Ukrainian Association of Biobank Austria – Verein zur Vernetzung der ukrainischen Biobanken mit der europäischen Forschergemeinschaft
ZVR-Zahl 1062912887

Effective Date: July 30, 2024

HUMAN BIOSPECIMEN (HBS) VENDOR AGREEMENT AND TERMS AND CONDITIONS

Between HERHEL CLINIC (POLAND/ WARSAW/Krohmalna, 58, 00864:

22.07.2024 / (0074-09)

Contact:

And: **Ukrainian Association of Biobank Austria - Verein zur Vernetzung der ukrainischen**

Biobanken mit der europäischen Forschergemeinschaft ("Vendor")

Neue Stiftingtalstrasse 2
Graz,
8010
Austria
Telephone: +43-676-412-4733

Contact:
Svetlana Gramatiuk, Ph.D.,
MSc President
Email: gramatyuk@ukrainebiobank.com

RECITALS:

A. Herlel Clinic, Inc. (Margarita Kononenko herein) provides translational research services to

B. Ukrainian Association of Biobank Austria - Verein zur Vernetzung der ukrainischen Biobanken mit der europäischen Forschergemeinschaft ("Vendor" herein) is in the business of human health management, including but not limited to healthcare, laboratory analysis, preclinical trials, human stem cells (stem cells organoids) procurement, etc.

C. The Parties desire to develop a customer – vendor business relationship enhancing their respective businesses.

NOW, THEREFORE, in consideration of the covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties, intending to be legally bound, agree as follows:

1. **Orders:**

1.1. Herhel Clinic will send Vendor a written inquiry from time to time to procure Human Biospecimen (HBS) and Clinical Information from Vendor (as defined in the Order) in accordance with this Agreement and the terms and conditions herein (the "Terms and Conditions") and the applicable pricing set forth in the Order.

"Biospecimen" shall refer to any human stem cells, cells organoide or cells line transferred to Herhel Clinic "Clinical Information" shall refer to information of type cells or organoide, infection controle tests about the defined in more detail at Exhibit A to this Agreement, which is hereby incorporated by reference.

1.2. Vendor will notify Herhel Clinic within five (5) business days if procurement of Biospecimen is feasible. No proposal by Vendor shall be accepted or deemed accepted by 3 unless and until 5 accepts the proposal in a written Purchase Order, which is not obligated to accept.

1.3. Acceptance of an Order by the parties will be evidenced by execution of the Order by an authorized representative of each party. Any Order by Herhel Clinic will be subject to all Terms and Conditions set forth herein, unless explicitly stated otherwise in the Order.

1.4. Herhel Clinic reserves the right to cancel, in writing, any Order if by sole determination the procurement of the Biospecimen becomes impractical or is not carried out within the specified timelines.

1.5. In the event of an order cancellation, shall be liable for the Biospecimen delivered up to the time of cancellation and for the Biospecimen already collected as part of the order.

2. **Payment; Taxes.**
The Parties agree that all fees paid by Herhel Clinic to Vendor are solely to cover cost of data and specimen retrieval, collection, obtaining and preparing Materials by Vendor and not for purchase of Materials. While the Materials will be supplied free of charge, agrees to reimburse Vendor for its costs relating to acquisition, processing, project management, shipping and handling fees and any applicable sales taxes for the Materials. Payments to Vendor are done in Euro. Invoicing shall be made upon shipment of the Biospecimen to Herhel clinic and acceptance of these Biospecimen in accordance with the Order specifications as evidenced by the Order completion form. Herhel clinic agrees to pay such charges within 20 days after receipt of such invoice. Vendor is responsible for all applicable sales and use taxes in its residence country.

