BiSC REQUEST FORM

1. GENERAL INFORMATION	
Information of applicant	
Name:	**Position/role:**
Institution and working group:	**Contact details:**
If applicant is not PI **Name of Principal Investigator:**	*If applicant is not PI* **Contact details of Principal Investigator:**
Information of the request	
Date of request submission:	**Name of the project:**
Objective of the request: ☐ Publication *If yes, fill in section 2* ☐ TFG/MFP *If yes, fill in section 2* ☐ Application for a grant *If yes, fill in section 3*	**Request of (mark one or both):** ☐ BiSC data *If yes, fill in section 4* ☐ BiSC biological samples *If yes, fill in section 5*
Internal information *(to be filled in by BiSC)*	
Request code:	**BiSC Steering Committee resolution:**
Request is: ☐ Internal ☐ External	*If external* **BiSC responsible for the collaboration:**
Technical assessment:	**Overlapping concerns:**

2. SCIENTIFIC PUBLICATION
Background: *(max 100 words)*
Research hypothesis/objectives: *(max 100 words)*
Analysis plan (including study population, exposures, outcomes, main covariates and statistical analysis protocol): *(max 200 words)*
Potential publications: *(maximum 3)*
Foreseen authorship (including names of first, second and last authors, rules for other authorship): *Consider that for publishing with BiSC data you need to strictly follow our publication policy, you will find it on Annex III.*

Foreseen timeline: - Submission date: - Resolution date:	**Additional comments:**

3. APPLICATION FOR A GRANT	
Aim of the project: *(max 100 words)*	
Funding agency and name of grant:	**Foreseen timeline:** - Submission date: - Resolution date:
Conditions in which BiSC would participate: ☐ Partner with funding ☐ Provider of data with indirect funding (ie. technician, measure of biomarkers, etc.) ☐ Provider of data	**Additional comments:**

4. DATA REQUEST

BiSC data is organised in different codebooks depending on the way and moment of collection. Consider also that they are on different data cleaning status. The chart at the Annex I indicates the general organisation of the data. The official Codebook and variables' names can be found online, for which our Data Management team will provide you with the details. Bear in mind that for this request to be accepted you can be required to provide the final list of variables. If accepted, you will need to attach the list to this document.

Summary of the kind of data you would like to have (i.e. diet at 12w pregnancy):

5. MATERIAL/SAMPLES REQUEST

Fill in the table in the Annex II regarding the samples requested: type of sample, subject and period, number of samples of each type (N), quantity (in µl for biofluids, µg for DNA, RNA, and stools, or cm3 or mg for biopsies). Cells in grey indicate samples not collected.

Measurements are already funded: ☐ Yes ☐ No	**Method to be used (i.e. ELISA, EPIC array, etc):**

Biomarkers obtained (if it is a targeted approach, attach a list of them):

