**DATA TRANSFER AGREEMENT FOR NON-HUMAN PRIMATE DATA**

* **PREMISE DATABASE**

DATA TRANSFER AGREEMENT

**BY AND BETWEEN**

**UNIVERSITY CLAUDE BERNARD LYON 1 (UCBL)**, a public scientific, cultural and professional establishment whose registered office is 43 Boulevard du 11 Novembre 1918, 69100 Villeurbanne, represented by its authorized representative Frederic FLEURY, its President,

UCBL acting on its own behalf and on behalf of:

* **INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE** **(INSERM)**, a French public institution dedicated to research in the field of health and medicine, having its head office at 101, rue de Tolbiac — 75013 PARIS, FRANCE, represented by its General Director, Mr. Gilles BLOCH
* **INSTITUT NATIONAL DE RECHERCHE POUR L’AGRICULTURE, L’ALIMENTATION ET L’ENVIRONNEMENT (INRAE**), a public scientific and technological establishment, having its registered office at 147 Rue de l'Université - 75338 Paris Cedex 07, France, represented by its President Mr. Philippe MAUGUIN,

in the framework of the activities of the Mixed Research Unit “INSERM U1060 INRAE U1397: CARDIOVASCULAR RESEARCH LABORATORY, METABOLISM, AND NUTRITION DIABETOLOGY” herein referred to as “CARMEN Laboratory”, directed by Mr Hubert VIDAL.

Hereinafter the “Establishments”

**AND**

---------------- [legal form], whose registered office is………………………………………………………………………………,

represented by its authorized representative ……………………., its …………………….,

Hereinafter “XX”

The above-mentioned parties shall hereinafter individually be called “Party” and collectively be called “the Parties”.

**WHEREAS**

A specific database of combined of PET/MRI brain images from 20 adults Macaca fascicularis processed by scientists from the CARMEN Laboratory and owned by the Establishments (hereinafter “Establishments Database”) was developed within the framework of the RHU MARVELOUS : “New MR imAging to pReVent cErebraL and myOcardial reperfUSion injury” (ANR-16-RHUS-0009) of l’Université Claude Bernard Lyon 1 (UCBL), within the program "Investissements d'Avenir” operated by the French National Research Agency (ANR).

XXX wishes to have access to data from Establishments Database in the framework of Brain imaging data processing. In this context, the Establishments agreed to transfer the data to XXX exclusively for the Permitted Purpose.

Therefore, the Parties wish to specify in this agreement the access conditions and modalities of the transfer of data from Establishments Database for the Permitted Purpose.

**NOW IT IS HEREBY AGREED AS FOLLOWS**

**Article 1: DEFINITIONS**

When used in this agreement, the following words and expressions, beginning with a capital letter, have the following respective meanings:

« **Agreement** » means this Agreement, as well as any subsequent amendments thereof.

« **Data** » means all preclinical data of PET/MRI brain images from 20 adults Macaca fascicularis, then transferred and organized in the Database.

« **Database** » means the set of Data, organized in a systematic or methodological manner, and accessible by electronic means and/or via Internet, hosted on the CERMEP platform and developed and owned by the Establishments within the framework of the RHU MARVELOUS, as mentioned in the preamble.

**Article 2: OBJECT**

The purpose of this Agreement is to specify the conditions under which CARMEN Laboratory transfers the Data to XXX for the Permitted Purpose.

**ARTICLE 3: RIGHTS GRANTED**

3.1 Establishments grant a non-exclusive, non-transferable license to XXX to use the Data, for the duration of this Agreement, free of charge for the purposes of academic, non-commercial research and teaching and exclusively in the framework of Brain imaging data processing (hereinafter the « Permitted Purpose”) as described in the paper: “PREMISE: A database of 20 Macaca Fascicularis PET/MRI brain imaging available for research. Chalet, L. et al. DOI: 10.1101/2023.03.03.530981”.

The Permitted Purpose of the Data includes:

* Pre-processing, processing and post-processing of non-human primate PET/MRI brain images.

For the avoidance of doubt, the licence does not include using Data for (i) commercially-sponsored research or (ii) the diagnosis, treatment or medical care of patients.

3.2 XXX acknowledge and accept expressly that it is not allowed:

* To use Data for any other purpose than the Permitted Purpose;

• To sub-licence the Data to a third party without prior written agreement of the Establishments;

• To copy, duplicate, adapt, disclose, assign, distribute or supply to a third party for any purpose whatsoever the Data and/or allowing a third party to access and use the Data, without the express prior written consent of the Establishments;

* To use the Data as the basis of any commercial product without prior written agreement of the Establishments;
* To transfer the Data to a third party, without prior written agreement of the Establishments.

