

## **BISC Enrolment**

**Prepared/revised by:** Payam Dadvand / Jordi Sunyer, Estela Rodríguez, Júlia Huerta.

**Contact person:** Payam Dadvand ([payam.dadvand@isglobal.org](mailto:payam.dadvand@isglobal.org))

**BISC SOP coordinator:** Maria Foraster ([maria.foraster@isglobal.org](mailto:maria.foraster@isglobal.org))

### **1. PURPOSE AND APPLICABILITY**

The purpose of this SOP is to describe different aspects of the enrolment of BISC participants, encompassing the methods to promote the study, the way to approach potential participants, the inclusion and exclusion criteria, obtaining informed consent, and assigning the cohort ID to the participants.

### **2. RESPONSIBILITIES AND USERS**

1. The BISC steering committee is responsible for final review and approval of this SOP.
2. The project coordinator is responsible for ensuring that new versions of this SOP are available for the relevant members of the project team and its instructions are properly implemented.
3. This SOP will be principally applied by the BISC nurses in each hospital.
4. If the procedures of this SOP are changed, the change has to be documented according to instructions and it has to be communicated to the SOP coordinator and BISC steering committee. The changed SOP is subject to review and approval by the BISC steering committee.
5. The users of the SOP are obliged to work according to this SOP. All potential deviations in implementing this SOP have to be carefully documented (who changed, when, why, what changes, possible impacts) and reported.

### **3. DEFINITIONS**

HSJdD:	Hospital Sant Joan de Déu
HSP:	Hospital de la Santa Creu i Sant Pau
SOP:	Standard Operating Procedure
Participant:	A pregnant woman participating in the BISC study as a study subject

### **4. EQUIPMENT AND MATERIALS**

#### **4.1. Equipment**

- 4.1.1. Laptop

#### **4.2. Materials**

- 4.2.1. Promoting materials (Flyers, posters, video, BISC website)
- 4.2.2. Informed consent forms

## 5. PROCEDURES

### 5.1. Recruiting time

BISC participants will be recruited during weeks 11-15 of their pregnancy when they attend the recruitment centres (please see 5.2) for their first routine ultrasound examination. Given that this routine ultrasound examination asserts whether the pregnancy is singleton and the foetus is not at high risk of congenital anomalies (two inclusion criteria as described in 5.4), the participants will be recruited after their ultrasound examination.

### 5.2. Recruiting centres

BISC participants will be recruited through the following public healthcare centres:

- a) **Hospital Sant Joan de Déu (HSJdD):** This hospital will recruit participants from Barcelona city as well as Esplugues de Llobregat and Cornellà. Potential participants from Barcelona city will be approached right after their first routine ultrasound examination in HSJdD. Participants from Esplugues de Llobregat will be first approached in the two primary healthcare centres in Esplugues de Llobregat, namely "Lluís Millet" when they attend for their first pregnancy visit. They will be informed about the study by the BISC nurse and if they show interest to participate in the study, they will be offered an appointment in HSJdD for their first routine ultrasound examination, after which they will be enrolled in the study.
- b) **Hospital de la Santa Creu i Sant Pau (HSP):** This hospital will recruit participants from the Barcelona city. Potential participants from the Barcelona city will be enrolled right after their first routine ultrasound examination in its maternity department of the HSP. Moreover, potential participants will be first approached in two primary healthcare centres in Barcelona, namely "Guinardó" and "Pare Claret" when they attend for their first pregnancy visit. They will be informed about the study by the BISC nurse and if they show interest to participate in the study, they will be offered an appointment in HSP or Guinardó primary healthcare centre for their first routine ultrasound examination, after which they will be enrolled in the study.
- c) **Hospital Clinic de Barcelona (Maternity department):** This hospital will recruit participants from the Barcelona city. Potential participants from Barcelona city will be enrolled right after their first routine ultrasound examination in its maternity department. Participants will be also approached in the Barcelona primary healthcare centres "Manso" and "Numància".

### 5.3. Promoting the study

The following methods will be applied to promote the BISC among the potential participants:

- a) Digital and paper posters presenting BISC (see Annex I) will be displayed in the participating hospitals as well as all the primary healthcare centres in the catchment area of these

hospitals. In the Spanish healthcare system, each primary healthcare centre is assigned to a referral hospital and all the pregnant women attending each primary healthcare centre is instructed to give birth in that assigned referral hospital.

Flyers presenting BISC (see Annex 1) will be distributed in the participating hospitals as well as all the primary healthcare centres in the catchment area of these hospitals. The midwives/obstetricians of these primary healthcare centres will be involved in distributing these flyers.

