

ELIXIR-LU Hosting and Processing Agreement ("General Terms of Services")

REMARKS

[These introductory remarks are meant to provide background and instruction to the Data Provider. They are not part of the Hosting and Processing Agreement and shall be removed before the signature of the contract.]

The Luxembourg Centre for Systems Biomedicine at the University of Luxembourg ("UL/LCSB") is the Luxembourg node for ELIXIR, an intergovernmental consortium that brings together life science resources from across Europe. These resources include databases, software tools, training materials, cloud storage and supercomputers.

ELIXIR is coordinated by the ELIXIR Hub hosted by the European Molecular Biology Laboratory with Nodes in member states and other countries with the aim to provide seamless and sustainable data infrastructures for research in the life sciences. The national nodes are constituted of bioinformatics centres of excellence that represent a national strength and priority and provide nationally coordinated services.

This ELIXIR-LU Hosting and Processing Agreement constitute the general terms of services ("General Terms of Services") that govern the services provided by UL/LCSB (acting as member of the ELIXIR Luxembourg node) to the Data Provider. The General Terms of Services have been developed to enable UL/LCSB to provide Data Providers a secure platform (the Luxembourg ELIXIR Platform) to share their research data in order to fulfil their sustainability obligations and provide access to existing research data for new research projects.

The Luxembourg ELIXIR Platform is financed by the Government of the Grand Duchy of Luxembourg and UL/LCSB and the Services are provided in principle free of charge.

- (1) As such, the General Terms of Services are non-modifiable, except where stated otherwise.
 - a. Sections that require input by the Data Provider are highlighted in yellow.
 - b. For reasons of operability and traceability the following sections are non-negotiable:
 - i. 2. Warranties, responsibilities and liability by/of UL/LCSB.
 - ii. 4. Controlled access option
 - iii. 15. Governing law and jurisdiction
 - iv. Any notification periods.
 - c. Where Data Providers would like to propose a different wording in order to improve clarity, fairness and/or stringency, please contact us with your proposal.
- (2) The agreement is intended as a bilateral agreement to be concluded between, UL/LCSB and the Data Provider. In the case where a consortium of Data Providers wishes to conclude this agreement with UL/LCSB, each Data Provider, meaning each consortium partners that is a cohort owner and/or controls the use of data that will be hosted on ELIXIR-LU must become a party to and sign this agreement (multi-party agreement). For avoidance of doubt, the party to this agreement is usually controlling or responsible for the creation of data. The coordinator of the project cannot sign this agreement on behalf of the other consortium partners.

- (3) Data hosted on the Luxembourg ELIXIR Platform are considered either open or controlled access. The controlled access option is described in Figure 1 below.
- (4) UL/LCSB will conclude a Data Use Agreement with Users on behalf of the Data Provider. The Data Provider may download and review the template that UL/LCSB uses from the ELIXIR-LU website. The terms of the ELIXIR-LU Data Use Agreement are non-negotiable, however, wording may be subject to change, e.g. to improve clarity of the provisions. UL/LCSB will inform the Data Provider of any changes to the Data Use Agreement.
- (5) The Data Access Policy will be built upon the information provided by the Data Provider through the Data Information Sheet (DISH). The DISH template will be provided by UL/LCSB.
- (6) This agreement is by default concluded for 10 years, for the following reasons:
 - a. The Data Provider wishes to share its research data and make the data available for re-use in research, thereby fulfilling long-term sustainability obligations. The agreement needs to cover the entire time that ELIXIR-LU hosts and shares data provided by the Data Provider. (For reasons of reproducibility, the data will be archived for another 15 years after termination of the agreement.)
 - b. Any research projects using the data must have sufficient time to be conducted and its results published.
 - c. ELIXIR-LU is investing considerable efforts in order to host and share the data. These efforts need to be reflected and thus justified by impact through long usability of the data.

