blood cells, white blood cells and platelets
- **Client's laboratory examination**: a set of necessary laboratory examinations required to prove the Client's medical fitness for mobilization and subsequent MNC collection (includes the collection of samples for these examinations)
- **Medical examination of the Client:** outpatient examination by a physician necessary to prove the Client's medical fitness for mobilization and subsequent collection of MNC (measurement of vital signs, medical history, current treatment, current medication, etc.)
- **Mobilization:** medically induced washout of haematopoietic stem cells from the bone marrow into the peripheral blood of the Client in order to achieve the optimal concentration of haematopoietic stem cells necessary for a possible autologous transplantation (e.g. for the purpose of haematopoietic reconstitution); the usual duration of mobilization is 4-6 days
- **Separator:** a certified device used to separate MNC and haematopoietic stem cells from the Client's peripheral blood
- **SÚKL**: supervisory authority State Institute for Drug Control
- **Autologous transplantation: a** medical procedure in which the Client is injected with his/her own previously collected MNC and haematopoietic stem cells (e.g. to restore haematopoiesis); the conditions for autologous transplantation are determined by the transplantation centre
- **Advanced therapy medicinal product:** somatic cell therapy medicinal product, tissue engineered medicinal product or combination thereof

- **MNC care**: separation of blood components to separate mononuclear cells and haematopoietic stem cells using established standard operating procedures via a designated and approved device in the Provider's collection room
- **MNC processing**: preparation of MNC for freezing, quality control of harvested MNC (cell viability, microbiological testing)
- **MNC archiving**: long-term storage of MNC in liquid nitrogen and/or liquid nitrogen vapour according to prescribed standard operating procedures
- **Transplantation centre: a** health service provider that has been granted the status of a highly specialised care centre and can therefore carry out transplants of haematopoietic cells, tissues and organs
- **Manufacturer**: an entity that holds an authorisation for the manufacture of the corresponding type of advanced therapy medicinal product
- **MNC release**: removal of MNC from archiving upon request of the Client, subject to compliance with the Conditions for Release and Distribution of MNC in a manner that allows the MNC to be used for autologous transplantation or for the production of advanced therapy medicinal product for autologous use
- **Release**: release of MNC in the required quality by the Provider's responsible person for distribution for autologous transplantation or production of advanced therapy medicinal product for autologous use
- **MNC distribution**: transport and delivery of the MNC to the transplantation centre or authorised manufacturer where the advanced therapy medicinal product is to be manufactured for autologous use
- **DNA isolation and storage**: extraction of deoxyribonucleic acid (DNA) from MNC sample and storage at -80° C for possible verification of genetic stability of MNC after thawing

GUIDE AND STEP SPECIFICATIONS

- ✓ Order
- ✓ Interview with MCP employee
- ✓ Sending the documentation to the Client
- ✓ Delivery of the Questionnaire on the health status of the applicant to the Provider
- ✓ Confirmation of preliminary medical fitness of the Client
- ✓ Arranging the date of medical and laboratory examination and the date of mobilization and MCP collection
- ✓ Submitting Invoices for Medical and Laboratory Examination Services, Mobilization and Follow-up Medical Examination after Mobilization
- ✓ Reimbursement of invoices for medical and laboratory examination services, mobilization and post-mobilization medical follow-up
- ✓ Personal attendance at medical examination and laboratory tests
- ✓ Delivery of the signed Contract and GTC by the Client during medical and laboratory examination
- ✓ Confirmation of the Client's medical fitness by the Provider
- ✓ Sending of Invoice for Single MNC collection, MNC testing and processing and MNC freezing
- ✓ Payment of the invoice for one-time MNC collection, MNC testing and processing and MNC freezing by the Client
- ✓ Mobilization of the Client
- ✓ Subscription MNC
- ✓ Examination of MNC
- ✓ MNC processing
- ✓ Freezing MNC
- ✓ Certificate of Deposit MNC
- ✓ Storage of MNC

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- ✓ Release of MNC
- ✓ MNC edition
- ✓ MNC distribution
- ✓ Follow-up medical examinations after mobilization

All actions are coordinated by an authorized employee available to the Client on behalf of MCP.

III. CLIENT INTERACTION

The Client undertakes to provide full cooperation for the fulfilment of the subject matter of the Contract throughout its duration, in particular:

1. The Client is obliged to provide true and complete information about his/her health condition at all times before and during the validity of the Contract for the proper performance of the Provider's obligations.

