

# THE MEDICAL INFORMATICS PLATFORM

## MIP INSTALLATION AND LICENSE AGREEMENT

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# The Medical Informatics Platform Installation and License Agreement

## BETWEEN

Centre hospitalier universitaire vaudois (hereinafter : “CHUV”).

## AND

CENTRE: NAME – ADRESS (hereinafter: the “CENTRE”).

## PREAMBLE

**WHEREAS** the Medical Informatics Platform (MIP) is an innovative IT solution using open source software that provides an interface for various investigators (clinicians, neuroscientists, epidemiologists, researchers, health managers) enabling them to access and analyze medical data currently locked in hospitals or medical research CENTRES.

**WHEREAS** the MIP was developed as part of the sub-project 8 of the Human Brain Project, a EU funded H2020 FET Flagship Project, to unlock access to CENTRE data while preserving data privacy.

**WHEREAS** the HBP Flagship Project was launched by the European Commission's Future and Emerging Technologies (FET) scheme in October 2013 and is scheduled to run for ten years.

**WHEREAS** the MIP consists in two components:

- one “MIP LOCAL” which is being installed in the CENTRES and contains pseudonymised data that can only be accessed and analyzed by the accredited staff from within the CENTRE, and
- one “MIP federated node” which installed on a second server in the CENTRE, contains anonymized data and can be connected to other MIP-Federated Nodes in other hospitals/CENTRES. Upon signed agreement between data providers from the MIP network, accredited investigators can query multiple MIP federated nodes and obtain aggregate results. Queries of the MIP-Federated Nodes do not allow to copy or upload any data, nor to see individual patient’s data.

**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** 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 of the Human Brain Project.

**NOW, THEREFORE**, the Parties agree as follows:

## **SUBJECT-MATTER**

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This AGREEMENT binds the Parties in the context of the INSTALLATION and USE of the Medical Informatics Platform for research only.

It is covering the DISTRIBUTION, INSTALLATION and USE of the Medical Informatics Platform in the CENTRE.

This AGREEMENT does not cover any aspect of data sharing. These aspects will be covered in a different contract "Data Sharing Agreement".

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## **DEFINITION OF TERMS**

**AGREEMENT** means this Installation and License Agreement;

**CENTRE** means any hospital, clinic, research institute or university entering into this AGREEMENT where the Medical Informatics Platform is installed pursuant to the terms of this AGREEMENT;

**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;

**INSTALLATION** means the process of downloading and installing the SOFTWARE on the CENTRE IT infrastructure and servers;

**LICENSE** means the GNU General Public License v. 3 (<https://www.gnu.org/licenses/gpl-3.0.en.html>) reproduced in Annex III;

**MEDICAL INFORMATICS PLATFORM (MIP)** means an IT platform comprising a suite of open source software, including a front-end interface for EXTERNAL USERS designed to allow privacy preserving data sharing within and across hospitals/CENTRES in Europe, based on the use of software installed locally in the CENTRE;

**MIP** means the Medical Informatics Platform made available by CHUV under the terms of this Agreement and installed in the CENTRE.

**MIP LOCAL** means the primary component of the MIP software installed in the CENTRE, which contains pseudonymized data from the CENTRE and can only be accessed by users from the CENTRE.

**MIP FEDERATED NODE** means the optional component of the MIP software installed in the CENTRE, which contains anonymized data from the CENTRE and can be connected to the MIP FEDERATE NETWORK upon authorization by the CENTER and under its control.



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

**MIP IT TEAM** means the team from CHUV or its partners listed in ANNEX I supporting the installation and maintenance of MIP in the CENTRE;

**PACKAGE** means the suite of SOFTWARE and the instructions to install the SOFTWARE on the CENTRE IT infrastructure;

**SERVICE** or **SERVICES** refers to the services provided to CENTRE by CHUV pursuant to the SLA;

**SERVICE LEVEL AGREEMENT (SLA)** means the agreement attached in ANNEX IV defining the SERVICES to be provided by CHUV to the HOSPITAL;

**SOFTWARE** means the suite of open source software listed in ANNEX II contained into the MIP, including all UPDATES and UPGRADES of such open source software

**SYSTEM** means the information system made available through the MIP.

## ARTICLES

### 1 SCOPE

Pursuant to the terms of this AGREEMENT, CHUV and, on its behalf, the MIP IT TEAM will provide CENTRE with:

- 1.1. The PACKAGE;
- 1.2. The LICENSE;
- 1.3. The SERVICES.