- b) Promotion of the project is supplemented with a video describing its objectives and importance. This video will be run on the screens at the waiting areas of the participating hospitals and their referral primary healthcare centres to inform the target audience (i.e. pregnant women). The video will also be promoted via other communication channels and social networks such as hospital websites.
- c) The BISC website (<http://biscproject.org/>) presents information regarding the project, including, among othersthe promotional video described above about different aspects of the project. The website offers potential participants the possibility to register their contact details, through which the BISC nurses will be able to approach them. The participating hospitals in their websites will provide link to the BISC website. Moreover, the BISC project and website will be promoted through institutional and personal social media including Twitter, Instagram, and Facebook.
- d) Public lectures and periodical press releases will be applied to promote BISC project among general public.

Note: Posters and flyers are included at the end of this SOP.

#### 5.4. Inclusion/Exclusion criteria

BISC will recruit pregnant women

- a) with singleton pregnancy
- b) aged between 18-45 years
- c) within weeks 11-15 of their gestation
- d) able to communicate in Spanish/Catalan with the BISC team
- e) resident in the catchment area of the hospitals (i.e. they live anywhere in Barcelona city or Esplugues)
- f) Initially plan to give birth in one of the BISC recruiting hospitals as detailed in section 5.2. In case of planning delivery at home, this will be registered in the participant's history to plan the collection of birth data with the midwife who is going to carry out the home delivery.

The following exclusion criteria should be applied:

- a) having a severe chronic health condition that could limit the ability to communicate or attend the follow-ups (e.g. severe mental health conditions)

- b) having a plan to leave the catchment area of the hospitals **before** delivery or having a plan to leave Barcelona Province **after** delivery (Note: If the potential participant does not know whether she will move out of Barcelona/Barcelona Metropolitan Area, she should **NOT** be excluded. Only having a plan to leave is an exclusion criterion.)
- c) Being classified as high-risk for congenital anomalies at the first routine ultrasound measures.

Notes:

- In case of use of artificial reproduction techniques for the current pregnancy, either donated oocyte or sperm, the participant will be included, but this situation will be registered in the participant's history.
- Participants should be able to communicate with the BISC team, which means they need to have a minimal understanding of Spanish/Catalan. An English paper version of the questionnaires will be available for those participants that need it.

### 5.5. Informed consent

Prior to the enrolment into the study, the BISC nurse shall provide the potential participant with detailed information on the study aims and objectives and the tasks that participants are expected to accomplish from the BISC nurse. Moreover, the BISC nurse shall highlight the volunteer nature of the participation and the ability of the participant to leave the study whenever she wishes together with assurances that not accepting to participate or leaving the study by no means would affect the healthcare that she would receive. The potential participant will be then given as much time that she needs to properly study the informed consent sheet in a peaceful environment without perceiving any need to rush or any pressure to accept. The BISC nurse should be available to the potential participant to answer the queries that might arise when studying the informed consent sheet.

### 5.6. Assigning cohort ID (ID1)

Once the participant has been enrolled, the BISC nurse will assign her an ID number. All data from the participant will be unequivocally linked using the ID number.

The ID is an eight digit number (HHFFFMR) generated according to the following specifications:

- The first two numbers (HH) will identify the hospital where the participant was recruited.
- The following four numbers (FFFF) will identify the recruited participant inside each of the hospitals. As each of the participants is expected to have a partner and a child, this number will ultimately identify each of the families participating in the study.
- The seventh number (M) will identify the different members of a family: 1 for mother, 2 for partner and 3 for offspring.
- The last number (R) is 1 by default and is designed to be used in special cases such as when a participant is enrolled for a second time. In such cases, it will allow to discern between the different participations of a same subject.

#### 5.6.1 New cohort ID2 (for communication to volunteers – update march 2021)

In order not to give the original cohort ID to the participant via the mobile phone (WhatsApp) or mail to avoid relate the ID with a phone number or e-mail, a new cohort ID2 has been created. The ID is given to the volunteers when they are contacted to fill in a questionnaire online. The relation ID1-ID2 will be protected by the VPN and the conversion from ID2 to ID1 will be done when creating the databases.

The ID2 consists of **7 numbers (4) and letters (3)** (FFFFHMR) generated according to the following specifications:

- **FFFF** – These are 4 numbers and will identify the recruited participant inside each of the hospitals. As each of the participants is expected to have a partner and a child, this number will ultimately identify each of the families participating in the study. (from 0001 to 9999)
- **H** – Is a letter and will identify the hospital where the participant was recruited: **J** for Sant Joan de Deu, **M** for Maternity and **P** for Sant Pau
- **M** will identify the different members of a family: **M** for mother, **P** for partner and **C** for the child.
- **R**: is a letter (A, B, C.....) and is **A** by default and is designed to be used in special cases such as when a participant is enrolled for a second time (B), third (C).... In such cases, it will allow to discern between the different participations of a same subject (ex. Mother participating with the second child).