2. The Client is obliged to deliver and complete all documentation required by the Provider at all times before and during the term of the Agreement.

3. The Client is obliged to provide up-to-date personal data, including contact details, at all times before and during the term of the Agreement.

4. The Client is obliged to personally undergo the Medical Examination Services and collection of all samples for laboratory testing (even repeated) to prove the Client's eligibility for mobilization and MNC collection at the Provider's workplace at a time demonstrably agreed and agreed by both Parties.

5. The client is required to personally complete mobilization including daily medical and laboratory examinations and MNC collection within less than 14 days from the date of completion of the Medical and Laboratory Examination Services. The 14 day period is the maximum time period for acceptance of the physician's determination of the Client's eligibility for MNC collection based on the Client's Medical Examination Services and laboratory test results.

6. The client is obliged to personally undergo the subsequent medical and laboratory examinations after mobilization and to follow all instructions related to the monitoring of the health condition to the extent specified by the Provider. In the event that the Client fails to attend the aforementioned health check-ups, the Client assumes full responsibility for his/her health condition and the Provider shall not be held liable for any health complications.

IV. CUSTOMER'S RIGHTS

1. The client has the right to request the release and distribution of MNC to a transplant center or authorized manufacturer at any time upon written request. The release of the MNC must be demonstrably announced at least 30 calendar days before the planned distribution. The distribution of the frozen MNC product with the relevant documentation shall be provided by the Provider exclusively through a domestic or foreign carrier that is authorised to distribute human tissues and cells according to the legislative standards applicable in the Czech Republic or the EU.

2. The Client has the right to request the shredding of the MNC at any time without giving any reason upon written request. The Provider shall undertake to shred the MNC without

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undue delay within 30 calendar days from the date of proven receipt of the request. The contract shall terminate on the date of shredding of the product.

In the event that the Contract is not terminated by delivery for distribution of MNC, but the Contract is terminated by other means, the MNC will be shredded upon termination of the Contract.

In the event of the Client's delay in payment of invoices longer than 3 months, the Provider is entitled to immediately withdraw from the Contract. The Contract shall terminate on the 95th day of default in payment of invoices.

By signing the Contract, the Provider expressly declares and is liable to the Client that in the event of termination of the Provider's activity to operate a tissue facility pursuant to Act No. 296/2008 Coll., on quality assurance and safety of human tissues and cells intended for use in humans, as amended, the Provider will ensure the preservation of MNC samples and documentation, as well as the traceability and availability of stored tissues and cells for the purpose of their use, in accordance with the aforementioned Act on Human Tissues and Cells.

The Client agrees that in the event of termination of the Provider's activities with the involvement of a third party, solely in order to ensure the availability of stored MNC in accordance with the requirements of Act No. 296/2008 Coll., on Human Tissues and Cells, as amended, and other related legislation, the accompanying documentation to the stored MNC will be provided to the contracted third party in order to ensure all legislative requirements, in particular for the traceability and availability of MNC. The Provider shall be entitled to use the services of a third party to provide the services, and the Provider shall be liable to the Client for the performance of the third party as if the Provider had performed the services itself.

In the event that the Client is unable to dispose of the frozen MNC, the Provider shall be entitled to deal only with a legally established authorized person of the Client.

The Client is obliged to provide true and complete information about his/her health condition during the entire period of the Contract when communicating with the Provider. This information is necessary for the proper performance of the Contract by the Provider. The Parties agree that if the Client knowingly conceals, fails to disclose or provides false/incomplete information about his/her health condition, the Provider shall not be liable for any damage to the Client's health, reduced quality and quality of the services provided or for any shredding of the MNC.

V. CONDITIONS FOR THE ISSUE AND DISTRIBUTION OF MNC

1. The Client shall request the MNC in writing. In the application, the Client identifies the transplantation centre/manufacturer of the advanced therapy medicinal product, which must have a Manufacturing Authorisation Decision or adequate foreign certification.

2. In agreement with the transplantation centre/manufacturer of the advanced therapy medicinal product and the Client, the method of distribution of the MNC sample will be arranged through the holder of the authorisation for distribution in the field of human tissues and cells granted by SÚKL for domestic transport. Only a carrier holding a certification for distribution in the field of human tissues and cells granted by another EU Member State with international scope may be used for foreign transport.

