



Qatari Birth Cohort - QBIC

PARTICIPANT INFORMATION SHEET

We invite you to take part in this research project which we believe will help us to gather useful information about the impact of environmental exposures and genetic factors on health and wellbeing of children and their parents. You are being invited because you are pregnant or your wife is pregnant, you are over 18 years old and you are a Qatari or you are living in Qatar for the past 15 years and intend to give birth in Qatar. We hope by taking part you will help us to gather the information we need. In this letter, we have provided answers to questions that you might wish to ask about the research.

What is this research and what is the Purpose of this research?

This is a birth cohort epidemiological study where we prospectively observe women during their pregnancy, their children, and we also collect data from the father of their child/children so as to determine the genetic and life-course influences on childhood health, development and/or common complex diseases development that may persist in adulthood. Therefore, the aim of the Qatar Birth Cohort project is to assess the synergetic role of environmental exposures and genetic

factors in the development of chronic disease of woman and child health and/or obstetric characteristics with high prevalence in the state of Qatar. All the information we are going to collect will help us understand the causes of illness, which will help us to develop better ways of improving health and wellbeing.

Why have you been invited to participate as a research subject?

We are inviting every Qatari and Non-Qatari (that lives in Qatar for the past 15 years) pregnant woman and their husbands coming to the Primary Health Care centers, to take part in the Qatari Birth Cohort project. All the information we are going to collect will help us understand the causes of illness, which will help us to develop better ways of improving health and wellbeing of mothers and their children.

Do I have to participate?

No. Your participation is voluntary. Whether you decide to take part in the project is entirely up to you. If you decide you want to and later you change your mind, you can withdraw at any time.

Whatever you decide your medical care will not be affected in any way.

What procedures will be carried out and why?

For the pregnant women: If you accept to participate you will be asked to:

Visit 1- End of 1st beginning of 2nd trimester (12-15 weeks of gestation)

- Visit Qatar Biobank facilities at building 17 at Hamad Medical City where trained staff will
- Introduce you to the study and will ask you to read and sign a consent form.
- Once you accept to participate at QBIC study by signing the consent form, you will be
- Interviewed by our trained staff for approximately 1 hour
- Then you will go under a clinical examination. This examination will include:
 - Anthropometry measurements (i.e. Height, weight, waist circumference and hip circumference, bioimpedance analysis)
 - Cognitive function test
 - Grip Strength
 - Vision
 - Cardiovascular system (i.e. Blood pressure, electrocardiogram, arterial

- stiffness, carotid ultrasound)
- Respiratory function (by spirometry)
- Fetus ultrasound measurements
- You will be asked to donate sample of blood (approximately 48ml), urine, saliva and feces

Visit 2- Third Trimester (30-34 weeks of gestation)

- Visit duration: around three (3) hours
- You will have to visit Qatar Biobank facilities at building 17 at Hamad Medical City
- You will be interviewed by our trained staff for approximately 1 hour
- Then you will go under a clinical examination similar to visit 1. This examination will include:
 - Anthropometry measurements (i.e. Height, weight, waist circumference and hip circumference, bioimpedance analysis)
 - Cognitive function test
 - Grip Strength
 - Vision
 - Cardiovascular system (i.e. Blood pressure, electrocardiogram, arterial stiffness, carotid ultrasound)
 - Respiratory function (by spirometry)
 - Fetus ultrasound measurements
- You will be asked to donate sample of blood (approximately 48ml), urine, saliva and feces

Visit 3- Delivery day

- Our trained staff will visit the maternal unit where you will deliver and collect the following
- biological samples and birth information. There are no expected major risks or discomfort,
- Since our trained staff will not interfere with the delivery process.
- Biological samples:
 - Cord blood (40ml)
 - Placenta tissue
 - Cord tissue
 - Colostrum (the first milk)
 - Breast milk, Note: Both colostrum and breast milk will be collected with regard to your convenience.
 - Meconium and feces (we will ask you to keep the first four diapers containing your baby's stools and our staff will collect them)



