# RESEARCH CONSENT FORM

## 1. Title of research

Qatar PREgnancy CovId OUtcome Study (Q-PRECIOUS)

## 2. Principal Investigator

Dr. Salwa Abu Yaqoup

## 3. Why are we inviting you to join this research?

The investigator and colleagues at Hamad Medical Corporation (HMC) [Women Wellness and Research Center] are conducting this research.

We are inviting you to join because [have had suspected COVID-19 or confirmed SARS-CoV-2 infection (the virus that causes COVID-19) in their pregnancy to consent to join this research study, collecting information about pregnancy. This form gives information about the study including the aims, risks and benefits of taking part.]

## 4. What should you know about this research?

- We will explain the research to you
- Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate)
- Please feel free to ask questions or mention concerns before deciding, or during or after the research
- You can say yes but change your mind later
- We will not hold your decision against you

## 5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at:
[Dr. Salwa Mohd Abu Yaqoub; email: Sabuyaqoub@hamad.qa]
If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:

- HMC Institutional Review Board (HMC-IRB) Chair at 5554 6316
- HMC-IRB Office at 4025 6410 (from Sunday to Thursday between 7:00am-3:00pm) or email at irb@hamad.qa

## 6. Why are we doing the research?

This study aims to collect information about COVID-19 and SARS-CoV-2 in pregnancy and babies from around the world into a register which the research team will use to share information with healthcare professionals around the world, allowing them to improve the care they give.

We would like to find out more about the effect of COVID-19 on early pregnancy, the growth of babies, early delivery and possible infection of babies.
Information will be held on a secure database and used anonymously to produce regular updates for healthcare professionals. You have been chosen to consider taking part because you have had likely or confirmed COVID-19 during your pregnancy or just afterwards.

**7. How long will the research take?**

We think that you will be in the research for almost 2 years.

We expect the research to last for 4 years

**8. How many people will take part?**

We plan to study around 1500 pregnant women. The research will include All HMC hospitals and quarantine sites people across all locations.

**9. What happens if you take part?**

If you agree to join, we will ask you to do the following:

- Study visits and telephone call:
  During pregnancy: you are expected to have 1 study visit initially. This visit will be after being diagnosed as confirmed or suspected corona and accepted to participate. This visit will last around 30-45 minutes during your hospital/quarantine stay. During this visit the doctor will ask you questions about your demographic information, past history, current symptoms and pregnancy information. If you have been previously diagnosed this visit will occur over the phone.
  Telephone call: You may receive a total of 7 telephone calls. This will occur every week for the first 4 weeks after your diagnosis and then in the second and third trimester and near to your delivery.
  After delivery:
  Telephone call: you will receive a telephone call to ask you about your baby and your general health. This calls will occur at 6 week after delivery then at 6 and 12 months.
- There is no procedure will be done. It is only questions and answers.
- Your primary doctor will obtain the initial visit information and all the telephone call will be conducted by our research personal.

**10. Could the research be bad for you?**

- This research aim to collect data about your pregnancy and your baby after being diagnosed as suspected or confirmed COVID case. There is no anticipated risk or harm.
- Some information might be of interest for local and international researcher. Hence we might keep a link to your information in a secured place. Such information will only be shared after approval from HMC.

There are also some privacy risks that are unlikely, but that you should know about:

- Although we will protect your information (see Section 12), people may develop ways in the future to link your medical information in our databases back to you. For example, someone could compare information in our databases with information from you in another database and be able to identify you. It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.
- There also may be other privacy risks that we have not foreseen.

**11. Could the research be good for you?**

There are no benefits to you from joining this research. However, possible benefits to others include understanding corona disease during pregnancy and how it affects you and your baby.

**12. What happens to information about you?**

We will make efforts to secure information about you. This includes using a code to identify you in our records instead of using your name. We will not identify you personally in any reports or publications about this research.

We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have a need to review information will have access. These people might include:

- Members of the research team whose work is related to the research or to protecting your rights and safety
- Representatives of the Ministry of Public Health Qatar who make sure the study is done properly and that your rights and safety are protected
- Your doctors and nurses
- We plan to use data from this study in other projects in the future. This might include sharing the data with other researchers. Although we will keep a link between your identity and the data about you, we will not provide that link to anyone we share the data with. In some studies the linking information might be required, in such cases it will be provided after approval from HMC.

**13. What if you don't want to join?**

You can say no and we will not hold it against you.

**14. What if you join but change your mind?**

You can stop participating at any time and we will not hold it against you.

[Include if you will interact with volunteers more than once. Otherwise delete] We will tell you about any new information that might affect your health or welfare, or might affect your willingness to continue in the research.

If you stop participating, we will ask you for permission to access your baby and your medical files to collect information about your doctor/hospital visit. The data will be collected from Cerner only. We will not be contacting you.

**15. What else should you know?**

This research is funded by HMC

**16. Additional Choices**

We would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

_____YES, you may contact me

_____NO, you may NOT contact me

Signature Page for Capable Adult

Volunteer

*I voluntarily agree to join the research described in this form.*

Printed Name of Volunteer

Signature of Volunteer Date

Person Obtaining Consent

*I document that:*

- *I (or another member of the research team) have fully explained this research to the volunteer.*
- *I have personally evaluated the volunteer's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

*I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.*

Printed Name of Witness

Signature of Witness Date