The Medical Informatics Platform
Data Sharing and Processing Agreement

BETWEEN

Centre hospitalier universitaire vaudois (hereinafter: "**CHUV**").

AND

Research Center / Hospital: NAME (hereinafter: the "**CENTER**").

PREAMBLE

WHEREAS the Medical Informatics Platform (MIP) is an innovative DATA processing and analysis system that provides an interface for various investigators (clinicians, neuroscientists, epidemiologists, clinical researchers, health managers) enabling them to access and analyze ANONYMIZED DATA currently locked in hospitals, research centers and public databases.

WHEREAS the MIP was developed as part of the sub-project 8 of the Human Brain Project, an EU funded H2020 FET Flagship Project, to allow access to Hospital or Research center data while preserving DATA privacy. The HBP Flagship Project was launched within the European Commission's Future and Emerging Technologies (FET) scheme in October 2013 and is scheduled to run for ten years, WHEREAS its legacy will continue in EBRAINS, a sustainable European Research Infrastructure, that was launched in 2020 during HBP SGA3, the HBP`s last specific grant agreement.

WHEREAS Users of the MIP can explore models and variables, configure and apply statistical methods on clinical and research DATA, visualize and dynamically interact with the results.
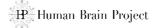
WHEREAS the clinical impact of the MIP specifically addresses EU health priorities to reduce the burden of brain diseases by leveraging personalized medicine and treatment.

WHEREAS CENTER datasets and other medical datasets contain vast amounts of DATA on health and diseases, which are an enormous asset to clinical investigators.

WHEREAS most of these datasets and repositories are largely underused due to data protection and patient confidentiality, or because of access requirements, the format of the DATA contained and/or the lack of infrastructure to PROCESS them.

WHEREAS the Centre Hospitalier Universitaire Vaudois (CHUV) is attached to the Department of health and social action of the State of Vaud;

WHEREAS, subject to the approval of the State government, the General Manager of CHUV is entitled to decide about collaborations with other health institutions and to sign collaboration agreements legally binding for CHUV;

WHEREAS CHUV is the legal entity responsible for the development of the Medical Informatics Platform and the management of the infrastructure within the framework of sub-project 8 and Service Category 5 of the Human Brain Project.

NOW, THEREFORE, the Parties agree as follows:

SUBJECT-MATTER

This Agreement binds the parties in the context of the PROCESSING of DATA through the Medical Informatics Platform.

This Agreement is complementary to the <mark>MIP SERVICE AGREEMENT AND SOFTEARE LICENCE,</mark> which covers the installation and use of the Medical Informatics Platform within the CENTER.

DEFINITION OF TERMS

AGREEMENT means this Data Processing Agreement;

AGGREGATES means the results of DATA PROCESSING, aggregation and compilation by the ALGORITHMS resulting in ANONYMOUS DATA;

ALGORITHMS defines the advanced computing analysis tools, which will PROCESS and compile DATA and generate the AGGREGATES;

ANONYMIZED DATA means DATA which has undergone a protocol to remove any information that may identify a natural person, either directly or indirectly;

CONSENT means a freely given, specific, informed and unambiguous indication of the PATIENT's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the PROCESSING of PERSONAL DATA relating to him or her, including, where applicable, explicit consent;

CONTROLLER means the natural or legal person, public authority, agency or other body which, alone or jointly with others, who determines the purposes and means of the processing of PERSONAL DATA;

DATA means PERSONAL DATA made available by CENTER through the MIP, including in the form of PSEUDONYMIZED DATA;

EXTERNAL USER means an end user accredited by the MIP data management for the MIP FEDERATE NETWORK.

GDPR means the General Data Protection Regulation 2016/679;

Research Center means the Research Center willing to make available DATA, through the MIP, to be PROCESSED, compiled and aggregated through the ALGORITHMS in order to provide USERS with AGGREGATES, allowing them to do research and improve knowledge on the brain related diseases;

IDENTIFIABLE NATURAL PERSON means a natural person 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;

INTERNAL USER means a USER internal to the CENTER accredited by the CENTER to access the MIP LOCAL;

MIP means the MIP is the system allowing a Research Center to make available ANONYMOUS DATA, and the USER to benefit from the results of advanced computing analysis and aggregation on the DATA made available;

MIP DATA GOVERNANCE STEERING COMMITTEE (MIP DGSC) means the committee responsible for the development and exploitation of the MIP FEDERATE NETWORK.

