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**DATA ACCESS AGREEMENT**

**INSERM,** (hereinafter referred to as ”Inserm” or “Provider”), having its registered offices at 101 rue de Tolbiac 75013 Paris France, represented by its PDG Gilles Bloch by virtue of the powers conceded to François Chambelin, Regional Delegate Paris 5

AND

**The Bristol University** (hereinafter referred to as “Recipient”), an institution with a principal place of business at **[ADRESSS]** represented by [NAME]

Individually identified as a “Party” and collectively referred as to the “Parties”

**Background**

* Inserm and Recipient acknowledge that they are participating in carrying out the research project called “Early-life stressors and LifeCycle health” in short “LIFECYCLE” (“Project”), funded by the EU H2020 grant 733206 starting on 1st of January 2017 and ending on 31st of December 2022;
* The Parties have entered in the LIFECYCLE consortium agreement (“Consortium Agreement”) and the present agreement (“Agreement”) is entered into in order to carry out the Consortium Agreement;
* Inserm has collected certain personal data in the EDEN Cohort study which are described in Annex 1 and designated hereinafter by “Cohort Data”;
* Recipient wishes to receive or have access to the Cohort Data in order to carry out the Project and more especially the *Lifecycle subtask D4.2, D6.1 & D6.2*, as specified in Annex 2;
* The Parties further acknowledge that the use of the Cohort Data by Recipient shall be governed by the terms of the present agreement plus all applicable provisions of the Consortium Agreement and that the terms of the Consortium Agreement will prevail.

**THE PARTIES AGREE AS FOLLOWS**:

1. **DEFINITIONS**

The terms used herein shall have the meaning outlined below:

1.1. Applicable Law*:* Any European and each Party’s national law and regulation applicable to processing (eg. collecting, storing, processing, transfer and use) of Personal Data, including the Directive 95/46/EC (on the protection of individuals with regard to the processing of personal data and on the free movement of such data) and any implementation thereof in national law, and any data protection law applicable in the country of the Recipient (incl. the EU General Data Protection Regulation Regulation (EU) 2016/679 as of May 25th, 2018).

1.2. Cohort Data: Cohort Data means the data-copies/subsets (Personal Data) from the original cohort, made available by the Provider under this Consortium Agreement via and on his own server and in the DataSHIELD environment (Cohort Data are detailed in Annex 1).

1.3. Coded*:* Processed through reliable and safe information and communication technologies, in such manner that the Recipient cannot, without disproportional efforts, identify any individual Subject involved.

1.4. Informed Consent*:* The written, signed and dated consent from the Subject or its legal representative, based on sufficient and understandable information, covering for the processing,collecting, storage and use of its Personal Data.

1.5. Permitted Use*:* The purpose for which the Personal Data are made available to Recipient under this Agreement which purpose is limited to those described in Section 3 below.

1.6. Personal Data: Has the meaning as defined by the EU Directive 95/46/EC. For the purpose of this Agreement Personal Data will be Coded Personal Data only.

1.7. Project: the action entitled “Early-life stressors and LifeCycle health” in short “LIFECYCLE”

1.8. Provider: the Party making avaliable the Cohort Data to Recipient.

1.9. Recipient*:* Includes any employee, agent and person receiving access to Personal Data pursuant to this agreement.

1.10. Security Breach*:* Any unauthorized use, access or processing of Personal Data.

1.11. Subject*:* The individual from whom the Personal Data originates.

1. **PURPOSE**

This Agreement establishes the terms and conditions under which Provider will share with Recipient the Cohort Data described in Annex 1 and Recipient will use the Cohort Data for the purpose of the Project described in Annex 2.

**3. SCOPE AND REPRESENTATION**

3.1. The Parties agree to abide by all Applicable Laws. It shall be the responsibility of each Party to effect and maintain all registrations for the processing of Personal Data that are required by Applicable Law.

3.2. Provider represents that to the extent applicable, it has obtained Informed Consent from each Subject in accordance with its Applicable Law, which Informed Consent allows for the transfer of the Personal Data for the Permitted Use.

**4. PERMITTED USE**

Recipient shall use the Personal Data for the sole purposes of performing the Project. Use outside of the Project and/or use after the Project ends shall be subject to separate written agreement(s) with the Provider.

