

DATA USE AGREEMENT – ELIXIR

This DATA USE AGREEMENT (the **AGREEMENT**) is dated **[effective date]**.

BETWEEN

- (1) **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, Grand-Duchy of Luxembourg, registered in the register of trade and companies of Luxembourg under No J20, with VAT number LU19805732, acting for the LUXEMBOURG CENTRE FOR SYSTEMS BIOMEDICINE, based in Campus Belval, 7 avenue des Hauts-Fourneaux, L-4362 Esch-sur-Alzette, Grand-Duchy of Luxembourg, represented by its Director, Prof. Dr. Michael Heneka hereinafter "**UL/LCSB**",

AND

- (2) **[LEGAL NAME OF THE USER INSTITUTION]**, a **[organization corporate form]** having its registered office at **[legal address]**, duly represented by **[name of legal representative]** (the **USER INSTITUTION**),

[AND] OR [IN THE PRESENCE OF]

[NAME OF THE MAIN APPLICANT], an **[individual researcher]** employed at the USER INSTITUTION and in charge of the research project detailed in ANNEX 1, with professional address at **[address]**, **[country]** (the **PI**),

WHEREAS

- (A) the parties hereby agree to conclude the AGREEMENT within the framework of the "European Life-Science Infrastructure for Biological Information" (**ELIXIR**);
- (B) ELIXIR is a European research infrastructure organised in the form of a central hub and distributed nodes, which operates, manages and sustains, in the broadest sense of these terms, an interlinked collection of biological data resources, tools and literature; ELIXIR is an infrastructure consortium of global significance based on the principles of open access and data sharing, established for the support of scientists of all disciplines;
- (C) the DATA PROVIDER(s) (as defined below) stores biomedical data (the DATA, as defined below) with ELIXIR and is prepared to provide access thereto to the DATA USERS (as defined below) under the conditions listed in this AGREEMENT;
- (D) UL/LCSB acts as the Luxembourg node for ELIXIR and is responsible for sharing the DATA hosted on the LUXEMBOURG ELIXIR PLATFORM (as defined below) on behalf of the DATA PROVIDER(s);
- (E) the USER INSTITUTION is **[description of type of institution and activity]** and is the home institution of the DATA USERS who wish to access to the DATA under the conditions listed in this AGREEMENT and subject to additional terms and conditions referred to herein;
- (F) each of the parties recognises as a priority the need to respect the fundamental interests and rights of DATA subjects, including the need to preserve the security and confidentiality of the DATA, given in particular their extreme sensitivity;

THE PARTIES HAVE DECIDED AS FOLLOWS:

1. DEFINITIONS

ACCESS means open or controlled access to DATA from the LUXEMBOURG ELIXIR PLATFORM provided by UL/LCSB.

DATA means data, including personal, biomedical, technical and any other data provided by the DATA PROVIDER to the DATA USERS through the LUXEMBOURG ELIXIR PLATFORM and described in Annex 1.

DATA ACCESS COMMITTEE means a committee that reviews the application of access from the USER INSTITUTION and grants/declines individual access rights for DATA USERS based on the DATA ACCESS POLICY. The DATA ACCESS COMMITTEE comprises representatives of UL/LCSB. The DATA PROVIDER may decide to appoint a representative of its choice to the DATA ACCESS COMMITTEE, with a veto right on decisions regarding DATA access.

DATA ACCESS POLICY means the access control policy determined by the DATA PROVIDER on the basis of which the DATA ACCESS COMMITTEE grants or denies access to DATA by DATA USERS, and determines the conditions of such access.

DATA PROTECTION LAW means the applicable data protection laws, such as the GDPR, as well as its implementing and successors texts.

DATA PROVIDER means the individual(s) or entity(ies) mentioned in ANNEX 1, who/which store(s) DATA on the LUXEMBOURG ELIXIR PLATFORM and determine(s) the conditions of access thereto. Any reference made to DATA PROVIDER in this Agreement, shall be deemed made to the relevant DATA PROVIDER(S) of the relevant DATA. Under no circumstance can a DATA PROVIDER be held liable for DATA contributed by another DATA PROVIDER.

