Contract no. PL

for Biological Material qualification, preparation and storage service

concluded on in Warsaw by and between:

Polski Bank Komórek Macierzystych sp. z. o. o. with its registered seat at Al. Jana Pawła II 29, 00-867 Warsaw, e-mail adress: biuro@pbkm.pl, phone number: (22) 436 40 50, entered into the Register of Entrepreneurs of the National Court Register maintained by the District Court for the Capital City of Warsaw, 13th Commercial Division, under the KRS number 0001010154, National Official Business Register Number (REGON): 017452559; Tax Identification Number [Numer Identyfikacji Podatkowej, NIP]: 525-22-39-973; Share capital PLN 4 669 350,00, represented by:

Jakub Baran - President of the Management Board,

Tomasz Baran - Vice President of the Management Board,

hereinafter referred to as "PBKM", and:

PARENT - MOTHER

First name

Surname

Maiden name of the parent's mother

Address of residence, street, house number, apartment number

Postal code | Place

Country

PESEL [Personal Identification Number] | Identity card series and number

Mobile phone number

e-mail

Correspondence address **same as the Mother's** **other**

Street, house number, apartment number

Post code, city/town, country

collectively referred to as the “Parties”, under which the Parties jointly agree as follows: The contract is concluded as part of the offer:

Selected offer

Pregnancy type	
Chosen option	

Whenever in this Contract a reference is made to any of the following, it shall mean:

Personal Data - this is to be understood as information regarding the Mother, Father and Child provided in the Contract and in the medical questionnaire, as well as those obtained actively by PBKM in order to perform the contract.

Controller - this is to be understood as the Child from the moment of reaching majority, the Parent/Parents of other persons who are the Child’s statutory representatives, who are authorized under the law to exercise parental authority over the Child until his or her age of majority or after his or her age of majority if the Child is legally incapacitated, and the Parents of a Child who has reached majority, who are authorized by the Child to dispose of the Biological Material on his or her behalf upon meeting the appropriate terms and conditions of the Contract.

Child - this is to be understood as the person from whom Biological Material is acquired following birth and umbilical cord severance.

eShop - the web service at https://klient.pbkm.pl managed by PBKM and allowing the online purchase of services.

FamiCord Suisse SA - a Swiss joint-stock company registered under the number CHE-113.983.891, seat: c/o Studio Fiduciario Pagani SA, Corso Pestalozzi 3, 6900 Lugano, which provides the service of storing part of the Biological Material in Switzerland to Parents who choose the SwissSafety package.

Stem Cells - this is to be understood as cells isolated from Umbilical Cord Blood and/or Cord tissue, to be used for therapeutic purposes.

Umbilical Cord Blood - this is to be understood as the blood of the fetus acquired during birth by puncture of the umbilical cord.

Medical questionnaire - this is to be understood as a form that provides information about the health of the Mother, which the Mother is required to complete by answering the questions regarding her health and the health of the Child’s Father and the Parents' immediate family accurately, truthfully and to the best of her knowledge. Some of the answers may prevent Biological Material acquisition or storage. The medical questionnaire was drafted by specialist physicians with the support of the PBKM Medical Department, based on the current state of medical knowledge and relevant guidelines (including, but not limited to the guidelines of the Ministry of Health, WHO, National Centre of Tissue and Cell Banking, American Association of Blood Banks), which may be subject to change during the term of the Contract.

Placental Tissue- this is to be understood as a whole placenta.

Biological Material - this is to be collectively understood as Umbilical Cord Blood, Umbilical Cord and cells isolated from them and Placental Tissue.

MSC/MSC cells - this is to be understood as primary culture mesenchymal stromal stem cells isolated from an Umbilical Cord fragment, which do not constitute a medicinal product ready for administration (provisions of § 6 section 13 of the Contract).

PBKM Non-Public Health Care Institution - a healthcare entity under the name: Non-Public Health Care Institution of the Polski Bank Komórek Macierzystych - an organizationally separate internal unit of the PBKM which consists of two organizational cells, a medical diagnostic laboratory and a umbilical cord blood bank, located in Warsaw. PBKM Non-Public Health Care Institution performs medical procedures associated with the preparation, testing, freezing and storage of the acquired Biological Material and provides medical transport of the Biological Material following acquisition or to a transplantation center.

My PBKM Customer Panel - the Customer Panel in eShop, activated by the Parents entering login credentials, via which the Parents conclude this Contract with PBKM and select the offered service options and gain access to information concerning the services provided and their own Contract account.

Customer’s Written Declaration - a document available in the Customer Panel to be printed by the Parents on their own, which becomes available after the Contract is generated and which the Mother, together with the Father of the Child (if he is party to

the Contract), shall personally sign and effectively deliver to the PBKM seat within 7 days from the date of concluding the Contract, via any of the following channels (in person, by courier, or through the Poczta Polska services, with the possibility of tracking the parcel). The Customer's Written Declaration includes declarations related to the consents to the processing of sensitive personal data, voluntary consent to the acquisition of Biological Material and the Mother's peripheral blood, as well as the declaration on the joint and several liability for the undertakings under the Contract, to be submitted by the Child's Father.

Emergency Biological Material Acquisition - this is to be understood as the use of a Umbilical Cord Blood (Red option) or Umbilical Cord Blood and Umbilical Cord (Blue option) or Umbilical Cord Blood, Umbilical Cord and Placental Tissue (Platinium option) acquisition kit available at the hospital/clinic where childbirth takes place. Emergency acquisition of Biological Material excludes the possibility of using of other services arising from the extended facultative service offer stipulated under § 8 of the Contract, except for the Transplant Assistance package described under § 8 section 1, Transplant Assistance Plus package described under § 8 section 6 and 120+ package described under § 8 section 2.

Reference Sample - this is to be understood as a portion of frozen material that is secured to perform additional tests done before using the Biological Material for therapeutic purposes.

Parent/Parents - this is to be understood as the Mother or Father or both Parents of the Child, who are the Child's statutory representatives, who are authorized to exercise parental authority over the Child until his or her age of majority and who have not been deprived of the right to exercise this parental authority under a final ruling of a competent court.

Umbilical Cord - this is to be understood as an acquired umbilical cord fragment from which MSCs may be isolated.

Contract - this is to be understood as the contract for qualification, preparation and storage of Biological Material.

PLUS CASSETTE Freezing - this is to be understood as freezing the Umbilical Cord Blood-derived Stem Cells in a freezing bag which consists of two parts.

Acquisition Kit - a kit provided to the Parents for the acquisition of Biological Material and the Mother's blood, which consists of appropriate components for Biological Material acquisition and an instruction for use. Kit contents differ, depending on the selected service option.

§ 1 Date and place of childbirth

1. The Parents unanimously declare that the expected childbirth date is scheduled for:

2. The planned place of childbirth is the healthcare facility - hospital/clinic:

   NOTE! Where a hospital/clinic in Warsaw is indicated as the place of delivery or where actual delivery happens at a hospital/clinic in Warsaw, the Basic Fee may be increased depending on the hospital/clinic where the Biological material was acquired (provisions of paragraph 9 section 2c of the Contract).

Hospital/clinic name

City/town/street

3. Pregnancy practitioner (full name)

City/town of the practice

4. Birth School/Midwife

5. The Parents agree to inform PBKM about the childbirth immediately, not later than within 3 hours of its end by phone using the 24-hour dedicated phone number +48 606 657 098.

6. PBKM shall send an Acquisition Kit to an address indicated by the Parents in eShop with the use of its own transport or a courier service, or shall deliver it via a PBKM representative within seven days from payment of the initial fee, but not earlier than two months before the expected childbirth date.

7. The Parents are required to take the Acquisition Kit to the place of childbirth and provide it to the medical personnel involved in childbirth.

8. If the Parents forget the Acquisition Kit or do not provide it for any other reason, acquisition may not be performed, subject to the provisions of section 9 below.

9. In some hospitals/clinics it is possible to use a kit available at the hospital/clinic as part of Emergency Biological Material Acquisition. If the Parents express their will to use such a kit, the extent of services selected by the Parents may be modified, as the Acquisition Kit available at the hospital/ clinic may be available in a different variant than the variant originally selected by Parents

, as well as the use of the facultative service offer stipulated under § 8 of the Contract, shall be excluded, except for the Transplant Assistance package described under § 8 section 1, Transplant Assistance Plus package described under § 8 section 6 and 120+ package described under § 8 section 2. The Parents are required to return the Acquisition Kit received to the PBKM office address indicated in the recitals of the Contract at their own expense.

§ 2 General provisions

1. The Contract sets forth the terms and conditions of a service consisting in the qualification, preparation and storage of Biological Material, as well as the rights and obligations of the Parties in this respect.

2. Under the Contract, PBKM agrees to organize and coordinate the acquisition of the Biological Material at the indicated place of childbirth and to prepare and qualify it, and then store it according to the Contract. The Parents agree for PBKM to organize and coordinate Biological Material acquisition to the entity indicated by the Parents.

3. The Parents also agree for PBKM to entrust the activities set forth under the Contract - except for the storage activities - to third parties professionally performing such activities as part of their business. Due to the above, the Parents submit a statement as per § 16 section 4 of the Contract.

4. During the term of the Contract, PBKM recommends to provide information on any potential serious diseases of the Child in the form of own information or to provide a copy of the medical history or a copy of hospital admission/discharge papers.

§ 3 Biological Material acquisition

1. Biological Material shall be collected to the Acquisition Kit at the place of childbirth indicated by the Parents when completing the form in the My PBKM Customer Panel, which is confirmed in the contents of this Contract. Should the place of childbirth be changed, the Parents are required to immediately notify PBKM to coordinate the acquisition of Biological Material in the new place. Should the place of childbirth be changed, the provisions of paragraph 2 below shall apply accordingly, whereby if the new place of childbirth is a hospital/clinic with which PBKM has concluded no separate Biological Material acquisition contract, the Parents are required to sign the relevant statement, confirming that they are aware that the acquisition of the Biological Material is performed at the exclusive request of the Parents, and the staff of this facility was not trained in acquiring Biological Material for PBKM customers. If PBKM is not informed about the change of the place of childbirth, PBKM shall not be responsible for Biological Material acquisition coordination and collection.

2. If the place of childbirth is a hospital/clinic which has concluded a separate collaboration contract with PBKM for the acquisition of Biological Material, the acquisition may be performed as part of this separate contract by qualified medical personnel previously trained by PBKM, as far as possible, in acquiring appropriate Biological Material, making use of the opportunities provided by the hospital/clinic.

3. If the place of childbirth is a hospital/clinic with which PBKM has concluded no separate Biological Material acquisition contract, PBKM agrees to take efforts to entrust the Biological Material acquisition on behalf of the Parents to a qualified midwife or physician employed or practicing at this hospital/clinic, whereby the Parents are required to mark the relevant statement in the eShop when concluding the contract, confirming that they are aware that the acquisition of the Biological Material is performed at the exclusive request of the Parents, and the staff of this facility was not trained in acquiring Biological Material for PBKM customers.

4. The final decision on acquiring Biological Material is made by the physician assisting with the childbirth, together with the person authorized to perform the acquisition, taking into consideration the conditions of the childbirth and the general condition of the Child before cord severance. Especially the physician may decide whether or not to continue with the acquisition in the case of: complications during childbirth, excessive bleeding, the need to submit the Placenta Tissue for examination, e.g. histopathology childbirth dynamics and other physiological reasons, and PBKM shall be released from any and all responsibility for the lack of acquisition within this scope.

5. On the day of childbirth, a peripheral blood sample shall also be collected apart from the Biological Material from the Child's Mother in the amount of approximately 2x7,5 ml. The blood collected from the Child's Mother is attached to the Acquisition Kit. The Mother's consent for drawing blood is a necessary condition for proper performance of the service by PBKM, and the consent statement is included in the consents in the eStore and in the Customer's Written Declaration document.

6. The person acquiring the Biological Material drafts an acquisition protocol to be attached to the Acquisition Kit. The Biological Material acquisition protocol shall include the following information: Mother's name and surname, Mother's PESEL Personal Identification Number, date of acquisition Biological Material and maternal blood, seal of the hospital/clinic where the acquisition occurred, information on current health of Child's Mother received from her prior to Biological Material acquisition, signature of the acquiring person.

§ 4 Transportation

PBKM shall ensure transportation for the Acquisition Kit from the place of acquisition to the PBKM laboratory, after receiving telephone information from the Parents - according to the provisions of § 1 section 5 of the Contract.

§ 5 Testing and preparation

1. An Acquisition Kit with the acquired Biological Material and peripheral blood of the Child's Mother shall be delivered to the PBKM Non-Public Health Care Institution in order to conduct proper preparation and tests to determine the volume and complete blood count, cord length and Placental Tissue completeness and quality of the Biological Material, detect possible bacterial, fungal and viral infections, and other specialist tests necessary for qualification.

2. PBKM shall conduct the necessary tests and preparation activities, subject to all the regulations applicable in this respect, laboratory standards and the standard developed and supervised by the PBKM Medical Department.

3. All the Mother's and Child's peripheral blood tests are to check the health condition of the Mother and the Child and determine the medical quality of the Biological Material for future use of the Biological Material as part of therapy.

4. Testing and preparation results shall be included in the test protocol drafted according to the template developed by the PBKM Medical Department.