3. **Shipping and Risk of Loss.**
Vendor will deliver the Materials to Herhel Clinic in accordance with the delivery schedule described in the Order. The Materials must be packaged appropriately for the type of Biospecimen and shipped to the Herhel Clinic office (unless otherwise stated by 3 in the Order) by a reputable overnight or express service chosen by Vendor unless specifically requested by 3 in the Order. Vendor will cover the cost of shipment and assume the risk of loss of the Biospecimen until delivery to the address designated by Herhel Clinic

4. **Specifications.**
Vendor shall provide Herhel Clinic with the Materials (Biospecimen and Information) in accordance with all Specifications listed in the Order, including all Quality Control (QC) Criteria. In the event Vendor is unable to meet a specification to which it has agreed, it shall provide with reasonable notice.

5. **Information.**
Vendor shall deliver all Information as requested by the Order specifications to Herhel Clinic in an electronic format in a complete, accurate and timely manner no later than forty-eight (24) hours prior to the shipment date of the associated Biospecimen for frozen and fixed Biospecimen and no later than forty-eight (24) hrs after the shipment for fresh Biospecimen. Herhel Clinic reserves the right to reject Biospecimen that are not accompanied by each of the data fields set forth in Order.

6. **Personal Data Protection.**
Herhel Clinic works with Vendors in compliance with updated Common Rule (USA, effective July 19, 2018) and General Data Protection Regulations (EU, effective May 25, 2018) and guarantees to its Customers that Herhel Clinic will not receive, transfer or provide access to any "Protected Health Information" ("PHI") as defined in 45 C.F.R. Section 164.501 or Personal Data as defined in the General Data Protection Regulation (EU) 2016/679. Only de-identified Data should be delivered to Herhel clinic .

7. **Herhel Clinic Use**:

7.1. Herhel Clinic may use obtained Biospecimen for commercial purposes including, but not limited to, drug development, biomarkers, diagnostics development, assay development, product development, etc.

7.2. Herhel Clinic can transfer Biospecimen received from Vendor to the third parties under corresponding customer and/or collaboration agreements provided, that such third parties do not transplant, infuse, or transfer into a living human body any Biospecimen or part thereof.

7.3. Herhel Clinic agrees to comply, and will ensure that its employees, customers and/or collaborators comply, in all respects with all federal, state and local laws, statutes, rules and regulations applicable to the procurement, transfer, use, handling marketing, distribution and disposal of the Biospecimen and Information.

7.4. Herhel Clinic will not, and will ensure that its employees, customers and/or collaborators will not identify or contact, or attempt to identify or contact, or aid any person or entity in identifying or contacting any donor, donor family or source of a Biospecimen or Clinical Information.

7.5. Herhel Clinic A sample of and Informed Consent Form ("ICF") that has been approved by s Institutional Review Board ("IRB"), which authorizes Vendors to obtain Biospecimen from its patients and transfer the Biospecimen to for commercial purposes in compliance with all applicable federal, and local laws is provided in **Exhibit A**.

8. **Vendor Representations**:

8.1. For all cases for which Biospecimen are cultivated or processing and submitted to Herhel clinic, Vendor warrants that patients or donors have signed an appropriate Informed Consent Form (ICF) and that their approval to the use of their samples and data covers enterprises as provided in Exhibit B.

8.2. Vendor warrants that it has obtained all of the necessary rights with respect to the Biospecimen and Clinical Information to permit their transfer by Vendor to Herhel Clinic pursuant to the laws, statutes and regulation of the country of Biospecimen' acquisition.

8.3. Vendor represents and warrants, that on the date of receipt by of the Biospecimen, that each Biospecimen was obtained in accordance and will conform to technical Specifications as set forth in Section 4 of this Agreement.

8.4. Herhel clinic has 6 (six) business days from receipt of the Biospecimen to notify Vendor, in writing, if such Biospecimen(s) do not conform to the specifications. The notification must contain a quality report. The defective Biospecimen will either be returned to Vendor in reasonably good condition upon the Vendor's request or disposed of by XXXX in accordance with all applicable laws, rules and regulations regarding disposal of the Biospecimen.

8.5. Vendor's sole remedy is the replacement of the non-conforming Biospecimen with a Biospecimen conforming to the specifications within 10 business days after receipt of written notification from Herhel Clinic.

