# HUMAN MATERIAL TRANSFER AGREEMENT FOR RESEARCH PURPOSE

This Human Material Transfer Agreement (the “**Agreement**”) is entered into and made effective as of ***latest date of signature below*** (the “**Effective Date**”) by and between:

1. ***Cliniques universitaires Saint-Luc*** a legal entity existing under the laws of ***Belgium,*** with offices located at ***Avenue Hippocrate 10, 1200 Brussels*** (“**CUSL**”); and
2. ***………………………………………………………*** (“**Recipient**”).

 (Each of the CUSL and Recipient are referred to herein individually as the “**Party**” or collectively as the “**Parties**”.)

# WHEREAS:

1. CUSL material is a Human Corporate Material Bank within the meaning of the law of 19 December 2008 concerning the collection and use of human biological material for human application or scientific research purposes ;
2. The CUSL owns or controls the CUSL Materials (as defined below) and warrants that its transfer is authorized;
3. Recipient is an organization engaged in research and wishes to obtain access to the CUSL Materials for use in connection with an internal research activity; and
4. The CUSL is willing to supply the CUSL Materials to Recipient for such use under the terms and conditions of this Agreement.
5. CUSL acts as a Biobank in the meaning of the Belgian RD of 9 January 2018 regarding biobanks (as defined in the annex 1)

**NOW THEREFORE** the Parties agree as follows:

# Subject and Scope of the Agreement

* 1. The CUSL will supply samples of the CUSL Materials to Recipient pursuant to this Agreement and in such quantities as are reasonably necessary to perform the Research, as requested by Recipient and subject to the CUSL and Research Ethics Committee (Comité d’Ethique Hospitalo-Facultaire Saint-Luc-UCL) approval (***[ref Number], dated DD/MM/YYYY***). The CUSL may also provide Recipient with anonymized Confidential Information and Data related to the CUSL Materials to facilitate the performance of the Research. The Recipient will have the limited right to use the CUSL Materials and the related CUSL Confidential Information and Data solely for the approved Research as described in Annex 2 and shall not use the CUSL Materials or the CUSL Confidential Information or Data for any other purposes whatsoever without the prior written consent of the CUSL and the “Comité d’Ethique Hospitalo-Facultaire Saint-Luc-UCL”.
	2. The CUSL Materials and the Confidential Information related to these CUSL Materials are and shall remain the property of the CUSL. In the case of transfer of any CUSL Material, the Confidential Information related to this CUSL Material to Recipient pursuant to this Agreement shall not be construed as a sale or any other form of transfer of ownership or other rights to the CUSL Material.
	3. Should CUSL provide Recipient with Personal Data within the meaning of the applicable legislation on the Processing of Personal Data, adequate provisions are described in **Annex 5**

# Delivery, use and processing of the CUSL Materials

* 1. The Recipient shall be in charge of the logistic aspects of the transport of the CUSL Materials and, as such, shall pay all carriage or freight costs incurred on such supply, as specified in annex 3.
	2. The CUSL shall send anonymized Material and data to the attention of the Recipient and shall not provide the Recipient with any Data or key to decode or identify the patients/donors except the unique identification code assigned to each donation and each MCH derived thereof from it . The Recipient shall not attempt to contact any donor. The Recipient shall refrain from tracing or identifying the identity of the donor.
	3. The Recipient shall use the CUSL Materials, Derivatives, Data and Confidential Information in compliance with all applicable legislation. The CUSL Materials shall only be used by Recipient for the Research and in strict compliance with the terms and conditions of this Agreement. Recipient shall not carry out any other activity with the CUSL Materials that is not strictly necessary for the Research. Recipient shall have no right to transfer, provide, grant, sublicence, access to, or otherwise make available any CUSL Materials to any Third Party without the prior written consent of the CUSL.
	4. The CUSL warrants that the donors have consented pursuant to the the applicable legislation on the processing of Personal Data) and to the Law of 19 December 2008 concerning the collection and use of human biological material for human application or scientific research purposes to the use of their CUSL Materials and related Confidential Information for the purposes of the research.
	5. The CUSL Materials shall not be used by Recipient in any research that is, or may be, subject to consulting or commercial licensing or contracted research obligations to a Third Party, without the prior express written permission of the CUSL.
	6. The CUSL Materials shall only be used in Recipient’s premises and by those of Recipient’s employees and/or personnel who are directly involved with the performance of the Research and under the supervision of Recipient’s principal investigator responsible for directing the Research. The Recipient shall be responsible for ensuring the compliance by such individuals with the terms and conditions of this Agreement and shall be liable hereunder with respect to any breach thereof which is caused by such individuals.
	7. The CUSL Materials are made available to the Recipient for investigational use. The Recipient acknowledges and agrees that none of the CUSL Materials, nor any CUSL Materials treated therewith, shall be administered to or otherwise used in human beings.
	8. About the CUSL Materials left in the CUSL and not concerning CUSL Materials transferred to Recipient under this Agreement, the Recipient acknowledges that the CUSL shall be free, in its sole discretion, to use these CUSL Materials left for any and all purposes, including without limitation the rights at any time, and without notice or obligation to Recipient, to distribute, license or otherwise transfer or convey to Third Parties the CUSL Materials.
	9. Recipient shall keep the CUSL Materials and Data and Confidential Information at its premises in a secure environment, protected against theft, damage, loss, misuse and unauthorized access and in conformity with the applicable legislation. Except for the use and consumption of the CUSL Materials and/or Derivatives in performance of the Research, the Recipient shall not otherwise dispose of any the CUSL Material without the CUSL’s prior written consent.
	10. Recipient shall ensure that all CUSL Materials shall be handled with the greatest care to prevent any infection related to know or unknown pathogens for all investigators. In any case, the CUSL shall not be liable for any injury or disease contracted by the Recipient investigators when handling CUSL Materials.
	11. Recipient shall ensure that there is complete traceability of tissue and data, from the CUSL to use and destruction if applicable. This means that: each sample and aliquot shall have a unique identifier, samples shall be labelled appropriately so that identification and traceability of the samples are maintained through the CUSL, each sample shall be associated with the relevant version of processing and storage SOPs. Each sample shall be associated with any significant event (such as a freezer thaw) that might impact on the characteristics of that sample. It shall be possible to identify the location of any sample at all times, including identifying those that have been distributed to researchers or disposed of. This includes aliquots and derivatives of samples such as sections of tissue, components of tissue microarrays (TMAs) and extracts of nucleic acids.

