

#### DATA SHARING FOR RESEARCH AGREEMENT

#### between

Wilhelm Schulthess-Stiftung Lengghalde 2 8008 Zürich, Switzerland

represented by

and

(hereinafter referred to as "WSS")

and

(hereinafter referred to as "XXX")

(hereinafter individually referred to as "Party" or collectively as "Parties")

# Preamble

xxx

# 1. Statement of Work

- 1.1 The Parties hereby undertake to perform the research work described in the XXX application attached as Enclosure 1 (hereinafter referred to as "the Project") which shall be an integral part of this Agreement.
- 1.2 Each Party hereby undertakes to collaborate with the other Party during the Project in accordance with this Agreement and to provide each other in due time with documentation, information and data necessary to accomplish the Project according to Enclosure 1.
- 1.3 The Parties further undertake to carry out the Project in accordance with the Swiss federal "Loi relative à la recherche sur l'être humain" (LRH RS 810.30), The Ordonnance relative à la recherche sur l'être humain à l'exception des essais cliniques (ORH), the Loi fédérale sur la protection des données (LPD) and all applicable laws.
- a. The Project will involve the use of Health Data as defined below in Article 4.



- b. The Parties have obtained or will obtain approval of the part of the Project involving the use of Health Data in accordance with a protocol submitted to and approved by the competent authorities ("Protocol") as required by the ORH.
- c. XXX shall be the sponsor of the part of the Project involving Health Data in accordance with the ORH ("Sponsor").
- d. The WSS shall be the project leader responsible for the protection of the human participants taking part in the Project at the WSS ("Research Subjects"), inter alia:

WSS shall in all respects and at all times protect the personal rights of the Research Subjects, including regarding informed consent procedures and personal data protection, and assist the Sponsor to obtain all approvals required according to applicable law to perform the Project and meet the requirements of this Agreement.

- 1.4 Any modifications to the scope of the Project, any priorities and scientific options to be decided in the course of the Project shall be subject to prior mutual written agreement of the Parties and to the agreement of Innosuisse
- 1.5 In case of discrepancies or contradiction between this Agreement and any of its enclosures, the Agreement itself shall prevail.

### 2. Term of Agreement

This Agreement shall become effective upon its due signing by the Parties and will remain effective until the completion of the Project.

## 4. Results and Intellectual Property

- **4.1** All results, patentable or not, copyrightable or not, obtained in the performance of the Project by a Party ("Results") shall be communicated to the other Party in form of common meetings followed by written minutes of such meetings, written reports or written publication drafts. Each Party shall keep the Results of the other Party confidential until their publication, according to the Art 6.1 and 6.2 herein below, unless otherwise agreed upon by the Parties in writing.
- **4.2** Each Party herewith declares that the results and intellectual property rights generated in the performance of the Project by any of their employees are deemed Results hereunder and belong to the Party with which the respective employees are employed in accordance with the applicable law.
- **4.3** The Parties agree that any and all Results generated by one Party (for the avoidance of doubt, including any its employees) solely and that its share in jointly generated Results shall be owned by such solely or jointly generating Party. Ownership in jointly generated Results shall be determined in accordance with the respective share that each Party has contributed to such Results.
- 4.4 With the exception of Sect 4.6b, the Parties agree that, with the exception of patent rights and software and subject to article 4.5, each joint owning Party shall be free to use for any purpose including sublicensing, all Results jointly generated in performance of the Project, without the consent from and without an obligation to compensate another joint owning Party. For protection and commercialization of jointly owned inventions, jointly owned patent rights as well as for commercial use of jointly owned software, the joint owning Parties shall agree within 6 months on the Parties' right of use, and rights and obligations for protection and commercialization, in advance in writing. Regardless to the above, for non-commercial research and academic activities the Parties shall be free to use the jointly owned inventions and software without the agreement of the other Parties.



- **4.5** Each Party shall remain the sole owner of all its rights to its pre-existing intellectual property rights ("Background IP") and neither right or license is granted hereunder to the other Party, save for a limited non-exclusive non-transferable right to use, during the Project term, such Background IP that originated from the Parties involved in the Project, and to the extent necessary for the purpose of performing its research tasks under the Project only.
- **4.6** Certain Results represent personal data related to the health status of the Research Subjects in accordance with the definition of the LRH Article 3 f. ("Health Data").

