# HUMAN MATERIAL TRANSFER AGREEMENT FOR RESEARCH PURPOSE

This Material Transfer Agreement is entered into and made effective as of 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. ***Université catholique de Louvain –*** SSS/…./XXX, a legal entity existing under the laws of ***Belgium***, with offices located at ***Place de l’Université 1, 1348 Louvain-la-Neuve*** (“**Recipient**” or “UCLouvain”).

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

# WHEREAS:

1. CUSL owns or controls human body material 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; and
2. 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
3. CUSL is willing to supply the CUSL Materials to Recipient for such use under the terms and conditions of this Agreement; and
4. CUSL acts as a Biobank in the meaning of the Belgian RD of 9 January 2018 regarding biobanks.

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

# Subject and Scope of the Agreement

* 1. CUSL will supply samples of the CUSL Materials to Recipient in such quantities as agreed between the Parties and as reasonably necessary to perform the Research ([**Protocol title – Principal investigator’s name**]), subject to the CUSL and Research Ethics Committee (Comité d’Ethique Hospitalo-Facultaire Saint-Luc-UCL) approval (***[ref Number]***).

If needed, CUSL shall also provide Recipient with Confidential Information and Data related to the CUSL Materials to facilitate the performance of the Research.

CUSL grants Recipient, who accepts, a limited right to use and to consume the CUSL Materials and related Confidential Information and Data solely for the approved Research as described in Annex 2. Recipient shall not use the CUSL Materials or the related Confidential Information or Data for any other purposes whatsoever without the prior written consent of CUSL and the “Comité d’Ethique Hospitalo-Facultaire Saint-Luc-UCL”.

* 1. The CUSL Materials and the Confidential Information related to these CUSL Materials are and shall remain the property of the CUSL.

The supply of any CUSL Material and/or the Confidential Information related to this CUSL Material to Recipient shall not be construed as a sale or any other form of transfer of ownership rights.

# Delivery, use and processing of the CUSL Materials

* 1. **Delivery of the CUSL Materials.** 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. **Financial considerations.** The financial aspects are specified in annex 4.
	3. **Data.**

CUSL shall only send pseudonymized and/or anonymized CUSL Material and Data to Recipient and shall not provide the Recipient with any Data or key to decode or identify the Donor except the unique identification code assigned to each donation and each human body material derived therefrom. Recipient shall refrain from tracing or identifying the identity of the Donor and shall not attempt to contact any Donor.

CUSL warrants that the Donors have consented, pursuant to 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 the CUSL Materials and related Confidential Information for the purposes of the Research.

* 1. **Use rights related to the CUSL Material granted to Recipient.**

Recipient agrees to use the CUSL Materials, Derivatives, Data and Confidential Information:

* in compliance with all applicable legislations;
* only if strictly needed for the performance of the Research and in strict compliance with the terms and conditions of this Agreement;
* only on its premises or on the premises of the authorized Representatives;
* only for investigational use and acknowledges that none of the CUSL Materials, shall be administered to or otherwise used in human beings

Notwithstanding the above, the CUSL Materials may be kept at the UCLouvain biolibrary and used for further research. Traceability and compliance with applicable legislation will be the responsibility of the Recipient, including but not limited to obtaining authorization from the Ethics Committee for any new research. The CUSL Material shall be destroyed or returned to the CUSL if it is no longer used.

The CUSL Materials shall not be used by Recipient in any research activity that is, or may be, subject to consulting or commercial licensing terms. Recipient shall not contract any research obligations with a Third Party, without the prior express written permission of CUSL.

Recipient has the right, under the supervision of Recipient’s principal investigator responsible for directing the Research, to submit the CUSL Materials to those Representatives:

- who are directly involved with the performance of the Research and only if their access to such CUSL Materials is needed, and

- subject to conditions at least as stringent to those of this Agreement; and

- provided Recipient informs CUSL hereof and maintains traceability; and

- provided this submission does not lead to a commercial use.

Recipient shall be responsible for ensuring the compliance by the Representatives with the terms and conditions of this Agreement and shall be liable hereunder with respect to any breach thereof.

Recipient shall keep the CUSL Materials, 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.