### 2 LICENSE

CHUV distributes, makes available to the CENTRE and installs the SOFTWARE on the CENTRE's dedicated server, pursuant to the terms of the LICENSE.

CENTRE is entitled to copy, reproduce, distribute, modify, translate, create derivative works out of, the SOFTWARE (or the resulting derivative work) in any medium, with or without modifications, in source form, provided it strictly complies with the terms of the LICENSE, meaning that the CENTRE shall ensure that:

- a) The SOFTWARE carries prominent notices stating that CENTRE modified it, and giving a relevant date;
- b) The SOFTWARE must carry prominent notices stating that it is released under the LICENSE and any conditions added under section 7 of the LICENSE.
- c) CENTRE must license the entire SOFTWARE (including all derivative works), as a whole, under the LICENSE to anyone who comes into possession of a copy of the SOFTWARE.



d) If the SOFTWARE has interactive user interfaces, each must display appropriate legal notices.

All appropriate copyright and other proprietary notices and legends shall be retained on the SOFTWARE, and CENTRE shall maintain and reproduce such notices on all authorized copies of the SOFTWARE and related documentation including in any scientific publications.

### **3 SERVICES**

CHUV provides to CENTRE the SERVICES listed in the SERVICE LEVEL AGREEMENT.

Such SERVICES may be, at all times, delegated by CHUV to a third party, subject to prior approval of the CENTRE.

### **4 CENTRE OBLIGATIONS**

CENTRE is responsible for providing the required IT infrastructure dedicated for MIP to be installed and commit IT resources for the INSTALLATION, in compliance with the applicable data protection regulations.

CENTRE shall accept the INSTALLATION of the SOFTWARE locally on its IT infrastructure dedicated to MIP.

CENTRE is responsible for ensuring that MIP is used for research purpose only. MIP has not been designed as a clinical diagnostic software. CENTRE is also responsible for ensuring that any data stored into the MIP has been pseudonymised according to standards and that any data stored in the MIP FEDERATED NODE has been anonymized.

CENTRE is responsible for complying with the terms of the LICENSE.

### **5 TERM AND TERMINATION**

This AGREEMENT is valid for an indefinite period of time (the “Term”).

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

This AGREEMENT shall be automatically terminated in the event of termination of the HBP Flagship Project.

In the event of termination of this AGREEMENT, CHUV will stop providing the SERVICES.

### **6 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.

## **7 NO WARRANTIES**

The SOFTWARE is provided to the CENTRE “AS IS” without any warranty of any kind.

The Parties make no warranties, either explicit or implied, with respect to the MIP, the SOFTWARE, and/or the SERVICES and/or as to any matter including but not limited to, warranties of ownership, novelty, patentability, originality, accuracy, non-infringement, merchantability, quality or fitness of the MIP and/or the SOFTWARE, the SERVICES for a particular purpose.

The SERVICES are provided by CHUV to the CENTRE without any warranty and without any obligation of result.

## **8 LIABILITY**

Each Party shall only be liable towards the other in the event of fraud or gross negligence resulting in direct damages for the other party. Any other liability incurred by a party as a result of a breach of the obligations contained in this AGREEMENT and/or as a result of the MIP, the SOFTWARE and/or the SERVICES is excluded.

## **9 APPLICABLE LAW AND PLACE OF JURISDICTION**

This AGREEMENT shall be governed by the laws of Switzerland.