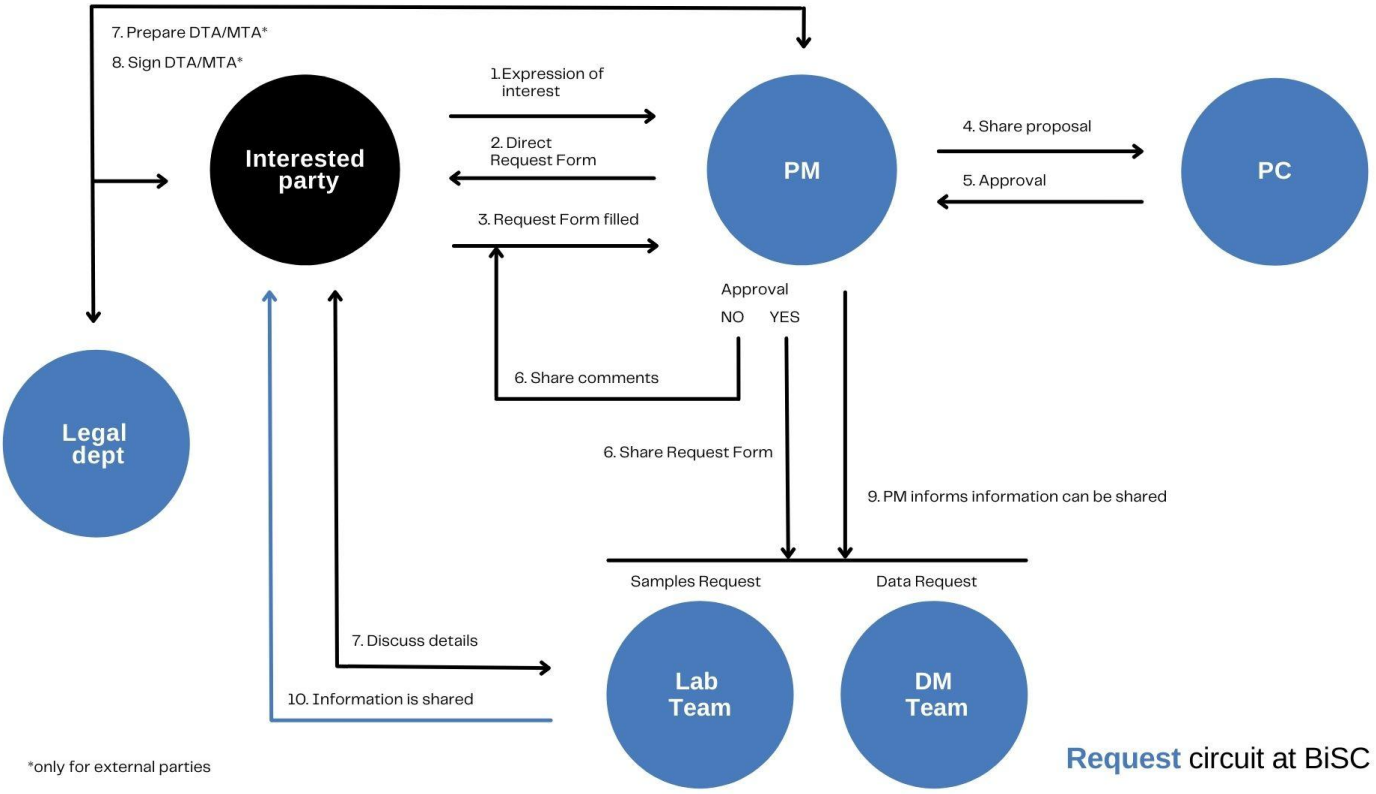
NEXT STEPS

Once finished send this form via e-mail to Clara Tapia (clara.tapia@isglobal.org) with the Subject "**Request form_Name of the project**" in order for it to be reviewed by the BiSC Steering Committee. Expect to receive the approval and/or comments of the request in the maximum period of 1 month after submitting.

Regarding data, (after approval) if the proposal is to apply for a grant we will send you the summarised data for the whole sample of the study.
If the proposal is for a scientific publication you will receive the details to sign a Data Transfer Agreement (DTA) in case you are an external collaborator.

Regarding samples, (after approval) if the proposal is to apply for a grant the biological samples will be booked for your project in case it is funded. We will keep the samples booked for a maximum period of one year.
If the proposal is for a scientific publication you will receive the details to sign a Material Transfer Agreement (MTA) in case you are an external collaborator.

The complete circuit is shown on the following flowchart.



Request circuit at BiSC

PM: Project Manager | PC: Publication Committee | DM: Data Management

ANNEX I - Data details

1) CLINAPSIS CODEBOOK

Reference table of Clinapsis questionnaires. Currently, all BiSC hospital record data for prenatal period is registered in Clinapsis.

Questionnaire	Visit	Description
Midwife12w	12w	Background 1st Trimester: sociodemographic data, medical background, familiar background, fertility and contraception, previous obstetric history, previous pregnancies, clinical examination, anthropometry, and blood pressure.
Hosp1visit	12w	1st Trimester Visit (rutinary): current pregnancy data, symptomatology, analytics, 1st Trimester ultrasound and pregnancy perception.
MareEV12w	12w	1st Trimester Lifestyle: physical activity, tobacco, alcohol, time-activity and commuting, sleeping habits, Mediterranean diet.
MareExp12w	12w	1st Trimester Expositions: home address, animals at home, access to green spaces, noise, water, radiation, home ventilation, cosmetics, hair, hygienic products, Covid-19.
T_Hogar	12w	1st Trimester Home Characterization: General characterization, parent's bedroom, living room, energies.
T_12w	12w	1st Trimester Exposition (access to green spaces and cleaning) and Lifestyle (time-activity and commuting)
ShortV	12w	1st Trimester questionnaire short version: tobacco, alcohol, activity, Mediterranean diet, noise,
Hosp2trim	20w	2nd Trimester Visit (rutinary): 2nd trimester visit data, symptomatology, analytics, 1st Trimester ultrasound and pregnancy perception.
SCL90r	20w	Mental health test.
20wFFQ	20w	Food Frequency Questionnaire, Covid-19.
Padre_1T	20-32w	Partner's Questionnaire: sociodemographic data, tobacco, and alcohol.
SCL90r-p	20-32w	Partner's mental health test.
Midwife32w	32w	3rd Trimester Clinical Examination: clinical examination, anthropometry, blood pressure, registration for neuropsychological tests, Edinburgh Postpartum Depression Scale (EDPS).