DATA USER means the PI and any other individual researcher or investigator or group of researchers or investigators registered with the LUXEMBOURG ELIXIR PLATFORM to whom access to the DATA has been granted by the DATA ACCESS COMMITTEE and who access, process or use DATA; DATA USERS' access to the DATA as well as use and processing thereof is performed exclusively under the PI's and USER INSTITUTION's joint liability.

ELIXIR-LU means UL/LCSB, acting as Luxembourg node for ELIXIR and providing hosting services to DATA PROVIDERS and controlled access to the DATA stored on the LUXEMBOURG ELIXIR PLATFORM.

GDPR means 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 (General Data Protection Regulation).

LUXEMBOURG ELIXIR PLATFORM means the Luxembourg ELIXIR platform hosted by UL/LCSB.

PERSONAL DATA : means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

PUBLICATIONS means, without limitation, articles published in a printed or electronic form on the press, reviews, books, public display and other written and verbal presentations (including private or publicly accessible conferences, meetings and similar events) of research and/or research results.

RESEARCH PROJECT means the research project described in ANNEX 1 and for the purpose of which access to DATA is granted to DATA USERS hereunder.

The terms 'controller', 'processor', 'recipient', 'data subject', 'processing' and 'personal data breach' have the same meaning in this Agreement as in the DATA PROTECTION LAW.

2. OBJECT OF THE AGREEMENT

2.1 The purpose of the AGREEMENT is to define the terms on which access to DATA is granted to DATA USERS, and the further use of such DATA by the USER INSTITUTION and DATA USERS.

2.2 DATA ACCESS.

- a. Access to DATA is provided by ELIXIR-LU to the DATA USERS under the conditions determined in the AGREEMENT.
- b. The USER INSTITUTION (either directly or through the PI):
 - i. provides to ELIXIR-LU a list of individuals to be approved by the DATA ACCESS COMMITTEE as DATA USERS, and
 - ii. undertakes to update constantly the list of DATA USERS with ELIXIR-LU, as necessary to reflect changes or departures in affiliated researchers and personnel in good time to allow ELIXIR-LU to revoke related access rights at the effective date of such change. These updates are made by email to: lcsb-datastewards@uni.lu and other secure transmission channels.
- c. ELIXIR-LU makes no particular commitment as regards the constant availability, continued operation and performance of the LUXEMBOURG ELIXIR PLATFORM, or the uninterrupted access to DATA. ELIXIR-LU will endeavour to inform the USER INSTITUTION and/or (at UL/LCSB's choice) the DATA USERS in advance in case of planned interruption of such access.

2.3 RESEARCH USE.

- a. The USER INSTITUTION is liable for ensuring that DATA is used solely:
 - i. in connection with the RESEARCH PROJECT as described in ANNEX 1; and
 - ii. in compliance with DATA PROTECTION LAW.
- b. Any use of the DATA outside the strict scope of the RESEARCH PROJECT, or any modification of the RESEARCH PROJECT will require:
 - i. the prior submission of a separate DATA access request to ELIXIR-LU, and
 - ii. the prior written validation thereof by the DATA ACCESS COMMITTEE (subject to potential restrictions or conditions set out therein).
- c. DATA USERS will use the DATA and the LUXEMBOURG ELIXIR PLATFORM exclusively in accordance with the terms of this AGREEMENT.
- d. The USER INSTITUTION is liable for ensuring that DATA USERS will not:
 - i. attempt to link DATA to/with other information or data, including DATA to which access has been granted hereunder, or which is freely available without restriction, unless specifically authorised by the DATA ACCESS COMMITTEE, or
 - ii. analyse or make any use of the DATA in such a way that has the potential to:
 - A. circumvent pseudonymisation or similar measures taken to protect the confidentiality of DATA subjects' identity; or
 - B. lead to the identification of any DATA subject; or
 - C. otherwise compromise the confidentiality of any DATA subject's identity in any way.