8.6. If Vendor is unable to replace a Biospecimen, Herhel Clinic shall be entitled to cancel its Order and obtain a full refund of any sums previously paid by Herhel Clinic for such Biospecimen.Vendor represents and warrants that to the best of its knowledge based upon the representations of the sites from which the Biospecimen are collected, and review of the applicable clinical records, all Biospecimen were

obtained from individuals believed to be Hep-B/C and HIV-1/2, syphilis and communicable disease negative at the time of procurement (unless otherwise requested in the Order.) Vendor shall notify , as soon reasonably possible upon learning that a Biospecimen delivered to 3 was obtained from a patient who was infected with Hep-B/C and HIV -1/2, syphilis or any other infectious disease that should be disclosed to anyone handling such samples, pursuant to industry standards.

8.7. Biospecimen and Information are provided and transferred to Herhel Clinicfor use with commercial purposes with the donor's consent as required by all applicable laws, statutes and regulations of the country of acquisition and the European Union. Vendor hereby disclaims any proprietary interest in the Biospecimen and Information and in the results that Herhel Clinic may perform with the Biospecimen and Information. Vendor shall not seek to enforce, on its own behalf or no behalf of any other entity or person, any right, title and interest to the Biospecimen and associated Information, including any rights in the data, results or information generated by either Party during the course of this Agreement and arising from use of the Biospecimen and associated Information, or intellectual property rights related thereto. Vendor warrants that it shall not infringe the intellectual property rights of any third party by completing its obligations under this Agreement.

8.8. Upon reasonable advance written notice and during normal business hours, Herhel Clinic or its designated representative may access Vendor's offices to inspect the tissue processing and storage procedures; and access examples of donor consent forms, subject to any requirements of applicable law.

9. **Indemnity**. Each Party agrees to indemnify and hold harmless the other Party and its directors, employees and agents, from and against all liabilities, including reasonable attorney's fees and costs, resulting from any claims by any third party to the extent such claims arise from a material breach or alleged material breach of this Agreement or the negligence or willful misconduct of the indemnifying party or its respective employees and agents. The indemnifying Party will have the right to control all litigation and settlements for which it provides indemnity; provided, the indemnifying Party shall not settle any claim that imposes any liability or other restriction on the indemnified Party or that admits fault of the indemnified Party, without prior written consent of the indemnified Party.

10. **Insurance**. Each party shall maintain the. adequate provision is made by way of insurance or indemnity arrangements sufficient to meet their obligations and liabilities under this Agreement and the Applicable Laws. The parties shall ensure they have valid professional indemnity insurance. Upon request from a party, the other party shall provide satisfactory evidence of such insurance, and each party shall provide written notice to the other party of any cancellation, reduction or material modification of its insurance coverage promptly upon such party becoming aware of any such change.

11. **Limitation of Liability**. No party shall be liable to another party in connection with this Agreement for any indirect, consequential, punitive, or other damages suffered by such party or any other person, including but not limited to the loss of, delay of, or from the use of clinical data biospecimens or from any analyses based on or obtained from the clinical data, biospecimens and/or sequence data, except to the extent that damages of such nature are incurred by a third party and are included within the indemnifiable claims for which a party is responsible.

12. **Term and Termination**. This Agreement will become effective on the Effective Date set forth above and shall continue in effect until terminated by either party upon 30 days written notice to the address set forth above or such other address as later designated by a Party in writing; provided, however that Vendor shall be compensated for all expenses accrued through the date of such termination. Any Order accepted by Procuring Party prior to the date such termination becomes effective shall be carried out on the terms set forth herein. Sections 5, 6, 7, 8, 9, 10, 11, 13, 15 and 18 shall survive the termination of this Agreement.