5. Following preparation, the Biological Material shall be frozen at the PBKM Non-Public Health Care Institution, subject to the standard developed by the PBKM Medical Department.

6. PBKM recommends the following virology tests to be performed once again:

a) HBV DNA

b) HCV RNA

c) HIV RNA

d) HEV RNA

e) syphilis tests

from peripheral blood of the Mother 3 months after the Child's birth. In the case of a positive result, PBKM shall inform about the necessity to send the results to PBKM within fourteen days as of the date of receipt.

7. PBKM informs that according to the provisions of Article 29 section 1 of the Act dated 5 December 2008 on preventing and combating infections and infectious diseases in humans (consolidated text: Polish Journal of Laws of 2023.1284 consolidated text) a laboratory diagnostician or another person authorized to independently perform laboratory diagnosis activities, if the results of Biological pathogen testing are positive, pursuant to the provisions issued based on section 7 item 1, is required to report this fact to the competent state sanitary inspector determined pursuant to the provisions issued based on section 7 item 2. The report shall be submitted immediately, however not later than within 24 hours as of the receipt of the result. The information provided shall include the name and surname, date of birth, PESEL Personal Identification Number, and where an individual has been assigned no such number - passport series and number or identification number of a different document, based on which it is possible to establish personal data, gender, residence address, type of Biological pathogen and its characteristics, and other information relevant for epidemiological supervision according to the principles of modern medical knowledge. Biological pathogens determined in immunochemical screening tests may yield a different result than confirmation tests or tests to detect HBV, HCV, HEV, HIV genetic material. The waiting time for final virology results submitted by PBKM is longer than the mandatory time for reporting suspected positive results to Sanepid [Polish sanitary inspection authority]. Due to the above, PBKM informs and notifies of the possibility that the Parents shall receive information about a positive infectious agent testing results from Sanepid earlier.

8. According to current medical knowledge, the time from the acquisition of Biological Material (Umbilical Cord Blood) to processing initiation should not exceed 72 hours. In exceptional cases, it is acceptable to extend it to 96 hours. In case of Umbilical Cord Blood that is processed after96 hours from birth, PBKM shall perform additional tests, i.e. CD34 and MNC viability, the results of which shall be sent to the Parents within approximately 8 weeks from the date of birth. The results shall be sent by registered mail to the correspondence address indicated in the Contract or provided in the My PBKM Customer Panel

§ 6 Qualification for storage

1. By signing the Customer's Written Declaration, the Child's Mother shall consent to the collection of her peripheral blood and testing it for IgM and IgG Toxoplasma gondii antibodies, HBs-Ag, anti-HBc, anti-HCV, anti-HIV 1, 2, syphilis test, CMV IgM, CMV IgG, HBV DNA, HCV RNA, HEV RNA, HIV RNA. Due to the nature of the Contract, the Child's Mother authorizes the Child's Father - if he is a party to the Contract - to collect, browse, review her blood test results.

2. Since the purity level and other components of the acquired Biological Material depend on natural factors beyond the control of PBKM and the personnel acquiring the Material, PBKM cannot guarantee that the Biological Material shall meet all the qualification criteria determined pursuant to the Contract nor that the acquisition shall be sterile.

3. If, as a result of the preliminary qualification performed by the PBKM Medical Department based on the volume/quantitative/physiological criteria set forth by the Scientific and Medical Council, the acquired:

a) Umbilical Cord Blood - the blood cannot be prepared due to insufficient volume (the required minimum volume of Umbilical Cord

Blood acquired is 10 mL), it shall be destroyed according to the procedure applicable at PBKM. PBKM shall not be responsible for the destruction of Umbilical Cord Blood excluded from preparation due to insufficient volume.

b) Umbilical Cord - due to an insufficient fragment (the required minimum fragment is 10 cm), incorrect tissue appearance or an infection detected in the Mother by HBs-Ag, anti-HBc, anti-HCV, anti-HIV 1, 2 virologic testing, syphilis test, equivocal or positive Toxoplasma Gondii: IgM, HBV DNA, HCV RNA, HEV RNA, HIV RNA, the cord cannot undergo the preparation or MSC isolation procedure and shall be destroyed according to the procedure applicable at PBKM. PBKM shall not be responsible for the destruction of Umbilical Cord excluded from preparation or MSC isolation due to an insufficient fragment/ incorrect tissue appearance/ viral infection in the Mother. PBKM shall not be responsible for the disposal of the Umbilical Cord in the case of Umbilical Cord Cell Isolation Package is selected , in the event of an unsuccessful isolation attempt - no MSC cells.

c) Placental Tissue - placenta due to incompleteness (it is required to obtain the whole placenta in one piece), abnormal tissue appearance or viral infection HBs-Ag, anti-HBc, anti-HCV, anti-HIV 1, 2, syphilis test, Toxoplasma Gondii: IgM doubtful or positive detected in the Mother, cannot undergo the preparation procedure and is destroyed according to the procedure in force in PBKM. PBKM is not responsible for the destruction of Placental tissue whose incompleteness / abnormal tissue appearance / virological infection in the Mother precludes its preparation.

4. Due to the fact that the volume and quality of the acquired Biological Material depends on individual physiological factors, such as: thickness, length and vasculature of the umbilical cord and placenta and its condition, as well as the blood vessel closure rate and the course of childbirth, PBKM shall not be responsible for the volume of the acquired Umbilical Cord Blood, for the length and quality of the acquired Umbilical Cord or for the incompleteness of the Placental Tissue.

5. Based on the results of tests performed, in accordance with the criteria set forth by the Director of the PBKM Medical Department, as well as in accordance with PBKM standards, the following shall be qualified for freezing and submitted for storage:

5.1 Umbilical Cord Blood aliquots which meet the qualification criterion and contain at least 100 million cells (10×10^7), subject to the provisions of section 6 below, provided that:

a) if the number of Umbilical Cord Blood-derived Stem Cells is at least 300 million cells (30×10^7), the material is fully qualified for storage;

b) if the number of Umbilical Cord Blood-derived Stem Cells is in the 100-299 million cells range ($10\text{-}29{,}99 \times 10^7$), it is qualified for storage, the Parents cover the full Initial Fee and Basic Fee, and PBKM agrees to store the Umbilical Cord Blood free of charge for 18 years from the acquisition date.

5.2 If fewer than 100 million cells are obtained from Umbilical Cord Blood, this material is disqualified from storage and the aliquot is destroyed. PBKM shall not be responsible for the destruction of the Umbilical Cord Blood aliquot excluded from storage due to an insufficient number of cells.

5.3 Prepared Umbilical Cord fragments meeting the preliminary qualification standards described in § 6 point. 1b) or aliquots yielding no fewer than 0.5 million isolated MSC cells within 8 weeks of Umbilical Cord acquisition if the Umbilical Cord Cell Isolation Package is selected.

5.4 Prepared fragments of Placental Tissue that meet the initial qualification standards described in § 6 point 1c) .

5.5 If the results of the Toxoplasma Gondii test are negative for IgM and equivocal or positive for IgG antibodies, the potential use of Umbilical Cord/MSCs shall be limited only to the Child or other recipients (the Child's biological siblings, the Child's biological parents, the Child's biological grandparents, the Child's biological descendants) positive for Toxoplasma Gondii. In this case MSC isolated from the Cord tissue administration into the cerebrospinal fluid is prohibited.

5.6 Preparation of Biological Materials, i.e. Umbilical Cord Blood, Umbilical Cord and Placental Tissue, is performed independently and in accordance with the service package selected by the Parents in the eShop. Disqualification of one Biological Material does not interrupt the preparation of other Biological Materials.

6. If, as a result of the qualification performed by the PBKM Medical Department based on the criteria set forth by the Scientific and Medical Council, PBKM identifies contamination/bacterial infection of Umbilical Cord Blood, it shall request that the Parents submit a declaration of will (subject to § 6 sections 9) including:

a) consent for storage of a contaminated/bacterially infected aliquot of Umbilical Cord Blood -derived Stem Cells; consent can be granted by phone, in paper form, via e-mail to: biuro@pbkm.pl or in the My PBKM Customer Panel,

b) cancellation of storage of a contaminated/bacterially infected aliquot of Umbilical Cord Blood--derived Stem Cells. Cancellation must be submitted in writing by registered mail to PBKM office's address.

7. If it is necessary for the Child to undergo medical consultations connected to a positive or equivocal virologic testing result of the Child's Mother, PBKM shall inform the Parents of these circumstances in the final qualification results within approximately 8 weeks from the date of childbirth. The Parents agree to perform genetic testing of the Child's blood for HBV DNA and/or HCV RNA and/or syphilis. If the virologic testing and syphilis test results of the Child's Mother are positive, PBKM shall recommend consultations with an infective diseases specialist.

8. If the CMV test of the Child's Mother's blood yields a positive or equivocal result, a PBKM physician shall contact the Parents by e-mail immediately and suggest performing a CMV DNA test in the Child and sending its result to the PBKM office, or shall suggest contacting a reference center. PBKM declares that a positive/equivocal test result for CMV infection in the Child is not a contraindication for the storage

of Biological Material, and referring the Parents for additional consultations with a pediatrician or an infective diseases specialist is only to review the Child's health status.

9. If within 10 days as of the date of providing information in the My PBKM Customer Panel about the final qualification and contamination/bacterial infection of the Cord blood (§ 6 section 6 of the Contract) the Parents fail to make a statement of will covering consent for the activities specified under § 6 section 6 items a-b, this shall mean their consent for storage of umbilical cord blood- derived stem cells. Should the Parents fail to meet the 10-day time limit indicated in sentence 1 and send a statement on ceasing the storage of Umbilical Cord Blood-Derived Stem Cells after this time limit, the Basic Fee mentioned under § 9 section 6.9 shall not be reimbursed, and PBKM shall charge the Parents with the fees for storage in proportion to the actual storage period of Biological Material.

10. Should the Mother's blood test yield positive results for HIV infection, PBKM will perform an infection confirmation test. If the result of HIV infection in the mother's confirmation test is positive, PBKM shall refuse to accept the Biological Material for storage. The material shall be destroyed according to the procedures applicable at PBKM. PBKM shall not be held responsible for the destruction of the Biological Material the storage of which is excluded due to the Mother's peripheral blood results.

11. PBKM shall provide information on the initial qualification of the Biological Material in the My PBKM Customer Panel, and then it shall provide, within approximately 8 weeks as of the day of childbirth, after the physician issued their opinion, the interpretation of final Biological Material qualification results, divided into umbilical cord blood results,umbilical cord tissue test results and placental tissue test results in a separate message.

12. Informing the Parents about the final qualification of the Biological Material mentioned under § 6 section 11 above is conditioned upon the payment of the Initial Fee.

13. PBKM informs and reserves, while the Parents acknowledge that the stored MSCs isolated from the umbilical cord tissue do not constitute a medicinal product ready to administer, and they are only a primary culture material that may be used as a basis to create MSC cell preparation constituting an advanced therapy medicinal product as defined in Article 2 (33b) of the Pharmaceutical Law Act (Polish Journal of Laws of 2022 item 2301). The Contract does not cover any use of MSCs to manufacture a medicinal product. Such a procedure may be carried out only upon the order of a physician for an individual patient, after additional qualification of Biological Material that, after the abovementioned qualification, may be qualified or disqualified as a source of MSCs. Administration - in the current legal status - is only possible as part of a medical experiment that requires the consent of a relevant ethics committee and the fulfillment of relevant legal requirements in this respect, as well as separate payment for the product manufacturing service and its administration by the medical entity performing therapy. The final decision on the use of MSC cells in a patient's therapy is always made by the doctor, and the PBKM is not involved in or influenced by such decisions.

14. PBKM informs and emphasizes that the storage of tissues and cells does not guarantee qualification of the Biological Material for transplantation or use in humans, nor does it guarantee the ability to produce a finished medicinal product for advanced therapy medicinal products (ATMP). The clearance of Biological Material for clinical use or as starting material for the production of an ATMP may require additional questions regarding the health status of the Mother, Father, and the Child who is the donor of the Biological Material, as well as, in some cases, additional tests. The extent of additional questions or tests depends on the decision of the treating doctor for each patient. The final decision regarding the clinical use of tissues and cells is always made by the doctor, and PBKM does not participate in or have any influence on such decision-making process.

§ 7 Services variants and storage

1. As part of the services provided by this Contract, PBKM offers the following proposal variants to the Parents:

1.1. Red - basic offer, covering the organization and coordination of umbilical cord blood acquisition and storage of the Biological Material.

1.2. Blue - extended offer, covering the organization and coordination of Umbilical Cord Blood and Umbilical Cord acquisition, as well as storage of such Biological Material.

1.3. Platinium - extended offer, covering the organization and coordination of Umbilical Cord Blood, Placental Tissue and Umbilical Cord acquisition, as well as storage of such Biological Material.

2. The service of Biological Material storage provided by PBKM is of a continuous nature and consists in the storage of Biological Material over the individual years during the term of this Contract. When storing Biological Material, PBKM shall ensure compliance with all the requirements and standards arising from the applicable laws in this respect.

3. The Biological Material qualified for storage by PBKM and the Biological Material (Umbilical Cord Blood) contaminated/infected with bacteria, regarding which the Parents made a statement concerning its storage, shall be stored in containers adjusted for this purpose and compliant with the applicable standards in this respect.