The Recipient shall be able to track shipments from dispatch to receipt, whether or not a courier is used.

* 1. The Parties shall comply with all applicable laws, regulations, guidelines and approvals, including, without limitation,
		+ (i) the legislation on human tissue including the law of 19 December 2008 concerning the collection and use of human biological material for human application or scientific research purposes and the Belgian RD of 9 January 2018 regarding biobanks (ii) the the applicable legislation on the processing of Personal Data ,
		+ (iii) the law of 22 August 2002 relating to patient’s rights,
		+ (iv) the law on experiments including the lax of 07 May 2004 on human experiment,
		+ (v) the Helsinki Declaration ‘World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects’ and any approvals required from a Research Ethics Committee (including but not limited to regulations relating to the use and welfare of laboratory animals), when applicable.
	2. Recipient shall deliver to the CUSL a final quality assessment report, when all samples have been returned, used or destroyed, including use of the samples, quantity already used, tests done, compliance with respect of the traceability.
	3. In case of clinically relevant information for the donor(s) are generated or if discoveries or new safety information are made during the Research that may have implications for the donor(s) or his/her/their family members, the Recipient shall provide a full report to the Research Ethics Committee (Comité d’Ethique Hospitalo-Facultaire saint-Luc-UCL) and send a copy to the CUSL. The Research Ethics Committee (Comité d’Ethique Hospitalo-Facultaire saint-Luc-UCL) and the CUSL will inform the donor(s) of such findings as appropriate pursuant to the Law of 19 December 2008 concerning the collection and use of human biological material for human application or scientific research purposes and the Law of 22 August 2002 relating to patient’s rights.
	4. The Recipient must keep accurate records regarding its use of the Materials and, if required by the CUSL, the Recipient will allow the CUSL to conduct (or to direct an appropriate Third Party to conduct on the CUSL’s behalf) during normal business hours an audit of the Recipient’s use of the Materials and records arising from such use to verify their accuracy. The audit will be at the CUSL’s expense unless the audit reveals that the Recipient is using or had used the Materials in a manner or to an extent not authorized by this Agreement, in which case the Recipient will pay all reasonable expenses associated with the audit.
	5. Recipient’s right to use the CUSL Materials Data and related Confidential Information shall expire upon the expiration or earlier termination of this Agreement. Upon such termination or expiration, Recipient shall, upon request and as directed by the CUSL, destroy or return to the CUSL all remaining samples of the CUSL Materials and related Data and Confidential Information in Recipient’s possession. If the remaining CUSL Materials has been destroyed, a written document must certify that all CUSL Materials in the Party’s possession has been destroyed and the procedure used to do it (if applicable). The foregoing shall not relieve Recipient of its obligations under this Agreement.
	6. If and to the extent that the CUSL discloses or otherwise makes available to Recipient any of the CUSL’s Confidential Information, this information shall be subject to the same restrictions on use as apply to the CUSL Materials.

2.18 In accordance with the law, the CUSL and the persons responsible for collection may receive compensation covering up the costs of removal or operations performed within the CUSL. The financial aspects are specified in annex 4.