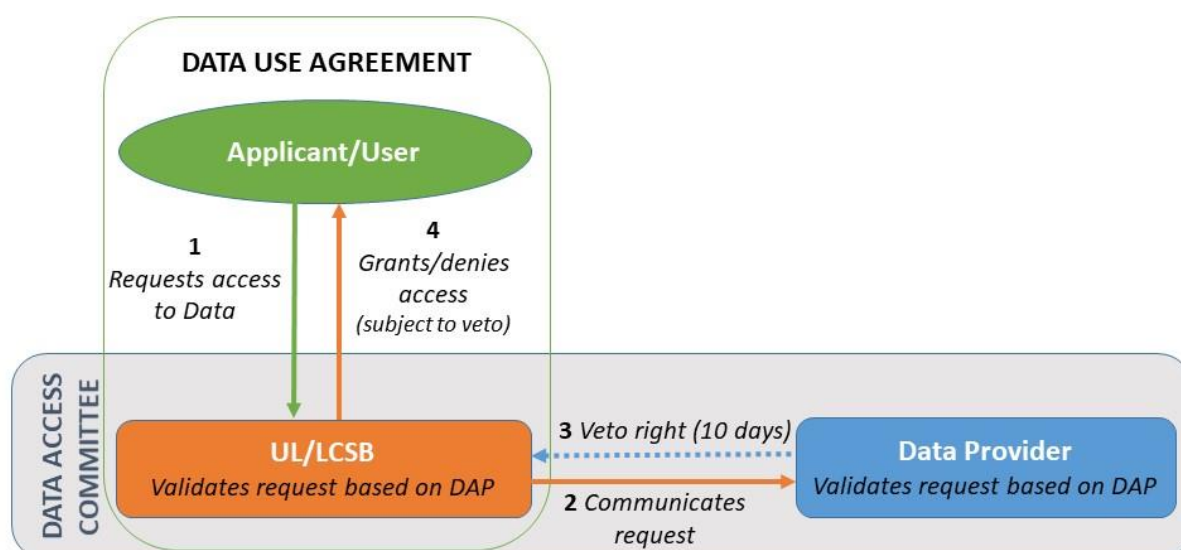


Figure 1: Schematic overview of controlled access. Representatives of both, UL/LCSB and the Data Provider, form the Data Access Committee (DAC). To gain access to restricted Data, (1) users must apply for access to UL/LCSB, UL/LCSB representatives of DAC validate the data access request based on the Data Access Policy (DAP). (2) In case of approval this request is communicated to the Data Provider if (3) the Data Provider does not exercise its right to veto the request within two (2) calendar weeks of being notified, (4) UL/LCSB grants access to the data and concludes the Data Use Agreement with the User.

CONTACT

For questions and support, please contact Venkata.Satagopam@elixir-luxembourg.org

[Change Records]

Version	Date	Changes	Contributors
Version 1	October 2018		Regina Becker Clemens Ostrowicz
Version 2	July 2019	<ul style="list-style-type: none">▪ Merging of former Services Agreement with General Terms of Services▪ Remarks added, incl. details of controlled access▪ Change records added▪ Annexes revised▪ General changes to improve clarity of the provisions▪ Termination provisions	Linda Ebermann Romain Gérard Regina Becker Venkata Satagopam
Version 2.2	October 2020	<ul style="list-style-type: none">▪ VAT number added▪ Definition of Anonymisation extended, reference to WP29 included▪ Options for anonymised data added▪ List of services extended▪ Additions to 15. Miscellaneous (e.g. list of confidential information, pandemics added to force major)▪ Minor wording and format changes	Elodie Simonian Benedetta Marsicola Sandrine Munoz Wei Gu Linda Ebermann
Version 2.3	May 2023	<ul style="list-style-type: none">▪ Clarification of the responsibility for data minimisation▪ Minor change to controlled access option in Annex A	Vilem Ded Marina Popleteeva
Version 2.4	March 2024	<ul style="list-style-type: none">▪ University address and head of LCSB information update	Marina Popleteeva

ELIXIR-LU HOSTING AND PROCESSING AGREEMENT (the “**General Terms of Services**”)

between

[...] duly represented by [...], hereinafter “**the Data Provider**”

and

the University of Luxembourg, a Public Institution of Higher Education and Research, having its registered office at 2, place de l’Université, L-4365 Esch-sur-Alzette, registered in the register of trade and companies of Luxembourg under No J20, with VAT number LU19805732 acting for its Luxembourg Centre for Systems Biomedicine, 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, G.D. Luxembourg, duly represented by its Director Prof. Dr. Michael Heneka, hereinafter “**UL/LCSB**”

Individually referred to as a “**Party**” or collectively referred to as the “**Parties**”.

Preamble

Whereas,

- UL/LCSB disposes of a centralized IT infrastructure that allows data hosting;
- UL/LCSB is a member of the Luxembourg node (the “**Luxembourg Node**”) for the European Life-Science Infrastructure for Biological Information (“**ELIXIR**”) an intergovernmental consortium that brings together life science resources from across Europe;
- the Data Provider is [PLEASE INSERT DESCRIPTION] and wishes to store biomedicine data (the “**Data**”) and provide access to such Data to third parties under the conditions listed in these General Terms of Services;
- each of the Parties recognises as a priority the need to respect the fundamental interests and rights of Data subjects (the “**Data Subjects**”), including the need to preserve the security and confidentiality of the Data;
- the infrastructure of Data processing is designed to allow compliance with binding European legislation on the protection of personal data (hereinafter the “**Data Protection Law**”), in particular the EU General Data Protection Regulation 2016/679 (GDPR). It is of high importance to process the Data in compliance with relevant applicable laws and regulations, including, without limitation, privacy and medical secrecy laws applicable to the activities of the Parties;

The Parties hereby agree as follows:

1. Definitions

Anonymisation shall mean the process of irreversibly transforming Data into any information that does not relate to an identified or identifiable person or to personal data rendered anonymised in such a manner that the Data Subject is not or no longer identifiable following the former Working Party 29 opinion 05/2014 on Anonymisation Techniques.

Data shall mean biomedical data, including personal and anonymised data, provided by the Data Provider to the Luxembourg ELIXIR Platform and identified and listed in Annex D.

Data Access Committee shall mean the committee formed by representatives of UL/LCSB and the Data Provider, that reviews the application of access from Users and grants/declines access based on the Data Access Policy determined by the Data Provider.

Data Access Policy shall mean access control policy determined by the Data Provider on the basis of which UL/LCSB, acting on behalf of the Data Provider, grants to Users controlled access to Data stored on Luxembourg ELIXIR Platform. The Data Access Policy is detailed in Annex D.

Data Protection Law shall mean the EU Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, as well as its implementing and successors texts.

Data Catalog means the platform where third parties can search the metadata for Data hosted by UL/LCSB.