MIP IT TEAM means the team from CHUV responsible for the installation, deployment and maintenance of the MIP within the CENTER.

MIP LOCAL means the MIP installed locally on the CENTER servers containing PSEUDONYMIZED DATA;

MIP FEDERATE NODE means the part of the MIP installed in each HOSPITAL or Research Center that includes a server with fully ANONYMISED DATA and software that further preserve data privacy of ANONYMIZED DATA by returning only AGGREGATES or randomly altered DATA when queried;

MIP FEDERATE NETWORK means the network of all authorized, active and connected MIP federated nodes;

PATIENT(S) means natural persons submitting DATA to the CENTER.

PERSONAL DATA means any information relating to an identified or IDENTIFIABLE NATURAL PERSON, including data relating to health;

PERSONAL DATA BREACH means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, PERSONAL DATA transmitted, stored or otherwise PROCESSED;

PROCESSING means any operation or set of operations which is performed on PERSONAL DATA or on sets of PERSONAL DATA, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

PSEUDONYMIZED DATA means DATA which has undergone an encryption of the identifying entries in the record (such as HOSPITAL number, name, date of birth, etc.) in such a way that only the holder of a particular private cryptographic key may be able to reverse the process;

USER(S) means a person accredited to connect to the MIP interface.

1. SCOPE

This AGREEMENT covers the PROCESSING of DATA by the CENTER through the MIP.

2. MIP

The MIP comprises:

- a software to be installed locally by the CENTER in order to be able to PROCESS and give access to PSEUDONYMOUS DATA to INTERNAL USERS;
- a set of tools and ALGORITHMS developed for the CENTER to safely PROCESS and make available DATA in the form of ANONMYOUS DATA to EXTERNAL USERS;
- a set of tools and ALGORITHMS developed to generate, based on PSEUDONYMOUS DATA, AGGREGATES and virtual cohorts using characteristics and biomarkers and to run statistical analysis and data-driven modelling;
- an online interface for EXTERNAL USERS.

3. TYPE OF DATA

The CENTER understands and agrees that two (2) types of DATA will be PROCESSED by the MIP:

- PSEUDONYMIZED DATA
  The MIP will PROCESS the DATA in such a manner that the DATA can no longer be attributed to a specific PATIENT without the use of additional information.
  CENTER (and INTERNAL USERS) will only have access to and control over the PSEUDONYMIZED DATA. PSEUDONYMIZED DATA will not be shared nor made accessible to EXTERNAL USERS in any way.

- ANONYMIZED DATA
  At each level of the MIP, state of the art filters will ensure that DATA is PROCESSED by ALGORITHMS in order to generate AGGREGATES which will prevent EXTERNAL USERS to refine their queries and analysis with the aim to narrow it down to one individual patient, thus ensuring maximal anonymity and confidentiality.

4. PURPOSE OF PROCESSING

The DATA provided by CENTER will only be PROCESSED for scientific purposes through the MIP using AGGREGATES.

The DATA will be accessible to the ALGORITHMS to generate AGGREGATES usable by the EXTERNAL USER of the MIP. The DATA provided by CENTER will only be accessible to EXTERNAL USERS in the form of ANONYMIZED DATA. EXTERNAL USERS will be able to run statistical analysis and machine learning experiments based on specific hypothesis on the MIP.

In the case of specific request for commercial use, a special amendment to this AGREEMENT will be discussed to cover the case.

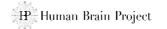### 5. OBLIGATIONS OF THE CENTER

5.1 CONTROLLER

CENTER is the sole CONTROLLER of the DATA in the view of the GDPR.

As CONTROLLER, CENTER shall be solely responsible towards PATIENTS to comply with GDPR obligations (right of access, portability, right to modify or erase, etc.).

As CONTROLLER, CENTER shall be solely responsible towards PATIENTS for any PERSONAL DATA BREACH. CENTER shall be solely responsible to comply with GDPR obligations in the event of PERSONAL DATA BREACH.

As CONTROLLER, CENTER shall take appropriate organizational and technical measure to ensure the security of the DATA.

As CONTROLLER, CENTER shall put in place an accreditation system in order to only give access to MIP LOCAL to INTERNAL USERS.

4.2 CONSENT

CENTER confirms that it is aware of its obligations in terms of CONSENT with respect to the DATA, including in terms of explicit CONSENT to the PROCESSING of those DATA by and through the MIP.