The Parties acknowledge and agree that WSS shall provide only anonymized, pseudo-anonymized and/or coded personal data (meaning it has gone through a procedure whereby it cannot be linked to an individual Research Subject's personal data pertaining to the Project) to XXX ("Anonymized Health Data"). XXX is not entitled to ask for or receive, and WSS is not obliged to deliver non-anonymized, non-pseudo anonymized or uncoded personal data of Research Subjects to XXX hereunder, unless required to meet its obligations as Sponsor under applicable law.

Each Party shall have the right to use the Anonymized Health Data in accordance with the Protocol and the consent of the Research Subjects as well as the applicable data protection laws, and the following:

- a. The Anonymized Health Data that is accidentally not anonymized shall be treated as confidential by both Parties. In the event of the delivery and receipt of non-Anonymized Health Data, XXX shall immediately notify WSS thereof and WSS shall deliver Anonymized Health Data instead. EPFL undertakes to destroy such non-Anonymized Health Data so that it cannot be recovered in any form and EPFL shall promptly confirm such destruction to WSS in writing.
- b. For Anonymized Health Data obtained from WSS ("Anonymized Health Data"), WSS grants to XXX no rights of re-use of the Anonymized Health Data, nor the right to license such Anonymized Health Data to any third party, except for (i) its contractors and employees for the performance of the Project, and (ii) for noncommercial research and development activities of XXX.
- c. The Parties shall limit the disclosure of such Anonymized Health Data to its contractors, sublicensees, or its respective directors, officers, and employees in each case who have a legitimate need to know and who are bound in writing to observe the confidentiality obligations of this Agreement or similarly stringent provisions
- d. The Parties shall also implement appropriate technical and organizational measures to ensure an adequate level of security for all processing of such Anonymized Health Data, taking into account the likelihood and the severity of the risks for the Research Subjects' rights and freedoms. The Parties shall store such Anonymized Health Data only in Switzerland, in the European Union, or in a Country that has adequate data protection legislation according to the European Commission and/or Switzerland, as applicable.
- e. To the extent required under applicable law, the Parties shall enable the exercise of rights by Research Subjects, including, if applicable, access rights, the right to rectification and erasure, the right to object to processing or to restrict processing, the right of data portability, and rights relating to automated processing.
- f. Subject to Art 4.6a above, the Parties hereby agree not to adapt, modify, hide or delete any of the Anonymized Health Data received under this Agreement.



g. The Parties shall assist each other by appropriate measures and by providing information, insofar as this is possible, for the fulfilment of the obligation to respond to requests for exercising the Research Subjects' rights, for the management of data breaches, or for the compliance of other obligations prescribed by the applicable law, such as conduct a privacy impact assessment, security obligations, or any request from the supervisory authority. The Parties agree to assist any supervisory authority upon request, and accept to provide a copy of this Agreement to the competent supervisory if necessary.

### 5. Confidentiality

- **5.1** Each Party ("the Recipient") agrees to keep confidential and not to use for another purpose than the performance of the Project all information belonging to the other Party ("the Disclosing Party") with which it may come in contact during the course of the Project, provided that such information have been clearly labeled as confidential by the Disclosing Party or, if disclosed orally, have been confirmed in writing as being confidential within ten (10) days from their disclosure (hereinafter referred to as "Confidential Information"). Each Party shall be responsible for the compliance by its personnel with these confidentiality obligations.
- 5.2 The obligations under <u>article 5.1</u> shall not apply to any Confidential Information that:
  - was in the public domain or open to the public at the time it was transmitted to Recipient, or
  - became public or open to the public for reasons other than an action or omission attributable to Recipient, or
  - was in Recipient's possession, without any limitation regarding its disclosure at the time it was transmitted to Recipient, provided that such prior possession is supported by a written evidence, or
  - was obtained in good faith by Recipient and without any commitment relating to confidentiality from a third party entitled to disclose it.

Such obligations shall neither apply to any portion of Confidential Information required to be disclosed as a result of a court order or pursuant to a government action, provided that the Recipient shall inform the Disclosing Party of any such order or action to give the Disclosing Party the opportunity to request a protective order.