All disputes concerning intellectual property arising under this AGREEMENT shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Lausanne unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon. If, and to the extent that, any such dispute has not been settled pursuant to the mediation within 60 calendar days of the commencement of the mediation, the courts of Lausanne shall have exclusive jurisdiction.

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

## **10 AMENDMENT**

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 CENTRE.

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

## **12 MISCELLANEOUS**

This AGREEMENT supersedes any and all prior agreements or understandings relating to the subject matter hereof. This AGREEMENT may not be modified except by a written instrument signed by authorized representatives of the Parties.

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.

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.

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.



**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

Date:

Signed for and on behalf of

**CENTRE**

by: \_\_\_\_\_

Title:

Date:



# 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 analysis system that provides an interface for various investigators (clinicians, neuroscientists, epidemiologists, 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, a EU funded H2020 FET Flagship Project, to unlock access to Hospital or Research center data while preserving DATA privacy. The HBP Flagship Project was launched by the European Commission's Future and Emerging Technologies (FET) scheme in October 2013 and is scheduled to run for ten years.

**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 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 of the Human Brain Project.

**NOW, THEREFORE**, the Parties agree as follows:

## **SUBJECT-MATTER**

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

This Agreement is complementary to the INSTALLATION AGREEMENT, which covers the installation and use of the Medical Informatics Platform within the CENTER.

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## **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, 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;

HBP MIP, Installation and License Agreement



**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 FEDERATED 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 ANONYMOUS 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 analysis enough 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 hypothesis on the MIP.

In the case of specific request for commercial use, a special amendment to this AGREEMENT will be HBP MIP, Installation and License Agreement



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 HBP MIP, Installation and License Agreement



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 will be provided by 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 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.

The MIP IT TEAM shall keep complete log and records of accounts created, access requests, research led on the platform and results obtained. 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.

This AGREEMENT shall be automatically terminated in the event of termination of the HBP Flagship Project.

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

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:



- 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.

- 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] \_\_\_\_\_



## ANNEX I – GNU General Public License

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Version 3, 29 June 2007

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Some devices are designed to deny users access to install or run modified versions of the software inside them, although the manufacturer can do so. This is fundamentally incompatible with the aim of protecting users' freedom to change the software. The systematic pattern of such abuse occurs in the area of products for individuals to use, which is precisely where it is most unacceptable. Therefore, we have designed this version of the GPL to prohibit the practice for those products. If such problems arise substantially in other domains, we stand ready to extend this provision to those domains in future versions of the GPL, as needed to protect the freedom of users.

Finally, every program is threatened constantly by software patents. States should not allow patents to restrict development and use of software on general-purpose computers, but in those that do, we wish to avoid the special danger that patents applied to a free program could make it effectively proprietary. To prevent this, the GPL assures that patents cannot be used to render the program non-free.

The precise terms and conditions for copying, distribution and modification follow.

## **TERMS AND CONDITIONS**

### **0. Definitions.**

“This License” refers to version 3 of the GNU General Public License.

“Copyright” also means copyright-like laws that apply to other kinds of works, such as semiconductor masks.

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To “convey” a work means any kind of propagation that enables other parties to make or receive copies. Mere interaction with a user through a computer network, with no transfer of a copy, is not conveying.





An interactive user interface displays “Appropriate Legal Notices” to the extent that it includes a convenient and prominently visible feature that (1) displays an appropriate copyright notice, and (2) tells the user that there is no warranty for the work (except to the extent that warranties are provided), that licensees may convey the work under this License, and how to view a copy of this License. If the interface presents a list of user commands or options, such as a menu, a prominent item in the list meets this criterion.

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The “source code” for a work means the preferred form of the work for making modifications to it. “Object code” means any non-source form of a work.

A “Standard Interface” means an interface that either is an official standard defined by a recognized standards body, or, in the case of interfaces specified for a particular programming language, one that is widely used among developers working in that language.