4. To confirm the acceptance of Biological Material for storage, PBKM shall make available a storage certificate in the "My PBKM"

Customer Panel. Drafting and issuing the storage certificate is conditioned upon providing personal data of the Child pursuant to § 16 section 2 of the Contract.

§ 8 Extended facultative offer of PBKM services

PBKM offers additional facultative services to the Parents in the form of separate packages:

a) Transplant Assistance Package

b) 120+ Package

c) DNA Package

d) Umbilical Cord Cell Isolation

e) Transplant Assistance Plus Package

f) SwissSafety Package

g) Costs Reimbursement Guarantee Package

h) Price Stability Guarantee package

Prices for individual packages are visible when entering into the Agreement in the eShop at the address https://klient.pbkm.pl.

1. **Transplant Assistance Package** - Stem Cell Transplantation Assistance. This is a package that facilitates the use of Stem Cells derived from Cord Blood used in standard therapeutic/therapeutic transplants excluding administration as part of medical therapeutic experiments.

1.1 As part of the Transplant Assistance Package, PBKM offers assistance in the following medical procedures, when the transplant material is qualified by the attending physician:

- Hematologist or transplantologist consultation
- Transplantation HLA test
- CD 34+ cells and nucleated erythrocytes count (from a defrosted reference sample)
- Cells viability test and WBC count (from a defrosted reference sample)
- Delivery of cells from the place of storage (also in the case of the SwissSafety Package) to every transplantation center in the world.

1.2 If the Umbilical Cord Blood is not obtained, fails to meet the qualification standards for preparation as per § 6 section 3a) or, fails to meet the qualification standards for storage as per § 6 section 5.2, 10, or the storage of a contaminated/bacterially infected aliquot of Umbilical Cord Blood-derived Stem Cells is cancelled, the fee for this package will not be charged.

2. 120+ Package

2.1 If the acquired volume of Umbilical Cord Blood harvested is equal to or higher than 120 mL, PBKM shall offer the Parents a division into two separate freezing cassettes, with all the costs of storing the other freezing cassette covered for the entire contract term. Division into two separate cassette is also available if the SwissSafety Package was selected.
2.2 Where the volume of the acquired Umbilical Cord Blood is below 120 mL, the cost of the 120+ Package incurred by the Parents shall not be reimbursed.
2.3 The condition for executing the 120+ package is that Umbilical Cord Blood is acquired into the specially labelled Acquisition Kit received by the Parents from PBKM. Should blood be acquired into a different Acquisition Kit, this package will not apply.

3. DNA Package

3.1 The DNA Package provides for DNA isolation from the Child's acquired umbilical cord blood. The DNA concentration, its clarity and total amount in the deposited sample shall be determined for the isolated material. The frozen DNA sample may be used for diagnostic purposes at the Parents' or DNA donor's discretion, at a written request of the authorized person.

3.2 The condition for isolation and depositing the DNA material is to qualify the acquired Umbilical Cord Blood for storage according to the Contract terms and conditions, as well as the standards set forth by the PBKM Medical Department.

3.3 Should the DNA not be isolated, the fee for this package will not be charged.

3.4 The condition for executing the DNA Storage package is acquiring Umbilical Cord Blood into the specially labelled Acquisition Kit received by the Parents from PBKM. Should blood be acquired into a different Acquisition Kit, this package will not apply. Execution of this package is also not possible when the Emergency Biological Material Acquisition Kit available at the hospital/clinic is used.

4. Umbilical Cord Cell Isolation Package

4.1 The Umbilical Cord Cell Isolation Package is intended for the Parents, who selected the umbilical cord acquisition option as part of the executed Contract. This package offers the possibility to isolate mesenchymal cells (MSC) from the acquired umbilical cord. The

package shall be executed immediately following the Umbilical cord acquisition and cannot be executed at a later stage, without a medical indication for the use of MSC cells.

4.2 The condition for executing Umbilical cord cells isolation is only the umbilical cord being qualified for storage in accordance with the provisions of the Contract.

4.3 Should the isolated cells fail to meet the quantity criteria for qualification as per § 6 section 5.4, the fee for this package will not be charged. PBKM shall not be responsible for the disposal of the Umbilical cord that is disqualified due to an unsuccessful isolation attempt (no MSC cells).

4.4 PBKM informs and stipulates that the storage of umbilical cord fragments does not guarantee the isolation of MSC cells after thawing, as MSC cells may not be present in the prepared umbilical cord fragment.

4.5 PBKM recommends to isolate Umbilical Cord cells, as only then PBKM may guarantee to the Parents that, after thawing the portion to use it in therapy, the MSC cells will be present in the preparation (if they are successfully isolated and meet all the qualification criteria).

4.6 The provisions of § 6 section 13 of the Contract shall apply accordingly to MSC cells acquired as part of this Package.

4.7 The condition for executing the Umbilical Cord Cell Isolation Package is acquiring Biological Material into the specially labelled Acquisition Kit received by the Parents from PBKM. Should blood be acquired into a different Acquisition Kit, this package will not apply. Execution of this package is also not possible when the Emergency Biological Material Acquisition Kit available at the hospital/clinic is used.

5. Transplant Assistance Plus Package - Stem Cell Transplantation Assistance. This is a package that facilitates the use of Stem Cells extracted from Cord Blood and MSCs extracted from a piece of Cord Cord used in standard therapeutic/therapeutic transplantation and administration as part of medical therapeutic experiments.

5.1 As part of the Transplant Assistance Plus Package, PBKM ensures the following -for standard transplantation of haemopoietic stem cells acquired from umbilical cord blood, as well as for administrations of stem cells from umbilical cord blood as part of experimental medical treatments, assistance in the following medical procedures, when the transplant material is qualified by the attending physician:

- Haematologist or transplantologist consultation
- Transplantation HLA test
- CD 34+ cells and nucleated erythrocytes count (from a defrosted reference sample)
- Cells viability test and WBC count (from a defrosted reference sample)
- Complete blood count (CBC)

5.2 If the Umbilical Cord Bloodand Umbilical Cord are not obtained, fail to meet the qualification standards for preparation as per § 6 sections 3a)and 3b), or fail to meet the qualification standards for storage as per § 6 sections 5.2, 10, or the storage of a contaminated/bacterially infected aliquot of Umbilical Cord Blood- derived Stem Cells is cancelled, the fee for this package will not be charged.

5.3 In the case of standard transplantations, PBKM shall ensure delivery of haemopoietic stem cells acquired from umbilical cord blood from the storage site (also for the SwissSafety Package) to every transplantation centre in the world.

5.4 When Parents are willing and where it is possible for the Child or patients being the Child's relatives (Child's biological siblings, Child's biological parents) to undergo experimental medical treatment with an advanced therapy medicinal product of mesenchymal stem cells from the umbilical cord (MSC cells) - stored at PBKM (Family Material) or from material from an honorary donor, PBKM guarantees to the Parents, within the list of medical entities cooperating with PBKM in ordering the manufacture of medicinal products, that such a medical entity conducting the medical therapeutic experiment will provide the Parents with a discount in relation to the administration of the product manufactured by PBKM. The discount will be granted for no more than five administrations of the medicinal product. The discounts will be expressed as an amount that will depend on the type of biological material stored by the Parents in PBKM, and the discount in the specified amount will be taken into account by the medical entity conducting the medical therapeutic experiment in the amount of each administration (up to 5 administrations). Discounts are granted on the day of purchasing the package and the list of medical entities granting them is available to Medical Consultants of PBKM and Medical Services Sales Specialists.

5.5 In addition to the services described above, when Parents are willing and where it is possible for the Umbilical Cord Blood- -derived stem cells to be used in the Child, the Transplant Assistance Plus Package includes coordination of the Child's eligibility confirmation for the autologous administration of Stem Cells acquired from Umbilical Cord Blood (hereinafter: the Procedure) where the Child whose Umbilical Cord Blood was obtained is diagnosed with cerebral palsy or an autism spectrum disorder. The Procedure may be performed once all the conditions specified in the rules for this package and set forth in section 5.6 below have been met jointly. PBKM offers coordination of the Child's application for qualification to the autologous administration of stem cells, performance of necessary tests mentioned under item 5.1 above and transportation of an aliquot of the Child's stem cells to the center, which is to perform the administration, as well as coverage of the costs incurred for the Child's stay at the center related the administration for up to 2 days. The costs of the Child's stay shall be paid by PBKM directly to the center or reimbursed to the Parents based on a listing of costs/invoices issued by the center.

5.6 Conditions for performing the Procedure (5.5 above), to be met jointly, are as follows:

a) Qualification of the acquired umbilical cord blood for storage according to the Agreement

b) Qualification of the stored umbilical cord blood to be used by the PBKM Medical Director, assuming at least 1x107 TNC/kg of the Child's weight upon qualification.

c) Qualification of the Child for the Stem Cells Administration Procedure by the competent doctor in charge of the Child's treatment as part of the experimental medical treatment (which is beyond the control of PBKM).

d) Obtaining all the required consents related to participation in the medical experiment (which is beyond the control of PBKM)

5.7 Parents acknowledge that autologous administration of stem cells acquired from umbilical cord blood as part of treatment for diseases such as cerebral palsy or autism is a non-standard procedure and is performed at healthcare entities collaborating with PBKM, which are independent of PBKM. These entities administer stem cells as part of experimental medical treatment. When Parents submit a written statement confirming their willingness to use the Procedurę, PBKM shall indicate the entities where the Procedure may be performed. Qualification is performed by the healthcare entity. If the Child is not eligible for the Procedure, PBKM shall cancel the Parents' subscription fee for the storage of umbilical cord blood-derived stem cells for the period of one year.

5.8 Without the Transplant Assistance Plus Package, the costs of the above and all other services related to standard medical/therapeutic transplantation and administrations as part of experimental medical treatment shall be incurred entirely by the Parents.

6. SwissSafety Package

6.1 The package includes an option to divide the stored Biological Material between two sites and have it stored by PBKM in Poland and by FamiCord Suisse SA in Switzerland. Choosing the package involves the Parents concluding a Biological Material Storage Contract with FamiCord Suisse when the qualification criteria described under item 6.2 below are met.

6.2 The SwissSafety package may only be delivered if the Umbilical Cord Blood meets the following criteria:

a) qualification for preparation (at least 10 ml),

b) qualification for storage (at least 100 million cells),

c) qualification for storage in case of Umbilical Cord Blood contamination/bacterial infection if Parents submit a further storage declaration (§ 6 Section 6 a). Failure to submit the declaration by the designated deadline is equivalent to providing consent for Umbilical Cord Blood-Derived Stem Cells to be stored and the SwissSafety package to be executed.

6.3 If the terms indicated under Section 6.2 above are not met, the condition to execute the SwissSafety package is not fulfilled, the Parents shall be bound by the terms and conditions of this Contract, and the entire Biological Material shall only be stored in Poland.

6.4 Should the Umbilical Cord Blood meet the qualification requirements, the Package provides for storage in the following manner:

a) Umbilical Cord Blood-Derived Stem Cells: 80% of this Biological Material will be stored in Switzerland, 20% of the Biological Material will be stored in Poland;

b) 50% of the Umbilical Cord vials will be stored in Poland, 50% of the vials will be stored in Switzerland (if Umbilical Cord was acquired, as chosen by the Parents, and met the qualification criteria for storage);

c) 50% of the Placental Tissue vials will be stored in Poland, 50% of the vials will be stored in Switzerland (if Placental Tissue was acquired, as chosen by the Parents, and met the qualification criteria for storage);

d) should the additional 120+ package be selected and should it be executed, Umbilical Cord Blood-Derived Stem Cells will be stored divided into two independent freezing cassettes at a proportion of 2 x 20% of the Biological Material to be stored in Poland and 2 x 80% of the Biological Material to be stored in Switzerland.

e) should the number of the Umbilical Cord Blood-derived stem cells be in the 100-299 million cells range, the umbilical cord blood-derived stem cells shall be stored in Switzerland at PBKM's cost without charging Parents with the cost for 18 years from the birth date.

6.5 Biological Material is transferred to the FamiCord Suisse SA site in Switzerland using specialized transport. PBKM will make every effort to ensure that the transfer is completed within 6 months of the date of acquisition Biological Material, however with the option of extending it to 12 months from the date of acquisition the Biological Material. The Parents choosing this package grant their consent for the Biological Material to be transferred to the indicated site in Switzerland. The address of the laboratory where the Biological Material will be stored will be indicated on the storage certificate referred to in point 6.6 below.

6.6 Biological Material transfer will be confirmed by FamiCord Suisse by means of a storage certificate within 30 days from the date when the Biological Material was transferred to Switzerland. The certificate will be available in the "My PBKM" Customer Panel.

6.7 If Parents conclude the Biological Material Storage Contract with FamiCord Suisse SA, the Biological Material storage fees payable to PBKM will be reduced appropriately, which is reflected in the price table at the end of the contract.

6.8 Should the Umbilical Cord Blood fail to meet the qualification standards for preparation as per § 6 section 3a), the fee for this package will not be charged.

