

GENERAL TERMS AND CONDITIONS of the MediXbank Biobank

Article I

Introductory Provisions

1. MediXbank is an archive of biomedical information and biological material samples maintained for the purposes of future biomedical research and scientific research projects in the Slovak Republic or abroad (hereinafter referred to as the “**Biobank**”). The Biobank is operated at Novozámocká 1/67, 949 05 Nitra, Slovakia.
2. The operator of the Biobank is the non-profit organisation **MediXbank, n.o.**, with its registered office at Novozámocká 1/67, 949 05 Nitra, Slovakia, Company ID No.: 37 986 805, registered with the District Office Nitra under Registration No.: VVS/NO-6/2021 (hereinafter referred to as “**MediXbank**”). MediXbank is a healthcare provider on the basis of a final and binding decision of the Ministry of Health of the Slovak Republic.
3. The subject matter of the Biobank’s activities is the collection, processing, storage and distribution of biological material samples and associated data (hereinafter collectively referred to as the “**Samples**”) for use in scientific research activities, as well as bioinformatic and biostatistical processing of genomic data obtained from the Samples.
4. The purpose of the Biobank’s activities is to support the implementation of biomedical research and scientific research projects in the fields of medicine, pharmacy, public health, biophysics, biochemistry and biomedicine. The Biobank ensures the availability of Samples and information derived therefrom for specific scientific research needs and purposes beneficial to the public, with a view to utilising their scientific relevance for the benefit of society in the field of science and research.
5. The Biobank collects and archives Samples with the consent of their originators in accordance with the applicable laws of the Slovak Republic and exclusively in pseudonymised form so as to ensure the protection of the personal data of Sample originators under all circumstances. The scope of use of a Sample by the Biobank is likewise limited by the consent granted by its originator.
6. For the avoidance of any doubt and for the purpose of regulating the mutual rights and obligations between the various entities involved in the activities of the Biobank, MediXbank hereby issues, in accordance with Section 273(1) of Slovak Act No. 513/1991 Coll., the Commercial Code, as amended (hereinafter referred to as the “**Commercial Code**”), these *General Terms and Conditions of the MediXbank Biobank* (hereinafter referred to as the “**GTC**”). These GTC shall be binding upon all entities cooperating with MediXbank in matters relating to the activities of the Biobank.

Article II

Conditions for Acceptance and Archiving of Samples

1. The Biobank accepts and archives Samples in accordance with applicable legal regulations and on the basis of the informed consent of the Sample originators, namely:
 - a) directly from voluntary originators who provide their Sample at a MediXbank healthcare facility; or
 - b) indirectly from other partner or contracted healthcare providers who guarantee in advance that they are authorised to provide the Samples to the Biobank on behalf of their originators.(hereinafter collectively referred to as the “**Donors**” or individually as a “**Donor**”)

2. The Biobank does not provide Donors with any financial compensation or any other form of remuneration for providing a Sample. Upon prior agreement with the Biobank, a Donor may be reimbursed for direct expenses incurred in connection with providing a Sample to the Biobank.
3. The Donor warrants to the Biobank that the Samples:
 - a) have not been stolen, misappropriated, or obtained unlawfully or in any other manner contrary to good morals;
 - b) have not been obtained contrary to the will of the originators or without their knowledge and informed consent;
 - c) have been obtained in accordance with the laws applicable in the country where the collection was performed and may lawfully be provided and made available to the Biobank under the applicable laws of that country; and
 - d) have been exported in compliance with the customs regulations of the country where the collection was performed and imported in compliance with the customs regulations of the Slovak Republic and the European Union.
4. When providing Samples, the Donor shall also provide the Biobank with all required documentation relating to the Samples, the Sample originators and the informed consents governing their use. The Donor shall truthfully and completely complete all forms and statistical reports provided by the Biobank and shall provide all relevant clinical information relating to the Samples.
5. The Donor further warrants that, prior to providing the Samples, it shall inform the Biobank of all relevant information concerning or affecting the Samples and their handling, including, without limitation, viral load, infectiousness due to communicable disease, or any suspected, potential or confirmed hazard.
6. The Biobank undertakes to inform the Donor if, during work with a Sample, it discovers medically relevant information relating to the Sample of which it had not previously been informed by the Donor, provided that such information may have an impact on any future healthcare provided to the originator of the Sample.
7. Upon transfer of a Sample, the Donor relinquishes ownership of the Sample and any future financial or other claims relating to the Sample, including copyright and related rights in works created in connection with work performed on the Samples. The right of the Sample originator to erasure of his or her data under applicable legislation shall not be affected by this provision.
8. The Biobank declares that it archives Samples within the scope of the informed consent granted by the Sample originator for an indefinite period during which the Samples remain usable for scientific research purposes.
9. The Biobank declares that it shall use the Samples exclusively for the scientific research purposes specified in Article I, Section 4 of these GTC and that under no circumstances shall it knowingly misuse the Samples for the purpose of obtaining financial or other benefit for itself or for any cooperating entity. The Biobank shall use the Samples exclusively within the scope of the consent granted for their use and in accordance with applicable ethical principles in the field of science and research.

Article III

Privacy and Personal Data Protection

1. Should MediXbank come into contact with personal data of Sample originators, it undertakes to process such data for scientific research purposes in accordance with the currently applicable and effective legislation governing personal data protection, in particular Regulation (EU) 2016/679 of the European Parliament and

of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, repealing Directive 95/46/EC, and the relevant provisions of Slovak Act No. 18/2018 Coll. on Personal Data Protection and on Amendments to Certain Acts.

