#  AGREEMENT FOR SERVICES

This Agreement for Services (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. ***Université catholique de Louvain,*** a legal entity existing under the laws of ***Belgium,*** with offices located at ***Place de l’Université 1, 1348 Louvain-la-Neuve* (« Recipient »)**

# 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;
2. The Recipient is properly qualified and has the necessary personnel, expertise, facilities and experience to provide the Service requested by CUSL.

**The parties hereto agree to the terms and conditions contained herein:**

1. **Subject and Scope of the Agreement:**
	1. This Agreement provides for a contractual framework to the Service described in Appendix A attached hereto.

CUSL will supply samples of human body materials (“CUSL Materials”) to Recipient pursuant to this Agreement and in such quantities as agreed between the Parties in Appendix B.

If necessary for the performance of the Service, CUSL shall also provide Recipient with Confidential Information and Data related to the CUSL Materials.

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 performance of the Service as described in Appendix A. 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.

1. **Delivery**. CUSL 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.
2. **Financial considerations**. The financial aspects are specified in Appendix C.
3. **Use and processing of the CUSL Materials**
	1. CUSL Materials and the Confidential Information related to these CUSL Materials are and shall remain the sole and exclusive property of CUSL. The supply of any CUSL Material and/or the Confidential Information related to this CUSL Materials to Recipient shall not be construed as a sale or any other form of transfer of ownership rights.

CUSL shall only send pseudonymized and/or anonymized CUSL Materials and Data to Recipient and shall not provide the Recipient with any Data or key to decode or identify the patient.

* 1. Recipient agrees to use the CUSL Materials, Derivatives, Data and Confidential Information only for the duration and the performance of the Service and in strict compliance with the terms and conditions of this Agreement. The Recipient guarantees that the Material will not be used or transferred to any third party, without the prior agreement of CUSL.

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

The Recipient assumes all liability for direct damages which may arise from its use, storage, subprocessing or disposal of the Material.

The CUSL Materials delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The Recipient will be solely responsible for the use of the CUSL Materials under this Agreement.

Recipient shall ensure the complete traceability of the CUSL Materials and related Data. This means that it shall be possible to identify the location of any sample of the CUSL Materials at all times. The Recipient shall be able to track shipments from dispatch to receipt, whether or not a courier is used.

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.

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 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.

1. **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.

* 1. 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.
	2. 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.
	3. 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.
1. **Data protection**

The parties shall comply with the data protection laws and regulations applicable to this agreement. Pursuant to art. 28.3 GDPR the parties have concluded a data processing agreement attached in Appendix D.

1. **Intellectual Property Rights**
	1. Background. 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.

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.

* 1. Results.CUSL shall own all rights, title and interest in the results arising out from the Service and shall have the exclusive right to make a commercial use thereof.
1. **Term and termination:**

This Agreement shall have effect as from its Effective Date and unless earlier terminated shall expire upon the completion of the Service. 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. 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.

1. **Force majeure:** Neither Party shall be liable for failure to perform or delay in performing any obligation under this Agreement if the failure or delay is caused by any circumstances beyond its reasonable control, including but not limited to storms, floods, other acts of nature, fires, explosions, riots, war or civil disturbance. If such delay or failure continues for at least thirty (30) days, the Party not affected by such delay or failure shall be entitled to terminate this Agreement by notice in writing to the other.
2. **Miscellaneous:**
	1. This Agreement sets forth the entire understanding between the Parties concerning the subject matter hereof. No amendments, modifications or supplements to this Agreement may be made, except by means of a written document which is signed by authorized representatives of both Parties.
	2. The provisions of this Agreement are severable. If any provisions of this Agreement are determined invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not affect the validity or enforceability of the remaining provisions.
	3. The failure of a Party to assert a right or insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other. All waivers of any right under this Agreement to be effective must be in writing.
	4. No Party shall use, either directly or indirectly, the name of any other Party, or any of their officers, employees, students or board members in any publicity or advertising unless a copy is submitted to and approved in writing by the other Parties.
	5. Neither Party shall have the right to assign this Agreement without the prior written consent of the other Party.
3. **Litigation:** The Parties shall endeavour to resolve out of court any disputes arising between them out of or in connection with this Agreement. If no amicable settlement can be arrived at after two (2) months from the date on which the first Party to take action has notified the other Party of the existence of a controversy, the litigation will be referred to the French-speaking courts of Brussels, Belgium.

The Agreement shall be construed, governed, interpreted and applied according to Belgian law.