# Confidentiality

* 1. Unless otherwise expressly stated, each Party shall use the Confidential Information of the other Party (“Other Party’s Confidential Information”) solely for performing activities under this Agreement and for no other purpose, and shall not disclose or otherwise provide it to any Third Party without the other Party’s prior written consent or unless otherwise permitted hereunder.
	2. Each Party shall hold the Other Party’s Confidential Information at all times in strict confidence and, without limiting the foregoing, shall exercise the same degree of care that it exercises with respect to its own information which it desires to maintain as confidential (but in no event less than a reasonable degree of care).
	3. Each Party shall limit the disclosure of the Other Party’s Confidential Information to its directors, consultants, contractors (“Representatives”) and employees whose performance of activities under this Agreement justifies the need to know such information, who have been advised of the existence and terms of this Agreement, and who are legally obligated to protect Confidential Information from unauthorized disclosure or use on terms at least as stringent as those contained herein. This is also in application for its Affiliates’ agents. Each Party shall be liable for acts by any of its employees or Representatives in violation of this Agreement as if they were actions or omissions of that Party.
	4. A Party receiving Information (“Receiving Party”) from the other Party (“Disclosing Party”) shall be under no obligation with respect to any Information which the Receiving Party can establish by reasonable written evidence:
1. is or becomes generally available to the public through no fault of the Receiving Party; or
2. is or becomes rightfully in the possession of the Receiving Party on a non-confidential basis through a third party who, as far as the Receiving Party is aware, is not bound by confidentiality obligations to the Disclosing Party or otherwise prohibited for some other reason from disclosing the Information to the Receiving Party; or
3. Was in the Receiving Party’s possession prior to disclosure hereunder and was acquired lawfully and not directly or indirectly from the Disclosing Party; or
4. Was independently developed by the Receiving Party or its Affiliates without the aid, application or use of the Disclosing Party’s Confidential Information.

 Confidential Information shall not be deemed to be within the foregoing exceptions merely because it is (1) specific and embraced by more general information in the public domain or Receiving Party's possession or (2) a combination of exempted information from multiple sources.

 The burden of establishing the existence of any such an exception rests with the Receiving Party.

* 1. Upon termination or expiration of this Agreement, or earlier if so agreed in writing by the Parties, each Party shall either deliver all copies of the Other Party's Confidential Information to the other Party or, at the other Party's option, destroy and/or erase (where held electronically) and certify with a written document that all such information in the that Party’s possession has been destroyed and/or erased (as applicable), however, that one copy may be retained by the that Party solely for legal archiving purposes in a secure location and under its own liability.
	2. Any Party shall notify the other Party immediately upon discovery of any unauthorized use or disclosure of Confidential Information, or any other breach of these confidentiality obligations by said Party or any of their agents, directors, consultants, contractors and employees and will cooperate with the other Party in every reasonable way to help the other Party regain possession of its Confidential Information and prevent its further unauthorized use or disclosure.

# Intellectual Property Rights

* 1. Except as otherwise expressly set forth herein, nothing in this Agreement shall be construed as granting, creating or conveying any license or other rights (express or implied) by either Party to the other Party with respect to or under any Intellectual Property Rights.
	2. The CUSL hereby grants to Recipient a non-exclusive, royalty-free, personal, non-assignable license to use the CUSL Materials and the related Data and Confidential Information solely for carrying out the Research and subject to the terms of this Agreement.
	3. If the Research which involves the CUSL Materials and the related Confidential Information results in an invention, improvement or substance, whether or not patentable (“Invention”), Recipient and the CUSL will have the right to use such Inventions and Results for their own and internal non-commercial research (non-commercial meaning the absence of revenue from third parties).
	4. Unless a delay is required to protect Intellectual Property Rights or publication in a peer-reviewed journal, Recipient shall fully and promptly, i.e. within 3 months, disclose in writing to the CUSL all Data, if legally permitted, that may be of interest for inclusion in the CUSL’s database. Submission of those Data to the CUSL does not affect the requirement for Recipient to maintain their own research records.
	5. If a valorization of the research results can be considered, Recipient will promptly inform CUSL. The Parties will immediately take appropriate measures to preserve this potential valorization and will start negotiations in view of concluding an agreement with respect to this valorization, including an agreement on intellectual property rights. The agreement can attribute the right of valorization and/or the intellectual property rights to Recipient, to CUSL or to both in a given proportion. The Parties shall negotiate in good faith, taking into account the specific contributions of each Party to the research that is subject to valorization. Every agreement within this scope stands on its own and will have no bearing on other research to be valorized.

# Publications and notifications

CUSLs have been heralded as essential tools for translating biomedical research into practice, driving precision medicine to improve pathways for global healthcare treatment and services.

However, it is extremely difficult to identify the contribution of any specific CUSL Material to research published in scientific articles because they are either cited in a confusing, heterogeneous, and unstandardized way, or they are not cited at all. The systematic and standardized citation of CUSL Materials in journal articles is needed for the fair recognition of the impact of CUSL Materials on health research, both in qualitative and quantitative terms. For these reasons:

* 1. It is the intent of the Recipient to publish the Results (obtained from the CUSL Materials) . Recipient shall provide the CUSL with a copy (pdf) of the publication.
	2. CUSL Materials maybe acknowledged in various sections, including Materials and Methods, Acknowledgements and References. For further information, Recipient shall have a look at specific literature on his matter (see: Bravo *et al.*, BMC Medicine 2015 Feb 17; 13: 33 “*Developing a guideline to standardize the citation of bioresources in journal articles (CoBRA)*”.
	3. Any publication or presentation using CUSL Materials shall include an acknowledgement using the text below:

## Examples:

***Ex1: This research has been conducted using the Biobanque (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_), referenced as (BE\_ \_\_\_\_\_\_\_\_\_\_); Biobanque (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_); BE\_(\_\_\_\_\_\_\_\_\_\_\_\_\_\_);***