Hosp3trim	32w	3rd Trimester Visit (part of BiSC Project (32w) and rutinary (37w)): 3rd trimester visit data, symptomatology, fetal neurosonography, fetal echocardiography, echography, maternal echocardiogram, pregnancy perception, morphometric parameters, blood analytics.
Mare32w	32w	Background 3rd Trimester: sociodemographic data, medical background, Perceived Scale Stress (PSS10), Covid-19.
MareExp32w	32w	3rd Trimester Expositions: home address, animals at home, access to green spaces, noise, water, radiation, home ventilation, cosmetics, hair, hygienic products, work exposure.
MareEV32w	32w	3rd Trimester Lifestyle: physical activity, tobacco, alcohol, drug use, time-activity and commuting, sleeping habits, Mediterranean diet.
T_Hog_2	32w	3rd Trimester Home Characterization: General characterization, parent's bedroom, living room, energies.
T_32w	32w	3rd Trimester Exposition (access to green spaces and cleaning) and Lifestyle (time-activity and commuting)
Short_2	32w	3rd Trimester questionnaire short version: tobacco, alcohol, activity, Mediterranean diet, noise,
HospFinGes	Birth	End of pregnancy: complications during pregnancy, hospitalisation, and treatments during pregnancy.
Parto	Birth	Delivery Characteristics: Delivery information and complications, Covid-19, baby data and complications.

2) AIR POLLUTION EXPOSURE CODEBOOK

Reference table for collected data (mainly prenatal period):

RELATED TO MEASUREMENTS			
Data	**Data type**	**Visit**	**Description**
Nitrogen dioxide (NO_2)	Personal, home-indoor, home-outdoor	12w 32w 6m 18m	NO_2 concentrations measured during 1 week. Time-adjusted concentrations for the whole pregnancy are also available. Data obtained with the Gradko tube (passive samplers). 12w and 32w visits are measures for mother's exposure, 6m and 18m visits are measures for child's exposure.
Fine particles ($PM_{2.5}$) and	Personal	12w 32w	$PM_{2.5}$ and its chemical constituents' concentrations for 48-h personal measurements. Time-adjusted concentrations for the whole pregnancy are also available. Only available for the pre-covid period. Full list of chemical components available: Absorbance/Black Carbon (BC), Elemental Carbon (EC), SiO_2, Al_2O_3, CaO, Fe_2O_3,

chemical components			K_2O, MgO, Na_2O, P_2O_5, TiO_2, SO_4^{2-}, Pb, V, Cr, Mn, Co, Ni, Cu, As, Se, Cd, Sn, Sb, Li, Be, Sc, Ti, Zn, Ga, Ge, Rb, Sr, Y, Zr, Mo, Cs, Ba, La, Ce, Pr, Nd, Sm, Eu, Gd, Tb, Dy, Ho, Er, Tm, Yb, Lu, Hf, Ta, W, Tl, Bi, Th, U.
Black Carbon (BC)	Personal	12w 32w	Black carbon concentrations for 48-h personal measurements. Both continuous data (1-minute time resolution) and averages for longer periods are available (up to 48h average). Time-adjusted concentrations for the whole pregnancy are also available. Only available for the pre-covid period (few data available for visit 32w). Data collected with the MicroAeth AE51.
Temperature and humidity	Home-indoor	12w 32w	Temperature and humidity of the participant's bedroom measured over one week. Data is available on a continuous basis (1-minute time resolution) or averaged over larger-periods.
Physical Activity and Sleep	Personal	12w 32w	Different variables of physical activity measures and sleep quality measures obtained during one week with the Actigraph monitor.
GPS location	Personal	12w 32w	Coordinates of location tracking the movements of the participants during one week. Data was obtained through ExpoApp (a mobile phone app).
Inhaled doses: Black Carbon (BC)	Personal	12w 32w	Black carbon inhaled doses for 48-h personal measurements. Both continuous data (1-minute time resolution) and 48-h average are available. Only available for the pre-covid period (few data available for visit 32w). The inhaled doses have been estimated using the BC concentrations measured with the MicroAeth AE51 and the physical activity levels obtained with the Actigraph.