13. **Intellectual Property**. Ownership of Intellectual Property existing as of the Effective Date or developed or obtained outside of this Agreement is not affected by this Agreement, and no party shall have any claims to or rights in any such pre-existing Intellectual Property of another party,

except as may be otherwise expressly provided in any other written agreement between the parties. Unless otherwise agreed in writing, each party retains ownership of all Intellectual Property developed solely by it or its employees from the activities performed under this Agreement.

14. **Confidential Information**. "Confidential Information" means all proprietary, confidential and non-public information (including the identity of customers and suppliers of a party) disclosed by one party to the other party pursuant to this Agreement, regardless of the method of disclosure or format of the information. Each Party shall use and disclose all Confidential Information of the Party solely for the purpose of carrying out its obligations under this Agreement. Neither Party will, during the term of this Agreement, and for a period of three (3) years thereafter, without the disclosing Party's prior written consent, disclose to any third party any of the disclosing Party's Confidential Information except as permitted by the Agreement. Confidential Information does not include information that the receiving Party can demonstrate in written instruments maintained in the ordinary course of business: a) prior to or following the time of disclosure becomes publicly available through no fault of the receiving Party; b) is known to the receiving Party at the time of disclosure; c) becomes known to the receiving party through disclosure by other sources having the legal right to disclose such Confidential Information other than the disclosing Party; or d) is developed independently by the receiving Party without use of any Confidential Information of the disclosing Party, as evidenced by competent written records. A Party may disclose Confidential Information of the disclosing Party that is required by law, governmental agency or tribunal to be disclosed after giving the disclosing Party reasonable prior written notice of such requirement and after providing reasonable assistance to the disclosing Party, at the disclosing Party's sole cost, in its efforts to prevent or limit such disclosures. Notwithstanding anything in this Agreement to the contrary, (i) XXXX shall have the right to disclose non-individually identifiable information regarding the Biospecimen and Clinical Information, subject to any requirements in the Informed Consent; and (ii) the receiving Party shall have the right to disclose the Confidential Information of the disclosing party to its employees, consultants and subcontractors (collectively, the "Representatives") who have a need to know such information in the performance of such Party's obligations hereunder subject to obligations of non-use and confidentiality no less restrictive than those set forth herein. A breach of this Section 10 by a party's Representative(s) shall constitute a breach of this Section by such party.

15. **Return of Confidential Information.**

All of a Disclosing Party's Confidential Information, and all copies thereof, shall be and remain the property of the Disclosing Party. All such Confidential Information and any and all copies and reproductions thereof shall, upon the fifteen (15) days after:

(a) the receipt of written request of the Disclosing Party or

(b) the expiration or termination of this Agreement, be promptly returned to the Disclosing Party or destroyed (and such destruction confirmed in writing provided to the Disclosing Party) at the Disclosing Party's direction; provided that

(i) during the term of any license hereunder a Receiving Party shall not be obligated to return or destroy any licensed information

(ii) in no event shall Analyses be required to be returned or destroyed and

(iii) this Agreement need not be returned or destroyed.

16. **Non-Solicitation:**

16.1. In the event the Vendor is given or learns of the identity of the HBS end-user ("Customer") under and/or pursuant to an Order, the Vendor shall not attempt to contact them regarding the Order unless given permission in writing by Herhel Clinic. In the event Herhel Clinic does not come to an agreement with the Customer within twelve months of obtaining an Order, the

Vendor shall then be free to contact the Customer directly. Herhel Clinic may permit the Vendor to contact Customer prior to twelve months. Such permission shall be in writing. A Customer shall be defined as an individual or a project group with a disease-specific and application-specifically shared within a company, and not include the client company as a whole unless the company is of such a small size that the purpose represents for testing of bio specimens of human participants as the sole focus of the company. Specifically exempt from this clause shall be (a) purchasing managers responsible for Biospecimen sourcing within a client company (unless the company is of such small size that testing of bio specimens of human participants purpose represents the sole focus of the company) or (b) managers of academic core facilities for Biospecimen sourcing.

16.2. The Parties shall treat as Confidential Information, whether or not it is so marked in writing, the identity of the Customers and Suppliers to any other person or entity unless permitted in writing by both Parties, or as required by law or other regulatory agency.

