**University of Bristol**

**INMA – Environment and Childhood Project**

**DATA USE AGREEMENT**

1. This agreement is between the **INMA – INfancia y Medio Ambiente [Environment and Childhood] Project coordination group**, hereinafter termed “the cohort study”, and **University of Bristol**, hereinafter termed “User”.

Both parties mutually agree to enter into this Agreement to comply with the following specific paragraphs.

2. This Agreement addresses the conditions under which the Cohort Study will disclose and the User will have access to and use the data file(s) specified in section 6. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in section 6 and overrides any instructions, directions, agreements, or other understanding in other prior communication from the Cohort Study. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the Cohort Study point­of­contact specified in section 5 or the Cohort Study signatory to this Agreement shown in section 15.

3. The parties mutually agree that the User does not obtain any right, title, or interest in any of the data furnished by the Cohort Study. Further, it is mutually agreed that data attained by the User under this agreement shall not be used for any commercial purpose.

4. The parties mutually agree that the following named individual is designated as "Custodian" of the file(s) on behalf of the User and will be personally responsible for the observance of all conditions of use and for establishment and maintenance of physical safeguards to prevent unauthorized access, disclosure or use. The User agrees to notify the Cohort Study within fifteen (15) days of any change of custodianship.

Tim Cadman\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Name of Custodian)

University of Bristol \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Company/Organization)

Oakfield House\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Street Address)

Oakfield Grove\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Street Address)

Bristol\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (City/State/ZIP Code)

BS82BN\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Phone No. ­ and E­Mail)

5. The parties mutually agree that the following named individual will be designated as "point­of­contact" for the Agreement on behalf of the Cohort Study.

**Aitana Lertxundi**

Preventive Medicine and Public Health department, University of Basque Country (UPV/EHU),

C/Sarriena Leioa, 48940, Bizkaia (Spain)

E-mail: aitana.lertxundi@ehu.eus

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6. The User represents and warrants that such data file(s) will be used solely for the following purpose:

***MATERNAL EXPOSURE TO URBAN ENVIRONMENTAL STRESSORS AND DEPRESSION IN THE POSTNATAL PERIOD***

The User represents and warrants further that the facts and statements made in any study or research protocol or project plan submitted to the Cohort Study for each purpose are complete and accurate. Further, the User represents and warrants that said study protocol(s) or project plans, represent the total use(s) to which the data file(s) specified in the present section is established. The User represents and warrants further that, except as specified in an Attachment to this Agreement, the User shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person. The User agrees that, within the User organization, access to the data covered by this Agreement shall be limited to individuals on a need­to­know basis only and for Project purposes only.

The User also represents and warrants that will respect the privacy rights of the donors and thus refrain from tracing or identifying the identity of any donors who provided the data.

The following data file(s) is/are covered under this Agreement. File Year(s)

**Data listed in the approved proposal file titled "env-pnd-daa-inma\_revised EC V\_TC DEF", accessed through DataShield**

7. The User agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use or access to the data.

8. In an effort to avoid simultaneous submission of similar articles to scientific journals, the User agrees to notify the Cohort Study upon the submission of any and all manuscripts submitted for publication based on findings from analysis of the Cohort Study data, and appropriate co-authors included based on their collaboration. Notification shall include the title of each manuscript, an abstract for each manuscript, authorships, and the name(s) of the journal(s) to which the manuscript(s) will be submitted. Notification shall be directed to the Cohort Study point­of­contact specified in section 5 or the Cohort Study signatory to this agreement shown in section 15.