3. NON-TRANSFERABILITY

3.1 The USER INSTITUTION will not, and procures that DATA USERS will not, transfer or disclose the DATA, in whole or part, or any material derived from the DATA to any third-party (including employees, agents, representatives, director and contractors of the USER INSTITUTION who are not DATA USERS) except:

- a. in an aggregated form so that no individual DATA (or means to access, infer or

reconstruct such individual DATA) is disclosed, or

- b. if a separate DATA access request has been filed with, and approved in writing beforehand by the DATA ACCESS COMMITTEE.

4. INFORMATION OF DATA USERS

4.1 The USER INSTITUTION undertakes:

- a. to distribute a copy of this AGREEMENT and explain its contents to each DATA USER, including any subsequent amendments or additions;
- b. to implement and distribute any such guidelines, policies, procedures and instructions as necessary to ensure DATA USERS' compliance with the obligations contained in this AGREEMENT and DATA PROTECTION LAW; and
- c. to ensure that the DATA USERS have reviewed and understand the principles for responsible research use and DATA handling as defined in the Data User Responsibility Agreement.

5. PUBLICATION, DISSEMINATION AND ACKNOWLEDGEMENT

5.1 The USER INSTITUTION ensures that the PI agrees that his/her personal data (at least his/her name, contact details, title and home institution), information on the RESEARCH PROJECT (comprising its abstract and the PUBLICATIONS) may be posted on the UL/LCSB and/or any ELIXIR web site.

5.2 The USER INSTITUTION (both in its own name and in the name of DATA USERS):

- a. agree that the objective of the ELIXIR initiative is to promote the dissemination of research findings from DATA stored with ELIXIR-LU as widely as possible through scientific publication or other appropriate public dissemination mechanisms, and adhere and intend to contribute to this objective; consequently, they undertake to publish their research results in PUBLICATIONS;
- b. undertake to acknowledge the DATA PROVIDER's and ELIXIR-LU's role and contribution to the RESEARCH PROJECT in all PUBLICATIONS resulting from any analyses of the DATA and quote the DATA PROVIDER and ELIXIR-LU as authors in all PUBLICATIONS resulting from any analyses of the DATA;
- c. agree to protect the confidentiality of DATA (and the identity of DATA subjects) in any PUBLICATIONS by taking all possible care to limit the possibility of identification.

5.3 RESEARCH USE REPORTING. With a view to ensuring that ELIXIR-LU's policies and procedures applicable to the access to and use of DATA are respected, the USER INSTITUTION (either directly or through the PI) undertakes to provide to the DATA ACCESS COMMITTEE, once per year, a report detailing how the DATA have been used and any results generated as a result of the use of the DATA, including a status on patent (or similar) applications and PUBLICATIONS (with a copy thereof).

6. INTELLECTUAL PROPERTY

6.1 UL/LCSB recognises the importance of the subsequent development of intellectual property (IP) and associated protection rights (IPR) on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public.

6.2 However, by requesting access to the DATA, the USER INSTITUTION and DATA USERS acknowledge and support the objective of ELIXIR's policy on IP, that is:

- a. achieving maximum public benefit of the DATA distributed through the LUXEMBOURG ELIXIR PLATFORM, and
- b. treating the DATA as 'pre-competitive' assets.

6.3 Consequently, USER INSTITUTION and DATA USERS will refrain from making IP claims derived directly from the DATA and which may result in restrictions, conditions or otherwise create obstacles to the distribution and use of the DATA.

6.4 Without prejudice to the above provisions and to the ownership of the DATA, the USER INSTITUTION or the DATA USERS, as the case may be, shall obtain ownership of those results and inventions and any intellectual property therein developed or created through the use of the DATA, pursuant to article 2.3 of the present AGREEMENT, either (i) independently of or (ii) not directly derived from such DATA, by the USER INSTITUTION or DATA USERS, hereinafter the “Generated IP”. The USER INSTITUTION and the DATA USERS commit and ensure that their use of such Generated IP shall not prejudice to ELIXIR’s policy on IP, as defined above, and shall not restrict the use of the DATA by ELIXIR-LU, the DATA PROVIDERS, or any other USER INSTITUTION and DATA USERS.