16.3. In the event one Party has not conducted business with a Customer or Supplier prior to the date of the Order under which the Customer / Supplier's identity was disclosed, that Party shall only deal with the Customer or Supplier through the other Party for a period of two (2) years following the date of the above referenced Order; provided, however, any party may work directly with any Customer or Supplier provided the scope of the work is outside of the services and procurement offered by the other party pursuant to this Agreement.

16.4. The Parties agree that there is no adequate remedy at law for the breach of this Section 11; accordingly the Parties agree that the non-breaching Party has the right to enjoin such violation by injunction or other equitable remedy. This remedy is not exclusive and is in addition to any other remedies available.

17. **Entire Agreement**. This Agreement and Orders hereunder constitute the entire understanding and agreement between the Parties or with respect to the subject matter hereof. Any change to this Agreement and any Orders accepted by both Parties must be in writing, signed by both Parties. In the event of any conflict between the Terms and Conditions of this Agreement and any Order, the Terms and Conditions of this Agreement shall govern unless otherwise expressly set forth in Order.

18. **Modification**. No amendment, changes, extensions or modifications to this Agreement shall be valid and binding unless in writing and signed by the parties' duly authorized individuals.

19. **Governing Law; Arbitration; Venue**.

19.1. This Agreement and all of its Annexes is governed by Austrian law excluding any collision law.

19.2. Any dispute, claim, difference or controversy arising out of, relating to or having any connection with this Agreement, including any dispute as to its existence, validity, interpretation, performance, breach or termination or the consequences of its nullity and any dispute relating to any non-contractual obligations arising out of or in connection with it (a "Dispute"), shall be referred to and finally resolved by arbitration.

19.3. The arbitral tribunal shall consist of one arbitrator, who shall be appointed in accordance with the Rules.

19.4. The seat or legal place of arbitration shall be Vienna, Austria.

19.5. The language used in the arbitral proceedings shall be English.

20. **Compliance with Law**. Each party shall fully comply with all applicable federal, state, and local laws and regulations in its performance of this Agreement.

21. **Cumulative Remedies**. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such party, and the exercise by a party of any one remedy shall not preclude the exercise of any other remedy.

22. **Assignment**. Neither Party may, without the prior written consent of the other Party, assign this Agreement to third party, said consent not to be unreasonably withheld. The foregoing notwithstanding, either Party may, without the prior written consent of Vendor, assign this Agreement in whole or in part to an affiliate or in connection with the transfer or sale of all or substantially all of that Party's assets or capital stock, or in the event of its merger. This Agreement is not transferable. There are no third-party beneficiaries to this Agreement. Any other individual that wishes to receive Biospecimens from the Vendor is required to execute a separate Agreement.
23. **Headings**. The captions or headings in this Agreement are made for convenience and general reference only, and shall not be construed to describe, define or limit the scope or intent of the terms and conditions of this Agreement.
24. **Notice**. Any notice will be in writing and will be delivered personally, mailed by certified mail, return receipt requested or delivered by reputable overnight courier service to the applicable address set forth above (or such other address as either Party will hereafter specify in writing)**.**
25. **Severability**. Should any term of this Agreement be declared void or unenforceable by any court or arbitrator having jurisdiction hereof, such declaration will have no effect on the remaining terms of the Agreement.
26. **No Waiver**. The failure of either party to enforce any rights granted hereunder or to take action against the other party in the event of any breach hereunder will not be deemed a waiver by that Party as to subsequent enforcement of rights or subsequent actions in the event of future breaches.
27. **Publicity**. Neither Party may disclose the existence of this Agreement to third parties. Neither Party shall disclose the terms of this Agreement to a third party without the prior written consent of the other Party, except that either Party may disclose such terms as required by law or to a Party's third party attorneys or accountants.