- Birth outcomes per child:
 - Date and time of delivery
 - Delivery type
 - Gender
 - Gestational age
 - Birth weight
 - Height
 - Head circumference
 - Apgar score

Visit 4- 2 days after delivery

- Visit duration: around 15 min
- Our trained staff will visit the maternal unit two days after delivery and you will be asked to:
 - Complete (self-administered) a set 10 questions about your emotional status
 - Collect 48 ml of blood from you
 - Collect the diapers
- **Important Note:**
Please, note that any of your visits in Qatar Biobank as part of QBIC study is not replacing your regular maternity follow up with your physician at the OB/Maternity healthcare units.

For the father: Paternal Visit

- Visit duration: around 3 hours
- You will be able to agree to participate at any time during your wife's pregnancy. If you accept to participate you will be asked to:
 - Visit Qatar Biobank facilities at building 17 at Hamad Medical City where trained staff will introduce you to the study and will ask you to read and sign a consent form. Once you accept to participate at QBIC study by signing the consent form, you will be
 - Interviewed by our staff for approximately 1 hour
 - Then you will go under a clinical examination. This examination will include:
 - Anthropometry measurements (i.e. Height, weight, waist circumference and hip circumference, bioimpedance analysis)
 - Cognitive function test
 - Grip Strength
 - Vision
 - Cardiovascular system (i.e. Blood pressure, electrocardiogram, arterial stiffness, carotid ultrasound)
 - Respiratory function (by spirometry)
 - You will be asked to donate sample of blood (approximately 48ml), urine,

saliva, feces, and semen;

- You may participate in all these clinical tests or only in some of them (although the quality of the study and the capacity to make predictions would improve if you will participate in all of them)

Are there any risks and discomforts involved? What safety precautions are we taking in this research?

There are no expected major risks or discomforts from being in the research. You might experience some discomfort from the blood draws. You may feel some pain, bruising, redness and itching at the blood draw site.

In very few occasions fainting may also be possible. You may also feel emotional pain if you discover you or your child have a health problem identified through the study.

The main risk of providing your data is a possible risk of loss of confidentiality through unauthorized disclosure of your health or genetic information, although this is highly improbable. Since information will be kept electronically there may be computer security breaches. To prevent this, a series of measures will be taken including the keeping of all main electronic data and biological data in anonymized form and having in a distinct secure position the connection of ID information with information that could localize you.

POSSIBLE PREGNANCY RISKS

Optional, only include in studies involving pregnant women

There are no expected major risks or discomforts from being in the research related particularly to pregnancy. You may feel emotional pain if you discover you or your child have a health problem identified through the study.

What are the benefits of the study?

We cannot promise any benefits to you or your child from your taking part in this research. Your participation will mainly help researchers understand more about how to improve mother and child health including how genes and environmental exposures are related to health and disease. This could eventually benefit people in the future if it is discovered that a disease or condition can be managed or treated based on a person or group's genetic make-up. However, you will be

provided, if you so wish, with results of clinical testing. Knowledge resulting from these tests may empower the person or family members to plan for or make specific health decisions.

Women in high risk for post-partum depression will be referred to Hamad Women's Hospital for further investigation.

In case of Injury or if you wish to make an enquiry during the research, who do you contact?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team

at Qatar Biobank: 4454 6747 or Biomedical Research Department, Ministry of Public Health at 44070773 .

This research is being overseen by Qatar Biobank Institutional Review Board ("IRB"). You may talk to them at (974) 44548351 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Are there any financial or other compensation which might be provided to research participants?

We appreciate your taking part in this study. Please be aware that we will not pay any participant for taking part in this study

How long will your participation in this research be?

Your involvement in the data/sample collection portion of this research will occur over the period of five years. We expect that your data/sample collected now will be included in this research study for 10 years. Then both your data and samples will be retained at the Qatar Biobank for more than 20 years.