3.3 The Establishments are the sole owners of the Data. Except as provided in this Agreement, XXX shall not hold any other rights to Data of any kind whatsoever.

3.4 Furthermore, XXX expressly undertakes to:

• implement procedures to ensure that all employees authorized to access the Data respect and maintain the confidentiality and security of the Data;

• process the Data exclusively for the need of the Permitted purpose.

XXX acknowledge and accept that these obligations are obligations of result and constitute an essential condition of the consent of the Establishments.

Establishments may verify by any means that the Data are used in accordance with the terms and conditions of this Agreement.

**ARTICLE 4:** **INTELLECTUAL PROPERTY** **– PUBLICATIONS – CONFIDENTIALITY**

4.1 XXX recognizes that the Establishments are the sole and unique owners in their capacity of producer of the said Database, as provided for in article L.341-1 of the Intellectual Property Code.

This Agreement does not transfer any intellectual property right other than the non-exclusive right of use the Data provided to XXX for the Permitted Purpose.

It is hereby agreed between the Parties that the Establishments retain the right to transfer the Data to a third party and to use them for their own purposes.

XXX shall promptly provide, whether patentable or unpatentable, a full written disclosure to the Establishments of any invention, improvement, or discovery made in the Permitted Purpose (“Invention”). XXX shall not file any application for intellectual property right (e.g including but not limited to patent applications) relating to Data or Invention without the prior and express written permission of the Establishments.

Unless otherwise agreed upon by the Parties, the Establishments shall have the right to obtain patent protection, at its expense, for Inventions for which patent protection is not pursued by XXX, and XXX shall cooperate and assist in preparing, maintaining and filing of such.

In case XXX file any application for intellectual property right relating to Data or Invention, XXX shall grant to the Establishments, free of charge, a non-exclusive, sub-licensable, royalty-free, perpetual, worldwide license to use under its intellectual property right relating to Data or Invention.

In any event, XXX may retain a royalty-free right and license to practice the Invention for its own internal research or educational purposes only.

4.2 XXX may, consistent with academic standards, publish or present the results of the Permitted Purpose, provided such publication or presentation does not disclose confidential information. The Establishments will be acknowledged, consistent with academic standards, in all such publications or other public disclosures by coauthorship or acknowledgement, whichever is appropriate.

XXX will submit to the Establishments for review a copy of the proposed publication (including abstracts, or presentation to a journal, editor, meeting, or seminar) resulting from the Permitted Purpose prior to submission for publication or presentation.

XXX shall, in any use of the Data, such as publications or presentations, cite as a reference the following paper: PREMISE: A database of 20 Macaca Fascicularis PET/MRI brain imaging available for research. Chalet, L. et al. DOI: 10.1101/2023.03.03.530981, within the framework of the RHU MARVELOUS: “New MR imaging to pReVent cErebraL and myocardial Reperfusion injury” (ANR-16-RHUS-0009) of l’Université Claude Bernard Lyon 1 (UCBL), within the program “Investissements d’Avenir” operated by the French National Research agency (ANR).

4.3 “Confidential Information” shall mean all disclosed information relating to the Data (whether in writing, orally or communicated by any other means) which is communicated by any Party (“the Disclosing Party) to the other Party (“the Receiving Party”), or by a third party acting on behalf of the Disclosing Party or the Receiving Party, but not including which:

* at the time of disclosure hereunder is in the public domain;
* after disclosure hereunder enters the public domain, except through breach of this Agreement by a party;
* was in the Receiving Party’s possession prior to the time of disclosure by or on behalf of the Disclosing Party as demonstrated by clear and convincing written evidence, and was not acquired directly or indirectly from the Disclosing Party;
* becomes available to any party from a third party which, to the knowledge of the Receiving Party, is not legally prohibited from disclosing such Confidential Information;
* the Receiving Party can demonstrate by clear and convincing written evidence was developed by or for the Receiving Party independently of the disclosure of Confidential Information by the Disclosing Party or;
* is required by law to be disclosed, provided that the Receiving Party gives the Disclosing Party notice of the required disclosure and an opportunity to seek appropriate legal relief to prevent such disclosure or limit its use and further disclosure.