6.9 The price table detailing the fees for storing Biological Material in Poland where the SwissSafety package is not executed:

Fuli storage fees table for the contract*				
	annual fee	prepayment for 5 years	prepayment for 10 years	prepayment for 18 years
1 material				
2 materials				
3 materials				

* If monthly payments/installments are selected, all types of fees (annual fee and prepayments) in the table include the fee increase in accordance with the provisions of the contract in § 9, pkt. 9.1

6.10 Parents may cancel the SwissSafety package by withdrawing from the Contract in accordance with § 12 Section 5. Withdrawal from the Contract must occur before birth, however without having to adhere to the 14-day withdrawal period.

6.11 The condition for executing the SwissSafety package is that Umbilical Cord Blood is acquired into the specially labelled Acquisition Kit received by the Parents from PBKM. Should blood be acquired into a different Acquisition Kit, this package will not apply. Execution of this package is also not possible when the Emergency Biological Material Acquisition Kit available at the hospital/clinic is used.

6.12 In case it is necessary to use the Biological Material stored in Switzerland for treatment in Poland, PBKM shall organize the transport of such Biological Material from Switzerland to Poland at its own expense. However, if the Biological Material stored in Switzerland needs to be used for treatment outside of Switzerland but not in Poland, the Clients shall organize and pay for the transport of such Biological Material to the place of use on their own. PBKM shall ensure the delivery of the Biological Material (stored both in Poland and Switzerland) to every transplantation center in the world in case the Parents choose and pay for the additional Transplant Assistance or Transplant Assistance Plus Package.

7. Costs Reimbursement Guarantee Package

7.1 The Costs Reimbursement Guarantee package includes:

- Guaranteed reimbursement of the initial fee if all Biological Materials from the service option selected by the Customer are not qualified for preparation/storage or if the storage is cancelled - subject to the provisions of item 8.2.
- Waiving the handling fees mentioned under paragraph 9 section 6.5 if one, two or all Biological Materials obtained as part of the service option selected by the Customer are found not eligible for preparation/storage or if storage is cancelled - subject to the provisions of item 8.3.

7.2 Reimbursement of the initial fee shall apply in the following cases:

- Failure to qualify any of the acquired Biological Materials from the selected service option for processing, in accordance with the provisions of paragraph 6 section 3 a-c.
- Failure to qualify any of the acquired Biological Materials from the selected service option for storage, in accordance with the provisions of paragraph 6 section 5.2, 5.3, 5.4 and 10.

7.3 Handling fees shall be waived in the following cases:

- Failure to qualify one, two or any of the acquired Biological Materials from the selected service option for processing, in accordance with the provisions of paragraph 6 section 3 a-c.
- Failure to qualify one, two or any of the acquired Biological Materials from the selected service option for storage, in accordance with the provisions of paragraph 6 section 5.2, 5.3, 5.4 and 10.

7.4 The condition for executing the Costs Reimbursement Guarantee package is that the initial fee, along with the amount due for the package, are paid in accordance with paragraph 9 section 5.1 prior to the acquisition of the Biological Material.

7.5 If the Biological Material is not acquired and an intact collection kit is returned to PBKM, the fee for this package shall be reimbursed in accordance with the provisions of paragraph 12 section 5.

7.6 The Costs Reimbursement Guarantee package does not cover the cancellation of storage of a contaminated/bacterially infected umbilical cord blood stem cells unit, in accordance with the provisions of paragraph 6 section 6b.

8. Price Stability Guarantee package

8.1 The Price Stability Guarantee package ensures that the annual subscription fee will remain unchanged for 5 years, counted from the moment the child is born. PBKM waives the right to index the amount of the annual subscription fee, however, it reserves the right to amend the annual subscription fee amount during the term of the Contract where such an amendment results from a change in the VAT rate, which is independent of PBKM.

8.2 The condition for executing the Price Stability Guarantee package is that the initial fee and basic fee, along with the amount due for the Price Stability Guarantee package, are paid in accordance with paragraph 9 section 5.1 and 9 section 6.1 prior to the acquisition of the Biological Material.

8.3 If Umbilical Cord Blood, Umbilical Cord and Placental Tissue are not acquired, fail to meet the qualification standards for processing as per paragraph 6 section 3a-c, or fail to meet the qualification standards for storage as per paragraph 6 sections 5.2, 7 and 10, or the storage of a contaminated/bacterially infected aliquot of Umbilical Cord Blood- derived Stem Cells is cancelled, the Price Stability Guarantee package fee will not be charged provided that this results in the complete Contract termination. In accordance with the provisions of paragraph 6 section 5.1 b) of the Contract and fail to meet the qualification standards for processing of other Biological Materials, the fee for the Price Stability Guarantee package will not be charged.

§ 9 PBKM fees

1. The Parents agree to pay PBKM fees for signing and performing the Contract, as set forth in the provisions of the Contract and the Price Table.

2. The Parents agree to pay PBKM the following types of fees:

a) the initial fee (payment before childbirth) that covers the cost of the Acquisition Kit and the costs of acquiring, transporting to the place of preparation and preliminary preparation activities. The Initial Fee may be increased to include the fee for any Costs Reimbursement Guarantee package selected by the Parents, as mentioned under paragraph 8 section 9 of the Contract;

b) additional fees that cover the costs of optional services: health and life insurance for the Child in a specified insurance company - a separate service provided by a third party not covered by the Agreement and a cost reimbursement guarantee package;

c) the basic fee (payment after childbirth) that covers the costs of tests, preparation of relevant Biological Material and freezing of stem cells isolated from the selected source and includes fees for additional packages selected by the Parents, as set forth under § 8 of the Contract (except for the reimbursement guarantee package - § 8.9 of the Agreement, for which the fee is added to the fee before delivery), if any, the basic fee that covers the costs of tests, preparation of relevant biological Material and freezing of stem cells isolated from the selected source and includes fees for additional packages selected by the Parents, as set forth under § 8 of the Contract, if any and an additional cost of PLN 300 may be added to it, if the Biological Material is obtained at a hospital/clinic in Warsaw, which charge above-standard fees for the biological Material acquisition service. An up-to-date list of the above-mentioned Warsaw hospitals/clinics can be found on the website http: //www.pbkm.pl/szpitale, at the PBKM office, from medical consultants or the Customer Service Department (call center). A fee for SOLO DNA genetic testing may be added to the sum of the basic fee if this supplemental service is selected.

d) periodical fee that covers the costs of storing the appropriate amount of Biological Material during selected service periods.

3. All fees referred to in § 8 and § 9 of the Contract are set forth in the Price Table, constituting an integral part of the Contract in accordance with the selected package.

4. Initial fee (before childbirth)

4.1 The initial fee shall be payable no later than within two working days from the date of the Contract coming into force, in accordance with the provisions of § 17 section 1 of the Contract. The amount of the initial fee is set forth in the Price Table and it varies with the selected option and additional services.
4.2 The initial fee shall be reimbursed if the Parents terminate the Contract prior to initiating the acquisition of Biological Material and where the acquisition of Biological Material is not performed due to reasons on the part of the PBKM or persons to whom PBKM entrusted the acquisition. The initial fee shall be reimbursed to the Parents on the condition that they deliver to PBKM the unused and intact Biological Material acquisition kit.

5. Additional fees for selected optional services determined under § 8

5.1 The pre-birth fees shall be payable no later than within two working days from the date of the Contract coming into force in accordance with the provisions of § 17 section 1 of the Contract. The amount of the fees for the particular additional services selected is specified in the Price Table.

6. Basic fee (after childbirth)

6.1 The basic fee shall be payable following the final qualification of Biological Material, pursuant to an invoice issued by PBKM and in the amount depending on the selected option, Biological Material acquisition site (particular Warsaw hospital/clinic from the list, as mentioned under paragraph 9 section 2 c) increased by the costs of any optional services selected in the Contract, as set forth in the Price Table.

6.2 Standard costs of tests and processing of the relevant Biological Material and potential additional fee when Biological Material is acquired at a Warsaw hospital/clinic (referred to in paragraph 9 section 2 c) included in the Basic fee:
a) PLN 2720 for Umbilical Cord Blood,
b) PLN 1820 for Umbilical cord,

c) PLN 1810 for Placental Tissue,
d) PLN 400 - Biological Material is acquired at a Warsaw hospital/clinic from the list referred to in paragraph 8 section 2 c).

6.3 The lowest price from the last 30 days, counting from the date of entering into the Agreement, for standard costs of examinations and preparation of appropriate biological material is indicated on the Customer Panel during the entering into the Agreement in the eShop at the address https://klient.pbkm.pl.

6.4 Withdrawing from the acquisition of Biological Material shall lead to reducing the basic fee by the appropriate cost, depending on what type of Biological Material is not qualified for preparation.

6.5 Disqualification at the preliminary testing stage, as mentioned under § 6 section 3 a-c and 5.3, shall lead to reducing the basic fee by the appropriate cost, depending on what type of Biological Material is not qualified for preparation taking into account the handling fee relevant for this Biological Material. The handling fee shall amount to:

a) PLN 300 for Umbilical Cord Blood,

b) PLN 200 for Umbilical cord,

c) PLN 200 for Placental Tissue.

6.6 Disqualification of Biological Material from storage, as mentioned under § 6 section 10, shall lead to reducing the basic fee by the standard cost, depending on what type of Biological Material is not qualified for preparation, taking into account the handling fee specified under § 9 section 6.5.

6.7 In the case mentioned under § 9 section 6.4 and 6.5, the total costs of tests and preparation of relevant Biological Material qualified for storage shall be increased by the costs of any optional services selected by the Parents.

6.8 The basic fee may be divided into installments in the amounts set forth in the Price Table. Installment payment is associated with a ten percent increase in fees. The first basic fee installment shall be payable within 14 days from the date of issuing the invoice, following final Biological Material qualification for storage, while subsequent installments shall be payable in the following monthly periods, pursuant to invoices in accordance with the option selected by the Parents. Should the payment be divided into installments, failure to pay the subsequent installment by the designated due date shall result in the total of the remaining installments becoming immediately due and payable.

6.9 The basic fee shall be partially reimbursed if the results of tests performed reveal a contamination/bacterial infection of the Umbilical Cord Blood and the Parents did not consent to its storage in accordance with § 6 section 6 b). Part of the basic fee shall be reimbursed within 14 days from the date of PBKM receiving the Parents' statement. Reimbursement is conditioned upon meeting the deadline for returning the statement. The reimbursed part of the basic fee shall amount to the difference in the standard fee (specified under § 9 section 6.2 a) taking into account the handling fee, subject to the provisions of § 9 section 6.10 and 6.11 below) between the fee for the selected service option and the costs of storing Biological Material that the Parents have decided not to submit for storage, taking into account the handling fee relevant for this Biological Material specified under § 9 section 6.5.

6.10 Should the Parents be eligible for a current promotional offer and, consequently, be granted a discount from the basic fee, this discount shall be proportionally divided and allocated to the amounts specified under § 9 section 6.2 a-c), depending on the service option selected and the amount of Biological Material subject to preparation. The promotional discount is not granted from the additional fee of PLN 400 that will always be added if the Biological Material is acquired at a Warsaw hospital/clinic from the list referred to in paragraph 9 section 2 c) of the Contract.

6.11 Withdrawal from Biological Material acquisition or its disqualification, as mentioned under § 9 section 6.4 and 6.5, shall result in reducing the basic fee by the relevant costs determined under § 9 section 6.2 a-c) and proportionally reducing the relevant part of the discount granted, as allocated to this Biological Material, in accordance with § 9 section 6.10 above.

6.12 If in the Contract the Parents indicate a Warsaw hospital/clinic from the list referred to in paragraph 9 section 2 c) of the Contract, but the Biological Material is actually acquired at another hospital/clinic that is not included on the above list, the additional fee of PLN 400 shall not be added to the basic fee.

6.13 If in the Contract the Parents indicate a hospital/clinic that is not included on the list referred to in paragraph 9 section 2 c) of the Contract, but the Biological Material is actually acquired at another hospital/clinic that is actually on the above list, the additional fee of PLN 400 shall be added to the basic fee.

7. Periodical storage fee for 1 year

7.1 Starting from the end of the Contrast term's first year, the fee for Biological Material storage shall be payable in arrears for each year of the Contract duration. A year shall mean the period of consecutive twelve months as of the day of birth.

7.2 At any time during the term of the Contract, the Parents may decide to switch from the annual subscription payments scheme into payments for storage paid in advance for a period of five, ten or eighteen years, as mentioned under § 9 section 8. Switching to the advance payments scheme shall be effective as of the end of the pending annual subscription period. In such cases, the Parents agree to pay the fee in arrears for the storage year ended and in advance for the selected period. The fees applicable shall be those set forth in the Contract in the Price Table, subject to § 9 sections 10.3 and 10.4 hereof.

8. Periodical fees for storage payable in advance for a period of 5, 10 or 18 years

8.1 The Parents may cover the Biological Material storage costs in advance for a period of five, ten or eighteen years as of the day of

birth. Storage costs in the prepaid model include a discount granted on the amount corresponding to the one year periodical storage fee as per the Price Table, multiplied by the number of years in the selected prepaid period. Keeping of the right to the granted discount is conditioned by expiry of the agreed prepaid storage period of five, ten or eighteen years, without switching to other storage settlement model in the meantime. The costs of storage with the included discount are set forth respectively in the Price Table. The periodical fee is payable following final qualification of Biological Material, pursuant to an invoice issued by PBKM. Should no payment for the period of five, ten or eighteen years be made within six months from the payment due date, storage settlement shall be switched to the one year periodical fee, as per the Price Table. The previously issued invoice shall be corrected and replaced with invoices for one-year storage periods.