CENTER is solely responsible to strictly comply with its GDPR obligations (in particular Art. 9 (2) GDPR) and to obtain CONSENT of PATIENTS for the PROCESSING of their PERSONAL DATA by and through the MIP.

CENTER shall be responsible for the compliance of its DATA including obtaining the CONSENT from the PATIENTS, approved by the ethical body of reference in its geographical area.

CENTER is aware that should patients decide to withdraw his/her CONSENT, the relevant DATA must be erased immediately by CENTER from their MIP LOCAL.

CHUV is entitled to request CENTER to provide a blank version of the consent forms used by CENTER.

4.3 HOSTING

The DATA will be stored in a secured location at the CENTER defined facility. The DATA will not be copied nor moved from the CENTER servers. The DATA shall not be available or accessible to anyone other than CENTER or to the MIP IT TEAM.

CENTER will be hosting the DATA on MIP LOCAL. CENTER will be the only one having control over the servers where MIP LOCAL will be installed. DATA will not be copied nor moved from MIP LOCAL.

4.4 PSEUDONYMOUS DATA

CENTER shall be solely responsible for ensuring its` DATA to be pseudonymized. The required specifications and, in case requested, suitable TOOLS, will be provided by the MIP IT TEAM.

CENTER shall ensure that, at all times, additional information allowing PSEUDONYMIZED DATA to be attributed to an IDENTIFIABLE NATURAL PERSON is kept separately and controlled solely by CENTER and is subject to technical and organizational measures to ensure that the DATA are not attributed to an identified or IDENTIFIABLE NATURAL PERSON.

PSEUDONYMOUS DATA will be accessible to the ALGORITHMS which generate AGGREGATES usable by the EXTERNAL USERS of the MIP.
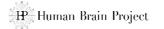
5   OBLIGATIONS OF CHUV

5.1   NO PROCESSING OF DATA

CHUV commits not to access nor PROCESS the DATA made available by CENTER for other purposes as those indicated in Article 4 of this AGREEMENT.

5.2   STANDARD CONTRACTUAL CLAUSES

Since it is based in a non-EU country, CHUV agrees, when PROCESSING the DATA, to comply at all times with the obligations contained in the standard contractual clauses for the transfer of personal data to

processors established in third countries under GDPR and, when required by CENTER, to enter into such agreement with CENTER.

5.3   MIP IT TEAM

CHUV shall provide CENTER with a list of the team members part of the MIP IT TEAM. For the purpose of the installation and support, all team members of MIP IT TEAM shall sign a Non-Disclosure Agreement (NDA) with the CENTER as attached in APPENDIX I.

For MIP Federated, the MIP IT TEAM shall keep complete log and records of accounts created, access requests and research led on the platform. These logs shall be stored and available for Ethics Commissions reviews if necessary.

5.3 MIP FEDERATE NETWORK

CHUV shall ensure that MIP FEDERATE NETWORK can only be accessed and analyzed, through the web-based user interface, by staff authorized by the MIP DGSC.

6   TERM AND TERMINATION

This AGREEMENT is valid for an indefinite period of time.

Either Party may terminate this AGREEMENT by serving a thirty (30) days written notice by certified mail to the other Party.

In the event of termination by CENTER, CHUV agrees to discontinue PROCESSING the DATA in order to generate AGGREGATES pursuant to the instructions of CENTER.

7   REPRESENTATIONS AND WARRANTIES

Each of the Parties represent and warrant that they have the unrestricted right and authority:

        a)   to enter validly into this Agreement;

        b)   to validly represent the party to this Agreement;

        c)   to perform all undertakings under or in connection with this Agreement;

and represent and warrant that this Agreement constitutes a valid, legal and binding obligation of the Parties, enforceable against the parties in accordance with its terms.

8   LIMITATION OF LIABILITY

Except in the event of PERSONAL DATA BREACH by CENTER or unlawful PROCESSING of PERSONAL DATA by CENTER, each Party shall only be liable towards the other for direct damages (including attorney's and court fees) suffered by the other Party in the event of fraud or gross negligence.

9   GOVERNING LAW AND PLACE OF JURISDICTION

This AGREEMENT shall be governed by the laws of Switzerland.

For all disputes arising under this AGREEMENT, which cannot be solved amicably, the courts of Lausanne shall have exclusive jurisdiction.