5.4 The address of the Recipient for delivery and notifications is as follows:

 ***To be completed***

1. **Representations, Warranties and Disclaimers**
	1. Each Party represents and warrants as of the Effective Date that it has the authority and is appropriately authorized to enter into this Agreement and to perform its obligations under this Agreement free of any restrictions or encumbrances.
	2. Recipient understands and acknowledges that the CUSL Materials are experimental in nature and may have unknown characteristics. All the CUSLl materials are being provided on an “as-is” basis with no warranties of any kind, express or implied, with respect thereto, and the CUSL hereby expressly disclaims the applicability of any express or implied warranties of merchantability, fitness for a particular purposes, or non-infringement of third party intellectual property rights. The CUSL cannot be held liable if the CUSL materials cannot offer the needed quality to conduct the research.
	3. Recipient understands and acknowledges that the CUSL cannot insure the quantity of the CUSL Materials needed for the Research. The CUSL is not responsible and cannot be held liable if there is not enough CUSL Materials.

* 1. Recipient shall be solely responsible for the conduct of the Research and for any use, handling or storage of the CUSL Materials (and any Derivatives) in connection therewith. Under no circumstances will the CUSL have any liability or responsibility for, and Recipient shall indemnify and hold the CUSL and its Affiliates harmless with respect to, any and all liabilities, obligations, losses and damages of any kind whatsoever arising from or in connection with any use, handling or storage of the CUSL Materials and/or Derivatives by or on behalf of the Recipient.
	2. The Recipient shall be responsible for and liable hereunder with respect to any breach of this Agreement which is caused by the actions of its Representatives and/or other personnel control having access to the CUSL Materials and/or Derivatives.

# Term and termination

* 1. This Agreement shall have effect as from its Effective Date and unless earlier terminated shall expire within (\_\_\_\_\_() as of the Effective Date.
	2. The Parties shall have the right, without prejudice to its other rights or remedies, to terminate this Agreement upon written notice with immediate effect, if at any time the other Party breaches any terms of this Agreement.
	3. The Parties shall have the right, without prejudice to its other rights or remedies, to terminate this Agreement upon sixty (60) days prior written notice.
	4. In case an event prevents pursuing this Agreement, the Parties will agree on termination terms.
	5. The provisions of this Agreement 3, 4, 5 and 6, shall survive the termination of this Agreement
	6. Recipient’s right to use the CUSL Materials or related Confidential Information shall expire upon the expiration or earlier termination of this Agreement pursuant to Section 2.14 of this Agreement.

# General provisions

* 1. **Force majeure.** No Party shall be in default hereunder by reason of any failure or delay of performance if and to the extent such failure or delay is caused by circumstances beyond its reasonable control and that by the exercise of due diligence it is unable to prevent, provided that the non-performing Party uses its reasonable efforts to overcome the same. Such causes shall include, without limitation, storms, floods, other acts of nature, fires, explosions, riots, war or civil disturbance, strikes or other labor unrests, delays in transportation, inability to obtain necessary labor, supplies, or manufacturing facilities, embargoes, and other governmental actions or regulations that would prohibit a Party from performing any other aspect of the obligations hereunder.
	2. **Entire agreement**. This Agreement (together with the Schedules attached hereto) is the final, full and exclusive expression of the agreement of the Parties and supersedes all prior agreements or understandings (whether oral or written) between the Parties with respect to the subject matter hereof. Any amendment or modification to this Agreement (or such Schedules) shall only be effective when made in writing and signed by authorized representatives of both Parties. In the event of any conflict between the terms of this Agreement and the content of one of the attached Schedule, the terms of this Agreement shall prevail.
	3. **Severability**. If any provision of this Agreement is found by a court of competent jurisdiction to be invalid or unenforceable, the remaining provisions of this Agreement shall remain binding upon the Parties hereto, and the Parties will use good faith efforts to replace the invalid or unenforceable part or provision with an alternative provision which accomplishes, to the extent possible, the original purpose of such part or provision.
	4. **Independent contractors**. The relationship between the Parties under this Agreement is that of independent contractors. This Agreement shall not be construed as creating or constituting a partnership, joint venture, agency or other similar relationship between the Parties. Neither Party shall have the power to bind the other nor to incur obligations on the other’s behalf without the other’s prior written consent.
	5. **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one single agreement between the Parties.
	6. **Governing Law and competent courts**. This Agreement and the Parties rights and obligations hereunder shall be governed by and interpreted according to the laws of ***Belgium*** without regard to its rules of conflicts of laws. The Parties shall endeavor, in good faith, to settle amicably any dispute. If the Parties have not reached a settlement of such dispute within ninety (90) days of written notice by one to the other of such dispute, the dispute shall be settled finally by the competent courts of Brussels, Belgium.

# Conflicts of interest

Conflicts of interest are situations in which financial or other personal considerations may compromise, an investigator's professional judgment in conducting or reporting research. The bias such conflicts may affect:– collection, analysis and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol, and use of statistical methods. Conflicts of interest can affect other scholarly duties in both biomedical and behavioral research, Problem occurs when secondary interests dominate, unduly influence, distort, corrupt the integrity of a physician’s judgment in relation to patients health, clinical research or medical education.