**5.3** The obligations under this article 5 shall remain effective for five (5) years after termination of this Agreement.

# 6. Scientific publications

- **6.1** The Parties are entitled to publish in scientific publications the Results obtained in the performance of the Project.
- **6.2** Prior to the publication of such Results, each Party (the "Submitting Party") agrees to submit to the other Party (the "Receiving Party") for review, a draft of the information to be disseminated.
- The Receiving Party shall then have one (1) month to notify the Submitting Party of any objection. If an objection is raised, discussion shall be held without delay to determine acceptable modifications to resolve the issue and allow a timely dissemination.
- Failure to respond within the abovementioned one (1) month period is considered as approval of the publication by the Parties.

### 7. No Warranties



- **7.1** Each Party shall perform the Project by applying its best scientific knowledge and best scientific standards. The Parties have only an obligation of means in the performance of the Project.
- 7.2 Neither Party makes any warranties, either express or implied, including but not limited to warranties of novelty, patentability, accuracy, non-infringement, merchantability, fitness for a particular purpose of the Project, the Results or the Background IP. Each Party agrees that its use of the Results or Background IP shall be at its sole risk and to the fullest extent permitted by the applicable law.

#### 8. Liability

- **8.1** Each Party shall be liable towards the other Party only in the event of fraud or gross negligence for any damages suffered in connection with this Agreement.
- **8.2** In the event that one of the Parties decides to commercialize products and/or services based on the Results, that Party shall bear the sole responsibility for the conception, use and commercialization of such products or services and shall be liable towards third parties in connection with this conception, use or commercialization.
- **8.4** To the extent permitted by law, in no event will any Party be liable for any special, incidental, consequential or indirect damages, or lost profits, arising in any way out of this Agreement, however caused and on any theory of liability. This limitation will apply even if the other party has been advised of the possibility of such damage.
- **8.5** Neither Party shall be entitled to commit the other Party to any obligation in connection with this Agreement, without the prior written consent of the other Party.

### 9. Force majeure

Neither Party shall be liable for any default or delay in the performance of its obligations under this Agreement if and to the extent such default or delay is caused, directly or indirectly, by: (i) flood, earthquake, elements of nature; or (ii) strikes, riots, civil disorders, epidemics, pandemics, rebellions or revolutions in any country("Force Majeure"). The concerned Party shall endeavour to mitigate the effects of such Force Majeure on the Project.

### 10. Communication

Any notice or communication to be given within the framework of this Agreement shall be forwarded to the following contact persons:

### Communication to Wilhelm Schulthess-Stiftung:

Vincent Stadelmann Schulthess Klinik, Lengghalde 2 8008 Zürich, Switzerland

e-mail: vincent.stadelmann@WSS.ch

phone: +41763216954

## Communications to XXX:

Commented [EPFL - GS1]: We don't understand the definition of damages and we would rather propose a more widely used clause for the limitation of indirect damages, see Art. 8.4.



### 11. Survival

The provisions of articles 4.4, 5, 7, 8, 9, 10, 11 and 12 shall survive any expiration or termination of this Agreement.

# 12. Applicable Law and Place of Jurisdiction

- 12.1 This Agreement shall be governed by the laws of Switzerland, without regard to its conflict of law provisions.
- 12.2 All disputes arising out of or in connection with the present Agreement, including disputes on its conclusion, binding effect, amendment and termination, shall be exclusively resolved by the ordinary courts in Lausanne, Switzerland.



This Agreement must be signed by the authorized representatives of the Parties. All signatures may be inscribed together on the same document or inscribed individually on separate documents that have the same content. Original signatures to this Agreement are not required to establish the effectiveness, authenticity, or enforceability of this Agreement. Photocopies bearing the signatures of the Parties are effective as originals.

XXX

Commented [AS2]: EPFL legal: not clear why this should be crossed out when the previous sentence on photocopies is kept. Could WSS please advise?

Place and date)	(Place and date)	
Signature)	(Signature)	
(name and title)	(name and title)	
· ·	Wilhelm Schulthess-Stiftung	
Place and date)	(Place and date)	
Place and date) Signature)	(Place and date) (Signature)	



Enclosure 1 Description of the Project

(to be completed)

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