Rec Ref: 20/NE/0284 IRAS ID: 287478

Participant Information Sheet (PIS)

Part 1

Study Title: Understanding COVID-19 Infection in pregnant women and their babies (periCOVID)

Chief Investigator: Professor Kirsty Le Doare

Principal Investigator: Insert name of local PI

Invitation to participate in the above study:

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following carefully and discuss it with others if you wish. **We will go through the information sheet with you and answer any questions you have.** We'd suggest this should take about 15 minutes.

Public Health England (PHE) is working with St George's, University of London (SGUL) to understand how coronavirus affects mothers and their babies, including the risk of infection in babies born to mothers who develop coronavirus infection in pregnancy and how you can pass immunity to your baby in the form of antibodies. You can find out more about the coronavirus outbreak on this website: https://www.gov.uk/government/topical-events/coronavirus-covid-19-uk-government-response.

Why are we following-up pregnant women and women who are breastfeeding and have received SARS-CoV-02 vaccine during the coronavirus pandemic?

The novel coronavirus outbreak is spreading rapidly and we know very little about the risk of infection in pregnant women and if or how the infection might be transmitted to babies or how it may affect them. We are also interested in understanding what protection is passed from mothers who have been vaccinated to their babies through

the umbilical cord and in breastmilk. In order to understand this, we would like to take regular samples from pregnant women and their babies, or from women who are breastfeeding and have received a SARS-CoV-02 vaccine to test for the novel coronavirus and immunity against the novel coronavirus. We also want to understand how you might pass protective antibodies via the placenta and in breastmilk to your baby and if this protects your baby from the coronavirus.

Why have I been invited?

We would like to invite you to take part in the periCOVID study because you are pregnant, and have had a coronavirus swab test or you are pregnant and breastfeeding and have had a COVID19 vaccine. Before you decide to take part, we would like you to understand why we are doing this, and what it would involve for you. Please ask us if there is anything that is not clear.

Do I have to take part?

It is up to you to decide whether or not to take part and you should not be placed under any pressure to do so. If you do decide to take part in the periCOVID study, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw from the study at any time and without giving a reason.

What will happen to me if I take part?

If you decide to take part, you will be asked to sign a consent form. If you are unable to sign then you would not be able to participate in this study. The doctor or midwife looking after you or the research team at your hospital will complete an online questionnaire about your health and, after your baby is born, the health of your baby. This questionnaire will use an identification number and will not have your name or any other personal information about you.

Expenses and payments

Unfortunately, we will not be able to reimburse any expenses for participants. However, we will endeavour to ensure this study does not cause you any additional

expense by collecting samples during your usual hospital visits and appointments, and arranging to meet you at your home if necessary.

What do I have to do?

We will arrange all the tests for you with the doctors and midwives who are looking after you or the research team. For women who are enrolled directly into the surveillance by SGUL, we will provide you with all of the equipment required for the collection of samples and to safely return them to the laboratory. It is at your doctor or midwife's discretion whether the samples are taken, however they will remain your property until they are sent to SGUL.

If you decide to take part, we will use the results from the throat swab which has already been done during your pregnancy if you have had one.

At delivery

If your swab test is negative, at delivery we will take a blood sample from you, and a cord blood sample. These samples will be 5ml each (about a teaspoon). We may ask to take a blood sample from your baby if it is not possible to obtain a cord blood sample; this would be 2ml (half a teaspoon).

If you swab test is negative and you have received a SARS-CoV-02 vaccine whilst pregnant, at delivery we will take a breastmilk (colostrum) sample (if possible), a blood sample from you, and a cord blood sample. These samples will be 5 ml each (about a teaspoon). We may ask to take a blood sample from your baby if it is not possible to obtain a cord blood sample; this would be 2ml (half a teaspoon).

If your swab test is negative and you have received a SARS-CoV-02 vaccine postpartum, after vaccination we will take a breastmilk (colostrum) sample (if possible), a blood sample from you, and a cord blood sample. These samples will be 5 ml each (about a teaspoon). We may ask to take a blood sample from your baby if it is not possible to obtain a cord blood sample; this would be 2ml (half a teaspoon).