The Parties recognize that they have no potential conflict of interest (COI), real or perceived. In witness whereof, this Agreement has been executed by duly authorized representatives on behalf of the parties and shall be in full force and effect as of the Effective Date (Date of last signature).

Effective date:

## [The CUSL] [Recipient 1 Name]

Signature:.........................................…........... Signature:.........................................….............

Name: xxxx Name:xxxx

Position: Head of the Biobank- CUSL - Head of

Pathology departement. Position:.

Date:.......................................................…. Date:.......................................................….....

Signature:.........................................…........... Signature:.........................................….............

Name:.Prof Jean-Louis Vanoverschelde....................................Name: xxxxx

Position:.Medical Director- CUSL………………………….....Position:……………………………………...

Date:.......................................................….... Date:.......................................................….....

# ANNEX 1

**Definitions**:

The following capitalized terms as used in this Agreement (whether in the singular or plural) shall have the respective meanings set forth below:

“**Affiliate**” means, with respect to a Party, any entity directly or indirectly controlling, controlled by, or under common control with such Party, where control means ownership of greater than 50% of the voting securities of an entity or such other relationship as result in actual control of the management, business, assets and affairs of an entity.

“**Biobank**” can be defined as a collection of human biological samples stored for medical-scientific research purposes, usually linked to phenotypic data called medical data. To collect material, CUSL have different strategies: they may collect tissue specifically for research purposes, but often contain residual samples as well. Residual samples refer to tissue that was taken in the course of clinical care and is leftover (e.g., a diagnostic biopsy or therapeutic removal of tissue). In many cases, the stored tissue will be most valuable for research when it remains linked to information about the person. Therefore, the included samples will often be stored coded and consequently will not be anonymous—if complete anonymization would be possible at all.

“**CUSL Materials**” means the specific Materials listed in Annex 2 of this Agreement and also includes the Data.

“**Confidential Information**” means any information disclosed after execution of this Agreement by the Disclosing Party to the Receiving Party for the Purpose, whether tangible or intangible, oral, visual, written or electronic, or in any other form. Information to which the Receiving Party gains access during visits to the facilities of the Disclosing Party shall also be Confidential Information**.** Confidential Information may include, but is not limited to, data, Know-How, formulas, compositions, processes, documents, designs, sketches, photographs, plans, graphs, drawings, specifications, software, source or object codes, algorithms, information about the methods, concepts and techniques on which software is based, chemical structures, amino/nucleic acid sequences, descriptions of cell lines, molecular models, clinical trial protocols, services, finances, financial models, business plans and marketing plans, reports, customer lists, pricing information, studies, results, findings, inventions, ideas and other knowledge. Confidential Information also includes the terms of this Agreement, as well as the fact that discussions are taking place with respect thereto.

Failure to expressly mark or designate any of the Confidential Information as confidential or proprietary shall not affect its status as Confidential Information under the terms of this Agreement.

“**Data**” means all clinical and pathological data related to the CUSL Materials. Those Data relating to patients shall remain confidential and no Data which would enable the Recipient to identify Data donors shall be provided by the CUSL to the Recipient. The Data are owned by the CUSL.

**“Information”** means any inventions (whether patentable or not), data, instructions, ideas, software, algorithms, discoveries, procedures, methods, techniques, formulae, biological sequences, advice and any other knowledge each in whatever form.

**“Derivatives”** means all products issued from Material. E.g.: RNA, DNA, unstained slide, proteins.

“**Finding**” means clinically relevant information for the donor(s) or discoveries or new safety information made during the Research that may have implications for the donor(s) or the his/her/their family members.

“**Intellectual Property Rights**” means all Patents, Trademarks, utility certificates and models, inventors’ certificates, copyrights, database rights, designs, domain names, Trade Secrets, Know-How and any other proprietary rights, priority rights, prior user rights, rights in Confidential Information and all other rights of a like nature in each case whether registered or unregistered and in any jurisdiction..

**“Know-How”** means any and all information such as unpatented inventions, formulae, designs, drawings, procedures and methods, together with accumulated skills and experience which could assist in the manufacture

and use of a product and bring to it a competitive advantage, which are in the possession of or developed by a Party

**“Materials”** means any tangible biological, chemical or physical materials, and any progeny, extracts, components, or functional sub-units thereof.

“**Patents**” means all patent applications and patents and any reissues, continuations, continuations in part, divisional applications, re-examinations, patent term extensions, supplementary protection certificates or the like and any substitutions, confirmations, registrations or additions of or to any of the foregoing.

“**Research**” means the specific research activities to be conducted by Recipient using the CUSL Materials, as set out in Annex 2 of this Agreement.

“**Research Ethics Committee**” means an independent body consisting of healthcare professionals and nonmedical members according to the applicable laws, whose responsibility it is to protect the rights, safety and well-being of human subjects involved in research and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial research protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.

“**Results**” means all data, information, results and inventions arising from any analysis conducted by Recipient within the framework of the Research using the CUSL Materials.

“**Third Party**” means any person or entity other than the Parties.