The “System Libraries” of an executable work include anything, other than the work as a whole, that (a) is included in the normal form of packaging a Major Component, but which is not part of that Major Component, and (b) serves only to enable use of the work with that Major Component, or to implement a Standard Interface for which an implementation is available to the public in source code form. A “Major Component”, in this context, means a major essential component (kernel, window system, and so on) of the specific operating system (if any) on which the executable work runs, or a compiler used to produce the work, or an object code interpreter used to run it.

The “Corresponding Source” for a work in object code form means all the source code needed to generate, install, and (for an executable work) run the object code and to modify the work, including scripts to control those activities. However, it does not include the work's System Libraries, or general-purpose tools or generally available free programs which are used unmodified in performing those activities but which are not part of the work. For example, Corresponding Source includes interface definition files associated with source files for the work, and the source code for shared libraries and dynamically linked subprograms that the work is specifically designed to require, such as by intimate data communication or control flow between those subprograms and other parts of the work.

The Corresponding Source need not include anything that users can regenerate automatically from other parts of the Corresponding Source.

The Corresponding Source for a work in source code form is that same work.

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b) The work must carry prominent notices stating that it is released under this License and any conditions added under section 7. This requirement modifies the requirement in section HBP MIP, Installation and License Agreement



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a) Convey the object code in, or embodied in, a physical product (including a physical distribution medium), accompanied by the Corresponding Source fixed on a durable physical medium customarily used for software interchange.

b) Convey the object code in, or embodied in, a physical product (including a physical distribution medium), accompanied by a written offer, valid for at least three years and valid for as long as you offer spare parts or customer support for that product model, to give anyone who possesses the object code either (1) a copy of the Corresponding Source for all the software in the product that is covered by this License, on a durable physical medium customarily used for software interchange, for a price no more than your reasonable cost of physically performing this conveying of source, or (2) access to copy the Corresponding Source from a network server at no charge.

c) Convey individual copies of the object code with a copy of the written offer to provide the Corresponding Source. This alternative is allowed only occasionally and noncommercially, and only if you received the object code with such an offer, in accord with subsection 6b.

d) Convey the object code by offering access from a designated place (gratis or for a charge), and offer equivalent access to the Corresponding Source in the same way through the same place at no further charge. You need not require recipients to copy the Corresponding Source along with the object code. If the place to copy the object code is a network server, the Corresponding Source may be on a different server (operated by you or a third party) that supports equivalent copying facilities, provided you maintain clear directions next to the HBP MIP, Installation and License Agreement



object code saying where to find the Corresponding Source. Regardless of what server hosts the Corresponding Source, you remain obligated to ensure that it is available for as long as needed to satisfy these requirements.

e) Convey the object code using peer-to-peer transmission, provided you inform other peers where the object code and Corresponding Source of the work are being offered to the general public at no charge under subsection 6d.

A separable portion of the object code, whose source code is excluded from the Corresponding Source as a System Library, need not be included in conveying the object code work.

A “User Product” is either (1) a “consumer product”, which means any tangible personal property which is normally used for personal, family, or household purposes, or (2) anything designed or sold for incorporation into a dwelling. In determining whether a product is a consumer product, doubtful cases shall be resolved in favor of coverage. For a particular product received by a particular user, “normally used” refers to a typical or common use of that class of product, regardless of the status of the particular user or of the way in which the particular user actually uses, or expects or is expected to use, the product. A product is a consumer product regardless of whether the product has substantial commercial, industrial or non-consumer uses, unless such uses represent the only significant mode of use of the product.

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If the disclaimer of warranty and limitation of liability provided above cannot be given local legal effect according to their terms, reviewing courts shall apply local law that most closely



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## ANNEX II - Service Level Agreement (SLA)

### 1 Definitions

**CLAIM** means a claim submitted by CENTRE to CHUV with respect to the SOFTWARE pursuant to this SLA;

**EXTERNAL CONNECTIVITY** is bi-directional network traffic that can be sent and received from a public IP address ensuring a remote access;

**INCIDENT** is an unplanned interruption to or reduction in the quality of the IT service provided by the MIP, including the failure of a configuration item that has not yet affected service (ITIL 2011);

**MIP LOCAL** means the primary component of the MIP software installed in the CENTRE, which contains pseudonymized data from the CENTRE and can only be accessed by users from the CENTRE.