Effective date:

**The CUSLUniversité catholique de Louvain**

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

Name: Pr. Etienne Marbaix and/or Pr. Christine Galant Name: Vincent Blondel

Position: Head of the Biobank-CUSL and/or Head of

Anatomopathology departement Position: Rector

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

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

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

Position: Medical Director- CUSL Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

Name:

Position:

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

**APPENDIX A**

**DESCRIPTION OF THE SERVICES**

**APPENDIX B**

**CUSL MATERIALS SPECIFICITIES**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **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

**APPENDIX C**

**FINANCIAL ASPECTS**

**APPENDIX D**

**DATA PROCESSING AGREEMENT**

**BETWEEN :**

Cliniques universitaires Saint-Luc a legal entity existing under the laws of Belgium, with offices located at Avenue Hippocrate 10, 1200 Brussels, hereinafter « Data Controller »

**AND,**

Université catholique de Louvain, a legal entity existing under the laws of Belgium, with offices located at Place de l’Université 1, 1348 Louvain-la-Neuve, hereinafter « Data Processor »

1. **Scope of the data processing Agreement**
	1. The **RECIPIENT** acts as a data processor as defined under article 4, 8) of the Regulation (EU) 2016/679 (“Data Processor”) for the **Cliniques universitaires Saint-Luc** who acts as data controller as defined under article 4, 7) of the Regulation (EU) 2016/679 (“Data Controller”), as the **RECIPIENT** processes Personal Data for the Sponsor a described clause 7.
	2. The **RECIPIENT** will stay the Data Controller of its own purposes, such as research purposes or software improvement. For these purposes, the **RECIPIENT** will respect all the data protection applicable laws.
	3. “Applicable Law” means any applicable data protection or privacy laws, including

(a) the Regulation (EU) 2016/679 also referred as the General Data Protection Regulation ("GDPR"),

(b) national applicable laws that are at least as protective as the aforementioned Regulation.

1. **Processing of Personal Data**
	1. Instructions: The Data Processor is instructed to process the Personal Data for the term of this Data Processing Agreement and only for the purposes of providing the service. Data Processor may not process or use Personal Data in another way than provided in the instructions, including with regard to transfers of personal data to a third country or an international organization, unless the Data Processor is required to do so according to Union or Member State law. In that case, the Data Processor shall inform the Data Controller in writing of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest.
	2. Data Processor shall at all times maintain a record of processing of Personal Data in accordance with Applicable Law 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.
2. **The Data Processor's obligations**
	1. The Data Processor must ensure that persons authorized to process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
	2. The Data Processor shall implement appropriate technical and organizational measures to prevent that the Personal Data processed is:

accidentally or unlawfully destroyed, lost or altered,

disclosed or made available without authorization, or

otherwise processed in violation of Applicable Law.

* 1. The Data Processor must also comply with the special data security requirements of clause 7.
	2. The appropriate technical and organizational security measures must be determined with due regard for:

the current state of the art,

the cost of their implementation, and

the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons.

* 1. 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 Data Processing Agreement are complied with, including ensuring that the appropriate technical and organizational security measures have been implemented.
	2. Taking into account the nature of the processing, the Data Processor shall assist the Data Controller, by means of appropriate technical and organizational measures, insofar as this is possible, in fulfilling its obligation to respond to requests from data subjects pursuant to laws and regulations in the area of privacy and data protection (such as, the right of access, the right to rectification, the right to erasure, the right to restrict the processing, the right to data portability and the right to object).
	3. The Data Controller is entitled to appoint at its own cost an independent expert, reasonably acceptable to Data Processor, who shall have access to the Data Processor's data processing facilities and receive the necessary information for the sole purpose of auditing whether the Data Processor has implemented and maintained said technical and organizational security measures. The expert shall upon the Data Processor's request sign a non-disclosure agreement provided by the Data Processor, and treat all information obtained or received from the Data Processor confidentially, and may only pass on, after conferral with Data Processor, the findings as described under article 3.9, (ii) below to the Data Controller.
	4. 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.
	5. The Data Processor must within 24 hours in writing notify the Data Controller about:

any request for disclosure of Personal Data processed under the Agreement by authorities, unless expressly prohibited under Union or Member State law,

any finding of (a) breach of security that results in accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data transmitted, stored or otherwise processed by the Data Processor under the Agreement, or (b) other failure to comply with the Data Processor's obligations under Clause 3, or

any request for access to the Personal Data (with the exception of medical records for which the Data Processor is considered data controller) received directly from the data subjects or from third parties.

* 1. Such a notification from the Data Processor to the Data Controller with regard to a breach of security as meant in Clause 3.9 (ii)(a) will contain at least the following information:

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);

The likely consequences of the Personal Data breach;

A proposal for measures to be taken to address the Personal Data breach, including (where appropriate) measures to mitigate any possible adverse effects of such breach.

The Data Processor shall document (and shall keep such documentation available for the Data Controller) any Personal Data breaches, including the facts related to the Personal Data breach, its effects and the corrective measures taken. After consulting with the Data Controller, the Data Processor shall take any measures needed to limit the (possible) adverse effects of Personal Data breaches (unless such consultation cannot be awaited due to the nature of the Personal Data breach).