RELATED TO MODELS		
Land use regression (LUR) Model // Dispersion model // Hybrid LUR – dispersion model		
Data	**Data type**	**Description**
Nitrogen dioxide (NO_2) Fine particles ($PM_{2.5}$) and chemical components	Home-outdoor (address), commuting route, workplace, global (time-weighted)	NO_2, $PM_{2.5}$ and BC concentrations estimated at home address, commuting route (if available) and workplace (if available) or combined (including home, commuting, workplace and the estimated time spent at each). The average concentrations can be provided at different time windows during the pregnancy, from daily/weekly averages, average per trimester or total pregnancy average.

Black Carbon (BC)		
Dispersion model		
NO_2 NO_x $PM_{2.5}$ PM_{10}	Home-outdoor (address), commuting route, workplace, global (time-weighted)	NO_2, NOx, $PM_{2.5}$ and PM_{10} concentrations for each of the different sources (background, road traffic exhaust and non-exhaust, road resuspension and others) estimated at home address, commuting route (if available) and workplace (if available) or combined (including home, commuting, workplace and the estimated time spent at each). The average concentrations can be provided at different time windows during the pregnancy, from daily/weekly averages, average per trimester or total pregnancy average. Sources of pollutants: Background, road traffic exhaust, road traffic non-exhaust, road resuspension, other.
Other models (fitted with LUR estimates, reference station measurements, and other covariates)		
Nitrogen dioxide (NO_2)	Personal	Personal NO_2 concentrations modelled throughout the pregnancy (weekly averages) using NO_2 measurements, LUR estimates, time-adjusted through the monitoring reference station of Palau Reial and other covariates. The average concentrations can be provided at different time windows during the pregnancy, from weekly averages, average per trimester or total pregnancy average.
Nitrogen dioxide (NO_2)	Home-indoor	Indoor NO_2 concentrations modelled throughout the pregnancy (weekly averages) using NO_2 measurements, LUR estimates, time-adjusted through the monitoring reference station of Palau Reial and other covariates. The average concentrations can be provided at different time windows during the pregnancy, from weekly averages, average per trimester or total pregnancy average.
Fine particles ($PM_{2.5}$)	Personal	Personal $PM_{2.5}$ concentrations modelled throughout the pregnancy (weekly averages) using NO2 measurements, LUR estimates, time-adjusted through the monitoring reference station of Palau Reial and other covariates. The average concentrations can be provided at different time windows during the pregnancy, from weekly averages, average per trimester or total pregnancy average.
Black Carbon (BC)	Personal	Personal BC concentrations modelled throughout the pregnancy (weekly averages) using NO2 measurements, LUR estimates, time-adjusted through the monitoring reference station of Palau Reial and other covariates. The average concentrations can be provided at different time windows during the pregnancy, from weekly averages, average per trimester or total pregnancy average.
Inhaled doses: NO_2 NO_x	Home-outdoor (address), commuting route, workplace,	NO_2, NOx, $PM_{2.5}$ and PM_{10} inhaled doses for each of the different sources (background, road traffic exhaust and non-exhaust, road resuspension and others) estimated at home address, commuting route (if available) and workplace (if available) or combined (including home, commuting, workplace and the estimated time spent at each). The average concentrations can be provided at different time windows during the pregnancy, from daily averages, average per trimester or total pregnancy average.

$PM_{2.5}$ PM_{10}	global (time-weighted)	

In order to gain access to the Codebooks or for any doubts on the variables or collection process, please contact Àlex Morillas (alex.morillas@isglobal.org). To proceed with your request, you are required to attach to this document the complete list of variables of your interest.

ANNEX II - Samples Codebook

	Mother						Child						Father		
	12w or 20w		32w		0y		0y		6mo		18mo		Any time		
	N	Quantity	N	Quantity	N	Quantity	N	Quantity	N	Quantity	N	Quantity	N	Quantity	Comments
Serum															
Serum glass															
Total blood															
Plasma															
Buffy coat															
Blood DNA															
Blood RNA															
Red cells															
Urine pool															
Urine morning															
Urine night															
Stools															
Hair															
Nail															

Rectal swab															
Vaginal swab															
Placenta RNAlater															
Placenta N2 liquid															
Placenta DNA															
Placenta RNA															
Buccal epithelial cells															

In grey samples that **have not** been collected.