2. MediXbank declares that, for the purpose of ensuring the maximum protection of the privacy of Sample originators, it has implemented appropriate safeguards for the protection of rights and freedoms together with technical and organisational measures aimed at minimising the processing of personal data. In the case of indirectly obtained Samples pursuant to Article II, Section 1(b) of these GTC, MediXbank possesses only pseudonymised Samples, and therefore the Biobank itself does not possess information concerning the identity of the Sample originator, but only the identification number assigned to the Sample together with the range of associated information relating to the Sample provided by the Donor. Only the Donor possesses the key enabling the assignment of the identification number to the identity of the Sample originator. If the originator objects to the further use of the Sample, the Sample may be identified and destroyed only after the Donor has been contacted and has designated the relevant Sample.
3. The Biobank undertakes to refrain from any activity aimed at obtaining additional information leading to the identification of the Sample originator.
4. Samples are stored within the Biobank with the consent of their originators and within the scope of such consent. Samples are stored properly and conscientiously, taking into account their biological nature and with due regard to international standards for the storage and preservation of biological materials.
5. The Sample originator may, at any time, voluntarily and unilaterally decide to terminate participation in further biomedical research without providing any reason, or withdraw consent to the use of the Sample. In such case, the Sample together with the associated data shall be removed from the Biobank and destroyed.
6. Further details concerning the processing of personal data by MediXbank are available on the MediXbank website. The Data Protection Officer of MediXbank may be contacted at: dpo@medixbank.com.

Article IV **Intellectual Property Rights**

1. The Donor acknowledges that if research conducted using the Samples results in the discovery of any new method, patent, invention or improvement, the creation of a work, know-how, or any other subject matter of intellectual property (hereinafter collectively referred to as the “**Research Results**”), the economic rights to the Research Results shall arise exclusively in favour of the Biobank in accordance with Slovak Act No. 185/2015 Coll., the Copyright Act, as amended (hereinafter referred to as the “**Copyright Act**”). This shall not affect the Donor’s right to be acknowledged as a cooperating entity in the research during any presentation of the Research Results.
2. The Donor undertakes that it shall not in the future assert against the Biobank any potential financial claims or proprietary rights relating to the Samples provided and the Research Results.
3. Any further rights and obligations relating to the Research Results, including, without limitation, notification of their creation, enforcement of rights, obligations of confidentiality and similar matters, shall be governed by the provisions of the Copyright Act, the Commercial Code and the relevant provisions of other applicable legal regulations. The Biobank shall be identified as the author and/or originator, as applicable.

Article V

Final Provisions

1. These GTC shall become effective and binding as of the date of their publication on the MediXbank websites at www.medixbank.com and www.biobank-medixbank.com, unless an earlier effective date is specified in the GTC.
2. The application of individual provisions of these GTC may be excluded or modified by a written agreement between the Biobank and the Donor.
3. Unless otherwise provided for in these GTC, any document shall be deemed duly delivered if delivered to the addressee personally, by registered mail with return receipt requested, or by courier to the address notified by the addressee no later than five (5) Business Days prior to the date of dispatch of the document. In the event of unsuccessful delivery of a document sent by registered mail, the seventh (7th) day following the deposit of the shipment at the post office shall be deemed the date of proper delivery. A document shall also be deemed duly delivered if the addressee refuses to accept delivery thereof, on the date of such refusal.
4. The legal relationships between the Biobank and the Donor relating to the provision of Samples shall be governed by these GTC. Only where a particular matter is not regulated by these GTC shall such relationships be governed by the relevant provisions of the Commercial Code and other legal regulations valid and effective in the Slovak Republic. Where the Donor is an entity having its registered office outside the territory of the Slovak Republic, this provision shall constitute a choice of governing law between the parties, namely the law of the Slovak Republic, excluding Slovak Act No. 97/1963 Coll. on Private International Law and Procedure, as amended.
5. Should any provision of these GTC be invalid at the time the legal relationship between the Donor and the Biobank is established, or should any provision subsequently become invalid, the validity of the remaining provisions shall remain unaffected. The invalid provisions shall be replaced by the relevant provisions of the Commercial Code and other legal regulations valid and effective in the Slovak Republic whose content and purpose most closely correspond to the content and purpose of the invalid provisions of the GTC.
6. Any disputes arising between the Donor and the Biobank in connection with the performance of obligations under these GTC, as well as any disputes arising from the legal relationship between the Donor and the Biobank, shall be resolved without undue delay through negotiations and mutual agreement. If the parties fail to reach an agreement, the competent authority for hearing and deciding the dispute shall be an independent court of general jurisdiction of the Slovak Republic, which shall decide the matter in accordance with the laws of the Slovak Republic. Where the Donor is an entity having its registered office outside the territory of the Slovak Republic, this provision shall constitute an agreement conferring jurisdiction upon Slovak courts in accordance with the applicable laws of the Slovak Republic and the European Union. The parties hereby designate the materially competent court of the Slovak Republic as the court having local jurisdiction over any dispute.
7. The division of these GTC into Articles and the headings of individual Articles serve solely to facilitate navigation within the text of the GTC and shall not be used for the interpretation of the GTC or for assessing the severability of any of their provisions..
8. The Biobank shall be entitled to amend these GTC, as well as any other documents referred to herein, unilaterally and without the Donor's consent. The Biobank shall notify the Donor of any amendments to the documents referred to in the preceding sentence by publishing their complete wording on its website within a reasonable period prior to their effectiveness. The Donor shall be responsible for verifying the current

wording of the documents referred to in the first sentence. Through its website, the Biobank shall also provide information regarding any changes to its identification details.

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The non-profit organisation is registered in the Register of Non-Profit Organisations maintained by the District Office Nitra under Registration No. VVS/NO-6/2021



Registered office:

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