# ANNEX 2

**RESEARCH PROJECT DESCRIPTION**

 **ANNEX 3**

**SPECIFICITIES FOR THE TRANSFER OF THE CUSL MATERIAL**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Paraffin** |  |
|  |  | Amount | Thickness | Coloration |  |
|  | Bloc |   | - |  - |  |
|  | Section |   |   | yes/no\* |  |
|  |  |  |  |  |  |
|  | **Frozen** |  | **Fresh Biopsy** |
|  | Amount | Thickness |  | Amount |   |
| Section |   |   |  |  |  |
|  |  |  |  |  |  |
|  | Unstained slide \*\* |  |  | **Cells** |
|  | Eppendorf\*\* |  |  | Cell density |   |
|  |  |  |  |  |  |
|  |  | **Extraction** |   |  |
|  | DNA |   | µg |  |  |
|  | RNA |  | µg |  |  |
|  | Protein |   | mg |  |  |

* \* If yes, specify the type of coloration
* \*\* put a cross

 **ANNEX 4**

**DESCRIPTION OF THE FINANCIAL ASPECTS**

 **ANNEX 5**

**DATA PROCESSING AGREEMENT**

The terms used in this Addendum shall have the meanings set forth in this Addendum. Capitalized terms not otherwise defined herein shall have the meaning given to them in the Principal Agreement. Except as modified below, the terms of the Principal Agreement shall remain in full force and effect.

In consideration of the mutual obligations set out herein, the Parties hereby agree that the terms and conditions set out below shall be added as an Addendum to the Principal Agreement. Except where the context requires otherwise, references in this Addendum to the Principal Agreement are to the Principal Agreement as amended by, and including, this Addendum.

1. **Definitions (Can be expanded if necessary)**
	1. In this Addendum, the following terms shall have the meanings set out below:

### Applicable Data Protection Legislation: means (a) European Union or Member State laws with respect to any Personal Data in respect of which any Party is subject to EU Data Protection Laws; and (b) any other applicable law with respect to any Personal Data or the applicable safeguards Patient Rights legislation in respect of which Party is subject to this legislation including laws, decisions, directives, instructions and codes of conduct, promulgated by the courts, data protection authorities and all other competent governmental authorities.

### Agreement: The whole of the Huma Material Transfer for Research Purpose Agreement

### Study: To add

### Study Participant: An individual that participates in the Study as set out in article 1.1.3 of this Addendum.

### Personal Data: All personal data that is collected, revised, processed, corrected of acquired in the context of the Study.

### Research Staff: All persons who are involved in the Study and who are employees, independent contractors or agents of the Data Processor, including but not limited to: pharmacy, laboratory, radiology, pathology and nursing staff.