If you need further details on the Codebook or the collection process, please contact Mariona Bustamante (mariona.bustamante@isglobal.org).

ANNEX III - Publication Policy

BISC publication policy

The success of the BISC project will be judged, in part, by the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that ensure appropriate use of the BISC project data, timely completion of projects, and adherence to the principles of authorship. Publications of methods and study results in peer-reviewed journals are among the main means of dissemination project outcomes mentioned in the BISC Description of Work (DoW).

1. Objectives

§ To encourage the publication of methods and results from the BISC project;

§ To ensure and expedite orderly and timely reports to the scientific community of all information resulting from the BISC project;

§ To ensure that abstracts and publications based on BISC project material are accurate and objective, and do not compromise the scientific integrity of this collective project;

§ To ensure that all investigators involved in BISC have the opportunity to be co-author of BISC papers when relevant; special attention will be given to provide junior researchers such as PhD students and postdocs with the opportunity to serve as first author of such papers;

§ To ensure that authorship of BISC papers adheres to the Vancouver guidelines (annex 1);

§ To prevent overlap of publications and duplication of analyses, both internally as well as externally with collaborations external to BISC but involving BISC cohorts;

§ To favour publication of data from all pooled cohorts over hospital-specific results.

2. Publications - general policy

1. A Publication Committee (PC) will be created. During the period 2020-2022 will be composed by the Steering Committee (SC)

2. All studies and centers contributing data and/or contributing work to specific papers will be offered co-authorships for such papers and authorship of all BISC papers will follow the Vancouver Protocol guidelines (Annex 1) – section 5.

3. Pooled analyses will be given preference over hospital-specific analyses. Proposals for all pooled and hospital-specific analyses that use data collected in the context of

BISC should be circulated to and approved by the PC first (Annex 4). Hospitals are free to conduct their own additional data collection and studies; however, they need to make sure that these data collections would not interfere with accomplishing the standard BiSC protocols and the resulting manuscripts would not overlap with the manuscripts that are going to be prepared based on the data from all the participating hospitals.

4. Proposals for external collaborations (e.g. with other EC or international projects) that involve some of the exposures, omics parameters, or health outcomes generated in BISC should be circulated to the BISC PC before the individual centre(s) agree participation. The intention is to avoid analyses and publications that partially cover proposed BISC publications and therefore may weaken these BISC publications.

3. Main BISC Publications – related to the main BISC deliverables

The tables in Annex 2 summarise the main manuscripts expected to arise directly from the BISC (WPs from AIRNB and HEI) objectives, responsible authors and foreseen timeline for preparation. *This table will be updated and agreed at regular intervals.* These are the main manuscripts that should be delivered to the funders and as such should be given priority over the additional papers listed in section 4/Annex 3.

The **lead authors** indicated in Annex 2 need to submit a proposal, including a detailed analysis protocol, to the PC before the start of the analysis (procedures and template in Annex 4).

A **Working Group** will be defined for each paper before the start of analysis *by the lead authors*, consisting of those researchers from the BISC consortium who will be directly involved in the specific paper (design, analysis plans, interpretation). This Working Group should include the experts of the different areas of research covered by the paper (e.g. exposure, omics, outcomes).

4. Submission of a proposal for additional papers

Investigators are encouraged to submit proposals for additional papers/scientific communications; these papers are encouraged to use data from more than one hospital. Pooled-analysis papers will be given preference over hospital-specific publications. All studies wishing to use data generated as part of BISC need to submit a formal proposal to the PC before the start of the analyses and must include as a minimum:

§ Title

§ Lead author(s) (junior and senior)

§ (Short) introduction (rationale and background)

§ Research hypotheses/objectives

§ Analysis plan, including exposures, outcomes and main covariates considered, and statistical analysis protocol.

§ Key references

§ Foreseen timeline and target submission date

§ Foreseen co-authorship

The PC will review the proposal to verify that the proposal format has been followed and to determine if there is potential overlap with any other papers or abstracts, proposed or in progress. The PC will then work with the authors to reduce or remove overlap. This procedure will remain in place after the end of the BISC contract with the ERC/HEI – a secretary will be appointed to oversee procedures post-BISC. Accepted manuscript proposals will be available on the BISC website **intranet** to help investigators determine available topics in advance.