3. The Provider declares and is responsible for the fact that it has a contract with a contractual partner who has the relevant distribution permit issued by SÚKL according to Act No. 296/2008 Coll. for the entire period of providing services for the storage of MNC for autologous use or for the production of advanced therapy medicinal product

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for autologous use, on quality assurance and safety of human tissues and cells intended for human use, as amended, (hereinafter also referred to as the contractual partner), and is able to ensure, through this contractual partner, the distribution of MNC without delay according to the requirements of the Client and the manufacturer of the advanced therapy medicinal product in the territory of the Czech Republic.

4. The provider guarantees the release of the MNC in accordance with the legislative requirements and the requirements of the transplant centre/advanced therapy drug manufacturer.

5. The Provider shall not be liable for the quality and usability of the MNC from the time of proven acceptance of the MNC by the agreed distributor.

VI. TERMINATION OF THE CONTRACT

1. Either party may terminate this Agreement by giving 3 months' notice. The period of notice shall commence on the first day of the month following the month in which the notice is delivered to the other party.

2. The Client has the right to withdraw from the Agreement without giving any reason, provided that:
   - If the Client has completed the Medical and Laboratory Examination Services and has not started mobilization and is no longer interested in a new date for any services, the Contract shall terminate with the Provider being entitled to CZK 13.900,- of the price paid for the Client's Medical and Laboratory Examination Services to assess the Client's eligibility for mobilization and for the collection of MNC from peripheral blood, the Client's mobilization and post-mobilization medical examination services. In the case of an invoice already paid for a one-off peripheral blood MNC collection, testing, processing and freezing of MNC, the Client is entitled to a refund of 100 % of this amount.
   - If the Client has completed the Medical and Laboratory Examination Services, has not commenced mobilization, and has demonstrably arranged a new mobilization date, the Contract shall continue, with the Client being obligated to re-complete and pay for the new Medical and Laboratory Examination Services if the new collection date exceeds 14 days from the original Medical and Laboratory Examination Services.
   - If the Client has completed the Medical and Laboratory Examination Services, mobilization has already begun, and is interested in arranging a new Collection date with or without mobilization in the future, a new Contract will be entered into with the Client. The Provider shall be entitled to 100 % of the amount paid by the Client for the Client's Medical and Laboratory Examination Services to assess the Client's eligibility for mobilization and for MNC collection from peripheral blood, mobilization and post-mobilization Medical Examination Services.
   - If he/she has completed the Medical and Laboratory Examination Services, mobilization has already begun, but does not wish to continue mobilization for any reason, and is interested in immediate MNC collection, the Contract shall continue and will be proceeded with in accordance with the Product B GTC, which the Client shall confirm in writing by his/her signature in case of consent.
   - If the MNC are not properly collected, or the planned volume of MNC that could be stored is not collected, or the MNC are classified as having a low shelf life, and the Client does not order a new collection date at the same time, the Contract shall be terminated with the Provider being entitled to a price of 12.000,- CZK which shall be set off against the Client's claim for a refund of 100 % of the price paid for the one-off collection of MNC, testing, processing of MNC and freezing of MNC.

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- If the MNC are not properly collected or the planned volume of MNC that could be stored is not collected or the MNC are classified as having a low shelf life, and the Client is interested in a new MNC product, the Contract shall be terminated with the Provider being entitled to a price of 12.000,- CZK, which shall be set off against the Client's claim for a refund of 100 % of the price paid for the one-time MNC collection, testing, MNC processing and freezing of MNC. For a new MNC product, a new Contract must be entered into according to the relevant product type.
- If MNC are collected in a volume lower than planned but which can be stored at the same time, the Provider shall offset the amount corresponding to the respective MNC volume against the invoice paid for the One-time MNC collection, examination and processing of MNC and freezing of MNC.

3. If the Provider fails to ensure a negative result of the microbiological examination of the MNC, the Contract shall be terminated and the Client shall be entitled to 100 % of the price paid for the one-time collection of MNC, examination and processing of MNC and freezing of MNC. If the Client is interested in a new MNC collection, the Contract shall continue and a new MNC collection date shall be offered. In this case the Provider shall bear all additional costs related to the new collection.

4. The Provider has the right to withdraw from the Contract in case of proven non-performance of the Client. In this case, the Provider is entitled to 100 % of the price of the product.

5. The Provider has the right to withdraw from the Contract in the event of proven untruthfulness of the information provided about the Client's health condition.