* 1. With respect to the CUSL Materials that remain on CUSL’s premises, Recipient acknowledges that CUSL shall be free, in its sole discretion, to use these CUSL Materials for any and all purposes, including without limitation of CUSL’s right to distribute, license or otherwise transfer or convey these remaining CUSL Materials to Third Parties, at any time, and without prior notice or any other obligation to Recipient
	2. Recipient shall ensure that all CUSL Materials will be handled with the greatest care to prevent any infection related to known or unknown pathogens. In any case, CUSL shall not be liable for any injury or disease contracted by the Recipient when handling the CUSL Materials, except in case of negligence, non-compliance to the Protocol or this Agreement by CUSL or in case of improper performance of its professional duties by CUSL team involved in the transfer and/or Research.

Recipient shall ensure that there is complete traceability of all CUSL Material and Data in case of use and destruction, if applicable. This means that it shall be possible to identify the location of any sample of the CUSL Material at all times; including identifying those that have been distributed or disposed of; including aliquots and Derivatives such as sections of tissue, components of tissue microarrays (TMAs) and extracts of nucleic acids.

More precisely, this means that:

* each sample and aliquot shall have a unique identifier,
* samples shall be labelled appropriately so that identification and traceability are maintained,
* each sample shall be associated with the relevant version of processing and storage SOPs (Standard Operating Procedures).
* each sample shall be associated with any significant event (such as a freezer thaw) that might impact on the characteristics of that sample.

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:
		1. 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,
		2. the applicable legislation on the processing of Personal Data,
		3. the law of 22 August 2002 relating to patient’s rights,
		4. the law on experiments including the law of 07 May 2004 on human experiment,
		5. 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 CUSL a final quality assessment report, when all the CUSL Material has been returned, used, consumed or destroyed, including assessment of the samples, the quantity used, the tests done, compliance with respect of the traceability.
	3. In case 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 within thirty (30) days following the findings of the information. The Research Ethics Committee (Comité d’Ethique Hospitalo-Facultaire saint-Luc-UCL) and the CUSL will inform the Donor(s) of such finding 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. Recipient must keep accurate records regarding its use of the CUSL Materials and, if required by CUSL, Recipient will allow 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 CUSL 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 CUSL 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. The CUSL material shall be destroyed or returned to the CUSL if it is no longer used. If the remaining CUSL Materials have been destroyed, a written document must certify that all CUSL Materials in Recipient’s possession have 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 CUSL discloses or otherwise makes available to Recipient any of CUSL’s Confidential Information, this information shall be subject to the same use restrictions as those that apply to the CUSL Materials.

# 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 Representatives whose performance of activities under this Agreement justifies the need to know such information and 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. Each Party shall be liable for acts by any of its 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 of confidentiality 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 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 in 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 that Party’s possession has been destroyed and/or erased (as applicable), however, that one copy may be retained by 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 Representatives and will cooperate with the other Party in every reasonable way to help regain possession of its Confidential Information and prevent its further unauthorized use or disclosure.

# Data Protection

# The Parties shall comply with all applicable laws and regulations regarding the protection of natural persons in processing of their personal data, which include the law of July 30th 2018 on the protection of natural persons with regard to the processing of personal data and the Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

* 1. The CUSL shall transfer to Recipient only anonymized or pseudonymised Data and Materials in accordance with the Law of 30 July 2018 on the Protection of Natural Persons with regard to the Processing of Personal Data.

# The Parties shall not disclose the Data and CUSL Materials to any person other that their Personnel as necessary to perform its obligations under this Agreement and ensure that such Personnel is subject to statutory or contractual confidentiality obligations.

# The Parties shall implement appropriate technical and organizational measures to protect Data and CUSL Materials against unauthorized or unlawful processing, loss, damage, or destruction, and to evaluate at regular intervals the adequacy of such security measures, amending these measures where necessary.

# Intellectual Property Rights

* 1. **Background.**

5.1.1. Ownership.

Each party retains exclusive ownership of the Intellectual Property Rights it held, or for which it held a license, prior to the date of signature of this Agreement or those that are generated or acquired at any time independently of this Agreement.