5. Authorship guidelines

All studies and centres contributing data and/or contributing work to specific papers will be offered co-authorships for such papers and authorship of all BISC papers will follow the Vancouver Protocol guidelines (Annex 1). A first list and ranking of authors should be proposed at the start of analyses, although changes during the course of the project are possible, depending on the implication of each co-author. It is the role of the coordinating author to propose fair and equal distribution of co-authorship, following the specific authorship guidelines provided in the next section. It is the role of the PC to resolve any disputes that may arise concerning co-authorships. The following guidelines for the order of authorship are provided for all main and additional BISC papers (Annex 2 and 3). Authorship will in principle be nominative (i.e. not group authorship).

- 1st author: Lead author

- Working group or writing/analysis team: researchers directly involved in the specific paper: important role in design, analysis, interpretation.

- No maximum number of co-authors, but a reasonable balance between partners/centres shall be maintained.

- Those researchers from the BISC consortium who have played an important role in BISC design, protocols and questionnaires, and/or who have played an important role in generating the data.

- Methodological papers: will only include those co-authors who have contributed to the specific method development presented.

- Last: Lead senior author(s)

- BISC PIs and/or WP leader(s) corresponding to the specific analyses should be included as co-author.

- Corresponding author is recommended to be a BISC PI.

6. Timelines and target dates

For all publications approved by the PC (Annex 2 and 3) a timeline and target date for submission will be set in discussion with the coordinating author. If analyses are delayed or there are delays in the publication for other reasons and the target date will not be met, the coordinating author should inform the PC. The PC will then discuss with the coordinating author a revision of the timeline or withdrawal of the proposal. In the latter case, the topic of the proposal will be open for other investigators.

The PC has the right to withdraw proposals unilaterally if it judges that no progress is made within a certain period (12 months) after the target date.

Before submission, the coordinating author must send a copy of the cover letter and final version of the manuscript (all those listed in Annex 2 and 3) to the PC in addition to all co-authors. The coordinating author must keep the PC and the co-authors informed as to the manuscript's progress through journal review. Upon publication of the manuscript, the responsible author must provide either a reprint or copies of the final publication to the PC and to the co-authors and send the complete reference as soon as possible.

Once published all BISC project presentations and publications will be placed in a web-repository on www.biscproject.org.

7. Author responsibilities

The lead author(s) is responsible for all phases of manuscript preparation, from conception through publication. These responsibilities include:

1. Submission of proposal to the PC (Annex 4)

2. In general, a PI could not have more than two active papers.

3. Preparation of analysis plan and the identification of variables needed;

4. Assignment of tasks to co-authors with clear deadlines for completion of these tasks where needed; The lead author should contact each co-author to discuss the outline of the paper, data analysis plan, results and draft papers.

5. If the analyses are delayed, inform the PC and discuss a new timeline and target date for submission;

6. Manuscript approval by all co-authors and PC before submitting to a journal. The lead author(s) will set clear deadlines with enough time (3 weeks) for judging the manuscript by the co-authors and the PC. Any manuscript submitted without these approvals may be asked to be withdrawn. If co-authors and PC members do not respond within the set deadline for manuscript approval this will be regarded as approval. If wanted, PC members are free to discuss manuscript approval within their own cohort steering committees;

7. Determination of the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each of the co-authors in the preparation of the manuscript following the specific authorship guidelines provided in this policy and following the Vancouver Protocol (Annex 1);

8. Choosing the journal to which the manuscript will be submitted and keeping the co-authors and PC informed about its fate. Lead authors will make their best efforts to ensure that papers are a) submitted to the potential highest Impact Factor journal; and b) electronically available through “open access” publications and/or an online directory, in accordance with the Grant Agreement.

9. Correspondence with co-authors, communication with the PC, and to journal editors.

10. Ensuring the findings of the manuscript remain strictly confidential until the publication of the manuscript. However, members of concerned organisations (as deemed appropriate by the PC) can be informed of results seven days before publication in confidence and coordination with an agreement with the publisher. It does not preclude previous presentation in a Congress as preliminary findings.