Data Use Agreement shall mean the data use agreement that the UL/LCSB shall conclude in its own name and on behalf of the Data Provider with Users regarding the access and use of Data hosted on the Luxembourg ELIXIR Platform.

Ethics Approval shall mean any documented decision by competent ethics authorities or bodies allowing the Parties to process the Data for the purposes and in the conditions set forth hereunder.

Hosting and Processing Agreement shall mean this agreement, concluded between the Data Provider and the UL/LCSB, and also referred to as “General Terms of Services”.

Luxembourg ELIXIR Platform shall mean the platform hosted by UL/LCSB and which will be used by UL/LCSB (1) to receive Data from the Data Provider, (2) to store Data and (3) to allow Users to access Data as per the Data Access Committee’s decisions.

Processing shall mean the acts of processing carried out by UL/LCSB on the Data whilst providing the Services.

Services shall mean secured Data storage services and other ancillary services (including the management of the Data Access Committee and other tasks mentioned in these General Terms of Services) provided by the UL/LCSB, including Luxembourg ELIXIR Platform. The scope of Services is described in Annex A.

User shall mean any legal person registered with Luxembourg ELIXIR Platform to whom access to Data hosted on the Luxembourg ELIXIR Platform has been granted by the Data Access Committee as per the Data Access Policy or otherwise with the Data Provider’s approval.

The terms ‘controller’, ‘processor’, ‘recipient’, ‘personal data’, ‘data subject’, ‘processing’, ‘pseudonymisation’ and ‘personal data breach’ have the same meaning in these General Terms of Services and in the Data Protection Law.

Other capitalised terms shall have the same meaning as in these General Terms of Services and/or its annexes.

2. Services provided by UL/LCSB

In the context of the ELIXIR programme, UL/LCSB acting as member of the Luxembourg Node provides the following Services:

- secure data transfer channels,
- secure storage of the Data on the Luxembourg ELIXIR Platform,
- storage of metadata of the datasets in a Data Catalog to further improve findability of the data,
- basic curation of the Data,
- re-pseudonymisation of the Data,
- support in data minimisation at the point of its submission to the Platform
- if applicable, management of the Data Access Committee in the conditions detailed in these General Terms of Services, and
- allowing Users to access the Data from the Luxembourg ELIXIR Platform.

The Services selected by the Data Provider are further detailed in Annex A.

UL/LCSB will make all reasonable efforts to maintain continuity of the Services and will provide, on a best effort basis warning of changes or discontinuities. However, UL/LCSB does not provide any

warranty as to the uninterrupted availability of the Services and accepts no responsibility for the consequences of any temporary or permanent discontinuity thereof.

Only Data that is compatible with general ELIXIR European framework and goals shall be eligible for the Services. The Data Provider has to ensure that the Data provided to the Luxembourg ELIXIR Platform is provided in a structured manner, easily readable and usable format and in accordance with guidelines UL/LCSB may issue from time to time.

UL/LCSB retains a right to refuse storing/hosting Data, or to discontinue with immediate effect the storage of Data on its Luxembourg ELIXIR Platform, in which latter case the Data Provider accepts that UL/LCSB may decide, in its discretion, to proceed immediately and without further notice to the destruction of all copies of Data held by UL/LCSB hereunder, if:

- the Data exceeds the limit of [PLEASE INDICATE THE LIMIT]; or
- the Data Provider fails to provide metadata; or
- the Data Provider does not respect the General Terms of Services; or
- the Data Provider unreasonably delays Data Access Committee decisions or denies access to Users; or
- the Data Provider is found in breach of its representations and warranties under Annexes A and/or D; or
- UL/LCSB is notified by Users or third parties about the illegal or infringing nature of Data; or
- based on reasonable grounds, UL/LCSB considers that Data is infringing third parties' rights or may otherwise be illegal or its processing in the course of Services be contrary to Data Protection Law.

The role of UL/LCSB is limited to the provision of the Services, UL/LCSB itself does not determine, nor has knowledge or control on, the quality of Data provided by the Data Provider.

Subject to applicable law, UL/LCSB takes no responsibility and assumes no liability for any Data or other materials posted, stored, or uploaded by the Data Provider on the Luxembourg ELIXIR Platform or for any loss or damage to any of such Data.

3. Data

The Data are identified and listed in Annex D.

4. Data Access

By accepting these General Terms of Services, the Data Provider understands and accepts that the European ELIXIR initiative is based on open access and data sharing in order to establish sustainable infrastructure for research in the life sciences. Data Provider expressly accepts to grant [open/controlled] access to the User to Data stored on, hosted on and/or transmitted to Luxembourg ELIXIR Platform under the conditions established in these General Terms of Services.

The Data Provider may choose one of the below Data access options (actual Data Provider's choices are determined in Annex A):

- **OPTION 1: Open access.** Open access allows any User registered with the Luxembourg ELIXIR Platform to access Data in an unrestricted manner. If the Data Provider retains this option, it undertakes to place exclusively anonymised Data on the Luxembourg ELIXIR Platform.
- **OPTION 2: Controlled access.** Controlled access permits the Data Provider to establish the Data Access Policy to control access to Data based on non-discriminating criteria. Based on the Data Access Policy, the Data Access Committee shall grant access to individual Users, control their access to Data. UL/LCSB shall enter into written Data Use Agreements with Users.