8.2 The Parents who covered the Biological Material storage cost in advance for a period of five, ten or eighteen years calculated from the date of birth, following the end of the paid storage period (whether it was paid in a single payment or in installments), if they do not report their willingness to make the payment for storage in advance for the next selected period, shall be automatically switched to storage payments for one year and be charged pursuant to the principles set forth under § 9 section 7 hereof, using the periodical storage fee rate for one year, specified on the basis of the amount of Biological Material stored. The Parents who want to continue settlements in the form of advance payments, shall submit to PBKM a statement of intent to pay in advance for the next selected period, either during the prepaid period or by the final deadline of seven days as of the end of the period already paid for. Applicable fees shall be those set forth in the Price Table, subject to § 9 sections 10.3 and 10.4 hereof.

9. Storage fees - payment in installments

9.1 The storage fees may be divided into installments in the amounts set forth in the Price Table. Installment payment is associated with a ten percent increase in fees.

9.2 Should the one-year storage fee be divided into instalments, the first periodical storage fee installment shall be payable within fourteen days from the date of issuing the invoice, starting from the end of the first year of the term of the Contract, pursuant to § 9 section 7.1, while subsequent installments shall be payable in the following monthly periods, pursuant to invoices.

9.3 Should the five-year, ten-year and/or eighteen-year storage fee be divided into instalments, the first periodical storage fee installment shall be payable within 14 days from the date of issuing the invoice, while subsequent installments shall be payable in the following monthly periods, pursuant to invoices in accordance with the option selected by the Parents.

9.4 Should the payment be divided into installments for a particular storage period, failure to pay the subsequent three installments by the deadline set forth in the invoices shall may result in the total amount of unpaid installments and remaining installments for the storage period declared becoming immediately due and payable and the installment system may expiring. Should the installments be paid ahead of the monthly payment schedule specified in the Contract, the fees amount shall remain unchanged and be as set forth in the Price Table.

10. Changes in payments and resignation from a part of the services provided, generał payment terms and conditions

10.1 Advance payments made for a period of five, ten or eighteen years for Biological Material storage shall be refundable pursuant to the rules described below. As under this section, PBKM shall reimburse proportionally the prepayment amount if the whole aliquot of Biological Material stored under the selected option is used for purposes of treatment of an authorized recipient/patient before the end of the prepaid storage period; section 10.2 below shall apply accordingly. Should the Contract - for reasons other than the Biological Material being used for the purposes of treatment of an authorized recipient/ patient - be terminated earlier than at the end of prepaid storage period, the discount granted for a period of storage of five, ten or eighteen years shall no longer apply and PBKM shall settle the already paid pre-payment according to standard payment rates for one year of storage set forth in the Price Table. Only the amount exceeding the product of payments for one year of storage according to standard rates and the sum of years of actual storage shall be subject to reimbursement. Nevertheless, in case if the product of payments for one year of storage according to standard rates and the sum of years of actual storage exceeds the prepaid amount, the Parents will be not obliged to pay any additional fees.

10.2 During the term of the Contract, the Parents may cancel storage of Umbilical Cord Blood and/or Umbilical Cord or MSC cells isolated from it (if the Parents decided to extend the service to include an additional package: Umbilical Cord Cell Isolation) and/or Placental Tissue. Cancellation shall result in switching to the fees set forth in the Price Table, according to the quantity of Biological Materials stored. Cancellation shall be effective upon the end of the pending annual subscription period.

10.3 Prices for storage shall be gross prices and include VAT tax at the applicable rate. Should the VAT rate applicable for Biological Material storage service be increased, PBKM shall notify the new rate in writing, allowing the Parents 30 days to cancel the Contract in writing. Should the Parents withdraw from the Contract, PBKM shall issue a final invoice for the Parents, covering the unpaid period of storage (until a Contract termination notice is received). Should no statement on withdrawal from the Contract be submitted, PBKM shall assume that the Parents are willing to continue the Contract under the new price terms and shall issue an invoice for the next period, increased by the new applicable tax rate.

10.4 During the term of this Contract, PBKM shall have the right to adjust the one year storage payment (by increasing it) respectively by the twelve month consumer price index, as published by the President of the Polish Central Statistical Office (Główny Urząd Statystyczny, GUS) for the period preceding the adjustment. Such adjustment shall not refer to the storage payments paid in advance for a period of five, ten or eighteen years. Should the price be increased by the GUS index, PBKM shall inform the Parents in writing about the situation and the amount of the increase. The Parents shall have the right to terminate the Contract in writing within 30 days as of notice receipt, by way of submitting a statement on withdrawal from the Contract. If the returned decision is a decision to withdraw from the Contract, PBKM shall issue to the Parents a final invoice for the unpaid period of storage (until a Contract termination notice is received). Should no statement on withdrawal from the Contract be submitted, PBKM shall assume that the Parents are willing to continue

the Contract under the new price terms and shall charge a payment increased by the relevant inflation rate for the next period.

10.5 Any and all overpayments recorded on the individual account assigned to the Contract shall be reimbursed to the account from which the overpaid amount was received.

§ 10 Other terms and conditions

1. If the joint and several liability of the Parents of the Child is not statutory or should its statutory joint and several nature cease to exist, the Parents agree for their liabilities resulting from the Contract to be joint and several for the entire term of the Contract, and undertake to sign a Customer's Written Declaration to that effect.

2. Any and all payments arising from the Contract shall be made to the bank account assigned individually to each contract. PBKM shall specify the individual account number assigned to the Contract in the My PBKM Customer Panel and the Parents shall also receive the information via a text message (SMS) or e-mail sent to the telephone number or e-mail addresses provided by them. The account number shall be confirmed along with the first issued invoice. The day of payment shall be the day when the Parent's /or the Child's other statutory representative's or other payer's account is charged with the amount.

3. If the Parents receive discounts when the Contract is concluded, resulting from applicable promotions or annexes to the Contract, and they fail to fulfil the conditions stipulated in the terms and conditions of those promotions or conditions stipulated in the annex, PBKM may charge the fuli amount of fees in accordance with the standard price list valid as of the execution of the contract.

4. Ali VAT invoices are issued by PBKM and made available to Parents in the „My PBKM" Customer Panel after the date of the service or after payment of the total amount indicated in the Price Table. If you choose the form of the invoice sent on paper, PBKM will send the document as an unregistered letter to the correspondence address indicated in the Agreement, the customer has the right to change the selected form of invoice delivery at any time during the term of the contract.

5. In the case of a delay in making the payments arising from the contract, PBKM shall request the Parents /or other statutory representatives of the Child to pay the arrears within the time limit indicated in the request. PBKM is authorized to charge statutory interest for each day of delay and to claim the amounts due in recovery proceedings.

6. If the Parents enter into the Contract using a special offer (the terms and conditions of which are set forth in separate terms and conditions of such an offer) and they receive discounts against the Initial Fee and/or Basic Fee and/or additional packages from the extended optional offer of PBKM services, the Parents shall return the amount of such discounts if they withdraw from the Contract or terminate it earlier than 10 years from the birth date for reasons other than medical reasons - which shall be understood as using the Biological Material for administration or transplantation. The amount of discounts subject to reimbursement referred to in previous sentence shall be determined proportionally to the period lasting from the date of withdrawal or termination of the Contract to the expiry of the 10-year term of the Contract. This means that after the end of each of the first ten years of duration of the Contract counted from the birth date the amount of the discount reimbursable by the Parents is decreased by 10% of the total discount amount determined under the special offer. In the event of withdrawal from the Contract or its termination before the end of the first full year or one of the subsequent years of its term by the Parents, the amount of the discount reimbursable by the Parents for such an incomplete annual period will be determined in proportion to the number of months remaining until the end of the full year of the Contract. Discount reimbursement does not pertain to a situation when the Contract cancellation results from an infection of the Biological Material, and the Parents send a cancellation notice in accordance with the provisions of the Contract within 10 days, as mentioned under § 6 section 9.

7. Special offers cannot be combined.

8. PBKM, as medical waste producer, has concluded an agreement with a medicinal waste removal company according to the Waste Act of 14 December 2012 and the Regulation of the Minister of Health of 5 October 2017 on the detailed procedure for medical waste management.

§ 11 Liability for non-performance and improper performance of the Contract

1. In the event of non-performance or improper performance of the Contract by PBKM for reasons attributable to PBKM, PBKM shall pay the Controller who is authorized at the time when the damage resulting from non-performance of improper performance of the Contract occurred: - contractual penalties in the amount of PLN 10 thousand (in words: ten thousand zloty) and - shall return the initial fee and the basic fee set forth in the Price Table in the amount actually paid. For the purposes of this section, non-performance or improper performance of the Contract for reasons attributable to PBKM shall be understood as damage resulting from:

a) destruction of the Biological Material as a consequence of exceeding the allowed time between collecting the Biological Material and its preparation and freezing, which occurred for reasons attributable to PBKM;

b) destruction of Biological Material during testing and preparation at the PBKM Non-Public Health Care Institution;

c) destruction of Biological Material during the process of freezing or storage in a manner not conforming to the applicable norms and PBKM standards;

d) destruction of Biological Material not justified by contractual provisions;

e) releasing the stored Biological Material to persons who are not authorized under the provisions of the Contract and the law.

2. PBKM's liability shall be excluded if damage occurred for reasons that PBKM was not to blame for or due to Force Majeure. Force Majeure shall be defined as an external event, that could not have been foreseen nor prevented; Force Majeure circumstances shall include, but not be limited to: fire, flood, earthquake, catastrophe, war, riots, strikes, embargos, state of epidemic or pandemic.

3. Provisions regarding the contractual penalties shall not exclude the possibility to seek compensation on general terms for damage resulting in connection with non-performance or unsatisfactory performance of the Contract.

4. PBKM hereby informs, and the Parents accept, that in connection with the fact that the acquisition of Biological Material takes place in non-sterile conditions during the Child's birth, in rare cases (global statistics indicate about 7% of collections) its contamination/bacterial infection, for objective reasons, is completely beyond the control of PBKM and the persons performing the acquisition. Detection of such contamination/infection is possible during final qualification (second state of testing) performed by PBKM. PBKM also informs that in the vast majority of cases such an infection does not constitute a counterindication for storing Biological Material - in such a case the final decision shall however belong to the Parents.

5. Should PBKM's business activities be suspended or terminated for any reason, requiring the assignment of the rights and obligations resulting from the storage to a third party, PBKM shall guarantee the possibility to have Biological Material stored by a third party specializing in this scope and duly authorized, pursuant to separate contracts made between PBKM and entities specializing and authorized in this scope and with the Parent's participation. The Parents shall not bear any costs in connection with the transfer of rights and obligations to such an entity. PBKM hereby informs that it fulfils the obligation to have such contracts in place and at the Parents' request it shall indicate to the Parents the entities with which current contracts have been concluded.

6. PBKM shall not be required to inform the Parents about any changes in the guidelines included in the Medical questionnaire and disclaims any liability for these changes, as well as any possible consequences for the future use of the Biological Material.

§ 12 Term, resignations, termination of the Contract

1. The contract is concluded for an indefinite period of time.

2. The Parents shall have the right to terminate the Contract by submitting a written statement, subject to a notice period of 3 months. Should the Contract be terminated earlier than after the storage period paid for in advance, payments shall be refunded on the conditions set forth under § 9 section 10.1 hereof. A written Contract termination notice should be sent by registered mail and should be made unanimously and signed by both Parents, or by one Parent who shall declare in writing that they represent also the other Parent's will, if they have jointly acceded to the Contract. If the Contract has been signed by one of the Parents, an effective Contract termination notice only requires the signature of this Parent.

3. Where the Contract is terminated, the Parents shall pay all the amounts for the previous storage period which were not paid and the due amounts in proportion to the actual storage period in accordance with the specification prepared by PBKM.

4. The Parents may withdraw from the Contract without stating a reason, by submitting a relevant statement in writing within fourteen days as of the day of entering into the Contract. In order to meet this deadline, it shall be enough to send a written statement before it lapses. If the parents entered into the Agreement outside the company premises during an unarranged visit of PBKM to the place of residence or usual stay of the parents or a trip, the period for withdrawing from the Agreement is 30 days.

5. In the case of withdrawal from the Contract on the conditions set forth in section 4 above, it shall be deemed that the Contract was never concluded and the Parents shall be released from aby obligations. PBKM shall return to the Parents the initial fee and pre-birth fees paid, if any. The refund shall be exercised immediately, not later than within fourteen days as of the date of receiving the written statement on withdrawal. The provision of the second sentence of paragraph 9 section 4.2 shall apply accordingly. The Parents shall return the unopened Biological Material collection kit, within fourteen days from the day of withdrawal from the contract and bear any direct costs of such return. In order to meet this deadline, it shall be enough to send the kit before lapse of the deadline. PBKM may suspend refunds of any received payments pending receipt of an unopened kit. A Contract withdrawal template - compliant with Polish law - may be found in Appendix No. 2 to the Consumer Rights Act of 30 May 2014 (Polish Journal of Laws of 2020, item 287).

6. If Biological Material was collected between the date of concluding the Contract and the 14-days' deadline for withdrawal, PBKM shall not reimburse the initial fee amount and the Parents shall refund to PBKM the cost of testing, preparation and freezing the Biological Material, if any such procedures have already been performed.