At a later stage we may decide to prolong the follow-up and evaluate health and wellbeing of your child as he/she grows and also evaluate your health. We will, however, re-contact you for this and ask again for your consent.

Will any of your information or samples collected be stored for future research or shared with others?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information. Other

research centers/units inside and outside Qatar participating in this study include Hamad Medical Corporation, Primary Health Care Corporation, Sidra Medical and Research Center, Qatar Biobank, Qatar Biomedical Research Institute, Qatar Energy and Environmental Research Institute, Anti-Doping Laboratory Qatar, Qatar University, Weill Cornell Medical College, Texas A&M Qatar and Center for Research in Environmental Epidemiology (Spain). All researchers receiving data including genomic data will only receive anonymized information with no capacity to identify specific individuals. If you so wish and specifically request you have the choice to indicate who will receive your own results (e.g. subject's family physician or family members). We expect that your data/sample collected now will be included in this research study at Qatar Biobank for more than 20 years. In the future, people who do research on your samples may need to know more about your health. Reports about your health will not have your name, address, phone number, or any other information that will let researchers know who you are. They will be identified by unique numbers that do not allow the researcher the ability to identify from whom samples were obtained.

At a later stage we may decide to prolong the follow-up and evaluate health and wellbeing of your child as he/she grows and also evaluate your health. We will, however, re-contact you for this and ask again for your consent.

Names of the sponsors of the research:

This research is being funded by the Ministry of Public Health. Other research centers/units inside and outside Qatar participating in this study include Hamad Medical Corporation, Primary Health Care Corporation, Sidra Medical and Research Center, Qatar Biobank, Qatar Biomedical Research Institute, Qatar Energy and Environmental Research Institute, Anti-Doping Laboratory Qatar, Qatar University, Weill Cornell Medical College, Texas A&M Qatar and Center for Research in Environmental Epidemiology (Spain).

What assurance can we give you of your anonymity and confidentiality?

Protecting the confidentiality of our participants is a top priority. We have put rigorous processes in place, including access control, computer security, confidentiality agreements and staff training.

The main risk of providing data is a possible risk of loss of confidentiality through unauthorized disclosure of health or genetic information, although this is highly improbable. Since information will be kept electronically there may be computer security breaches at QBB facilities. To prevent this, a series of measures will be

taken including the keeping of all main electronic data and biological data in anonymized form and having in a distinct secure position the connection of ID information with information that could localize the participants.

Non-coercive disclaimer:

You will be approached by a member of the research team with an invitation to take part in the project. If you do not wish to be approached, please let a member of staff know at the maternity reception desk when you attend for your first hospital appointment.

After agreeing to take part, if you change your mind or do not wish to take part in some aspects of the research, do you have an option to withdraw from the study without penalty?

You can withdraw from the research anytime. A decision to withdraw from the research will not be held against you. If you want to leave the project, please contact Qatar Biobank at 4454676 or at Ministry of Public Health at 44070773 and if you so wish and declare, any remaining tissue sample of yours that has been obtained for the study will be destroyed. It is possible that the research team can destroy the link between your genetic and medical information, but samples and data generated from your samples that have already been provided to other researchers or research centers or are placed in a formal research database cannot be withdrawn.

Details of the instances in which there might be incomplete disclosure of information:

There are no instances in which there might be incomplete disclosure of information. Our research team will introduce to the study and will provide all the information that you will need to know and answer your questions.

Who do you contact if you need further information?

If you have questions or concerns, talk to the research team at (+974) 44546747 Qatar Biobank or at (+974) 4407-0773 / 4407-0363 / 4407-5156, Biomedical Research Division, Ministry of Public Health, P.O. BOX 42, Doha-Qatar.

If you want to report a complaint related to your participation in the study, please contact the Ministry of Public Health Research Division by email at irb@MOPH.gov.qa or by phone at (+974)-4407-0981.

Please be sure you have read the above information, asked questions and received answers to your satisfaction. If you decide to participate, we will ask you to read and sign the consent form for the project.



PARTICIPATE NOW