1. **Processing of Personal Data of Study Participants**
	1. Processor and Controller shall:
		1. Comply with their respective obligations under Applicable Laws while processing or studying Personal Data in connection to the Study, and
		2. Not process any Personal Data other than necessary for the Study.
	2. The Parties agree to adhere to the principles of medical confidentiality in relation to the enrolled subjects involved in the Study. Personal Data which shall for the avoidance of doubt include personally identifiable information as defined in the Applicable Data Protection Legislation, including Data Protection Directive 95/46/EC and its repealing regulation, the General Data Protection Regulation – EU 2016/679, becoming applicable as of 25 May 2018, shall not be disclosed to Controller save where this is required to satisfy the requirements of the Study or for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by the enrolled subject in connection with the Study (provided that this shall not prevent **Data Processor** from providing data in pseudo-anonymous form, such as through the use of coded data).
	3. Each Party hereby agrees to comply with all Applicable Data Protection Legislation. In particular, the **Data Processor,** processing data on behalf of the **Data Controller** agrees to:
		1. Maintain technical and organizational security measures sufficient to comply at least with the obligations imposed on the **Data Controller** by Applicable Data Protection Legislation;
		2. Restrict the processing of Personal Data for and on behalf of the **Data Controller**, in accordance with the instructions of the **Data Controller** and for the purpose of the Study and to ensure the **Data Controller’s** compliance with Applicable Data Protection Laws; where **Data Processor** is of the opinion that a data processing instruction by **Data Controller** is in violation of Applicable Data Protection Legislation, **Data Processor** will immediately inform **Data Controller** thereof in writing;
		3. **Respond** promptly to all reasonable and justified enquiries by the **Data Controller** regarding the processing of Personal Data.
	4. **Data Processor** shall at all times maintain a record of processing of Personal Data in accordance with the Applicable Data Protection Legislation and if the **Data Processor** considers an instruction from the **Data Controller** to be in violation of the Applicable Law, the Data Processor shall promptly inform the Data Controller in writing about this.
	5. The Data Processor shall upon request provide the Data Controller with sufficient information to enable the Data Controller to ensure that the Data Processor's obligations under this Agreement are complied with, including ensuring that the appropriate technical and organizational security measures have been implemented.
	6. The Data Processor must give authorities who by Union or Member State law have a right to enter the Data Controller's or the Data Controller's processors’ facilities, or representatives of the authorities, access to the Data Processor's physical facilities against proper proof of identity and mandate, during normal business hours and upon reasonable prior written notice.
2. **Processing of Personal Data of Data Processor’s Research Staff**
	1. The **Data Controller** may collect, process, store and transfer Research Staff Personal Data for the purposes of management and control of clinical trials, evaluation, audit, supervision, legal, regulatory, administrative and compliance, provided the Personal Data are processed in conformity with the Applicable Data Protection Legislation.
	2. The **Data Controller** will limit the collection, processing, etc. of the Personal Data as referred to in article 8.1, to the following categories of Personal Data: name, professional
	3. In addition to the provisions of article 2 of this Agreement, the **Data Processor** represents that the Research Staff has consented to the collection and use of their personal data by **Data Controller** in accordance with the Applicable Data Protection Legislation for the purpose of complying with clinical practice regulations, for answering requests from any relevant authority, agency or ethics committee; and for general trial management and monitoring purposes by the **Data Controller.**
	4. When personal data of Research Staff is transferred to entities established outside the European Union, the **Data Controller** takes measures to ensure that **Data Processor’s** Personal Data will be appropriately protected in accordance with the Applicable Data Protection Legislation and regulations. In accordance with this Applicable Data Protection Legislation each member of the Research Staff has a right to access, correct and delete their personal data collected by the **Data Controller**. Should such member wish to exercise such rights, s/he may contact at e-mail address: XXXX@XXXX.XXX.
3. **Confidentiality and Security**
	1. The **Data Processor** and **Data Controller** undertake to treat all Personal Data strictly confidential. Unless **Data Controller** requires otherwise in writing, **Data Processor** will not disclose Personal Data to any third party other than:
		1. To those of its employees, approved subcontractors and their employees to whom such disclosure is strictly necessary for the performance of their obligations under the Agreement; or
		2. To the extent required by law, by any governmental or other regulatory authority, or by a court or other authority of competent jurisdiction
	2. Any disclosure is made subject to strict obligations of confidentiality and data protection which can in no way be less onerous than those imposed upon **Data Processor** under this Agreement.
	3. The **Data Processor** and **Data Controller** shall take all necessary and reasonable steps to ensure the reliability of any employee, agent or contractor who may have access to any personal data or company data, ensuring in each case that access is strictly limited to those individuals who require this data in their professional activity. Both Parties ensure that all such individuals are subject to confidentiality undertakings or professional or statutory obligations of confidentiality.
	4. Having regard to the technology available, the cost of its implementation and having regard to the nature, scope, context and purposes of the processing of Study Participant Personal Data, all Parties will warrant that these measures provide a level of security appropriate to the risks.
4. **Subcontracting and Subprocessing**
	1. In order for a Party to make use of a third party in order to perform any of its obligations under this Agreement, the other Party must approve such delegation in writing prior to such delegation taking place. The Party who will make use of this third party shall ensure that this third party has entered into a written agreement containing provisions no less protective of personal data than those of this Agreement. The **Data Controller** has the right to receive a copy of the relevant provisions of **Data Processor’s** agreement with the subcontractor or subprocessor.
	2. Any Party who wishes to make use of a third party as specified under article 3.1 will take appropriate technical and organisational measures to protect the security, confidentiality and integrity of Personal Data.
	3. If the **Data Processor** wishes to subcontract all or part of the processing of Study Participant Personal Data, it will first provide to **Data Controller** prior written notice of its intention to engage any subcontractor setting out the following information in sufficient detail:
5. The name and address of the proposed subcontractor;
6. The subject matter of the proposes subcontract;
7. The countr(y)(ies) where the proposed subcontractor intends to process Study Participant Personal Data;
8. A description of the technical and organisational measures implemented by the proposed subcontractor to protect the security, confidentiality and integrity of Study Participant Personal Data that will be processed by the proposed subcontractor;
9. Any additional information that the **Data Controller** may reasonably require.
	1. The **Data Processor** will **remain** liable for all acts and omissions of the approved Subcontractors as fully as if they were the acts and omissions of the **Data Processor** or its Research Staff.
10. **Reporting Data Security Incidents**
	1. Will be referred to as a Data Security Incident, any actual or potential:
		1. Breach of security that leads (or may lead) to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, any Study Participant Personal Data (or any media or carrier containing the same) held by the **Data Processor;**
		2. Unauthorized processing of any Study Participant Personal Data held by the **Data Processor;**
		3. Breach by **Data Processor** of the obligations of this DPA or any Applicable Data Protection Legislation;
		4. Breach of security that leads (or may lead) to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, any Research Staff Personal Data (or any media or carrier containing the same) held by the **Data Controller.**
	2. In case of a Data Security Incident, **Data Processor** shall inform **Data Controller’s** data privacy officer in writing promptly and without any undue delay, but in any event within two (2) business days of becoming aware of any accidental or unlawful destruction or accidental loss or damage, alteration, unauthorized disclosure or access to the Personal Data.
	3. Any notification as referred to in article 6.2 will contain at least the following information:
11. The nature of the Personal Data breach, stating the categories and (by approximation) the number of Data Subjects concerned, and stating the categories and (by approximation) the number of the personal data registers affected (datasets);
12. The likely consequences of the Personal Data Breach.
	1. Each Party will duly document any Data Security Incident and each Party will, at their own expense, take the measures that are reasonable necessary to remedy any existing Data Security Incident, to prevent any (re-)occurrence of a Data Security Incident and to mitigate the impact of such incident on the Study Participant(s) or the other Party.
	2. **Data Processor** agrees to assist **Data Controller** with its obligation, in accordance with the Applicable Data Protection Legislation, to notify a security breach to competent supervisory authorities and individuals, to the extent that it has relevant information for **Data Controller** to meet its notification obligations and/or is better placed to inform relevant authorities or individuals;
	3. **Data Processor** agrees to implement without undue delay appropriate security and mitigating measures, in agreement with **Data Controller,** to limit the potential adverse effects of a security breach.
	4. **Data Processor** agrees to allow the **Data Controller** to audit the **Data Processors’** compliance with the requirements specified herein on reasonable notice and/or to provide the **Data Controller** with evidence of its compliance with the obligations set out in this Article.
	5. Parties agree to collaborate to inform the Data Subject of the Data Security Incident affecting this Data Subject in accordance with the Applicable Data Protection Legislation.
	6. **Data Controller** agrees to warn Personnel (including the Research Staff) of Data Processor in case of a Data Security Incident concerning Personal Data of Personnel (including the Research Staff) working for the Data Processor.
	7. **Data Controller** agrees to warn Data Processor in case of a Data Security Incident concerning Data of Study Participants even if the data is anonymized or secured.
	8. **Data Controller** agrees to warn Data Processor in case of a Data Security Incident in relation with the use of the information system of the Processor by the persons working on behalf of Data Controller (e.g. CRA, …).
13. **Cross-border transfers of Personal Data**
	1. The Parties shall obtain prior written agreement one another to store or process personal data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein), which agreement may be made subject to the fulfilment of certain conditions, such as executing EU Model Clauses for such transfers (as approved by the European Commission).
14. **Assistance when handling requests from data subjects**
15. The Parties agree to use all reasonable efforts to assist each other to comply with Applicable Data Protection Legislation. For the avoidance of doubt, this includes providing the other with reasonable assistance in complying with data access requests from all enrolled subjects and consulting with the other prior to the disclosure of any Personal Data created in connection with the conduct or performance of the Study in relation to such requests. This includes, without limitation, the right of the data subjects to be informed about the processing of their Personal data. All requests will be handled at the **Data Controller’s** costs and expenses to the extent such expenses are not related to any requirements according to the Applicable Data Protection Legislation on the **Data Processor**. The final responsibility of enabling data subjects to exercise their rights lies with the **Data Controller.**
16. **Liability**
	1. The Parties agree that any data subject, who has suffered damage as a result of any breach of the obligations referred to in this Agreement by any party is entitled to receive compensation from the **Data Controller** for the damage suffered.
	2. **Data Processor** will indemnify **Data Controller** in respect of all losses, damage, costs, expenses and other liabilities incurred by or awarded against **Data Controller** in connection with any claim or action against **Data Controller** by any data subject, any third party or any public authority resulting from a breach by the **Data Processor** of any obligation specifically directed at him under the Applicable Data Protection Laws or under the Agreement. The indemnification is limited to the damage or loss the **Data Controller** can provide proof for and shall in all cases be limited to the amount for which the **Data Processor** is insured.
	3. **Data Processor** will not be liable for any losses, damage, costs, expenses or any other liability incurred by the usage of **Data Processor’s** ICT system or any other technological and digital tool owned by the **Data Processor** by the **Data Controller** or any of its employees or persons working on behalf of the Data Controller.
17. **Termination of the Agreement and obligations after the termination of the Agreement**