[OPTION 1: Data Provider hereby instructs UL/LCSB to control on behalf of the Data Provider access to Data.	[OPTION 2: The Data Provider hereby authorises and empowers:
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<p>The Parties note that the Data do not include personal data and thus that the Data Protection Law does not apply to the Services.</p>	<ul style="list-style-type: none">▪ UL/LCSB’s representatives in the Data Access Committee to decide on Data access requests by third parties applying to become Users and to access the Data (“Decision”),▪ UL/LCSB to communicate (emails accepted) such Decision to the Data Provider;▪ its own representatives to the Data Access Committee to exercise on its behalf a right to veto (by way of written/electronic notification, including via the Portal, addressed to the Data Access Committee) on the Decision within two (2) calendar weeks of their notification by UL/LCSB. In line with the objective of the ELIXIR initiative, the Data Provider undertakes to exercise its veto right only if legitimate reasons exist to object to the Decision. If the veto right is not exercised within this time limit, the Decision will be deemed to have been accepted by the Data Provider and UL/LCSB’s representatives in the Data Access Committee will be entitled to grant the User status to applicants and grants them access to the Data.▪ UL/LCSB’s representatives to sign a Data Use Agreement with a new User acting both in its own name and on behalf of the Data Provider once a Decision has been taken and no veto has been exercised. <p>The Parties note that, in such a case, the Luxembourg data protection authority (‘Commission nationale pour la protection des données’ or CNPD) has ruled that UL/LCSB and the Data Provider will act in capacity as joint controllers with respect to the decision to grant access to the Data.</p> <p>In line with article 26 of the Data Protection Law, the Parties have determined and declare that:</p> <ol style="list-style-type: none">1. The Data Provider will be in charge of and liable for:<ol style="list-style-type: none">a. collecting the Data,b. obtaining Data subjects’ documented, valid and informed consent, or Ethics Approval allowing for the Data processing set forth hereunder,c. informing Data subjects of Data processing set forth hereunder, or documenting the application of Data Protection Law’s exception to information duties,d. pseudonymising the Data, ande. reviewing the Data access request and approving the Decision or exercising its veto right;t
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	<p>2. UL/LCSB will be in charge of and liable for preparing the Decision in line with the Data Access Policy, communicating them to the Data Provider, and validating Users' access requests (where the Data Provider has not exercised its veto right).</p> <p>With respect to the remainder of the Services, the Parties note and agree that UL/LCSB acts as a processor to the Data Provider.</p>
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[OPTIONAL: The Data Provider may request UL/LCSB to store the Data on the Luxembourg ELIXIR Platform without allowing any access to Users for a limited period of time (the “Embargo Period”) which may not be longer than eighteen (18) months. The Data Provider shall pay UL/LCSB for the fees, costs and expenses associated with closed access storage and related services should the Data Provider fail to make the data available on the Luxembourg ELIXIR Platform for at least five (5) years after the end of the Embargo Period.]

The Data Access Policy established by the Data Provider should respect the following principles:

- contain clear and precise requirements for Data access;
- should not contain any discriminating criteria based, e.g., on nationality, gender, race, political opinions;
- should contain Data use conditions, including terms for publication and intellectual property provisions;
- should contain Data access restrictions stemming from personal data protection, ethics or other national legal requirements.

The access to the Data requested by User can be approved and given per entire datasets as defined in Annex D. Platform cannot produce subsets or give access to only selected variables within the Data. Data Providers can, with support of the Platform, minimise the Data and submit it as a new dataset along a new Access Policy in an amendment to Annex D.

5. Fees and payments

The Luxembourg ELIXIR Platform is financed by the Government of the Grand Duchy of Luxembourg and UL/LCSB, thus, the Services are provided in principle free of charge.

However, UL/LCSB reserves the right to apply fees in certain particular situations where the amounts of the Data stored by the Data Provider exceeds the limit of 10TB. Such fees will be agreed upon between the Parties according to the amount of excessive Data.

Should the public financing of the Luxembourg ELIXIR Platform be discontinued, UL/LCSB may request the payment of fees for the Services at any time by providing the Data Provider thirty (30) days written notice. Upon such notification, the Data Provider will have a possibility to terminate these General Terms of Services. After expiry of the notification date and if the Data Provider has not responded, the Services will be terminated in accordance with clause 14.