10 AMENDMENT

This AGREEMENT is subject to changes according to the work currently being done by the MIP DGSC, defining all the rules pertaining to the use of the MIP.

In any event, this AGREEMENT may not be modified except by a written instrument signed by authorized representatives of the Parties.

11 ASSIGNMENT

CHUV shall be entitled to assign this AGREEMENT or delegate its obligations under this AGREEMENT either in whole or in part without the prior written consent of CENTER.

CENTER shall not assign this AGREEMENT or its obligations under this AGREEMENT without prior written approval given by CHUV.
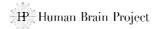
12 MISCELLANEOUS

This AGREEMENT constitutes the entire agreement and understanding of the parties and supersedes any prior agreements or understandings relating to the subject matter hereof.

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.

Nothing whatever in this AGREEMENT shall be construed as conferring rights to use in advertising, publicity, or otherwise the name and logo of either party or any of its respective marks or name of employees.

The terms of this AGREEMENT are severable such that if any term or provision is declared by a court of competent jurisdiction to be illegal, void, or unenforceable, the remainder of the provisions shall continue to be valid and enforceable.
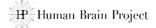
This AGREEMENT may be signed in counterparts, and by either party on separate counterpart, each which shall be deemed original, but all of which together constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have executed this AGREEMENT as one of the date first written above.

Signed for and on behalf of

CHUV

by _____

Title: General Manager or Chef du Département des Neurosciences Cliniques

Date:

Signed for and on behalf of

CENTER

by:

Title:

Date:

APPENDIX I: NON-DISCLOSURE AGREEMENT

This NON-DISCLOSURE AGREEMENT (hereinafter: "**this Agreement**") is made on

[date]

BETWEEN

NAME OF YOUR CENTER

(the "**DISCLOSING PARTY**")

AND

CHUV

(the "**RECEIVING PARTY**")

WHEREAS the DISCLOSING PARTY has developed, holds, owns and controls Confidential Information (as defined below) ;

WHEREAS the parties recognize that it is necessary for the DISCLOSING PARTY to protect Confidential Information which they are disclosing under strict confidentiality requirements;

WHEREAS the RECEIVING PARTY will have to access Confidential Information from the DISCLOSING PARTY in relation to their contractual relationship;

NOW, THEREFORE, THE PARTIES AGREE TO THE FOLLOWING:

1.   "Confidential Information" means:

a)   any and all information concerning the business of the DISCLOSING PARTY disclosed to the RECEIVING PARTY, either directly or indirectly, in writing, electronically, orally or by inspection, including, without limitation, personal data including patient's data, software related information, name of persons involved in the project and/or any other information related, directly or indirectly, to the business of the DISCLOSING PARTY communicated or disclosed by the DISCLOSING PARTY to the RECEIVING PARTY protected or not by any intellectual property right, registered or not, or any other right;

b) any information otherwise obtained, directly or indirectly, by the RECEIVING PARTY through inspection, review or analysis of the Confidential Information and/or related documents. Confidential Information may also include information from a third party which the DISCLOSING PARTY possesses and which is disclosed to the RECEIVING PARTY under this Agreement.

2. Confidential Information shall not, however, include:

a) Information made generally available in the public domain prior to the time of disclosure by the DISCLOSING PARTY;

b) Information which becomes publicly known and made generally available after disclosure by the DISCLOSING PARTY to the RECEIVING PARTY through no action or inaction of the RECEIVING PARTY;

c) Information in relation to which the RECEIVING PARTY has material evidence that it was already in his/her possession at the time of disclosure by the DISCLOSING PARTY as shown by the RECEIVING PARTY's files and records immediately prior to the time of disclosure;

d) Information in relation to which the RECEIVING PARTY has material evidence that the information was obtained from a third party lawfully in possession of such information, independently and without a breach of such third party's obligations of confidentiality or of this Agreement by the RECEIVING PARTY;

or

e) information which is independently developed by the RECEIVING PARTY without use of or reference to the DISCLOSING PARTY's Confidential Information, as shown by documents and other formal evidence in the RECEIVING PARTY's possession.