**5. RESTRICTIONS AND SPECIFIC OBLIGATIONS OF RECIPIENT**

5.1. Recipient shall refrain from any other use of the Personal Data than the Permitted Use.

5.2. Recipient agrees not to give access or transfer the Personal Data, in whole or part, to any third party without Provider’s prior written consent.

5.3. Recipient acknowledges that Subjects – and/or their legal representatives on their behalf – may withdraw or change their initial Informed Consent. Provider shall promptly notify Recipient of any withdrawal of or changes in the Informed Consent of a Subject, which may affect the use of such Subject’s Personal Data under this Agreement. Recipient shall follow the instructions of the Provider in the handling and/or disposal of the respective Personal Data.

5.4 At expiration or termination of the Agreement, Recipient shall delete the Cohort Data.

**6. PRIVACY, SECURITY AND PROTECTION**

6.1. It shall be the responsibility of each Party to effect and maintain all registrations for the processing of Personal Data that are required by Applicable Law. Each Party shall be responsible for its own processing of Personal Data in accordance with all Applicable Law. Provider shall be responsible for obtaining the proper Informed Consents obtained from Subjects.

6.2. Provider shall make available Coded Personal Data only. The Personal Data will be made available under a unique corresponding code and without any directly identifiable Personal Data. Provider shall keep decoding tables if required by and in accordance with its national Applicable Law or as mandatory by its institutional internal policies. Recipient shall refrain from tracing and/or identifying any Subject. In the event any Subject, for whatever reason, becomes identifiable to Recipient, Recipient agrees to preserve, at all times, the confidentiality of information pertaining to such Subjects. Recipient shall promptly inform the Provider in the event of any Subject becoming identifiable to the Recipient.

6.3. Parties shall adopt appropriate technical and organizational measures to prevent any Security Breach. Recipient shall promptly inform the Provider of any Security Breach and Parties shall take all reasonable actions necessary to remedy such Security Breach.

**7. CONFIDENTIAL INFORMATION AND PUBLICATION**

The Parties shall follow the terms of the Consortium Agreement to ensure the confidentiality of the information communicated as well as the communication and publication of the results of the study under the present Agreement.

For clarity sake, the Recipient will acknowledge Inserm in all publications of results using the cohort Data and Recipient will include as authors the following EDEN scientific : I. Annesi-Maesano, J.Y. Bernard, M.A. Charles, P. Dargent-Molina, B. de Lauzon-Guillain, P. Ducimetière, M. de Agostini, B. Foliguet, A. Forhan, X. Fritel, A. Germa, V. Goua, R. Hankard, B. Heude, M. Kaminski, B. Larroquey, N. Lelong, J. Lepeule, G. Magnin, L. Marchand, C. Nabet, F Pierre, R. Slama, M.J. Saurel-Cubizolles, M. Schweitzer, and O. Thiebaugeorges.

Recipient will inform Inserm of any such publication project and liaise with Inserm’s principal investigator at [barbara.heude@inserm.fr](mailto:barbara.heude@inserm.fr).

The Recipient will also acknowledge Inserm as the data source and Inserm’s funding as follows :

* The publication should refer to the methodological article presenting the first five years of the EDEN cohort: Heude B, Forhan A, Slama R, Douhaud L, Bedel S, Saurel-Cubizolles MJ, Hankard R, Thiebaugeorges O, De Agostini M, Annesi-Maesano I, Kaminski M, Charles MA;  EDEN mother-child cohort study group. Cohort Profile: The EDEN mother-child cohort on the prenatal and early postnatal determinants of child health and development. Int J Epidemiol. 2016 Apr;45(2):353-63.
* EDEN cohort funding and partners should be acknowledged as follows:  
  The EDEN study was supported by Foundation for medical research (FRM), National Agency for Research (ANR), National Institute for Research in Public health (IRESP: TGIR cohorte santé 2008 program), French Ministry of Health (DGS), French Ministry of Research, INSERM Bone and Joint Diseases National Research (PRO-A), and Human Nutrition National Research Programs, Paris-Sud University, Nestlé, French National Institute for Population Health Surveillance (InVS), French National Institute for Health Education (INPES), the European Union FP7 programmes (FP7/2007–2013, HELIX, ESCAPE, ENRIECO, Medall projects), Diabetes National Research Program (through a collaboration with the French Association of Diabetic Patients (AFD)), French Agency for Environmental Health Safety (now ANSES), Mutuelle Générale de l’Education Nationale a complementary health insurance (MGEN), French national agency for food security, French-speaking association for the study of diabetes and metabolism (ALFEDIAM).