**RELEASE** means a collection of hardware, software, documentation, processes or other components required to implement one or more approved changes, update or upgrade to the SOFTWARE. The contents of each RELEASE are managed and tested as a unit, and deployed as a single entity.

**SUPPORT** means the services by which CHUV may provide assistance to CENTRE to resolve issues with the MIP.

Definitions of the MIP Installation and License Agreement are hereby incorporated by reference.

### 2 SERVICES

The SERVICES will be provided to CENTRE for the duration of the Term of the MIP Installation and License Agreement. The SLA can be updated independently from the renewal or update of the MIP Installation and License Agreement.

The SERVICES include:

- **SUPPORT:**
  - Level 1;
  - Level 2;
  - Level 3.
- **End-user Assistance:**
  - User access management;
  - User and technical documentation.
- **INCIDENT Management:**



- INCIDENT report;
- Root-cause analysis;
- INCIDENT resolution.
- Availability Management:
  - Design service for availability;
  - Availability testing;
  - Availability monitoring and reporting.
- SOFTWARE Maintenance:
  - SOFTWARE maintenance;
  - RELEASE planning;
  - Emergency SOFTWARE release planning;
  - RELEASE management.

### 3 Support

There are three levels of support.

<b>Level 1</b>	<p>The first level support attempts to collect as much information and diagnostics about the INCIDENT as possible and best effort to resolve the issue on the spot.</p> <p>Every INCIDENT or user demand has to be reported to the first level support, which is responsible for managing the CLAIM. If the first level support is not able to resolve the INCIDENT right away, it will escalate the INCIDENT to second level support.</p>
<b>Level 2</b>	<p>The second level is devoted to INCIDENT and problem resolutions.</p> <p>If the second level support is not able to resolve the INCIDENT, it will escalate the INCIDENT to third level support.</p>
<b>Level 3</b>	<p>The third level is constituted by all third parties involved is the development of the SOFTWARE. If CHUV HBP MIP Team cannot fix the underlying cause of the INCIDENT, it escalates to the relevant open source software communities.</p>

#### 3.1 First-level Support

The first level support is provided by the HBP HLST team.

Contact address is [support@humanbrainproject.eu](mailto:support@humanbrainproject.eu).

Opening hours are from 9:00 to 17:00 Central European Time except bank holidays (federal and cantonal (Vaud)).

#### 3.2 Second-level Support

The second level support is provided by the CHUV HBP MIP team.



In cases when the first level support team cannot resolve an INCIDENT, it provides a request for support to the second level support team.

The second level support provides SERVICE in its domain of competencies. The SERVICE is provided on a best-effort basis during the opening hours from 9:00 to 17:00 Central European Time except bank holidays (federal and cantonal (Vaud)).

### **3.3 Third Level Support**

The third level support is provided by the CHUV HBP MIP team.

In cases when the second level support team cannot resolve an INCIDENT, it provides a request for support to the third level support team.

The third-level support team consists of the experienced members of the CHUV MIP team involved in the development of the MIP platform. They have all the necessary competencies to resolve the most complex INCIDENTS.

If appropriate, in cases when the source of the incident is a third-party component, third-level support team may propose integration of an alternative solution to the development team. In these cases, the development team decides on whether and when the change will be released, subject to internal HBP MIP development project coordination and prioritization.

The SERVICE is provided on a best-effort basis during the opening hours from 9:00 to 17:00 Central European Time except bank holidays (federal and cantonal (Vaud)).

## **4 End-user Assistance**

Users of the MIP can contact the first level support for assistance.

Assistance includes support in using the MIP, simple modifications of parameters, corrections to the DATA or any other request related to the MIP usage that the user or super-user cannot respond by his own means. The CLAIM should be accompanied by the expected solution deadline.