7. RESPONSIBILITY

7.1 ELIXIR-LU undertakes to provide access only to DATA for which:

- a. documented, valid and informed consents have been obtained from DATA subjects (or their legal representatives); and/or
- b. it is documented that prior consent of DATA subject was not necessary and the DATA is processed under another valid legal ground in accordance with DATA PROTECTION LAW; and/or
- c. required ethical committees’ or authorities’ approval has been obtained to distribute and allow DATA USERS to process the DATA for the RESEARCH PROJECT’s purposes.

7.2 The USER INSTITUTION undertakes, and procures that DATA USERS will:

- a. only access, use and process the DATA as strictly necessary for the RESEARCH PROJECT in accordance with the data minimisation principle, and
- b. ensure that DATA is completely deleted (backup copies included) at the end of the term of this AGREEMENT.

8. DATA PROTECTION

8.1 The parties will duly observe all their obligations under DATA PROTECTION LAW which arise in connection with this AGREEMENT and the processing of the DATA.

8.2 The parties acknowledge that:

- a. the DATA PROVIDER is the controller as regards the collection and processing of the DATA until and including the storage thereof on the LUXEMBOURG ELIXIR PLATFORM for subsequent use for research projects, and
- b. ELIXIR-LU is the DATA PROVIDER’s processor as regards the storage of DATA and making such DATA available on the LUXEMBOURG ELIXIR PLATFORM for subsequent use for research projects, and
- c. ELIXIR-LU and DATA PROVIDER act as joint controller with respect to the decision to grant access to the DATA.
- d. the USER INSTITUTION and DATA USERS are recipients and independent controllers as regards the access to DATA from the LUXEMBOURG ELIXIR PLATFORM and the subsequent use and processing of the DATA for the RESEARCH PROJECT’s purposes.

Each party is solely liable for ensuring its own compliance with applicable DATA PROTECTION LAW as regards the acts of processing of the DATA it carries out (or which are carried out on its behalf).

8.3 The parties undertake to co-operate in the event of and the USER INSTITUTION shall comply with any request made by ELIXIR-LU and/or DATA PROVIDER with respect to:

- a. a DATA subject's claim, request or exercise of statutory rights on his/her DATA, or
- b. in case of any request by supervisory authorities.

8.4 The USER INSTITUTION will, and procures that DATA USERS will:

- a. notify ELIXIR-LU of any errors detected in the DATA, and
- b. accept that DATA be reissued from time to time, with suitable versioning and, if DATA is reissued at the request of DATA subjects and/or as the result of ethical scrutiny, remove earlier versions of the DATA from subsequent analysis and publication and destroy/discard all earlier versions of DATA.

8.5 If the USER INSTITUTION or DATA USERS are located outside of (i) the European Union, (ii) the European Economic Area, or (iii) countries providing an adequate level of protection within the meaning of article 45.1 of the GDPR, the access to and transfer of DATA to the concerned DATA USERS will be subject to the entry by the USER INSTITUTION and UL/LCSB into a data transfer agreement based on the contractual clauses in ANNEX 2.

9. DATA SECURITY

9.1 ELIXIR-LU provides access to DATA in an encrypted format and through secure communication channels.

9.2 The USER INSTITUTION undertakes to implement and maintain at all times, throughout the duration of this AGREEMENT, a sufficient technical infrastructure and environment with technical and organisational measures appropriate with respect to the nature of the DATA, their extreme sensitivity, volumes exchanged and associated risks, in order to ensure the ongoing confidentiality, integrity, availability and resilience of the systems used by DATA USERS for the processing of DATA. The USER INSTITUTION is in particular liable for:

- a. any access to the DATA or the LUXEMBOURG ELIXIR PLATFORM by DATA USERS or through the latter's access accounts or credentials (including by third parties impersonating DATA USERS),
- b. implementing, testing, reviewing, regularly training DATA USERS on, and enforcing rules (including good practices in terms of information security, such as, clean desk policy, credentials management including non-sharing of credentials -including with other DATA USERS-, revocation of compromised credentials) applicable to all DATA USERS on the use of the DATA, access thereto and relevant credentials to ensure that DATA USERS comply at all times with the terms of the AGREEMENT and DATA PROTECTION LAW,
- c. revoking immediately compromised (lost, stolen or shared) credentials with ELIXIR-LU in writing (email accepted), and
- d. any access to and use of the DATA or the LUXEMBOURG ELIXIR PLATFORM by a DATA USER or a third party impersonating a DATA USER.