Example ID1 to ID2: **10037111 – 0371PMA**

## 6. QUALITY CONTROL

6.1. Training: The BISC nurses are expected to attend a specific workshop covering different aspects of the enrolment as described above.

6.2. Supervision: The BISC nurses will be supervised by the BISC PI in each participating hospital who will assure that the enrolment will be conducted according to this SOP.

6.3. Observation: The nurse who has been working with INMA-Sabadell birth cohort ([http://www.proyectoinma.org/en\\_index.html](http://www.proyectoinma.org/en_index.html)) from the beginning (2004) will pay periodical visits to participating hospital to observe the enrolment process, offer feedback, and answer the queries on practical issues raised by BISC nurses.

## 7. REFERENCES

N/A

## 8. ANNEXES

Annex I: Promotional flyers/posters of the BiSC

Barcelona Life Study Cohort **bisc**

**Participa!**

Junt amb altres 1200 embarassades, ens ajudaràs a:

- Saber quin impacte té la contaminació ambiental en l'embaràs i en el desenvolupament dels nens i nenes.
- Entendre quin és el rol de la placenta.

**EN QUÈ CONSISTEIX L'ESTUDI?**

Farem un seguiment exhaustiu del teu embaràs i els primers 18 mesos del teu fill/a:

- amb ecografies molt completes que avaluaran diferents aspectes de la placenta, el creixement i la formació neurològica i cardíaca del teu nadó.
- estimació precisa de l'exposició a:
  - la contaminació de l'aire,
  - la contaminació acústica,
  - l'activitat física, els espais verds i el stress
- el seguiment del desenvolupament cognitiu del teu fill/a.

**Si,**

- ✓ Estàs embarassada
- ✓ Tens entre 18 i 45 anys
- ✓ No presents cap malaltia important
- ✓ Vius dins de l'àrea dels Hospitals de Sant Joan de Déu, Clínic-Maternitat o Sant Pau.
- ✓ Durada mínima dos anys

Més info: visita [www.biscproject.org](http://www.biscproject.org)

BISC és un projecte finançat pel Consell de Recerca Europea (ERC) i està organitzat per l'Institut de Salut Carlos III i el Centre de Recerca Biomèdica en col·laboració amb l'Hospital Hospital de Sant Joan de Déu i l'Hospital Clínic i Maternitat i Hospital de Sant Pau i Sant Joan.

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Barcelona Life Study Cohort **bisc**

**Participa en l'estudi, junt amb altres 1200 embarassades, i ajuda'ns a:**

- Saber quin impacte té la contaminació ambiental en l'embaràs i en el desenvolupament dels nens i nenes.
- Entendre quin és el rol de la placenta.

BARCELONA LIFE STUDY COHORT 2021-03-31

Barcelona Life Study Cohort **bisc**

**En què consisteix l'estudi?**

Farem un seguiment exhaustiu del teu embaràs i dels primers 18 mesos del teu fill/a:

- amb ecografies molt completes que avaluaran diferents aspectes de la placenta, el creixement i la formació neurològica i cardíaca del teu nadó.
- estimació precisa de l'exposició a:
  - la contaminació de l'aire,
  - la contaminació acústica,
  - l'activitat física, els espais verds i el stress
- el seguiment del desenvolupament cognitiu del teu fill/a.

**Si,**

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Participa!  
Visita [www.biscproject.org](http://www.biscproject.org)

ISGlobal SJD NATAL CLINIC SAMD IDAEA HI ERC



**La contaminació és un dels factors que més malalties causen en adults, i especialment en infants, però encara no sabem de quina manera pot arribar a afectar al futur nadó durant l'embaràs, un dels períodes més vulnerables i determinants a la vida de les persones.**



**Barcelona Life Study Cohort (BISC) és un projecte de recerca dirigit a:**

- Saber quin impacte té la contaminació ambiental en l'embaràs i en el desenvolupament dels nens i nenes.
- Entendre quin és el rol de la placenta.

**EN QUÈ CONSISTEIX L'ESTUDI?**  
Farem un seguiment exhaustiu a més de 1200 embarassades i els primers 18 mesos del seus fills/es:

- amb ecografies molt completes que avaluaran diferents aspectes de la placenta, el creixement i la formació neurològica i cardíaca dels nadons.
- estimació precisa de l'exposició a:
  - la contaminació de l'aire,
  - la contaminació acústica,
  - l'activitat física, els espais verds i el stress
- el seguiment del desenvolupament cognitiu dels nadons.

**Més info:**  
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