**8. INTELLECTUAL PROPERTY**

No right, title or interest in and to the Cohort Data is granted to Recipient or implied hereunder.

Nothing in this Agreement shall affect the ownership of the background knowledge of each Party which will remain the ownership of the Party introducing it.

Ownership of the results shall follow the terms of the Consortium Agreement.

**9. TERM**

9.1 This Agreement is made at the last date of signature by the Parties and until December 31st 2022.

9.2 The terms of this Agreement can be modified or extended only by a written amendment signed by the authorised signatories of the Parties to this Agreement.

**10. WARRANTIES**

The Provider warrants that it is authorized to transfer the Cohort Data to Recipient and that it has obtained them in compliance with the applicable laws. The Provider warrants that all the Cohort Data provided to Recipient have been collected in accordance with the legislation/the regulations and that the expression of the wishes of the persons from whom the Cohort Data collected have been taken enables Recipient to use the Cohort Data within the scope of the Project. In no case patient identification will be provided to Recipient so that Recipient will not be able to link subjects to any personal identifying information.

Both Parties acknowledge and agree that the Cohort Data are made available with no warranties, express or implied, and Provider expressly disclaims any warranty of merchantability, fitness for a particular purpose and/or non-infringement of the Personal Data.

Recipient accepts the Cohort Data "as is" and acknowledges that it is experimental in nature and that it should be used with prudence and appropriate caution, since not all of its characteristics are known and it may have hazardous properties. Provider MAKES NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. Provider and its directors, officers, employees, or agents assume no liability and make no representations in connection with the use of the Cohort Data by Recipient.

**11. REPORTING OF SERENDIPITOUS FINDINGS**

Serendipitous findings (if any) that may be of direct and substantial consequence for the health or wellbeing of a Subject and/or its family members will be reported by Recipient to Provider. It is the responsibility of Provider to handle such serendipitous findings in accordance with its internal policies and applicable laws.

**12. LIABILITY**

Each of the Parties is liable, under the conditions of common law, for any damage that it, including its staff or property and any staff or property under its control, causes to the other Parties or to third parties as a result of or during performance of the Agreement.

The Parties mutually waive the right to demand compensation from one another for consequential damage that might arise in the context of the Agreement.

**13. GENERAL TERMS**

The Agreement may be terminated by either party at any time for any reason upon thirty (30) days written notice.

No party shall be entitled to assign or transfer this Agreement or the rights and obligations hereunder to any third party without the prior written approval of the other Party.

This Agreement including its appendixes represents the entire understanding between or among the Parties related to the Project and supersedes all previously or contemporaneously executed agreements related to the same purpose.

No failure or delay on the part of any party hereto to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof.

The parties hereto are independent contractors. Nothing contained herein shall be deemed or construed to create between or among the parties hereto a partnership or joint venture or employment or principal-agent relationship. No party shall have the authority to act on behalf of any other party or to bind another party in any manner.

**14. JURISDICTION**

The Parties shall endeavour to settle their disputes following terms of the Consortium Agreement.

Recipient and Inserm understand and agree that this Agreement may present original signatures and/or copies of signatures (in particular scanned partially-executed documents). Each copy of signature shall constitute an original signature for purposes of execution and proof of this Agreement. Each document presenting all requested signatures, whether originals or copies, will constitute a fully-executed Agreement and shall not challenge the authenticity of this document.