7. The Contract shall be terminated:

a) should the Biological Material not be collected due to conditions during childbirth or the Child's general bad condition before cord severance,

b) should all Biological Material referred to under § 6 section 3 a-c of the Contract be disqualified,

c) under the circumstances mentioned under § 6 section 10 of the Contract,

d) Should the Controller(s) decide to change the tissue and cell bank. In such a case the Contract shall be terminated on the day on which the Biological Material is handed over to the new storing entity authorized to store Biological Material and having appropriate accreditation for that purpose.

e) should all the stored Biological Material aliquots be used for the treatment of an authorized recipient.

8. PBKM may terminate the Contract if the periodical storage fee set forth in the Price Table is not paid by the Parents for a period of two consecutive years of the term of the Contract or if no payment of the basic fee is received within 6 months from its due date or if payment for a minimum of 6 monthly instalments for the basic fee is not received. In such a case PBKM shall send to the Parents a request for payment letter for the outstanding invoices, along with due interest, and shall inform the Parents that failure to make the outstanding payments by the deadline set forth in the request shall lead to Contract termination. Should the Basic fee or periodical storage fees not

be made, irrespectively of the resulting Contract termination, PBKM may initiate legal action against the Parents in order to collect the due payment for the performance of the Service.

9. Should the Contract be terminated for the reasons set forth under § 12 section 8 above, PBKM shall have the right to dispose of or destroy the Biological Material according to the applicable procedure. Disposing of the Biological Material shall mean placing it at the disposal of PBKM.

10. The Parents shall have the right to submit a relevant written statement regarding the disposal or destruction of the Biological Material within thirty days as of the Contract termination cause (the thirtieth day shall be the day of delivering the statement to the PBKM office). Disposing of the Biological Material shall mean placing it at the disposal of PBKM. If no such declaration is submitted, PBKM shall assume that the Parents agree to any disposal of Biological Material or its destruction, at the discretion of PBKM, without the obligation to inform the Parents on the decision.

11. If the Parents' instruction is for the Biological Material to be destroyed, the Parents shall be charged an additional fee in the amount of PLN 150, covering the cost of such a procedure. This procedure shall be confirmed by means of drafting a destruction handover certificate and a copy of such a certificate shall be sent by mail to the Parents upon their request.

12. Where the Parents terminate the Contract for a reason indicated under § 12 section 7 d) above, the Parents may decide about the terms for transferring the Biological Material. The following options are available:

a) arrangements for the Biological Material transfer shall be made by the bank receiving the Biological Material and PBKM shall not charge the Parents with any costs on this account. Transfer of the Biological Material arranged by the receiving bank shall not release the Parents from the obligation to pay PBKM any overdue payments and storage fees proportionally to the actual storage period, if the Parents pay in annual cycles.

b) arrangements for the Biological Material transfer shall be made in full by PBKM, who agrees to deliver it directly to the bank in Poland receiving Biological Material. PBKM shall charge the Parents with an amount of PLN 1500 to cover the cost of issuing the Biological Material to another bank, its transportation to another bank, along with its insurance and relevant administrative procedures. Payment of the amount indicated in the first sentence does not release the Parents from the obligation to settle with PBKM any overdue payments to PBKM and to pay for storage proportionally to the actual storage period if the parents pay in an annual cycle.

13. Should the Biological Material not be obtained within 2 months from the date indicated as the expected childbirth date, this Contract shall be deemed not concluded and PBKM shall return the initial fee paid, subject to the provisions regarding the Acquisition kit set forth in § 12 section 5 of the Contract.

§ 13 Disposing of the Biological Material before the Child's age of majority

1. Before the Child reaches the age of majority the Parents (or other statutory representatives of the Child) who exercise parental authority or care of the Child in accordance with the relevant provisions of law, may at any time dispose of the Biological Material for the purposes of treatment of the Child or other recipients (Child's biological siblings, Child's biological parents, Child's biological grandparents, the Child's biological descendants) in the case of transplantations and of patients being the Child's relatives (Child's biological siblings, Child's biological parents, Child's biological grandparents, the Child's biological descendants) in the case of administrations. Disposing of is understood as transfer of Biological Material to the entity providing therapy upon reception of a relevant document from such an entity, confirming the use of Biological Material for treatment.

2. PBKM shall at any time release the stored Biological Material directly to the entity performing cell administration or to an authorized representative of such an entity (within the scope of the reported demand) based on a direct original written instruction of the persons authorized according to the terms and conditions of the Contract, who present the following documents confirming the right to dispose of the Biological Material:

a) declaration of will from both Parents, with signatures certified by a notary public or declaration of both Parents confirmed by the doctor conducting the therapy and Hospital's/Clinic's attorney.

or

b) declaration from one Parent on having parental rights to the Child in the case of a divorce or an original or notary-certified court ruling depriving one of the Parents of parental rights and stating that the person with authority to take care of the Child is only one of the Parents or a court ruling establishing custody or guardianship

and

c) ID card/passport confirming personal information of the Controllers

3. Ruling of a Common court requiring the Biological Material to be issued shall not be necessary if a specialist physician confirms a threat to life or health of the Child or an immediate family member of the Child (biological siblings of the Child, biological parents of the Child, biological grandparents of the Child, biological descendants of the Child); such a case shall require a request from the specialist doctor and a written confirmation of the Parents' order to issue Biological Material to the particular Hospital/Clinic.

§ 14 Validity of the Contract after the child's age of majority

1. Upon reaching the age of majority, the Child shall obtain full right to dispose of the Biological Material for their own medical needs or the needs of third parties, unless the Child loses full capacity to enter into legal transactions. The Child's right to dispose of Biological Material upon reaching majority shall not depend on who is party to the Contract and shall be due to the Child even if the Child neither accedes the Contract nor replaces Parents with respect to the rights and duties arising under the Contract.

2. When the Child reaches majority, the Parents alone may not request destruction, provision or dispose of the Biological Material; this does not preclude the option to terminate the Contract according to its provisions.

3. Should the Contract be terminated by the Parents after the Child reaches majority, PBKM shall send to the Child, at the Parents' address, a request to replace the Parents with respect to the rights and duties arising under the Contract. Should there be no reaction to such a request, PBKM shall deem Contract termination to be effective and shall request the Parents to take a decision regarding the disposal of the deposited Biological Material.

4. PBKM consents for the Child, upon reaching the age of eighteen (majority), to accede to the Contract and assume the rights of a party alongside the Parents. Should the Child accede to the Contract (in writing), the Parents and the Child shall be jointly and severally liable for the obligations resulting from the Contract.

5. PBKM consents for the Parents, upon the Child reaching the age of eighteen, to have the right to assign in writing the rights and obligations resulting from the Contract to the Child, provided that the Child is solvent and is able to pay the amounts resulting from the Contract. If the Parents assign the rights and obligations arising under this Contract to the Child and the Child turn out to be insolvent, such an assignment shall be considered ineffective.

6. The Child that is a major may, by unilateral declaration of will, certified by a notary public, transfer any and all rights to dispose of the Biological Material to the Parents (or other statutory representatives of the Child); this may include the right to dispose of the Biological Material for medical needs of other recipients (the Child's biological siblings, the Child's biological parents, the Child's biological grandparents, the Child's biological descendants) in case of transplantations, and of patients being the Child's relatives (the Child's biological siblings, the Child's biological parents, the Child's biological grandparents, the Child's biological descendants) in case of administration.

7. When the Child reaches the age of majority, the validity of the Contract shall not be interrupted.

8. A Child who reaches majority may dispose of the Biological Material for therapeutic purposes upon presenting all of the following items:

a) appropriate document confirming the need for the Biological Material from the entity which is to undertake the treatment with the Biological Material;

b) own declaration with signature certified by a notary public;

c) ID card/passport.

9. PBKM hereby notifies that exercising the rights of a Controller after the Child reaches majority may be impaired, should the Parents not provide the Child's information.

§ 15 Complaints procedure

1. Any complaints connected with the performance of this Contract shall be submitted in writing or by e-mail, not later than within 1 month from the moment when the Parents learned about the circumstances constituting grounds for submission of the complaint. PBKM S.A.'s physical address as of the effective date of these terms and conditions is Al. Jana Pawła II 29, 00-867 Warszawa, e-mail for complaints: biuro@pbkm.pl.

2. PBKM agrees to handle the complaints within up to 30 days as of the receipt of the complaint.

3. Having considered the complaint, PBKM shall send the Parents a reply in the form corresponding to the received complaint (letter with confirmation of receipt or e-mail) to the address provided in the letter or the sender's e-mail address from which the complaint was sent.

§ 16 Processing and Protection of Personal Data

1. PBKM is the controller of personal data provided for the purpose of performing the Contract regarding qualification, preparation and storage of Biological Material, including sensitive (medical) data provided in the medical questionnaire related to the course of childbirth and the results of peripheral blood and biological material testing (viral and bacterial).

2. The Parents shall submit to PBKM the following personal information of the Child immediately after it becomes available: name(s), surname and Personal Identification Number (PESEL), allowing to identify the donor and the future Controller.

3. Provision of the Mother's data is voluntary, however also necessary to conclude the Contract. Provision of the Father's data is voluntary, but necessary should the Father be to assume the rights of a party to the Contract. Provision of the Child's data is voluntary, however necessary for exercising the rights of a party by the Child upon reaching majority.

4. The Parents - by marking the relevant consents - agree to the processing of the Parent's and Child's personal data by PBKM (or a third party with respect of the Mother's peripheral blood testing) for the purposes related to the performance of the Contract.

5. Personal data shall be processed in order to perform the Contract and based on the consent regarding special categories of data.

6. Personal data may be shared with other recipients in order to perform the Contract, in order to perform the PBKM's legal obligation, based on consent or for the purposes arising from the legitimate interests of the controller or a third party. Moreover, the Data may be shared with personal data processors upon the order of PBKM and with their authorized employees, provided that such entities process data pursuant to an agreement with PBKM and only as instructed and subject to confidentiality obligations. In the case of the SwissSafety package, personal information shall also be made available to Famicord Suisse SA (c/o Studio Fiduciario Pagani SA, Corso Pestalozzi 3, 6900 Lugano, Switzerland), which is the entity responsible for storage of Biological Material in the territory of Switzerland. Transfer of

data outside of the European Economic Area shall be based on the decision of the European Commission deeming Switzerland to be a country with adequate level of personal data protection.

7. PBKM shall be required to store personal data in compliance with the applicable laws, including, but not limited to protect them against unauthorised disclosure, takeover by an unauthorised person, processing in violation of the law and change, loss, damage or destruction. Personal data shall be stored for a period no longer than what is required to perform the Contract, and afterwards - for the period required to perform PBKM's contractual obligations and as required under the provisions of law.

8. The Parent shall at all times have the right to request access to their personal data and the Child's data and the right to correct, restrict processing, remove, transfer personal data and to object against the processing. Should data processing rules be breached, the Parents may file a complaint with the President of the Personal Data Protection Office.

§ 17 Final provisions

1. The Contract enters into force on the day when the Parents complete and confirm all the data, which shall result in automatic creation of a Contract document in the Parent's account in the My PBKM Customer Panel.

2. Any and all statements submitted by the Parents, as mentioned in the Contract, shall be deemed effective only if sent by registered mail, signed by both Parents or other statutory representatives, to PBKM's physical address within the time limit indicated in the Contract.

3. Pursuant to the Act of 1 July 2005 on collection, storage and transplantation of cells, tissues and organs (Polish Journal of Laws of 2020, item 2134), as amended, PBKM represents that it has obtained from the Ministry of Health an appropriate permit for the previously conducted procedures and activities in terms of storage and testing cells and tissues. This permit was extended on 12 June 2019 for a maximum period of five years, as stipulated by the provisions of law. PBKM shall inform the customers about any cancellation of the permission by the Minister of Health and Welfare or where the permit is not extended.

4. Each Party to the Contract shall be required to notify the other Party of each change to its registered office or place of residence and correspondence address within fourteen days from the change. If such information is not provided, notices or statements of the Party sent to the last indicated address of the other Party shall be considered as duly served. PBKM also reserves the right to change the location of the laboratory and the bank. If the Parents fail to fulfil the obligation to notify PBKM of their address change, causing PBKM problems with the delivery of correspondence and problems to contact the Parents, PBKM has the right to determine that the Parents have abandoned the Biological Material and hand over the Biological Material preparation to PBKM or to destroy the Biological Material. Any and all amendments to the Contract agreed upon by the Parties to the Contract shall require written form, otherwise being null and void.

5. Any and all disputes related to the Contract may be settled amicably, out of court by permanent consumer arbitration courts. Arbitration courts operate at State Trade Inspection offices.

6. In matters not stipulated under this Contract, the provisions of Polish law shall apply, and any potential disputes that could not be resolved amicably, shall be subject to Polish jurisdiction.

7. Any and all Appendices to this Contract that have been drafted while concluding the Contract and were approved by Parents, constitute an integral part hereof.

