

## DATA ACCESS AGREEMENT

This Agreement is made on Barcelona, on date of signing (hereinafter referred to as the “**Effective Date**”) by and between

The first party,

**BARCELONA INSTITUTE FOR GLOBAL HEALTH** (hereinafter referred to as "ISGlobal"), with tax number \_\_\_\_\_, having its registered offices at \_\_\_\_\_ represented by Mr. \_\_\_\_\_ with Spanish ID number \_\_\_\_\_, in his role as General Manager, by virtue of the powers conceded to him through the authorized deed of Notary of \_\_\_\_\_

The second party,

**Fundación para la Investigación Biosanitaria de Andalucía Oriental – Alejandro Otero** (hereinafter referred to as FIBAO or RECIPIENT), with tax number \_\_\_\_\_, having its registered offices at \_\_\_\_\_, with \_\_\_\_\_, in her role as Managing Director of FIBAO by virtue of the powers conceded to him/her through the authorized deed of the Notary of Granada,

I. FIBAO is the managing entity of the Biosanitary Research Institute of Granada (ibs.GRANADA), according to the collaboration agreement signed on March 14, 2012 between the Ministry of Health of the Government of Andalusia, the University of Granada, the Andalusian Service of Health. The mission of ibs.GRANADA is to develop and promote a multidisciplinary scientific space in biomedicine where research projects are developed that integrate basic groups with others whose objectives transcend towards translational research.

Collectively referred to the “Parties”

As a sign of acceptance and knowledge, \_\_\_\_\_, with Spanish ID number \_\_\_\_\_, as the principal investigator; and \_\_\_\_\_, with Spanish ID number \_\_\_\_\_ as the postdoctoral researcher, both belonging to the research group "E07-Research in Environmental Health and Childhood" of ibs.GRANADA

### **Purpose:**

This Agreement establishes the terms and conditions under which **ISGlobal** will allow the access to the already available data on the **Barcelona Life Study Cohort (BiSC)** to the Recipient and how the Recipient will use and ensure confidentiality of this Central Data.

Any other uses will be subject to prior approval by the parties which generated the data.

### **Background**

(A) ISGlobal and Recipient are collaborating together on the research project called “Maternal and Fetal Genetic Contribution to Placental miRNA Levels”, financed by the Fundació Academia de Ciències Mèdiques de Catalunya I Balears (Premi

Ciències Biomèdiques 2019), the Instituto de Salud Carlos III, and co-funded by European Union (PI19/00417 and PI20/01116 – ENTENTE project), starting on 01/12/2023 and ending on 31/03/2024.

- (B) ISGlobal and the Recipient participating in the project wish to enter into a Data Access Agreement.
- (C) The Parties have agreed to co-operate with each other in relation to the access and use of the data in accordance with the terms and conditions of this Agreement.

## **THE PARTIES AGREE AS FOLLOWS:**

### **1. DEFINITIONS AND INTERPRETATION**

<b>Central Data</b>	means the database housed in ISGlobal containing data on the Barcelona Life Study Cohort (BiSC) both molecular data (genetic and microRNA) and other variables of interest.
<b>Derivative Data</b>	Means all information not containing Central Data which requires the use of Central Data for being created and/or obtained.
<b>Project</b>	the research project entitled “Maternal and Fetal Genetic Contribution to Placental miRNA Levels”
<b>Major Activity</b>	the project objectives for the use of the data described in Schedule 2
<b>Providing Party</b>	means ISGlobal

### **2. PRINCIPLES**

- 2.1 This data access agreement covers the access of Central Data from ISGlobal and its exclusive use by Recipient only for the purpose of the Project according to the protocol.
- 2.2 The terms of this Agreement can be changed only by a written modification by the authorised signatories of the Parties (or their designated representatives) to this Agreement or by the Parties adopting a new agreement in place of this Agreement.
- 2.3 ISGlobal retains all ownership rights to the Central Data.

### **3. STRUCTURE OF THE MAJOR ACTIVITY**

- 3.1 The aims, objectives and activities to be carried out with Central Data under the Project are described in Schedule 2.

### **4. CONDITIONS OF ACCESS AND USE**

- 4.1 ISGlobal agrees to provide access to the Central Data specified in Schedule 1 to Recipient.

- 4.2 Recipient agrees that the Central Data can only be used for the purpose of executing the Project.
- 4.3 Recipient shall be responsible for complying with all conditions of ISGlobal data's use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorised use and disclosure of the Owner's Central Data provided under this Agreement. Receiving and reviewing applications for access to Derivative Data contained within the Central Data, will be discussed and agreed on writing by both parties.
- 4.4 Except as authorized in writing, Recipient shall not disclose, release, reveal, show, sell to anyone or otherwise grant access to the data covered by this Agreement to any person or institution outside the Parties.
- 4.5 Recipient will provide appropriate administrative, technical and physical safeguards to ensure the confidentiality and security of the Owner's Central Data and to prevent unauthorized use or access to it.
- 4.6 The Parties mutually agree that any Derivative Data or file (s) that is created from the original data may be retained by the Recipient in its premises until the Project has been completed.
- 4.7 The Agreement may be terminated by either party at any time for any reason upon thirty (30) days written notice. Upon such notice, the Owner will notify the Recipient to cease the use of the Central Data pertaining to the Owner, as well as destroy or return all Derivative Data created and/or obtained by the use of such Central Data. Recipient agrees not to retain copies of Central Data for itself and/or for third person.