3. The RECEIVING PARTY acknowledges that the Confidential Information disclosed on the basis of this Agreement (which integrates any other contractual relationship between the Parties) shall not be disclosed to third parties and remain the exclusive property of the DISCLOSING PARTY. The disclosure of any Confidential Information by the DISCLOSING PARTY under this Agreement is not intended to grant any right or license to the RECEIVING PARTY in relation to the Confidential Information, nor represent any assignment or share of the Confidential Information or related intellectual property to the RECEIVING PARTY.
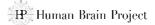
4.   The RECEIVING PARTY agrees:

a)   not to use the Confidential Information for any purpose other than in the context of the Medical Informatics Platform;

b)   not to disclose any Confidential Information to any third party or parties without the prior written agreement of the DISCLOSING PARTY and under the conditions set forth by the DISCLOSING PARTY;

c)   not make any copy, reproduction or save, physically or electronically, or make the Confidential Information or any part thereof available in any way, except upon the DISCLOSING PARTY's prior written approval;

The RECEIVING PARTY agrees that it shall take reasonable measures to protect the secrecy of and avoid disclosure and unauthorized use of the Confidential Information.

Without limiting the foregoing, the RECEIVING PARTY shall take all measures that it takes to protect its own confidential information of a similar nature, but in no case shall it take less care.

The RECEIVING PARTY shall promptly notify the party disclosing such Confidential Information of any use or disclosure of such Confidential Information in violation of this Agreement of which the RECEIVING PARTY becomes aware.

5.   If the RECEIVING PARTY is required by law or regulation to make any disclosure that is prohibited or otherwise constrained by this Agreement, the RECEIVING PARTY will provide the DISCLOSING PARTY with prompt written notice of such requirement so that the DISCLOSING PARTY may seek a protective order or other appropriate action. If, despite the measures taken by the DISCLOSING PARTY to protect the Confidential Information, the RECEIVING PARTY is legally required to disclose the Confidential Information the RECEIVING PARTY will do so reservedly and divulge only that information required by law.

6.   Nothing in this Agreement shall be understood as an exclusivity or a partnership between the parties, unless the parties decide otherwise in writing. The parties are therefore free to pursue discussions and business relations with third parties.

7.   The obligations of each RECEIVING PARTY under this Agreement shall survive until such time as all Confidential Information of the other party disclosed hereunder becomes publicly known and made generally by the DISCLOSING PARTY.
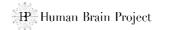
All documents and other support material containing or representing Confidential Information that has been disclosed to the RECEIVING PARTY, and all copies or extracts thereof that are in the possession of the RECEIVING PARTY, shall be and remain the property of the DISCLOSING PARTY and shall be promptly returned to the DISCLOSING PARTY upon request, but in any event, upon termination of this Agreement.

8.   Confidential Information is provided "as is", without any warranty of any kind to the RECEIVING PARTY. The DISCLOSING PARTY shall not be held liable of any consequences for errors or omissions in relation to the Confidential Information, its use or the results obtained on the basis of its use.

9.   The RECEIVING PARTY shall indemnify the DISCLOSING PARTY for any damages, loss, expenses or costs (including attorney's and court fees) incurred by the DISCLOSING PARTY or its Affiliates as a result of any violation of this Agreement, any third party claim against the DISCLOSING PARTY or any breach of any warranty contained in this Agreement.

10.   If any provision of this Agreement is found to be illegal or unenforceable, other provisions shall remain effective and enforceable during the term of this Agreement to the greatest extent permitted by law.

11.   Each of the parties represent and warrant that they have the unrestricted right and authority:

   d)   to enter validly into this Agreement;

   e)   to validly represent the party to this Agreement;

   f)   to perform all undertakings under or in connection with this Agreement;

and represent and warrant that this Agreement constitutes a valid, legal and binding obligation of the parties, enforceable against the parties in accordance with its terms.

12.   This Agreement shall be binding upon and shall inure to the benefit of the parties thereto, their affiliates and their respective permitted successors and assigns. This Agreement shall not be assigned by either party to a third party without the prior written consent of the other party thereto, which consent may be withheld in either party's sole discretion, and any purported assignment without such consent shall be void.

13.   This Agreement shall be governed and construed in accordance with the laws of Switzerland, to the exclusion of rules of international private law. The Courts of Lausanne Switzerland shall have exclusive jurisdiction, subject to an appeal to Cantonal Court or to the Swiss Federal Court.

SIGNED IN 2 ORIGINALS

THE RECEIVING PARTY

[Place], [date] _____

THE DISCLOSING PARTY

[Place], [date] _____