* 1. The Data Processor must promptly and reasonably assist the Data Controller (with the handling of (a) responses to any breach of security as described in 3.9 (ii) above and (b) any requests from Data Subjects under Chapter III of the GDPR (upon its entry into force), including requests for access, rectification, blocking or deletion. The Data Processor must also reasonably assist the Data Controller by implementing appropriate technical and organizational measures for the fulfilment of the Data Controller's obligation to respond to such requests. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the above will be reimbursed by the Data Controller to the extent such costs and expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to any breach of this Agreement by Data Processor.
	2. The Data Processor must reasonably assist the Data Controller with meeting the other obligations that may be incumbent on the Data Controller according to Union or Member State law where the assistance of the Data Processor is implied, and where the assistance of the Data Processor is necessary for the Data Controller to comply with its obligations. This includes, but is not limited to, at the request to provide the Data Controller with all necessary information about an incident under Clause 3.9 (ii), and all necessary information for an impact assessment in accordance with Article 35 and Article 36 of the GDPR. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the above will be reimbursed by the Data Controller to the extent such expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to breach of this Agreement by Data Processor.
1. **SubProcessors**

The Data Processor may only engage a subprocessor, with prior specific or general written consent from the Data Controller. The Data Processor undertakes to inform the Data Controller of any intended changes concerning the addition or replacement of a subprocessor by providing a reasonable prior written notice to the Data Controller. The Data Controller may reasonably and in a duly substantiated manner object to the use of a subprocessor. The Data Processor must inform the Data Controller in writing of the discontinued use of a subprocessor.

Prior to the engagement of a subprocessor, the Data Processor shall conclude a written agreement with the subprocessor, in which at least the same data protection obligations as set out in this Data Processing Agreement shall be imposed on the subprocessor, including obligations to implement appropriate technical and organizational measures and to ensure that the transfer of Personal Data is done in such a manner that the processing will meet the requirements of the Applicable Law.

The Data Controller has the right to receive a copy of the relevant provisions of Data Processor's agreement with the subprocessor related to data protection obligations. The Data Processor shall remain fully liable to the Data Controller for the performance of the subprocessor obligations under this Data Processing Agreement. The fact that the Data Controller has given consent to the Data Processor's use of a subprocessor is without prejudice for the Data Processor's duty to comply with this Data Processing Agreement.

1. **Confidentiality**
2. The Data Processor shall keep Personal Data confidential.
3. The Data Processor shall not disclose the Personal Data to third parties or take copies of Personal Data unless strictly necessary for the performance of the Data Processor's obligations towards the Data Controller according to this Data Processing Agreement, and on condition that whoever Personal Data is disclosed to is under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies. Notwithstanding the foregoing, the Institution shall remain Data Controller for its own processing in relation to the personal data processed for healthcare purposes.
4. The Data Processor shall ensure that its employees comply with this Data Processing Agreement.
5. The Data Processor shall limit the access to Personal Data to employees for whom access to said data is necessary to fulfil the Data Processor's obligations towards the Data Controller.
6. The obligations of the Data Processor under Clause 5 shall continue until such time as provided by Applicable Law and regardless of whether the cooperation of the parties has been terminated.
7. **Term and termination of the Data Processing Agreement**
8. Regardless of the expiry or termination, for whatever reason, of the Agreement, this Data Processing Agreement remains in force and applicable as long as the Data Processor processes the Personal Data for the Data Controller under the Agreement.
9. In case of termination of the Agreement, the Data Processor must provide the necessary transition services to the Data Controller. The Data Processor is obliged to reasonably assist Data Controller at Data Controller’s expense.

Notwithstanding 1. 2, upon termination of the Agreement, on instructions of the Data Controller, the Data Processor must destruct or send back the Personal Data to the Data Controller or another designated Processor

1. **INSTRUCTIONS**

***Based on the CPVP Recommendation n° 06/2017 of 14 June 2017***

**Object/purpose of the process:**

The data process operated by………………………..– acting as a processor–under the instructions of Cliniques universitaires Saint Luc - Controller- allow the collect and management of patient’s personal data to ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….

**Type of data:**

**Description of process - Instructions:**

**Data retention periods:**

**Process foundation and legitimacy:**

Medical healthcare

……………………..

………………………

**Purpose of the process:**

**Data subject:**

- Patients

- Healthcare professional (account data)

- indirectly: patient’s relative (genetic data may give information about relatives)

**Recipient category:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| ***Data protection Officer (DPO) of the Data Controller*** |  |
| Name : | *DE NEEF Violette**MOLLERS Géry* |  |
| Function : | *Juriste – DPO**CSSI - DPO* |  |
| Phone Number | *02 764 23 65**02 764 11 11* |  |
| E-mail : | *Rgpd-saintluc@uclouvain.be* |  |

|  |  |
| --- | --- |
| ***Data protection Officer (DPO) of the Data Processor*** |  |
| Name : | *REMY Michèle**NINANE Alain* |  |
| Function : | *Juriste – DPO**Responsable SGSI* |  |
| Phone number | *010.47 38 02**010 47 96 48* |  |
| E-mail : | *privacy@uclouvain.be* |  |