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| **INSERM (Provider)** | | |
|  |  |  |
| François Chambelin  Regional Delegate  Inserm DR Paris 5 |  |  |

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| --- | --- | --- |
| **Recipient (Recipient)** | | |
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**Annex 1 : Cohort Data**

**Variable list for proposal “Tasks 6.1,6.2: Socioeconomic inequalities in mental health trajectories”**

|  |  |
| --- | --- |
| **variable name** | **Table** |
| agebirth\_m\_y | core non-repeated |
| child\_id | core non-repeated |
| child\_no | core non-repeated |
| cohort\_country | core non-repeated |
| cohort\_id | core non-repeated |
| ethn1\_m | core non-repeated |
| ethn2\_m | core non-repeated |
| ethn3\_m | core non-repeated |
| eusilc\_income | core non-repeated |
| eusilc\_income\_quintiles | core non-repeated |
| mother\_id | core non-repeated |
| outcome | core non-repeated |
| parity\_m | core non-repeated |
| preg\_alc | core non-repeated |
| preg\_dia | core non-repeated |
| preg\_ht | core non-repeated |
| preg\_no | core non-repeated |
| preg\_smk | core non-repeated |
| sex | core non-repeated |
| age\_years | core yearly repeated |
| areases\_quint\_ | core yearly repeated |
| areases\_tert\_ | core yearly repeated |
| child\_id | core yearly repeated |
| edu\_m\_ | core yearly repeated |
| adhd\_age\_ | outcome yearly repeated |
| adhd\_avg\_ | outcome yearly repeated |
| adhd\_eval\_ | outcome yearly repeated |
| adhd\_instr\_ | outcome yearly repeated |
| adhd\_perc\_ | outcome yearly repeated |
| adhd\_pro\_ | outcome yearly repeated |
| adhd\_raw\_ | outcome yearly repeated |
| asd\_age\_ | outcome yearly repeated |
| asd\_avg\_ | outcome yearly repeated |
| asd\_eval\_ | outcome yearly repeated |
| asd\_instr\_ | outcome yearly repeated |
| asd\_perc\_ | outcome yearly repeated |
| asd\_pro\_ | outcome yearly repeated |
| asd\_raw\_ | outcome yearly repeated |
| child\_id | outcome yearly repeated |
| ext\_age\_ | outcome yearly repeated |
| ext\_avg\_ | outcome yearly repeated |
| ext\_eval\_ | outcome yearly repeated |
| ext\_instr\_ | outcome yearly repeated |
| ext\_perc\_ | outcome yearly repeated |
| ext\_pro\_ | outcome yearly repeated |
| ext\_raw\_ | outcome yearly repeated |
| int\_age\_ | outcome yearly repeated |
| int\_avg\_ | outcome yearly repeated |
| int\_eval\_ | outcome yearly repeated |
| int\_instr\_ | outcome yearly repeated |
| int\_perc\_ | outcome yearly repeated |
| int\_pro\_ | outcome yearly repeated |
| int\_raw\_ | outcome yearly repeated |
| lan\_age\_ | outcome yearly repeated |
| lan\_avg\_ | outcome yearly repeated |
| lan\_eval\_ | outcome yearly repeated |
| lan\_instr\_ | outcome yearly repeated |
| lan\_pro\_ | outcome yearly repeated |
| lan\_raw\_ | outcome yearly repeated |
| nvi\_age\_ | outcome yearly repeated |
| nvi\_avg | outcome yearly repeated |
| nvi\_eval\_ | outcome yearly repeated |
| nvi\_instr | outcome yearly repeated |
| nvi\_pro | outcome yearly repeated |
| nvi\_raw\_ | outcome yearly repeated |

**Variable list for proposal “Task 4.2 The effect of early life exposures on body mass index from early childhood to early adulthood”**

|  |  |
| --- | --- |
| **variable name** | **Table** |
| age\_months | core monthly repeated |
| child\_id | core monthly repeated |
| height\_ | core monthly repeated |
| height\_age | core monthly repeated |
| height\_mes | core monthly repeated |
| weight\_ | core monthly repeated |
| weight\_age | core monthly repeated |
| weight\_mes | core monthly repeated |
| agebirth\_m\_y | core non-repeated |
| areases\_quint\_preg | core non-repeated |
| areases\_tert\_preg | core non-repeated |
| child\_id | core non-repeated |
| child\_no | core non-repeated |
| cohort\_country | core non-repeated |
| cohort\_id | core non-repeated |
| ethn1\_m | core non-repeated |
| ethn2\_m | core non-repeated |
| ethn3\_m | core non-repeated |
| eusilc\_income | core non-repeated |
| eusilc\_income\_quintiles | core non-repeated |
| ga\_bj | core non-repeated |
| green\_dist\_preg | core non-repeated |
| green\_size\_preg | core non-repeated |
| greenyn300\_preg | core non-repeated |
| height\_m | core non-repeated |
| height\_mes\_m | core non-repeated |
| mother\_id | core non-repeated |
| ndvi300\_preg | core non-repeated |
| outcome | core non-repeated |
| parity\_m | core non-repeated |
| preg\_alc | core non-repeated |
| preg\_dia | core non-repeated |
| preg\_ht | core non-repeated |
| preg\_no | core non-repeated |
| preg\_smk | core non-repeated |
| prepreg\_weight | core non-repeated |
| prepreg\_weight\_ga | core non-repeated |
| prepreg\_weight\_mes | core non-repeated |
| sex | core non-repeated |
| age\_years | core yearly repeated |
| areases\_quint\_ | core yearly repeated |
| areases\_tert\_ | core yearly repeated |
| child\_id | core yearly repeated |
| edu\_m\_ | core yearly repeated |