CONSENTS

CONSENTS	
Acceptance of the Terms and Conditions and Privacy Policy I declare that I have read the Privacy Policy and the Terms and Conditions of the Service https://klient.pbkm.pl, I understand and accept the terms and conditions of service provided by Polski Bank of Stem Cells sp. z o. o. with its registered office in Warsaw through the Service https://klient.pbkm.pl.	
Confirmation of the authenticity of data and consent to disclose them to the child's father I certify that the Medical Questionnaire form I have completed via https://klient.pbkm.pl Medical Questionnaire form contains true information. The above data may be shared with the Father of the Child (if he is a party to the contract).	
Contract contents acceptance I declare that I have familiarized myself with the content of the Contract for qualification, preparation anD storage of Biological Material with Polski Bank Komórek Macierzystych sp. z o. o. in Warsaw. The content of the standard agreement is available here: https://www.pbkm.pl/oferta/dokumenty. I understand and accept the contents of the Agreement and any attachments. The content of my Agreement with variants of the service offering I have selected will be generated and will be available (upon completion of the order) for review in the Customer's account.	
Consent to data processing by PBKM I consent to the processing of the information provided in the medical questionnaire, related to the course of labor and the results of tests of peripheral blood and Biological Material (virological and bacteriological), which constitute a special category of personal data. I am aware that at any time I may withdraw my consent to process a special category of data, and withdrawal of consent will be equivalent to termination of the contract. Detailed information regarding PBKM's data processing is available in the Data Processing Policy data available on the PBKM website.	
Commitment to transfer and consent to the processing of the Child's data by the PBKM I consent to the processing of information obtained during the execution of the Agreement, which constitute medical data of the Child. I realize that at any time, but until the Child reaches 18 years of age by the Child, I may	

withdraw my consent to the processing of a special category of data, and the withdrawal of consent will be equivalent to termination of the Agreement. I undertake to transfer to PBKM sp. z o. o. with its registered office in Warsaw at Al Jana Pawła II Street II 29, 00-867 Warsaw, the personal data of my Child after delivery in the form of: name, surname, PESEL no. and possible medical information related to the test results and I consent to the processing by PBKM sp. z o. o. with its registered office in Warsaw at Al. Jana Pawła II 29, 00-867 Warsaw, these data for the purposes of the execution of the Contract for qualification, preparation and storage of Biological Material. Providing the data of the Child is voluntary, however it is necessary for execution of the Agreement for the benefit of the Child and realization of his/her rights as a Dispensary upon reaching the age of majority.	
Commitment to complete the documentation in writing PBKM I undertake to complete and submit signatures to the document - Written Declaration of the Client, together with the Father of the Child (if he is a party to the agreement) which will be generated and delivered to the registered office of PBKM sp. z o. o. (by registered mail) with statements regarding consents for the processing of sensitive personal data, voluntary consent for the acquisition of Mother's biological material and peripheral blood, and a statement of joint and several liability for obligations made by the Father of the child (for Parents who are not married married).	
Consent to the acquisition of Biological Material by PBKM I consent to the acquisition of Biological Material - in accordance with the contract for the qualification and preparation and storage of Biological Material concluded with Polski Bank of Stem Cells sp. z o. o. at the hospital/clinic indicated by me, and to collection of peripheral blood for necessary diagnostic tests.	
Consent to marketing telephone communications by PBKM I consent to the transmission of marketing content to the telephone number I have provided telephone number, including by means of automated calling systems, within the meaning of the Act of July 16, 2004. Telecommunications Law (i.e. Dz. U. of 2016, item 1489, as amended), by PBKM sp. z o. o., Al. Jana Pawła II 29, 00-867 Warsaw. The granting of consent is voluntary.	
Consent to use biological material for future scientific purposes I consent to the PBKM Biobank organizational unit's storage of Biological Material Biological Material and Data, including the processing by the PBKM Biobank of personal data contained in the Biological Material and Data. The Biological Material and Data may be used for scientific research, including projects, current as well as future in the field of biomedicine and biological sciences aimed at the search for and improvement of preventive, diagnostic and therapeutic methods/medical products or diagnostic or therapeutic measures, and for the transfer of pseudonymized Data and Biological Material to third-party entities that may be located in the European Economic Area or outside of it. The activities of these entities will comply with the requirements of Polish law, ethical standards in the field of scientific research and conditioned by the approval of the appropriate bioethics committees. I have familiarized myself with the information to whom my Data and/or Biological Material, and I have been informed that the current list of entities with which PBKM cooperates in the field of Biobanking and on what terms they are subject to qualification, is available on the PBKM website at: https://www.pbkm.pl/o-nas/biobank/lista-aktualnych-podmiotow and updated on a regular basis.	
Consent to the free transfer and storage in the PBKM Biobank of biological and genetic material biological and genetic material I give my informed consent for the voluntary and free transfer to the PBKM Biobank and for the further transfer for scientific purposes, stored by PBKM: 1. **Biological material**, not intended for use in accordance with the contract with PBKM, in including, but not limited to, the following: ∘ material constituting medical waste of the cord blood preparation process, i.e.. residues of plasma, erythrocytes and/or; ∘ material constituting medical waste of quality control testing, i.e., cord blood residues or cord blood preparation and/or; ∘ material constituting medical waste of quality control tests, i.e., residual peripheral blood or residual blood plasma after testing for infectious agents and/or; ∘ the entire preparation of cord blood/ umbilical cord and/or mesenchymal cells/ placenta, in the event that the Dispensaries opt out of storing the biological material in question biological material and/or; ∘ obtained cord blood/ umbilical cord and/or mesenchymal cells isolated from the umbilical cord/ placenta, in the event that the given biological material is found to be disqualified biological material that did not meet the standards described in the contract with PBKM and/or; ∘ biological material not intended for use in accordance with the contract with PBKM (residual material). residual material). (hereinafter collectively: "**Biological material**"). no form. 2. **genomic** and maternal and child health data, not allowing the identification of the donor, which are: ∘ medical data, i.e. health data obtained during donor qualification and childbirth, information collected through applications provided by PBKM and collected during contact with a PBKM employee and during qualification and processing of the Biological Material by PBKM (e.g., results of tests from the Mother's peripheral blood performed by PBKM or outsourced to third parties); ∘ medical data obtained as a result of Biobank processing of Biological Material; ∘ genomic data (acquired genetic information contained in the nucleotide sequence of the nucleic acid (DNA)) that do not allow identification of the donor; (hereinafter collectively: "Data") By giving my consent, I confirm that I have familiarized myself with the information on the activities of Biobank PBKM and the rules of using the collected Biological Material and Data for further transfer for scientific purposes available at: https://www.pbkm.pl/o-nas/biobank/informacje-o-dzialalnosci-biobanku. If you have any questions or concerns, please clarify them with an employee of the PBKM before completing the form.	
Consent to send invoices in electronic form I agree and accept as a form, the issuance and sending of invoices by PBKM sp. z o. o. with its based in Warsaw, to send invoices only in electronic form to the e-mail address provided.	

Consent for PBKM to send the contract in paper form By checking your consent, you confirm that you wish to receive the contract in paper form at the indicated mailing address and you agree to an additional fee of PLN 40.00 for preparation and mailing of the document.	
Consent to the sending of commercial information by PBKM I consent to sending commercial information by means of electronic communication electronic communication means within the meaning of the Act of 18 July 2002 on the provision of services by electronic means electronically (i.e. Journal of Laws of 2016, item 1030, as amended) to the provided e-mail address and in the form of SMS by PBKM sp. z o. o. with its registered office in Warsaw at Al. Jana Pawła II 29, 00-867 Warsaw. **The granting of consent is voluntary.**	
Consent to data processing by PBKM I consent to the processing of personal data by PBKM. I have been informed about the processing of personal data by PBKM. The consent is voluntary and may be withdrawn at any time, without affecting the paid storage of Biological Material Biological Material under contract with PBKM.	
Consent to be contacted again to participate in a clinical trial of a third party external I consent to PBKM processing my contact information (phone number and email address), in order to provide me with information about the possibility of my participation in a clinical trial conducted by an external entity or for the purpose of obtaining consent for the research conducted on my Biological Material and Data and other data whose scope goes beyond those mentioned in this consent.	

PRICE TABLE

FEES BEFORE CHILDBIRTH

within 2 days from the date of entry into force of the contract

Chosen option

Initial fee amount

FEES AFTER CHILDBIRTH

within 14 days from the invoice date

Chosen option

Basic fee amount

Selected additional services

120+ Package

Extended Umbilical Cord Cells Isolation

Transplant Assistance Plus Package

Total discounts granted

Your savings

Selected storage fee form

Payment per 1 year of storage

Storage fees:

Full storage fees table for the contract*

	prepayment for 5 years	**prepayment for 10 years**	**prepayment for 18 years**	**annual fee**
1 material				
2 materials				
3 materials				

* If monthly payments/installments are selected, all types of fees (annual fee and prepayments) in the table include the fee increase in accordance with the provisions of the contract in §§ 9, pkt. 9.1

Installments for Basic Fee:

Chosen number of installments

Instalment amount

for PBKM, date and signature

date and Mother’s signature

Appendix to the Contract – medical information on biological materials

Table of contents:

Abbreviations:

- PBKM – Polski Bank Komórek Macierzystych
- MSC – mesenchymal/stem cells
- MTE – medical treatment experiment
- FDA – Food and Drug Administration
- ATMP – advanced therapy medicinal products
- EMA – European Medicines Agency
- EBMT – European Society for Blood and Marrow Transplantation
- Biological material – material acquired during childbirth, i.e. umbilical cord blood, umbilical cord, placenta

1. Umbilical cord blood, stem cells – terms.

Umbilical cord blood is currently (also in Poland) a recognized source of hematopoietic stem cells. Stem cells are characterized by two basic features: a potentially unlimited number of divisions leading to their continuous self-renewal and the ability to differentiate into cells of different cell lines – the number of potential cell lines arising from a stem cell depends on its type. Hematopoietic stem cells ensure the continuous production of blood cells – leukocytes, erythrocytes and platelets. In modern medicine, haemopoietic stem cells are used for transplantation in haemato-oncological diseases (this is commonly referred to as a “bone marrow transplantation”). In Poland, haemopoietic stem cells acquired from bone marrow have been used for transplantation in children since 1984. Since 1994, haemopoietic stem cells derived from peripheral (venous) blood following prior pharmacological mobilization are used for treatment, and since 1998 – also haemopoietic stem cells contained in umbilical cord blood. Due to the type of relationship between the recipient and the donor, we can distinguish autologous transplantation (the recipient and the donor are the same person) and allogeneic transplantation (the recipient and the donor are two different persons, relatives or unrelated individuals).

2. Umbilical cord and placenta, umbilical cord- or placenta-derived cells – terms

Umbilical cord and placenta are another source of cells called mesenchymal stromal cells (MSCs). Umbilical cord tissue contains relatively more MSCs than umbilical cord blood or bone marrow. MSCs produced from tissue collected during childbirth are believed to be most valuable. This is due to the fact that this type of collection is completely non-invasive, and these cells probably have a greater regenerative potential. These cells have been used for many years in cell therapies, in medical therapeutic experiments (MTE), i.e. in conditions in which tissues or cells have been damaged and with the use of MSCs, it is possible to try to regenerate or reconstruct them. MSCs of different origins form the basis for the manufacture of a range of advanced therapy medicinal products (ATMPs) approved for human use by the FDA, EMA and other agencies issuing global drug marketing authorizations.

3. Indications for biological material acquisition

1. Umbilical cord blood-derived hematopoietic stem cells:

The most common practical application of umbilical cord blood-derived hematopoietic stem cells is currently their transplantation during the treatment of neoplastic or non-malignant (congenital or acquired) diseases in order to regenerate the pool of bone marrow hematopoietic stem cells producing red blood cells (erythrocytes), white blood cells (leukocytes) and platelets (thrombocytes).

Indications for umbilical cord blood acquisition:

a) standard medical indications – clinical:

- older siblings of the child (having the same biological parents) diagnosed with a disease that requires standard stem cell transplantation treatment
- willing to secure the biological material for the purpose of potential transplantation if the family has a history of a disease that requires haemopoietic stem cells transplantation treatment (positive family history).

b) medical indications – other:

- securing the umbilical cord blood for a child when a disease is suspected still before birth or abnormalities occur during pregnancy, for its future autologous use (MTE procedure),
- written decision concerning the transfer of Biological Material to a proper institution (a so-called public bank) in order to enter the Umbilical Cord Blood aliquot into the world register of honorary unrelated donors of haemopoietic stem cells.

c) scientific indications:

- written decision concerning the transfer of an umbilical cord blood aliquot to a scientific entity conducting research on stem cells

Detailed indications regarding diseases are available in the guidelines of the European Society for Blood and Marrow Transplantation (EBMT).

2. Mesenchymal cells:
2.1. Umbilical cord-derived:

Currently, the most common practical application of umbilical cord-derived MSCs are conditions in which normal tissue undergoes degeneration and stem cell administration is supposed to restore its proper functioning. Certain neurological, ophthalmologic, orthopedic conditions can be included in the medicine or therapy application area.

Indications for umbilical cord acquisition:

a) medical indications:

- advanced therapy medicinal product (ATMP) manufacturing

b) medical indications – experimental:

- necessity to secure biological material for potential experimental use in cases of previous family history (tests for tissue compatibility between the recipient and the donor of mesenchymal cells are not necessary) of a disease that allows for experimental administration of mesenchymal stem cells (positive family history)
- immediate family member diagnosed with a disease in which treatment may include MTE using mesenchymal cells; securing umbilical cord for the child.

c) medical indications – experimental – other:

- written decision to transfer biological material to allow using mesenchymal cells in MTE (e.g. cell therapy).

d) scientific indications:

- written decision to transfer umbilical cord-derived cells to a scientific entity conducting research on mesenchymal cells, including stem cells.