6. Privacy and Personal Data Processing

<p>[OPTION 1; Not applicable]</p>	<p>[OPTION 2: 6.1 Processing. The Data Provider has requested UL/LCSB, who has accepted, to provide the Services. In this context, the Data Provider expressly requests UL/LCSB to carry out the acts of processing on the Data that are necessary to provide the Services.</p> <p>The processing will:</p> <p>a. concern Data provided by the Data Provider to UL/LCSB in the context of these General Terms of Services, and any other Data category the Data Provider may instruct UL/LCSB to store or process from time to time</p>
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	<p>through the performance of this Hosting and Processing Agreement or documented instructions, and</p> <p>b. include the acts of processing detailed in or necessary for the performance of this Hosting and Processing Agreement, related documentation and UL/LCSB's internal procedures, and any other acts of processing the Data Provider may instruct UL/LCSB to carry out from time to time through documented instructions.</p> <p>The Data Provider undertakes:</p> <ul style="list-style-type: none"> - to transfer to UL/LCSB for the Services purposes only Data [that has been anonymised or] for which a documented, valid legal ground and informed consent of the Data Subject according to recognised ethical standards and/or appropriate Ethics Approval for transfer and use in ELIXIR has been obtained; - to transfer the Data to UL/LCSB using secure and encrypted communications channels agreed upon with UL/LCSB prior to Data transfer; - to comply with the Data Protection Law (and, in addition, to the extent applicable, Data Provider's local data protection law); - to only communicate anonymised or pseudonymised Data, acknowledges that the Luxembourg ELIXIR Platform is not designed or intended to store and handle 'full' personal data (e.g. not anonymised or pseudonymised) . The Data Provider declares being familiar with the UL/LCSB's infrastructure and processes, as well as with Luxembourg ELIXIR Platform's security measures (including without limitation the measures stated in Annex B to this Hosting and Processing Agreement) and declares them (a) adapted with respect to the nature, volume and sensitivity of the Data, and (b) as applicable, compatible with the documented, valid and informed consent obtained from Data subjects or the terms of Ethics Approval obtained in view of the Services; - to assist promptly UL/LCSB by providing all necessary information and documents (including relevant Data subjects' consent or Ethics Approval) that may be requested by competent authorities; - to inform UL/LCSB seven (7) working days before for any removal of Data due to Data subject's consent or Ethics Approval withdrawal; - to inform (email accepted) UL/LCSB when the Data have to be deleted or rendered anonymous in accordance with Data Protection Law or Data Provider's local data protection law with at least ten (10) working days' prior notice; - to appoint a point of contact to handle Data subjects' requests or exercise of their statutory rights on their Data. <p>UL/LCSB undertakes:</p> <ul style="list-style-type: none"> - not to perform any act of Processing nor to process the Data for purposes other than delivering the Services, performing its obligations under these General Terms of Services, complying with applicable law or otherwise as instructed by the Data Provider through documented instructions; - to assign to the Processing and give access to the Data exclusively to its personnel subject to a contractual or statutory confidentiality obligation; - to assist the Data Provider to the best of its ability in responding to: <ul style="list-style-type: none"> a. personal data protection statutory or regulatory requirements applicable to the Data Provider (such as, data protection impact assessments), b. Data subjects' requests or exercise of their statutory rights on their Data (being noted that the Data Provider shall be solely liable for handling such requests); c. the Data Provider's requests for information on Data processing conditions, d. the Data Provider's auditors requests, audits or inspections, and e. the Data Provider's local authorities' queries or audits. <p>In such case, UL/LCSB may charge justified fees (on a time and material basis) and expenses to the Data Provider;</p>
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	<ul style="list-style-type: none">- inform the Data Provider if UL/LCSB becomes aware that a Data processing operations hereunder, the Services or instructions issued by the Data Provider (including in the context of Data Access Committee's decisions) breaches Data Protection Law. <p>6.2 Subprocessing</p> <p>UL/LCSB may use subprocessors (the “Subprocessors”) for delivering Services to the Data Provider. Subprocessors include the entities listed in Annex A. Other Subprocessors may take part in the Data processing, subject to,</p> <ul style="list-style-type: none">a. informing the Data Provider beforehand in writing (email accepted),b. the Data Provider's not objecting such appointment (on reasonable grounds) within fourteen (14) days of such information. <p>UL/LCSB's and each Subprocessor must enter into a written processing agreement compliant with Data Protection Law requirements.</p> <p>The Data Provider hereby authorises and instructs UL/LCSB to transfer Data to Subprocessors, and the latter to process the Data. Where Subprocessors are located outside the EU/EEA, the Data Provider will cooperate with UL/LCSB (including by entering into standard contractual clauses with the concerned Subprocessors or by executing power of attorney to UL/LCSB to this end) to secure the transfers against Data Protection Law transfer restrictions, unless the Data Provider has reasonable grounds for objecting to the transfer.</p> <p>6.3 Security</p> <p>UL/LCSB undertakes:</p> <ul style="list-style-type: none">- to implement and maintain at all times, throughout the duration of the Data processing, technical and organisational security measures that are appropriate with respect to the nature of the Data and associated risks (including the measures stated in Annex B to these General Terms of Services);;- that it shall not attempt to identify any Data subject from the Data either by external matching of the Data or by any other means;- that in the event of inadvertently identifying any Data subject, it undertakes not to make any use of the identifying information for any purposes and to take all necessary steps to protect the interests of the Data subject including so far as possible restoring their pseudonymised status;- to grant access to Data to Data Provider whenever Data Provider shall require such access;- to only provide access to the Data to Users approved as per clause 4 of this Hosting and Processing Agreement;- without prejudice to clause 2 of this Hosting and Processing Agreement, to process and store the Data for the duration of these General Terms of Services except if legal provisions or competent authorities require earlier deletion or anonymisation. In such case, the Data Provider undertakes to inform UL/LCSB at least ten (10) working days after becoming aware of such provisions or after being notified by the competent authority of the mandatory removal or anonymisation of the Data. <p>UL/LCSB undertakes to inform (email accepted) the Data Provider of any personal data breach without undue delay after becoming aware of such data breach, with available details on the incident, its circumstances and the approximate volume of the Data concerned (to the extent known).</p> <p>In such a case, the Parties shall exchange all relevant information to enable them to respond effectively to authorities or Data subjects and shall endeavour to coordinate their crisis communication on this eventuality.</p> <p>6.4 Transfers outside of the EU</p> <p>Where Users are located outside of the European Union, the European Economic Area or countries providing an adequate level of protection within</p>
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	<p>the meaning of article 45.1 of Data Protection Law, the access to and transfer of Data to the concerned Users will be subject to the entry by the User and UL/LCSB into a data transfer agreement based on the contractual clauses in Annex C.</p> <p>The Data Provider hereby gives power of attorney to, and appoints UL/LCSB (who accepts) as its agent ('mandataire') to sign on its behalf such contractual clauses with concerned Users.</p>
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7. Ethics Policy