9. The following credit line and disclaimer will be used on all reports, publications and other materials resulting from use of the data (to be reviewed and updated at the time of submission of manuscripts): Data used for this research was provided by the INMA – INfancia y Medio Ambiente [Environment and Childhood] Project (www.proyectoinma.org), which is supported in part by funds. This study was funded by grants from Instituto de Salud Carlos III (Red INMA G03/176 and CB06/02/0041), Spanish Ministry of Health (FIS-97/1102, FIS-07/0252, FIS-PS09/00362, 97/0588, 00/0021-2, PI061756, PS0901958, PI14/00677 incl.FEDER funds, FIS-PS09/00090, PI041436, FIS-PI042018, FIS-PI06/0867, PI081151 incl. FEDER funds, FIS-PI09/02311 and FIS-PI13/02187, and FIS-FEDER 03/1615, 04/1509, 04/1112, 04/1931, 05/1079, 05/1052, 06/1213, 07/0314, 09/02647, 11/01007, 11/0178, 11/02591, 11/02038, PI12/01890 incl. FEDER funds, 13/1944, 13/2032, FIS-PI13/02429, 14/0891, 14/1687 and CP13/00054 incl. FEDER funds), Spanish Ministry of Economy and Competitiveness (SAF2012-32991 incl. FEDER funds), CIBERESP, Generalitat de Catalunya-CIRIT 1999SGR 00241, Generalitat de Catalunya-AGAUR (2009 SGR 501, 2014 SGR 822), the Conselleria de Sanitat Generalitat Valenciana, Department of Health of the Basque Government (2005111093, 2009111069 and 2013111089), the Provincial Government of Gipuzkoa (DFG06/004 and DFG08/001), Fundació La Caixa (97/009-00 and 00/077-00), Beca de la IV convocatoria de Ayudas a la Investigación en Enfermedades Neurodegenerativas de La Caixa, Fundació La marató de TV3 (090430), Obra Social Cajastur/Fundación Liberbank, Universidad de Oviedo, the EU Commission (QLK4-1999-01422, QLK4-CT-2000-00263, QLK4-2002-00603, CONTAMED FP7-ENV-212502, FP7-ENV-2011 cod 282957, HEALTH.2010.2.4.5-1, 261357, 308333, 603794), Agence Nationale de Securite Sanitaire de l'Alimentation de l'Environnement et du Travail (1262C0010), Consejería de Salud de la Junta de Andalucía (grant number 183/07) and Annual agreements with municipalities in the study area (Zumarraga, Urretxu, Legazpi, Azkoitia y Azpeitia y Beasain).

10. The parties mutually agree that the following specified Attachments are part of this Agreement:

* **env-pnd-daa-inma\_revised EC V\_TC DEF**

11. The User agrees that in the event the Cohort Study determines or has a reasonable belief that the User has made or may have made disclosure of the aforesaid file(s) that is not authorized by this Agreement, or has used the aforesaid files for commercial purposes, the Cohort Study in its sole discretion may require the User to: (a) promptly investigate and report to the Cohort Study the User's determinations regarding any alleged or actual unauthorized disclosure and/or uses, (b) promptly resolve any problems identified by the investigation; (c) if requested, submit a formal response to an allegation of unauthorized disclosure and/or use; (d) if requested, submit a corrective action plan with steps designed to prevent any future unauthorized disclosures and/or uses; and (e) if requested return data files to the Cohort Study. The User understands that as a result of the Cohort Study's determination or reasonable belief that unauthorized disclosures and/or uses have taken place, the Cohort Study may refuse to release further data to the User for a period of time to be determined by the Cohort Study.

12. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the data file(s) specified in section 6.

13. On behalf of the User the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Name and Title of Individual ­ Typed or Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Company/Organization)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Street Address)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (City/State/ZIP Code)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Phone No. – and E­Mail Address, If Applicable)

Signature (Date)

14. The Custodian, as named in paragraph 4, hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees personally and in a representative capacity to comply with all of the provisions of this Agreement on behalf of the User.

Tim Cadman

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(Typed or Printed Name and Title of Custodian of File(s)



10th March 2021

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Signature) (Date)

15. On behalf of the Cohort Study, the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

**Jesús Ibarluzea**

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(Signature) (Date)