## **5. CONFIDENTIAL INFORMATION**

- 5.1 In this Agreement, Confidential Information means any data or information (including Central Data and Derivative Data) of any kind (whether or not marked 'confidential') in any form or medium which is disclosed, divulged, communicated or made available (whether before or after the date of this Agreement) by ISGlobal to the Recipient, irrespective of whether it is in oral or a written form, or recorded or stored by electronic, magnetic, electromagnetic or other form, process or otherwise in a machine readable form or translated from the original language.
- 5.2 Throughout the term of this Agreement, Recipient shall be solely a bailee of all the Confidential Information described in Section 5.1 above, solely for the purpose of the Project according to the protocol. In no event Recipient shall use the Confidential Information for any purpose other than as may be required for the performance of the Project, or disclose or make available any of such Confidential Information to anybody, without ISGlobal's prior written consent.
- 5.3 Recipient shall be liable for any breach of such obligation by any of its officers, employees or representatives and, therefore, shall be responsible for any loss or damage caused to ISGlobal as a consequence of any unauthorized use or disclosure of the Confidential Information.
- 5.4 If the Central Data includes Personal Data, the provider will ensure that the informed consent is sufficient for its use of the data in the Project.

The Recipient agrees to comply with the provisions of the Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016.

- 5.5. The Recipient shall respect the privacy rights of the donors and thus refrain from tracing or identifying the identity of any donors who provided the data.
- 5.6 The Recipient obligations under clause 5 shall continue after the termination or expiry of this Agreement for a period of five (5) years from the Effective Date.

## **6. DURATION AND TERMINATION**

- 6.1 This Agreement enters into force on the Effective Date and it will end when finishes the Major Activity on 31/03/2024.

## **7. JURISDICTION**

- 7.1 The Parties expressly submit all and any such discrepancies that may arise between them in relation to the interpretation, application or performance of this mandate to the courts and tribunals of Barcelona, with an express waiver of any other jurisdiction to which they may be entitled.

### **List of annexes:**

This Agreement including its 2 annexes (Schedule 1 and 2) constitute the entire agreement between the Parties as to its subject matter and supersedes any prior oral or written understanding or agreement relating to the same subject matter.

Annex 1 – Schedule 1 - SPECIFICATION OF CENTRAL DATA

Annex 2 – Schedule 2 – MAJOR ACTIVITY – Terms of Reference

**IN WITNESS WHEREOF** the duly authorized signatories of the Parties signed this amendment in two (2) originals, both in the English language, both having the same validity, for and on behalf of

**BARCELONA INSTITUTE FOR GLOBAL HEALTH (ISGlobal)**

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**FUNDACIÓN PARA LA INVESTIGACIÓN BIOSANITARIA DE  
ANDALUCÍA ORIENTAL – ALEJANDRO OTERO (FIBAO)**

As a sign of acceptance and knowledge,

## **ANNEX 1 – SCHEDULE 1 - SPECIFICATION OF CENTRAL DATA**

The central data of the Barcelona Life Study Cohort (BiSC) consist of molecular data, both genetic of the mothers and the fetus, as well as the abundance of microRNAs in the placenta, as well as other variables of interest. All of them are hosted on the ISGlobal Yamabuki server.

## ANNEX 2 – SCHEDULE 2 - MAJOR ACTIVITY – Terms of Reference

### Objectives and justification of the work

To identify maternal and fetal genetic variants associated with placental miRNA levels (miQTLs). This will be the first study to identify placental molecular QTLs for miRNAs, which have been less explored in placenta. The project will provide knowledge on the genetic bases of placental function and the etiology of adult diseases with a developmental origin: diabetes, cardiometabolic risk, cancer and psychiatric problems.

Fundamentación teórica

Placenta is a key tissue for fetal development. Being born with small or large birth weight increases the risk of perinatal mortality and of chronic diseases in adulthood. Placental microRNAs (miRNAs), regulatory RNAs of around 22 nt that inhibit mRNAs through complementary binding to their 3'UTR, have been found to be crucial for placental function. Their levels are determined by genetic and environmental factors, however not much is known about the specific maternal and fetal genetic contribution.

### Material and Methods

The study will be conducted in the Barcelona Life Study Cohort (BiSC), a longitudinal study including 1000 mother-child pairs from the Barcelona area (<https://www.projectebisc.org/en/home/>).

Data on placental small non-coding RNAs obtained through next generation sequencing platforms is available for 450 mother-child pairs. Genome-wide genotypic data (GWAS) will be available for 1000 mothers and 600 children with the Genome Screening Array.

Identification of miQTLs will be conducted with TensorQTL and other tools that allow the accommodation of genetically related samples.

### Workplan

Dic 2023 | Quality control of fetal genetic data.

Dic-Jan 2024 | Identification of miQTLs.

Jan 2024 | Separation of the maternal and fetal contribution on the identified miQTLs.

Jan-Feb 2024 | Identification of targeted genes and pathways.

Feb-Mar 2024 | Colocalization of miQTLs with SNPs associated with diseases.

Mar 2024 | Writing scientific article