**Variable list for proposal “Task 3.1 Maternal exposure to urban environmental stressors and depression in the postnatal period”**

|  |  |
| --- | --- |
| **variable name** | **Table** |
| agebirth\_m\_y | core non-repeated |
| birth\_month | core non-repeated |
| blue\_dist\_preg, | core non-repeated |
| breastfed\_any | core non-repeated |
| breastfed\_ever | core non-repeated |
| child\_id | core non-repeated |
| child\_no | core non-repeated |
| cohab\_0 | core non-repeated |
| cohab\_1 | core non-repeated |
| cohort\_country | core non-repeated |
| cohort\_id | core non-repeated |
| con\_anomalies | core non-repeated |
| ethn1\_m | core non-repeated |
| ethn2\_m | core non-repeated |
| ethn3\_m | core non-repeated |
| eusilc\_income | core non-repeated |
| eusilc\_income\_quintiles | core non-repeated |
| green\_dist\_preg, | core non-repeated |
| lden\_preg | core non-repeated |
| mother\_id | core non-repeated |
| ndvi300\_preg | core non-repeated |
| no2\_preg, | core non-repeated |
| outcome | core non-repeated |
| parity\_m | core non-repeated |
| pm25\_preg | core non-repeated |
| pnd | core non-repeated |
| preg\_alc | core non-repeated |
| preg\_alc\_unit | core non-repeated |
| preg\_cig | core non-repeated |
| preg\_dia | core non-repeated |
| preg\_ht | core non-repeated |
| preg\_no | core non-repeated |
| preg\_smk | core non-repeated |
| sex | core non-repeated |
| ga\_bj | core non-repeated |
| prepreg\_dep | core non-repeated |
| age\_months | core yearly repeated |
| age\_years | core yearly repeated |
| age\_years | core yearly repeated |
| areases\_quint\_ | core yearly repeated |
| areases\_tert\_ | core yearly repeated |
| blue\_dist\_ | core yearly repeated |
| child\_id | core yearly repeated |
| edu\_m\_ | core yearly repeated |
| edu\_m\_ | core yearly repeated |
| fam\_split\_up\_ | core yearly repeated |
| green\_dist\_ | core yearly repeated |
| lden\_ | core yearly repeated |
| ndvi300\_ | core yearly repeated |
| no2\_ | core yearly repeated |
| pm25\_ | core yearly repeated |

**Annex 2 : Project**

**Requesting scientists :** DrTim Cadman and associated research team, the Bristol University

No other researchers will be accessing the data

**WP :** 1, 3, 4 and 6

**Lifecycle subtasks :**

D4.2 : Report on the relationships of early-life exposures with trajectories of cardiovascular and metabolic risk factors from birth to adulthood

D6.1 : Report on internalizing and externalizing behaviour and other mental health trajectories from birth to childhood, and their associations with psychopathology outcomes

D6.2 : Report on the effects of early-life stressors on mental health and psychopathology life course trajectories

D3.3:To generate integrated harmonised exposure indices for stressors in the urban environment, which include air pollution, noise, green space, connectivity and walkability measurements

**Specific proposals:**

“Tasks 6.1,6.2: Socioeconomic inequalities in mental health trajectories”

“Tasks 4.2: The effect of early life exposures on body mass index from early childhood to early adulthood”

“Tasks 3.3 Maternal exposure to urban environmental stressors and depression in the postnatal period”