22.07.2024 / (0074-09)

Ukrainian Association of Biobank Austria ("Vendor")

Herhel Clinic

Name: Margarita Kononenko

Title: Founder and CEO

Name: Svetlana Gramatiuk, Ph.D., MSc

Title: President

Effective Date: July 30, 2024

Exhibit A. Project Order TEMPLATE

ORDER #

Project Title	
Project Duration	
Project DIRECTOR	
Site MANAGER	

Qty. (case)	Indication	Biospecimen Description	Price per case (USD)	Total (USD)

Project Specifications (Scope of Work, SOW):

1. **Inclusion/exclusion criteria**
2. **Technical specifications**
3. **Required information includes: type of stem cells or cells line, organoid, summary of a infection control report, previous cryopreservation, media and kit cultivation, date of procurement (see attached CRF).**
4. **Infectious materials: all Biospecimen under this protocol MUST be tests from Hep-B/C and HIV-1/2, Herpesvirus and mycoplasma negative donors as determined during cultivation.**
5. **Shipment instructions: use UAB Austria World Courier account # for this project. Shipment should be done to XXXX's mail office address .**
6. **Timeline for procurement.**
7. **Payment schedule details.**

This document shall be governed by the terms and conditions of the

HBS Vendor Agreement and Terms and Conditions

Herhel Clinic use ONLY:

Prepared by: Margarita Kononenko_____
Date:

Vendor use ONLY:

Accepted by: Svetlana Gramatiuk_____
Date:

Effective Date: June 30, 2024

Exhibit B. Certificate of Quality Control for Biological Material

Certificate of Quality Control for Biological Material **Research Results and Storage Conditions** Date of Collection		
№ _____	SOP- QCT-ICB-11-057	Version 1.4
Type of Material	**Clinical trials**:	
	SOP - ICB-17P19A	
Sample ID_stem cells	**Sample ID_cells organoide**	
Cryopreservation Medium	CELLBANKER® 1	
Antibiotic-Antimycotic	Gibco™ Antibiotic-Antimycotic -	
Culture Medium	1. StemPro MSC SFM XenoFree 2. MesenPRO RS 3. Dakopatts, Glostrup, Denmark 4. MCBD, EGF, HMVEC with 10% dFBS. 5. STEMdiff™ Cerebral Organoid Kit (PAX6+/SOX2+/Ki-67+) 6. STEMdiff™ Cerebral Organoid Maturation Kit (Catalog #08571). 7. SkBMTM-2 Basal Medium with supplements (catalog #CC-3246 and #CC-3244, all from Lonza) 8. Different concentrations of GDF11 (LifeSpan BioSciences, Seattle, WA)	
Matrix	CELLstart – A1014201. CELLstart™	
Medium	1. PBS - (Irvine Scientific, № 9236) 2. PRIME-XV (Irvine Scientific, №31002) 3. PRIME-XV MatrlS F (Irvine Scientific, №31001) 4. PRIME-XV MSC Expansion SFM (Irvine Scientific, №91135) 5. Y-27632 (Dihydrochloride) to 15 mL 6. D-PBS (Without Ca++ and Mg++) 7. Anti-Adherence Rinsing Solution (Catalog #07010) 8. Organoid Embedding Sheet or Parafilm® into an empty, sterile, 100 mm dish 9. Intermediate progenitor cell markers: ASCL1, TBR2 10. Cortical plate/pre-plate/neuron markers: TUJ1, DCX, MAP2, TBR1, CTIP2	

Storage Conditions **Temperature Requirements**	

Effective Date: June 30, 2024

Exhibit C. Certificate of Infection Control

Specification

Comprehensive Material Testing for Sterility

Sample ID	
Quantity of Material	_____ cryotube 1D or 2D
Test of MALDI-ToF MS Bruker Biotyper	
PCR - Mycoplasma detection	
PCR - Hepatitis B	
PCR - Hepatitis C	
PCR- HIV-1/2	
PCR- HIV-6	
PCR - HTLV1	
The material is aliquoted and labeled on each cryovial	

Data