For a period of three (3) years after the expiration or earlier termination of this Agreement, each party will keep the Confidential Information (including without limitation the Data) strictly confidential. Each party shall use the Confidential Information only in the furtherance of its obligations under this Agreement. Except as otherwise permitted herein, each party will not disclose the Confidential Information without first obtaining the Disclosing Party’s prior written consent to such disclosure. The standard of care required of each Receiving Party in protecting the confidentiality of the Confidential Information will be the same standard of care that each Receiving Party uses in protecting its own confidential information of a similar nature, but in no event will Receiving Party use less than a reasonable standard of care. Each Receiving Party may disclose Confidential Information only to the Receiving Party’s employees or consultants on a need-to-know basis, provided that such employees and consultants are under confidentiality obligations sufficient to enable the Receiving Party to comply with all the provisions of this Agreement.

**ARTICLE 5: DATA TRANSFER**

Establishments will transfer the Data to XXX according to the following conditions:

* signature of the present Data Transfer Agreement by all the parties;
* authorized downloading of the Data hosted on the CERMEP platform.

**ARTICLE 6: LIABILITY - WARRANTY**

Data are provided “as is” without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. Establishments make no representation or warranty that the use of the Data will not infringe any patent or other proprietary right. Without prejudice to the generality of the foregoing paragraph, the Data provided under this Agreement are a research tool undergoing further development and are not intended to be a clinical diagnostic aid.

XXX is entirely responsible for the use of the Data made available to them. In no event shall Establishments be liable for any use by XXX of the Data, for any loss, claim, damage or liability, of whatsoever kind of nature, which may arise from or in connection with this Agreement or the use, handling or storage of the Data (including but not limited to loss of Data, Data being rendered inaccurate, losses being sustained by XXX or third parties or a failure of the Data to operate with any materials or software used by XXX).

**ARTICLE 7: TERM**

This Agreement shall take effect as of ………. (hereinafter the “Effective Date”). This Agreement will terminate upon: (a) completion of XXX’s Permitted Purpose or one (1) year after the Effective Date, whichever is earlier or (b) thirty (30) days’ written notice by Establishments to XXX.

Upon termination or expiration, XXX will discontinue its use of the Data and will (i) returned to the Establishments or, at Establishments’ option, destroy any remaining Data (including any modifications to the Data) in its possession or control and (ii) return to the Establishments any Confidential Information in its possession or control.

Any and all provisions, promises and warranties contained herein which by their nature or effect are required or intended to be observed, kept or performed after termination or expiration of this Agreement will survive the termination or expiration of this Agreement, as the case may be, and remain binding upon and for the benefit of the Parties hereto.

**ARTICLE 8: TERMINATION**

8.1 In the event of non-performance or improper performance by either Party of its obligations under this Agreement, the other Party may give notice to the defaulting Party to remedy the non-performance by registered letter with acknowledgement of receipt.

8.2 The defaulting Party shall then have a period of thirty (30) days to fulfil its obligations or provide proof of an impediment resulting from a case of force majeure within the meaning of article 1218 of the French Civil Code and the jurisprudence of the French courts. After this period of thirty (30) days and in the absence of performance of its obligations or demonstration of the occurrence of a situation consecutive to a case of force majeure by the defaulting Party, the aggrieved Party may terminate this Agreement by operation of law and without recourse to a judicial authority by the present Agreement by sending a new registered letter with acknowledgement of receipt notifying the defaulting Party of the termination.

The termination will then take effect as of the first presentation of this second registered letter with acknowledgement of receipt.

8.3 Notwithstanding such early termination of this Agreement, each Party shall be bound to to fulfill its obligations until the effective date of termination. Termination shall therefore in no way be construed as a waiver by the other Party of its right to the other Party to the exercise of its rights and to possible damages.

**ARTICLE 9: GOVERNING LAW- DISPUTES**

This Agreement shall be governed by French law.

The Parties shall endeavour to settle any dispute that may arise from the interpretation and implementation of this Agreement amicably. In event of continuing disagreement, the dispute shall be brought before the competent courts of France.

IN WITNESS HEREOF, THE PARTIES AGREE AND HAVE AUTHORIZED BELOW THEIR APPROVAL OF THESE TERMS.

|  |
| --- |
| **Organization receiving the Data**By his signature hereunder the project coordinator agrees to all the terms and conditions set forth at the present licence |
| **Name of the organization:**  **Name of the project coordinator:**  |
| ***Selected data and format of the BASE*****Data format Data modality**  **Nifti format in subject space MRI** **Nifti format in subject space PET - [15O]H2O PET - [11C]PK11195** |
| **Date :****Signature :**  |

**UCBL**

Name: Frédéric FLEURY

Title: President

Date:

Signature

VISA CARMEN Laboratory

Mr Hubert VIDAL

Director