6. By signing the Contract, the Provider expressly declares and is liable to the Client that in the event of termination of the Provider's activity to operate a tissue facility pursuant to Act No. 296/2008 Coll., on quality assurance and safety of human tissues and cells intended for use in humans, as amended, the Provider will ensure the preservation of MNC samples and documentation, as well as the traceability and availability of stored tissues and cells for the purpose of their use, in accordance with the aforementioned Act on Human Tissues and Cells.

7. The Client agrees that in the event of termination of the Provider's activities with the involvement of a third party, solely in order to ensure the availability of stored MNC in accordance with the requirements of Act No. 296/2008 Coll., on Human Tissues and Cells, as amended, and other related legislation, the accompanying documentation to the stored MNC will be provided to the contracted third party in order to ensure all legislative requirements, in particular for the traceability and availability of MNC. The Provider shall be entitled to use the services of a third party to provide the services, and the Provider shall be liable to the Client for the performance of the third party as if the Provider had performed the services itself.

8. In the event that the Client is unable to dispose of the frozen MNC, the Provider shall be entitled to deal only with the Client's legally established authorized person.

9. The Client is obliged to provide true and complete information about his/her health condition during the entire period of the Contract when communicating with the Provider. This information is necessary for the proper performance of the Contract by the Provider. The Parties agree that if the Client knowingly conceals, fails to disclose or provides false/incomplete information about his/her health condition, the Provider shall not be liable for any damage to the Client's health, reduced quality and quality of the services provided or for any shredding of the MNC.

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VII. PROTECTION OF PERSONAL DATA

1. In accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and in accordance with Act No. 110/2019 Coll, on the processing of personal data and on the amendment of certain laws, as amended (hereinafter referred to as "GDPR"), we are obliged to inform you as a data subject (hereinafter referred to as the "Client") about the processing of your personal data at Medicínský centrum Praha s.r.o. (hereinafter referred to as the "Administrator").

2. Within this legal relationship, the provider will process the client's personal data in accordance with Act No. 110/2019 Coll., on the processing of personal data, as amended.

3. Implementation of the contractual relationship:

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

   On the basis of this authorisation, the provider is not obliged to require the client's consent to the processing of personal data.

4. Data Controller:

   Medicínské centrum Praha s.r.o., with registered office at Mezi Vodami 205, 143 00 Prague 4, ID No.: 25032119, registered in the public register maintained by the Municipal Court in Prague, Section C, Insert 116020.

5. Scope of personal data processed:
   -first and last name , title
   -birth date/birth number
   -delivery (billing) address
   -email address
   -phone

6. Purpose of processing the data provided:

   These data are processed for the purposes necessary for the performance of the contract and the fulfilment of statutory obligations.

7. The period for which the personal data provided will be stored:

   The personal data will be stored by the administrator for the necessary period of time stipulated by the Health Services Act No. 372/2011 Coll. and its implementing regulations as amended

8. Personal data processor:

   Medical Centre Prague s.r.o., Mezi Vodami 205, 143 00 Prague 4

9. Client's rights regarding the protection of your personal data:

   -Under Article 15 GDPR, the client has the right to access personal data concerning him/her, under Article 16 GDPR the right to request the controller to correct inaccurate personal data concerning him/her, under Article 17 GDPR the right to erasure of

personal data concerning him/her. The data subject has the right to have the controller restrict the processing of the data subject's personal data in the cases listed in Article 18 GDPR.

-The client has the right to request that the controller inform him/her about the recipients of personal data pursuant to Article 19 GDPR. The controller does not carry out the processing of personal data by automated means, therefore the right to data portability under Article 20 GDPR does not apply.

-According to Article 21 of the GDPR, the Client has the right to object at any time to the processing of personal data concerning him/her if the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority pursuant to Article 6(1)(e) of the GDPR.

-The deletion of personal data that the health service provider is obliged to collect on the basis of a legal obligation (obligation imposed by law), i.e. in connection with the performance of the contract, cannot be claimed.

-The client has the right to file a complaint with the supervisory authority, which is the Office for Personal Data Protection. Postal address: the ÚOOÚ, Sochora 27, 170 00 Prague 7, e-mail address: posta@uoou.cz, mailbox ID: qkbaa2n.

10. The controller does not transfer or intend to transfer personal data to a third country or an international organisation.

These General Terms and Conditions come into force on 1 July 2024

Provider: MUDr. Radek Klubal
Managing Director
Medicínské centrum Praha s.r.o.

In Prague on: 1. 7. 2024

Client:

In Prague on: .....