9.3 Upon reasonable request of ELIXIR-LU, the USER INSTITUTION will make available to ELIXIR-LU all information necessary to demonstrate compliance with the obligations laid down in this AGREEMENT and allow for and contribute to audits conducted by UL/LCSB or any independent inspections by UL/LCSB's representatives, auditors or competent authorities, to ascertain compliance with this AGREEMENT, with reasonable notice and during regular business hours.

9.4 ELIXIR-LU reserves the right (in its sole discretion) to suspend the access or account of DATA USERS whose credentials have been compromised or revoked, or who have acted in breach of this AGREEMENT or the terms of use of the LUXEMBOURG ELIXIR PLATFORM, without prejudice to the right to terminate the AGREEMENT pursuant to clause 15 of this AGREEMENT.

10. CONFIDENTIALITY

- 10.1 The USER INSTITUTION will, and procures that DATA USERS will:
- a. treat the DATA as confidential information and keep it in strict confidence,
 - b. to only use, make/keep copies of the DATA for the sole purpose of the RESEARCH PROJECT or as strictly required by DATA PROTECTION LAW,
 - c. to protect the DATA, whether in storage, in process or in use, with the same degree of care as the USER INSTITUTION uses to protect its own sensitive/confidential information, but in no circumstances with less than reasonable care, and
 - d. ensure traceability and document any action of dissemination, retention and destruction of the DATA, and communicate such documentation to UL/LCSB upon request.

11. PERSONAL DATA BREACH

11.1 The USER INSTITUTION undertakes to, and procures that DATA USERS will, notify to ELIXIR-LU any personal data breach without undue delay after becoming aware of such data breach. All notifications and reports of data breaches should be submitted through <https://databreachreport.lcsb.uni.lu>.

11.2 Notifications under clause 11.1 should include:

- a. a description of the nature of the data breach as well as all factual details and any other useful information available regarding the data breach,
- b. a general description of the measures deployed by the USER INSTITUTION and/or DATA USERS to remediate the situation, including, where appropriate, measures to mitigate its possible adverse effects,
- c. where possible, the categories and approximate number of DATA subjects concerned and the categories and approximate number of DATA records concerned,
- d. a description of the likely consequences of the data breach,
- e. the name and contact details of the USER INSTITUTION's data protection officer or other contact point where more information can be obtained,

11.3 The USER INSTITUTION will continue to keep ELIXIR-LU apprised on any subsequent development and, until complete resolution of the case, provide at least weekly reporting on the personal data breach, countermeasures, risk assessments and other useful information (including competent authorities requests, decisions or injunctions).

12. LIABILITY

12.1 UL/LCSB, the DATA PROVIDER, copyright holders, and all other parties make no warranty express or implied as to the accuracy, quality or comprehensiveness of DATA to the USER INSTITUTION and the DATA USER.

USER INSTITUTION shall hold UL/LCSB/ ELIXIR-LU harmless against any claim from the DATA USERS:

- a. UL/LCSB, the DATA PROVIDER, and copyright holders exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by the USER INSTITUTION or DATA USERS that may arise (whether directly or indirectly) in any way whatsoever from the use by the DATA USERS of DATA or from the unavailability of, or interruption in access to, DATA or the LUXEMBOURG ELIXIR PLATFORM for whatever reason and;
- b. UL/LCSB and the DATA PROVIDER bear no responsibility for the further analysis or interpretation of the DATA.

12.2 DATA USERS are liable for keeping copies of the DATA, and UL/LCSB shall not be liable for damages incurred to the USER INSTITUTION by reason of the destruction or alteration of any sort of the DATA on the account of a DATA USER.