Regardless of the expiry or termination, for whatever reason, of the Agreement, this Data Processing Agreement remains in force and is applicable as long as the **Data Processor** processes thePersonal Data for the **Data Controller** under the Agreement.

* 1. After expiration or termination of the Agreement, the **Data Processor** will receive a reasonable delay to delete or anonymize all the Study Participant Personal Data that it has processed in connection to the study.
	2. This deletion or anonymization will not be required for the Personal Data that could in any way concern the impact of the Study on the health of the Study Participant, in which case the applicable law requires the **Data Processor** to retain the Study Participant Personal Data after completion of the Study. However, the purpose of this Personal Data collection or processing will be limited to the purpose of the applicable law and will not, in any possible way, be used for the purposes of this Agreement or any later agreement between the Parties. When this provision is applicable, **Data Processor** will inform **Data Controller** hereof immediately after the termination of the Agreement, stating the basis, term and scope of such obligation.
	3. Once compliance with the obligation to delete or anonymize the Personal Data is no longer impeded by Union or Member State law, the **Data Processor** shall as yet erase the data in accordance with the provisions in the Agreement.
1. **Other Provisions**
	1. Any changes in this Agreement are only valid if they have been agreed between the parties in writing.
	2. The parties shall adapt this Agreement according to amended or new regulations, additional instructions from the relevant authorities and progressive insight into the application of the GDPR (including but not limited to, case law or reports) and/or any other event that makes such adaption necessary.
	3. This Agreement is governed exclusively Belgian law.
	4. The Parties shall submit each conflict arising from or related to this Agreement only to the competent courts of Brussels, Belgium.