5.1.2. License rights.

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 existing Intellectual Property Rights.

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 subject to the terms of this Agreement, as detailed in article 2.

* 1. **Results.**

5.2.1. Ownership.

Parties have expressly agreed that all Results shall be the sole property of Recipient. In this regard, CUSL shall assign to Recipient all the Intellectual Property Rights, as and when they are created.

5.2.2. License rights.

If the Research which involves the CUSL Materials and the related Data and Confidential Information results in an invention, improvement or substance, whether or not patentable (“Invention”), Recipient hereby grants to CUSL 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) and for the patient care.

5.2.3. If a valorization of the Research Results can be considered, Recipient will promptly inform CUSL and LTTO (Louvain Technology Transfer Office). The Parties including LTTO 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. The agreement shall attribute the right of valorization to both UCLouvain and CUSL in a given proportion. The Parties shall negotiate in good faith, taking into account the agreements between the parties and without prejudice to Recipient’s intellectual property internal regulations. Every agreement within this scope stands on its own and will have no bearing on other research to be valorized.

* 1. 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 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.

# Publications and notifications

CUSL has been heralded as an essential tool 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:

6.1 It is the intent of Recipient to publish the Results (obtained from the CUSL Materials). Recipient shall provide the CUSL with a copy (pdf) of the publication.

6.2 CUSL Materials may be acknowledged in various sections, including materials and methods, acknowledgements and references. For further information, Recipient shall have a look at specific literature on this 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)*”.

6.3 Any publication or presentation using CUSL Materials shall include an acknowledgement using the text below:

***This research has been conducted using specimens from the CUSL Biobank collection (Belgian accreditation number BB190044), member of the Biothèque Wallonie Bruxelles (BWB) and of BBMRI-ERIC.***

6.4 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 CUSL Materials are being provided on an “as is” basis with no warranties of any kind, express or implied, with respect thereto, and 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. CUSL cannot be held liable if the CUSL Materials cannot offer the needed quality to conduct the Research.
	3. Recipient understands and acknowledges that CUSL cannot insure the quantity of the CUSL Materials needed for the Research. 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 CUSL have any liability or responsibility for, and Recipient shall indemnify and hold CUSL 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, except in case of negligence, non-compliance to Protocol or this Agreement by CUSL or in case of improper performance of its professional duties by CUSL team involved in the Research.
	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 .

# 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 Data and 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 Annexes 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 Annexes) 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 Annex, 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 Party 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 the 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.

Effective date:

## The CUSL Université catholique de Louvain

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: Pr. Etienne Marbaix Name: Pr. Vincent Blondel

Position: Head of the Biolibrary-CUSL

 Position: Rector

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: Pr. Jean-Louis Vanoverschelde Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: Medical Director- CUSL Position: Principal Investigator

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.

“**Agreement**” means this written human material transfer agreement between CUSL and Recipient, including the Annexes attached hereto.

“**Annexes**” mean the following annexes, which form an integral part of Agreement at the Effective Date:

Annex 1: Definitions

Annex 2: Research project description

Annex 3: Specificities for the transfer of the CUSL Materials

Annex 4: description of the financial aspects

“**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 CUSL owned tangible biological, chemical or physical materials, and any progeny, extracts, components, or functional sub-units thereof, as listed in Annex 2 of this Agreement.

“**Confidential Information**” means any information disclosed after execution of this Agreement by the Disclosing Party to the Receiving Party for the Research, 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 be anonymized and/or pseudonymised and shall remain confidential. *CUSL agrees that no Data which would enable the Recipient to identify Donors shall be provided by CUSL to the Recipient. The Data are owned by the CUSL.*

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

“**Donor(s)**” means the CUSL patient(s) who consented to the use of their biological samples as research material.

“**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.

**“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.

 “**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.

“**Protocol**” means the document describing the objective(s), design, methodology, statistical considerations and organisation of the Research including – but not limited to - the Research plan that defines the clinical tests to be performed and as set out in annex 2.

“**Representatives**” mean the agents, directors, consultants, contractors and employees of a Party having access to the CUSL Material and Data.

“**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 | Staining |  |
|  | 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**