Data Provider also undertakes to adhere to general ethical principles, including those related to research integrity and use of human biospecimens and Data related to human subjects for research purposes. Specifically, Data related to human subjects, human blood samples and other tissue, if any, will be transferred to the UL/LCSB only to the extent that the Data Provider can ensure that [the Data is anonymised or that] the Data subject has provided a documented, valid and informed consent to its specific use for scientific purposes and/or (depending on applicable legal provisions) necessary Ethics Approval has been obtained (covering each time the communication of Data to UL/LCSB and Users and generally the Services).

8. Publication – Dissemination

UL/LCSB undertakes to provide to the Data Provider a report detailing how the Data have been used and disseminated. This information will be stored on the ELIXIR website available on the Luxembourg ELIXIR Platform and also made available to potential Users.

With a view to ensuring that Users acknowledge the Data Provider's role and contribution to their research project in all Publications resulting from any analyses or use of the Data, the Data Provider will provide reasonable terms for publication as set forth in Annex D (e.g. acknowledgement / co-authorship).

9. Intellectual Property Rights

All intellectual property rights (including but not limited to author rights, trade marks, patents, know-how) on the infrastructure, software, documentation and other tools used for the provision of the Services will remain the exclusive property of UL/LCSB.

The Data Provider hereby grants to UL/LCSB a non-exclusive, royalty-free, irrevocable sublicensable license on the Data. Such license enables:

- UL/LCSB to provide the Services, and in particular to make the Data available to Users from the Luxembourg ELIXIR Platform in accordance with these General Terms of Services and the Data Access Committee's decisions, and
- Users to use the Data for non-commercial scientific research project and publication purposes only.

By accepting these General Terms of Services the Data Provider gives his/her consent for UL/LCSB to use Data Provider's corporate name and/or logo when communicating about the Services provided as a part of ELIXIR programme. For the avoidance of doubt, UL-LCSB reserves the right to use the Data Provider's corporate name in the Data Catalog.

10. Responsibility

a. Where there is a requirement to return incidental health-related findings to Data Subjects, the responsibility to ensure that appropriate Consent and mechanisms of feedback, which must have been consented to by the Data Subject and/or (as applicable) agreed in an Ethics Approval or by a competent authority, lies exclusively with the Data Provider and must be in place before Data is deposited on the Luxembourg ELIXIR Platform and/or made available in the context of the Services.

b. Where animal data is made available for research through the provision of Services, the Data Provider ensures that applicable guidelines and laws for the animals' welfare and care were followed during Data collection.

c. Where non-human genome data is made available through the provision of Services, the Data Provider ensures that their use and provision in the context of a Service is compliant with applicable laws and regulations including the Nagoya Protocol on Access to Genetic Resource and Benefit Sharing.

11. Representations and Warranties

When transmitting Data to the Luxembourg ELIXIR Platform Data Provider represents and warrants that:

- (1) that all information on the Data as given in the Data Information Sheet in Annex D is correct;
- (2) it has a right to post such Data to Luxembourg ELIXIR Platform and the posting and access of such Data by Users does not infringe, violate or misappropriate any intellectual property rights of third parties;
- (3) all applicable privacy and personal data laws and regulations (including the Data Protection Law) are respected, notably that all consents, waivers, authorisations from Data subjects and/or Ethics Approvals or other approvals required from competent public authorities necessary for the valid legal ground of processing have been obtained;
- (4) it remains responsible for managing the consent of Data Subjects which will address the following aspects. Consent should cover:
 - a. access to and linkage of Data that is stored in an electronic database;
 - b. sharing of Data with other researchers within and outside of the European Union/EEA (where applicable);
 - c. any decisions made regarding the management and communication of findings of incidental findings including any obligations Users may have to communicate such findings and any pre-set time-limits for the feeding back of results;
 - d. the possibility to use the Data for commercial purposes (where applicable).
- (5) it is responsible for informing UL/LCSB about any heterogeneity in the consent across the dataset and shall provide all necessary corresponding information;
- (6) it is responsible for informing UL/LCSB about any withdrawal of Data Subjects' consent without undue delay;
- (7) posting Data on Luxembourg ELIXIR Platform does not violate any rights of or cause injury to any person or entity and does not otherwise create any harm to third parties;
- (8) Data posted on Luxembourg ELIXIR Platform corresponds to the definition of Data provided above, notably that it results from or is related to biomedicine, and that it is presented in easily usable and structured form;
- (9) it shall not post on Luxembourg ELIXIR Platform any unsolicited or unauthorised advertising, promotional materials, junk mail, spam or any other form of solicitation (commercial or otherwise);
- (10) it shall not post, transmit or otherwise make available any virus, worm, spyware or any other computer code, file or programme that may or is intended to damage or hijack the operation of any hardware, software or telecommunications equipment or any hardware/software connected to Luxembourg ELIXIR Platform.