13. STORAGE DURATION

13.1 DATA will be destroyed, at the sooner of (1) the DATA being no longer used or strictly necessary for the research project or (2) the termination of the AGREEMENT for whatever reason.

13.2 Archiving of the DATA will be provided by ELIXIR-LU exclusively.

13.3 Where this AGREEMENT provides that the USER INSTITUTION or DATA USERS should destroy the DATA (regardless of the cause), any such destruction should be carried out in a secure manner so as to avoid any potential restoration or reconstruction of the DATA, and the USER INSTITUTION will issue to ELIXIR-LU without undue delay after such destruction a written certificate of secure destruction of the DATA, including a commitment to have destroyed all copies (including backups) of the DATA.

14. FINANCIAL PROVISIONS

14.1 LUXEMBOURG ELIXIR PLATFORM is financed by the Government of the Grand Duchy of Luxembourg and the UL/LCSB, thus the services are provided free of charge.

15. TERM AND TERMINATION

15.1 This AGREEMENT will be effective for a period of one (1) year from the date of the DATA ACCESS COMMITTEE granting access to the DATA to the (first) DATA USERS.

15.2 The parties may, but will not be obliged to, decide to extend this AGREEMENT after its term. If advance written notice and approval by the DATA ACCESS COMMITTEE is obtained to allow USERS to finish their research projects when they are using the DATA, the DATA will not need to be destroyed, unless if there is a compelling legal reason to do so; Section 13.1 remains unaffected. In any other case, the USER INSTITUTION (either directly or through the PI) will be required to file a new DATA access request with the DATA ACCESS COMMITTEE, which may take a decision in its own discretion. Should the parties decide to renew this AGREEMENT, the DATA ACCESS COMMITTEE will solely determine the conditions in which the DATA may be retained by the USER INSTITUTION during the transition between the two contractual periods. In the absence of such prior written decision, the USER INSTITUTION will, and procures that DATA USERS will destroy the DATA at the initial AGREEMENT's termination date.

15.3 UL/LCSB may terminate this AGREEMENT and immediately revoke access to DATA and the LUXEMBOURG ELIXIR PLATFORM upon any breach of this AGREEMENT (including without limitation in case of personal data breach) or rules identified herein or DATA PROTECTION LAW by the USER INSTITUTION or any DATA USER. The USER INSTITUTION should be solely liable for the consequences of such termination and revocation.

15.4 In case of termination or non-renewal of this AGREEMENT for whichever cause, the USER INSTITUTION shall, and procures that DATA USERS shall destroy the DATA at the date of termination, using endeavours conform to clause 13.3.

15.5 Any termination under this clause 15 will be automatic ('de plein droit'), without recourse to the courts and without compensation for the other party.

16. GOVERNING LAW, JURISDICTION

16.1 The AGREEMENT will be governed by Luxembourg law.

16.2 Any disputes, claims or litigation in connection with the AGREEMENT, which cannot be solved amicably, will be brought exclusively before the courts of the judicial district of

ANNEX 1 – DATA, DATA PROVIDER & RESEARCH PROJECT

[The Data Request Form submitted with the request to access the data can be attached. In case there were changes in provided information, the fields below shall be populated]

Title:

Link:

Data Use Restrictions:

Data Providers:

A. CONTACT INFORMATION:

Main applicant:

Position:

Mailing Address:

Institutional E-mail:

B. NAMES OF AUTHORIZED PERSONNEL

Include the names of all investigators, collaborators, post-doctoral researchers, research staff, and students who will have access to the controlled data in order to work on the Research Project. Please ensure that a valid institutional e-mail address for each name is included, along with a proper job title.

**Note that co-investigators or collaborators at other institutions must submit a separate Data Access Request.*

Name:

Position:

Affiliation:

Institutional E-mail:

Name:

Position:

Affiliation:

Institutional E-mail:

C. PROJECT INFORMATION:

Research Ethics Approval Number (if exists):

Project Title:

Project Website:

Project Purpose and Aims:

ANNEX 2 – STANDARD CONTRACTUAL CLAUSES