2.2. Placenta-derived:

Indications for placenta acquisition:

a) medical indications – experimental:

- necessity to secure biological material for potential experimental use in cases of previous family history (tests for tissue compatibility between the recipient and the donor of mesenchymal cells are not necessary) of a disease that allows for experimental administration of mesenchymal stem cells (positive family history)
- immediate family member diagnosed with a disease, in the case of which treatment may include MTE based on mesenchymal cells use.

b) medical indications – experimental – other:

- written decision to transfer biological material for the use of mesenchymal cells in MTE (e.g. cell therapy).

c) scientific indications:

- written decision to transfer placenta-derived cells to a scientific entity conducting research on mesenchymal cells, including stem cells.

4. Biological material acquisition

Biological material acquisition is carried out during childbirth.

Biological material acquisition is carried out by trained medical personnel. The scope of training includes current medical knowledge and clinical practice; among other things, it describes one of the basic medical ethical principles: “primum non nocere” – first, do no harm.

The above rule, along with the medical knowledge applied, means that decisions concerning acquisition of the biological material are always made individually, taking into consideration the course of delivery, health of the woman giving birth and health of her child.

The acquisition of biological material, i.e. umbilical cord blood, as well as the umbilical cord or placenta, is carried out during childbirth using a PBKM set dedicated for the specific biological material. The acquired biological material is transported from the place of acquisition to the PBKM laboratory. The biological material is processed and frozen by qualified personnel. Then it is stored at the PBKM laboratory under the appropriate, properly controlled conditions which enable long-term banking.

5. Contraindications for biological material acquisition

For the Mother			
Umbilical cord blood		**Umbilical cord and placenta**	
Absolute	**Relative**	**Absolute**	**Relative**
• a disease of the mother that requires treatment during pregnancy with the use of a method harmful for the fetus and its umbilical cord blood • active viral infections in accordance with the current rules applied at PBKM • untreated syphilis bacterial infection or if not enough time has elapsed since the end of treatment • Chagas disease	• active or history of neoplastic disease (depending on time since curative treatment) • history of viral diseases in accordance with the current rules applied at PBKM	• previous infection with hepatitis B or hepatitis C virus • ongoing Toxoplasma gondii infection (e.g. IgM equivocal or positive) • HIV infection • syphilis bacteria infection • Chagas disease	• previous Toxoplasma gondii infection (IgM negative) • clinical symptoms (e.g. active genital herpes or widespread genital warts) or positive results of microbial tests confirming active infection in the mother during pregnancy • generalized infection confirmed clinically or by laboratory tests on the day of childbirth • other diseases in the mother that may prevent biological material acquisition – the possibility of biological material acquisition should be reviewed by the mother with a PBKM representative when concluding the contract

For the Child		
Umbilical cord blood		**Umbilical cord and placenta**
Absolute	**Relative**	**Absolute**
• congenital generalized neoplastic disease • long-term exposure during fetal life to pharmacological agents and other substances toxic to the haemopoietic system	• active congenital non-malignant disease limiting the ability of umbilical cord blood to reconstitute the haemopoietic system • history of viral diseases in accordance with the	• visible defects or visible symptoms of umbilical cord/placenta infection • HIV infection • syphilis bacteria infection

• active viral infections in accordance with the current rules applied at PBKM • syphilis bacteria infection • visible defects suggesting genetic disease	current rules applied at PBKM	

6. Contraindications for biological material storage

According to the Contract concluded with PBKM, apart from contraindications for biological material acquisition identified before childbirth, there are also contraindications for umbilical cord blood, umbilical cord and/or placenta storage that are identified after childbirth.

a) for the mother

– results of tests carried out after childbirth (screening by Nucleic Acid Amplification Testing [NAT]) confirming an active infection with hepatitis B, C or E virus in the mother on the day of childbirth.

The above tests should be performed by the mother after childbirth if positive test results are obtained by PBKM, suggesting an active infection with hepatitis B or hepatitis C virus on the day of childbirth.

- in the event of equivocal/positive results of tests for IgM antibodies against Toxoplasma gondii or other equivocal/positive test results suggesting an infection of the mesenchymal cell preparation with Toxoplasma gondii, disqualification of the biological material is indicated according to the current state of knowledge.

If use is required in another recipient, the site administering mesenchymal cells decides on administering the preparation.

b) for the child

– results of tests carried out after childbirth (by polymerase chain reaction [PCR]), confirming an active infection with hepatitis B or hepatitis C virus in the child on the day of childbirth.

The above tests should be performed by the parents using the child's venous blood if the results of tests performed by the mother after childbirth (by NAT) are positive, suggesting an active infection with hepatitis B or hepatitis C virus on the day of childbirth.

7. Side effects of biological material acquisition

Correctly performed acquisition does not result in any clinical side effects.

8. Use of the biological material

1. Umbilical cord blood

There are approximately 80 diseases that constitute indications for autologous or allogeneic hematopoietic stem cell transplantation.

The list of selected diseases for which autologous (own) hematopoietic stem cells have been used for treatment includes, among others:

– proliferative diseases: lymphomas, acute myeloid leukemias, plasma cell myeloma, Hodgkin disease,
– autoimmune diseases: bone marrow aplasia, multiple sclerosis, scleroderma,
– solid tumors: neuroblastoma, Ewing's sarcoma, central nervous system tumors, soft tissue sarcomas, nephroblastoma and other infantile tumors,

The list of selected diseases for which allogeneic (e.g. from siblings) hematopoietic stem cells have been used for treatment includes, among others:

– proliferative diseases: acute lymphoblastic leukemias, acute myeloid leukemias, myelodysplastic syndromes, chronic myeloid leukemia, lymphomas, plasma cell myeloma, chronic lymphocytic leukemia
– non-proliferative diseases: acute acquired aplastic anemia, congenital immunodeficiencies, Fanconi anemia, Diamond-Blackfan anemia, congenital metabolism disorders.

In Poland, patients with other diseases (e.g. infantile cerebral palsy or autism) have been treated with their own umbilical cord blood since 2017. The results of clinical research published worldwide indicate that such administration is beneficial for patients. They are used in those types of diseases as part of medical experiments under the supervision of ethics committees. The US FDA approved 8 advanced therapy medicinal products (ATMPs) manufactured from Umbilical Cord Blood for use in humans.

It should be borne in mind that umbilical cord blood is not a universal remedy for all diseases. It provides an additional chance for the patient, but does not ensure 100% certainty of recovery. There are also limitations for the use of stored umbilical cord blood. It may happen that a disease requires the transplantation of allogeneic biological material (e.g. from siblings), and we only have the patient's own biological material; or the disease requires autologous transplantation, and we only have the siblings' umbilical cord blood. Thus PBKM advises to perform the procedure also in other children if it was decided to acquire material from one child.

PBKM advises to review not only the information available on the website www.pbkm.pl, but also publications from other reliable sources, before deciding to acquire and store stem cells. More information about the use of our blood units is available on the website https://www.pbkm.pl/baza-wiedzy/zestawienie-leczonych-pacjentow.

2. Umbilical cord and umbilical cord-derived cells

The umbilical cord is the tube that connects the mother and the child during pregnancy. It has three blood vessels: one vein that carries nutrients and oxygen from the placenta to the child, and two arteries that carry metabolic waste products from the child back to the placenta [1]. A substance called Wharton's jelly cushions and protects these blood vessels. The umbilical cord begins to form around the 4th week of pregnancy and usually reaches a length of approximately 22 cm.

The umbilical cord has been proven to be an easily accessible, reliable and useful source of non-immunogenic mesenchymal stromal cells (MSCs) for clinical applications [1, 6, 10].

Human umbilical cord-derived MSCs are self-renewing and multipotent stem cells, which means that they have the ability to differentiate into osteoblasts, chondrocytes, myoblasts, adipocytes, fibroblasts [2, 8]. In addition to their potential to differentiate into different lines, such as bone, cartilage, muscle, adipose tissue and ligaments, MSCs can regulate immune and inflammatory processes through paracrine signaling, enabling the use of umbilical cord-derived MSCs in the treatment of autoimmune diseases and immune-mediated complications after transplantation [2, 6, 7].

The umbilical cord is one of the best sources of MSCs as its acquisition is non-invasive and easy; moreover, it has been proven that the differentiation, migration or protective properties of umbilical cord-derived MSCs are better compared to other types of stem cells [2, 9].

The emerging evidence confirms the clear therapeutic potential of MSCs in many different diseases, from hematology to immunology, wound/burn healing, tissue regeneration, oncology [6, 8] and in the treatment of diabetic foot, fracture non-union [10, 11].

Currently, there are approximately 300 registered clinical trials on the use of umbilical cord-derived MSCs in the treatment of diseases, including but not limited to osteoarthritis, autoimmune and degenerative diseases [9].

The use of umbilical cord-derived MSCs has been shown to slow down disease progression and provide clinical improvement in motor and cognitive behavior in patients with multiple sclerosis; it improves clinical parameters in spinal cord injuries [2].

The use of MSCs is becoming increasingly common in the treatment of autism spectrum disorders [3, 4, 5].

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More information about the use of Blood or Umbilical Cord units from PBKM is available on the website:

https://www.pbkm.pl/baza-wiedzy/zestawienie-leczonych-pacjentow

3. Placenta-derived cells

Placental tissue is rich in various types of cells, such as mesenchymal stem cells, trophoblasts and endothelial cells, which have been proposed as potential sources of cells for use in medicine.

Placenta-derived mesenchymal stem cells (pMSCs) are a type of stem cells found in the placenta that have the ability to differentiate into different cell types, such as bone, cartilage, adipose tissue and muscle cells [1], as well as neurons [2,3].

It has been demonstrated that pMSCs may be useful for cell therapy in regenerative medicine, tissue engineering and wound healing. It has also been shown that pMSCs have immunomodulatory properties and they have been proposed as a possible treatment for autoimmune diseases. However, much remains to be discovered about the potential uses and benefits of pMSCs, and further research is needed to fully understand the similarities and differences between fetal and maternal pMSCs. It should be noted that pMSCs derived from the fetal and maternal placenta may have some key similarities and differences, which may have potential implications for their application in regenerative medicine. For example, fetal pMSCs may have a higher proliferation rate and a greater differentiation potential compared to maternal pMSCs. In addition, the different microenvironments of the fetal and maternal placenta can lead to the development of different traits in pMSCs [1].

MSCs are isolated from the chorionic villi in the placenta by a manual method optimized based on research [4].

Placenta-derived cells have a very low immunogenicity, so they can be used without donor–recipient immune matching. They are able to differentiate in vitro. They also have a cytoprotective effect by secreting biologically active compounds which protect other cells from death (apoptosis), reduce oxidative stress and stimulate the development of new blood vessels [5].

The results of the first clinical trials with the use of pMSCs have demonstrated their efficacy in the following applications:

- graft-versus-host disease: in patients with steroid-resistant disease [6]
- osteoarthritis [7]
- diabetes and critical limb ischemia [8]
- COVID [9]

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9. Available biological material storage options and associated consequences

Umbilical cord blood qualified for freezing is stored in special containers – so-called cassettes. PBKM offers storage services for the umbilical cord blood acquired – in a single Plus Cassette, in which blood in the bag is divided into two portions (at a 4:1 ratio) and stored in a single cassette. Acquired blood is tested, prepared and then transferred into a special freezing bag. This bag is then placed in a metal cassette and undergoes a controlled freezing process.

If the acquired volume of umbilical cord blood harvested is equal to or higher than 120 mL, PBKM shall offer storing the umbilical cord blood in two separate Plus Cassettes (4:1 ratio in each Plus Cassette). The condition to perform the division into two Plus Cassettes is choosing the 120+ Package before obtaining the biological material.

Both versions of dividing the acquired umbilical cord blood create a certain chance for independent use of each blood portion in the future. However, the abovementioned use possibilities are currently limited by the stem cells count in the stored umbilical cord blood, where in the case of standard indications this number determines the recipient's maximum body weight. Therefore, even if umbilical cord blood is stored in two independent portions, it may be necessary to use all the available umbilical cord blood at once, since only then the stem cells count will be sufficient.

Umbilical cord blood-derived hematopoietic stem cell expansion techniques are currently registered in the U.S. and are currently not routinely available to patients outside of the U.S. It is not possible to unequivocally determine how long it will take to implement a technology that could be used in the clinical setting in Europe. The final decision regarding the use of umbilical cord blood is made by the doctor in charge of the treatment. Currently in Poland, in the case of standard indications for transplantation, the whole available umbilical cord blood is administered as a rule; however, for experimental indications (e.g. cerebral palsy), administration of the total available amount of umbilical cord blood divided into several consecutive injections, e.g. every 2–3 months.

Depending on the selected umbilical cord storage option, following proper umbilical cord processing, it is stored in fragments or in the form of initially isolated MSCs.

After proper processing, the placenta is stored as fragments.

Unlike the standard applications of Haemopoietic Stem Cells, according to Polish law the use of MSCs is an experimental procedure. Until February 2024, PBKM has provided MSCs aliquots for 1897 patients who received them as part of the MTE procedure conducted at various clinical sites across Poland.