12. Disclaimer of Warranties

To the extent permissible pursuant to applicable law, the Services, any materials and third-party content, software, applications made available through or in relation to the Services, are provided on an "AS IS" basis without representations or warranties of any kind, either express or implied, including but not limited to accuracy, reliability or otherwise.

UL/LCSB's obligations with respect to the Services shall under no circumstances be construed as obligations of results.

13. Limitation of Liability

To the fullest extent permissible pursuant to applicable law, UL/LCSB, its officers, directors, employees and Subcontractors will not be liable for any indirect, incidental, special, consequential damages arising out of or in connection with the use of Services or access to Luxembourg ELIXIR Node, including without limitation, damages for loss of profits, goodwill or other tangible or intangible losses. In particular, the Data Provider is liable for keeping copies of the Data, and UL/LCSB shall not be liable for damages

incurred to the Data Provider by reason of the destruction or alteration of any sort of the Data on the Luxembourg ELIXIR Platform.

14. Termination and obligations of the parties after the termination

This Hosting and Processing Agreement will be valid for ten (10) years from their signature by the Parties and may be renewed upon mutual written agreement of the Parties.

UL/LCSB may terminate this Hosting and Processing Agreement without recourse to the courts ('de plein droit') at any time before its term by providing a one (1) year prior written notice, in case:

- the Data Provider does not ensure effective access management to the Data as provided in these General Terms of Services or in any other way commits a material breach of these General Terms of Services. The Parties hereby expressly agree that the breach of the clauses 6 (Privacy and Personal Data Processing), 7 (Ethics Policy) and 9 (Intellectual Property Rights), as well as any representation and warranty by the Data Provider under this agreement will in all circumstances be deemed as a material breach of these General Terms of Services;
- the Luxembourg ELIXIR Platform financing from the Government or European Union is discontinued, substantially reduced or otherwise if the economical balance of the ELIXIR project or the Services is compromised;
- UL/LCSB is subject to restructuration, cessation of the activities or change of control;
- the Data Provider causes the Data Access Committee to prevent the access of Data by delaying decisions and/or imposing decisions based on discriminating or illegal criteria;
- the Data transferred to the Luxembourg ELIXIR Platform is of such low quality that it is hard to use it or access for the Users;
- the Data have not been accessed by any User for longer than two (2) years.

The Data Provider may terminate the Hosting and Processing Agreement without recourse to the courts ('de plein droit') at any time before its term by providing a one (1) year prior written notice, and provided that the Data Provider shall ensure the continuity of any Access rights granted to Users on the Data provided by the Data Provider for the duration agreed at the time of the grant of the Access rights. UL/LCSB reserves the right to invoice the Data Provider if the latter terminates this agreement before five (5) years of effectiveness.

At the termination of the Hosting and Processing Agreement, UL/LCSB will:

- a. as part of the Services retain in all cases a copy of the Data so long as it is needed for the continuity of research projects and reproducibility of research results and in any case for no longer than fifteen (15) years, then delete all Data and existing copies; and
- b. if requested by the Data Provider return immediately a copy of the Data to the Data Provider.

15. Miscellaneous

Annexes

The annexes to the Hosting and Processing Agreement constitute an integral part of this agreement. In case of any discrepancies between this Agreement and its annexes, the following order of precedence, from the most prevalent to the least, shall apply:

1. Annexes A to D,
2. The Agreement.

Modification of these General Terms of Services

In case of changes to these General Terms of Services, the Data Provider will be notified with a thirty (30) days prior notice. If, after reception of such notice and subject to clause 5, the Data Provider does not notify its intention to terminate these General Terms of Services and continues to use the Services, he will be deemed to have accepted the amendments to these General Terms of Services..

Confidentiality

The Data Provider shall keep confidential all technical, business and financial information including, where appropriate and without limitation, all information, licenses, business plans, data, structures,

models, techniques, processes, software, source code, code, intellectual property, compositions, and compounds disclosed by UL/LCSB or obtained by the Data Provider through observation or examination of information (the "UL/LCSB Confidential Information").

The Parties undertake to enforce the present clause to their staff, contractors, suppliers and any third party involved.

Each Party undertakes, furthermore, to limit the dissemination of UL/LCSB Confidential Information relating to these General Terms of Services and its execution to members of its staff or sub-contractors where the performance of their activities require access to such UL/LCSB Confidential Information (need to know basis).

This obligation of confidentiality does not apply to cases where such non-application is required by the law, the public authorities or court order, or to enforce its legal rights under the present General Terms of Services.

Confidentiality does not apply to information already known by the receiving Party prior to its communication, to those obtained from third parties by legitimate means, to information developed independently, or to information made public by the disclosing Party.

The obligations of non-disclosure undertaken under this article shall stay in force from the effective date, and shall last five (5) years after the termination of these General Terms of Services, without prejudice to the protection of know-how and intellectual property.

Force Majeure

The Parties shall not be liable for failing to perform their obligations under these General Terms of Services, if such non-performance is attributable to revolt, acts of God, act of terrorism, wars, disasters, pandemics, interruption of the telecommunications network or of the electricity network or other circumstances beyond the control of, or otherwise unforeseeable by the defaulting Party (hereinafter referred to as "**Force Majeure**"). The obligations of such Party shall be suspended for the duration of such event of Force Majeure.