## **5 INCIDENT Management**

CENTRE raises an INCIDENT by contacting the MIP first level support using the e-mail address provided in section 2 of this SLA. The first level support registers the INCIDENT and provides its reference (ticket number) to the CENTRE.

The first-level support provider analyses root-cause of the INCIDENT and resolves it in the scope of its responsibilities and its domain of competence. In cases when it cannot resolve the INCIDENT, the first level support provider escalates the INCIDENT to the second-level support (CHUV HBP MIP team) and informs the end-user about the escalation.

The second level support provider analyses root-cause of the INCIDENTSs escalated by the first-level support and resolves it in the scope of its responsibilities and its domain of competence. In cases



when it cannot resolve the INCIDENT, the second-level support provider escalates the INCIDENT to the third-level support.

The third-level support provider analyses root-cause of the INCIDENT and resolves it in the scope of its responsibilities. The third-level support provider is an engineer experienced with the development of the HBP MIP who has all necessary competencies to resolve the most complex INCIDENTS. The third-level support provider is responsible for coordinating the plans for emergency software releases with the HBP MIP software development team.

## 6 Availability Management

THE CHUV HBP MIP team is responsible for designing the procedures and technical features to maximise the MIP availability levels.

The CHUV HBP MIP TEAM shall continuously monitor MIP availability, identify the areas where it must be improved, and implement measures for the availability maximization. The identification of areas for improvement and implementation of measures for improvement are done on a best-effort basis.

## 7 SOFTWARE MAINTENANCE

### 7.1 Maintenance Window

The maintenance windows planned for releasing MIP UPDATES or UPGRADES will be communicated at least 3 months in advance (usually year after year). There can be at most four upgrades per year.

### 7.2 Emergency RELEASES

Between the planned HBP MIP software maintenance windows, important and/or urgent corrections shall be released in the scope of emergency software RELEASES, subject to internal HBP MIP development project coordination and prioritization.

### 7.3 EXTERNAL CONNECTIVITY

To guarantee maximum level of platform availability, CENTRE shall permanently provide to at least two CHUV HBP MIP engineers a secure EXTERNAL CONNECTIVITY to super-user credentials for the MIP execution environment.

If CENTRE cannot provide permanent EXTERNAL CONNECTIVITY and credentials to CHUV HBP MIP engineers, it is recommended to at least grant a temporary EXTERNAL CONNECTIVITY and credentials to the MIP execution environment during the maintenance release windows, or intermittently on-demand, within a reasonable timeframe, for un-planned emergency operations.

In cases where CENTRE's data centre security policy strictly forbids any remote access and/or super-user credentials to third-party personnel, CENTRE and CHUV HBP MIP team will define a specific operation procedure.



#### **7.4 RELEASE management**

During the Term, RELEASES will be deployed in the CENTRE's private execution environment (MIP LOCAL) either by the CHUV HBP MIP team or by the CENTRE's IT responsible.

CENTRE shall install the RELEASES or allow MIP IT TEAM to proceed to the installation of the RELEASES.

The same terms of the LICENSE contained in the MIP Installation and License Agreement will apply to the RELEASES.

### **8 EXCLUSIONS**

This SLA does not apply to any INCIDENTS:

- occurring during maintenance of the SOFTWARE;
- due to factors outside CHUV's reasonable control (for example, a network or device failure at the CENTRE);
- failure of CENTRE to provide EXTERNAL CONNECTIVITY to MIP IT TEAM to MIP LOCAL or to CENTRE server;
- resulting from CENTRE's or third-party hardware or software, including VPN devices that have not been tested and found to be compatible by MIP IT TEAM;
- resulting from actions or inactions of CENTRE or third parties;
- caused by CENTRE's use of the SOFTWARE after MIP IT TEAM advised CENTRE to modify its use of the SOFTWARE, if CENTRE did not modify its use as advised;
- due to any act or omission of CENTRE or CENTRE's employees, agents, contractors, or vendors, or anyone gaining access to the SOFTWARE by means of CENTRE's passwords or equipment.