8. Preparation and submission of abstracts for meetings

Investigators are encouraged to submit abstracts for meetings and conferences in order to disseminate the findings of the BiSC project among the scientific community. The lead author is free to choose any national or international meeting or conference which may be interesting for presenting results from the BISC project. Authorships will be available for all studies and centres providing data for the abstract. It is the role of the lead author of the abstract to distribute authorships in a fair and equal way. Before submission of an abstract to any national or international organisation it should be sent at least 10 working days prior to the abstract submission deadline to all co-authors and the PC for review and approval. Any abstract submitted without these approvals may be asked to be withdrawn. If co-authors and PC members do not respond within the set deadline, this will be regarded as approval. The lead author of the abstract keeps the co-authors and PC informed about its fate.

9. Acknowledgment section

The acknowledgement section of a paper should include a reference to the funding, which is provided below for the Grant Agreement. In addition, this section should be used to thank medical staff and any other person who contributed substantially to the work of the project. All publications shall include the following statement:

"The research leading to these results has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme] under grant agreement No [785994] (AIR-NB project) and from the Health Effects Institute (HEI) with Agreement number #4959-RFPA15-1/18-1 (FRONTIER project).

This statement will have to be translated into the language of the publication, if not English.

Annex 1 – Vancouver Protocol

All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content.

Authorship credit should be based only on substantial contributions to 1) conception and design, or analysis and interpretation of data; and to 2) drafting the article or revising it critically for important intellectual content; and on 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

Annex 2 – Papers related to main BISC deliverables – Synthetic table.

Group of paper	Subgroups (details in annex 2b below)	Study population – WP implied	Timeline	Total nb of papers
AIR-NB				
Cohort description WP1	1.a. Population 1.b. Brain imaging 1.b. Neurodevelopment	All participants WP1	2022	5

Air pollution WP2	2.a. Total exposure 2.b. Inhaled dose 2.c. UFP 2.d. Urbanom 2.e. Home exposure	Home visits WP2	2021-2023	6-10
Placenta WP3	3.1. Placental function 3.2. Placental particles	All participants WP3	2022-2023	4-6
Causality WP4	4.1. Air pollution-pre-natal brain imaging 4.2. Air pollution -post natal brain imaging 4.3. Air pollution neurodevelopment 4.4. Bias adjustment 4.5. Multivariate 4.6. Mediation	All participants WP4	2022-2024	6-10

Annex 2b - Papers related to main BISC deliverables – Detailed paper list (Example)

Status publication	Proposed title	Study population	First author(s)*	Authorship agreement (1st, 2nd, last)	WP	Number of proposal	Draft circulated
preparation	BISC: cohort description	All women and babies	Dadvand P	Dadvand, Gómez-Roig Llurba, … Sunyer	1	1	Sep 2021

Annex 3 – Additional papers

Expected Publication	List of papers	Study population	Lead author(s)

Annex 4: Procedures for Internal* BISC Manuscripts (main and additional)

1. All authors of manuscripts wishing to use data generated as part of BISC need to **submit a formal proposal** to the Project Executive Committee (PC) before the intended start of the analyses, by completing the **proposal template**. The proposal should be sent to Clara Tapia by email: clara.tapia@isglobal.org.

2. The **PC will review the proposal** for scientific quality and fit with the BISC objectives; it will also determine if there is potential overlap with any other papers or abstracts, proposed or in progress. The PC will provide first feedback within 1 month of receiving the proposal. The PC will then work with the authors to reduce or remove overlap or may ask for a revised proposal to be submitted. If approved by the PC, the lead investigator will be informed by the project coordinator 7 days following the decision.

3. Once final PC approval has been received, the Project Manager will inform the **Data Management team** in order to obtain the data required for the approved analysis. Codebooks will be made available for all parts of the database, and from these the lead author(s) will select the variables needed for analysis. They may also be asked to help clean and prepare relevant parts of the database where needed.

4. The **database manager will then prepare an analysis dataset** in an agreed format (e.g. Stata) and send it to the lead author (using ftp). No additional data transfer agreement will be necessary for internal manuscripts as this should be covered by the BISC Joint Data Ownership Agreement.

5. This procedure will remain in place after the end of the BISC contract with the EC (for as long as the database can be maintained by ISGlobal). Accepted manuscript proposals will be available on the BISC website intranet to help investigators determine available topics in advance.

***Internal* manuscripts** are defined as manuscripts for which the lead author(s), in this case the senior author/researcher, is a researcher from within the BISC consortium and works at a partner institute.