However, the Party affected by Force Majeure shall without delay inform the other Party about the estimated duration of the event of Force Majeure; moreover, the Party affected shall use its best efforts to remedy the effects of such Force Majeure without undue delay. If a case of Force Majeure is expected to last for more than two months, the Party not affected by Force Majeure may terminate these General Terms of Services with immediate effect in writing, and the affected Party shall not be entitled to any compensation for loss or damage.

Severability

If any term hereof is held invalid, void or unenforceable by any court or body of competent jurisdiction or by virtue of any legislation to which it is subject or by virtue of any other reason whatsoever, it shall be void or unenforceable to that extent only and no further and the validity and enforceability of any of the other provisions herein shall not be affected thereby to the extent allowed by law.

Governing law and jurisdiction

These General Terms of Services shall be governed by and construed in accordance with the laws of Grand Duchy of Luxembourg.

Any controversy or claim arising out of or relating to these General Terms of Services that cannot be settled amicably shall be submitted to the exclusive jurisdiction of the competent courts of the city of Luxembourg.

For the Data Provider	For University of Luxembourg / Luxembourg Centre for Systems Biomedicine (UL/LCSB)
Name:	Name: Prof. Dr. Michael Heneka

Title:	Title: Director, LCSB
Date:	Date:
Signature	Signature

- Annex A Specific Terms of Services
- Annex B Technical and organisational measures (if applicable)
- Annex C C2C Standard Contractual Clauses (if applicable)
- Annex D Data Information Sheet (DISH)

ANNEX A SPECIFIC TERMS OF SERVICES

1. Options selected by the Data Provider:

- a. OPTIONAL: Closed access

From to (maximum for 18 months).

- b. OPTION 1: Open access

From to

By choosing the open access option, the Data Provider hereby:

- i. represents and warrants that any Data stored by the Data Provider on the Luxembourg ELIXIR Platform or otherwise communicated to UL/LCSB for sharing with Users,
A. do not relate to individuals/human beings, or
B. have been processed so as to (1) guarantee their complete Anonymisation, (2) avoid that any Data qualifies as personal data within the meaning of Data Protection Law; in such case, the Data Provider undertakes to review the Data's anonymisation process and status at least every 2 years; and
- ii. agrees to indemnify and hold UL/LCSB harmless or any Data subject or third-party claim, action, proceedings or sanctions should the representations and warranties under point i. be breached.
- c. OPTION 2: Controlled access

From to

UL/LCSB prepares Data Access Committee's decisions on access to Data, communicates such decisions to the Data Provider who has two (2) calendar weeks to exercise its right to veto; otherwise access is granted to the User

The decisions will be communicated to following list of contact points:

Name:

Title:

Email:

By choosing the controlled access option, the Data Provider hereby:

- I. represents and warrants that any Data stored by the Data Provider on the Luxembourg ELIXIR Platform or otherwise communicated to UL/LCSB for sharing with Users: (1) have been pseudonymised (within the meaning of Data Protection Law) so as to guarantee that the Data do not include information allowing Users or third-parties to identify directly or indirectly (except with unreasonable effort) the Data subject, and (2) are provided to UL/LCSB for sharing with Users either with Data subjects' consent or otherwise as permitted by Data Protection Law or by a documented decision of competent authorities; and
- II. agrees to indemnify and hold UL/LCSB harmless or any Data subject or third-party claim, action, proceedings or sanctions should the representations and warranties under point i. be breached;
- III. undertakes to communicate any changes to the list of contact points to UL/LCSB without delay. Data Provider can be requested to confirm the validity of the contact points on regular basis.

2. Description of Services

UL/LCSB will provide secure data transfer channels and host the Data in a GDPR-compliant ELIXIR Luxembourg data and computing environment. UL/LCSB will provide basic curation and, where applicable, re-pseudonymisation of the Data.

UL/LCSB further provides a service to store the metadata of the datasets in the Data Catalog to further improve findability of the data and to maintain a dedicated tranSMART running instance providing access to the Data.

UL/LCSB will manage the Data Access Committee in the conditions detailed in the Agreement. The Data will be made available to the Data User upon request.

3. Description of Data

[short summary of data/project]

The Data are identified and listed in Annex D

4. Description of Subprocessors (where applicable)

None.

**ANNEX B
TECHNICAL AND ORGANISATIONAL MEASURES**

[OPTION 1]: Not applicable	[OPTION 2]: <i>Description of Technical and Organisational Measures will be added by UL/LCSB.</i>
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ANNEX C (if applicable)
C2C STANDARD CONTRACTUAL CLAUSES

[If applicable, Annex C will contain the template for a Data Sharing Agreement for sharing of Personal Data with non EEA countries according to clause 6.4 of the Agreement. The template is provided by the European Commission and its terms are non-negotiable.]

**ANNEX D
DATA AND DATA ACCESS POLICY**

[The Data Information Sheet must be completed by the Data Provider before signature of this agreement. The DISH identifies and lists the data and defines the Data Access Policy as well as terms for publication. The DISH template is provided by UL/LCSB.]

The Data Information Sheet (DISH) below identifies and lists all Data and defines the Data Access Policy as well as terms for publication.