If your swab test is positive at any point during pregnancy, when your baby is born, the following samples will be collected from you: blood sample, placental swab (and sample of placental tissue if possible), cord blood, and breast milk (colostrum) if possible. We also plan to collect the following samples from your baby after birth: nasal and throat swab, and stool swab. A blood sample will be collected from your baby, if cord blood was not collected.

After delivery

If your throat swab is negative during pregnancy, we will not take any further samples after delivery.

If you swab test is negative and you have received a SARS-CoV-02 vaccine whilst pregnant, we would also like to collect a blood sample and, if possible, breast milk sample from you at 6 weeks post-delivery

If you swab test is negative and you have received a SARS-CoV-02 vaccine postpartum, we would also like to collect a blood sample and, if possible, breast milk sample from you at 6 weeks post-vaccination.

If your throat swab is positive at any point during pregnancy, after your baby is born, we would like to collect a throat swab, stool swab, and blood sample from your baby at 6 weeks post-delivery. We would also like to collect a blood sample and, if possible, breast milk sample from you. The doctor or midwife looking after you or the research team will help collect these samples. We will either give you the kits before discharge or post the kits to you and you will be able to take the samples yourself, except for the blood samples. For the blood samples, either a visit will be arranged for you and your baby to come back to your local site, or a community midwife will take the samples from you at your home. Your local doctor or midwife or research team will remind you to take the samples by phone, email and/or text.

What are the possible disadvantages and risks of taking part?

For some, blood sampling may cause momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of light-headedness when the blood is drawn, and rarely, an infection at the site of the blood draw. Whenever possible, we will aim to take some extra blood when you and your baby have your routine blood tests. We do not anticipate any other disadvantages from taking part.

What are the possible benefits of taking part?

We will tell you your and your baby's results when all the testing is complete, which will likely be towards the end of the study. Taking part will also help provide important information to protect pregnant women, women breastfeeding, their babies and healthcare staff looking after them. We will also produce a report of the overall results for the pregnant women in the surveillance for Public Health England to help guide care for women and their babies during the pandemic.

What if there is a problem?

Any complaint about the way you have been dealt with or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

Part 2

What if relevant new information becomes available?

Sometimes we get new information about the condition being studied. If this happens your research doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study he/she may ask you to sign an agreement outlining the discussion.

What will happen if I don't want to carry on with this study?

If you no longer want to be involved, you can withdraw from the study at any time by contacting your study doctor or nurse. The samples you have already provided will continue to be processed and later stored for future research projects, unless you expressly tell us not to do this. However, you and your baby will not be asked to provide any more samples.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you speak with the researchers who will do their best to answer your questions or concerns. The normal National Health Service complaints mechanisms are also available to you. You can find their contact details at the bottom of this information sheet.

St George's, University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. We would not be bound to pay compensation where: -The injury resulted from a drug or procedure outside the trial protocol and/or -The protocol was not followed. These arrangements do not affect your right to pursue a claim through legal action.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognized.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, contact details, date of birth and NHS number. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We may retrieve your coded data from our partners working on the UKOSS and PANCOVID studies. This information will not have your name or any identifiable information attached to it so it will not be directly traceable to you and your baby. Should you wish, you also have the opportunity to allow your and your baby's anonymised data and/or results to be used for future studies. If you do not want us to retrieve your data from UKOSS or PANCOVID, to store your or your baby's data or samples for use in future studies, these decisions will not prevent you from taking part in the periCOVID study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

https://www.sgul.ac.uk/about/our-professional-services/information-services/information-governance/data-protection/privacy-notice

For general information on how the NHS uses research data please visit https://www.hra.nhs.uk/information-about-patients/

What will happen to any samples I give?

Your samples will be coded with an identification number that is unique to you and your baby. The identification number will be stored with all the other samples until they are tested.

We will test your samples for coronavirus infection, to see if your immune system has made antibodies against the virus. Finally, we will sequence the genome of the virus to better understand its biology.

The samples will all be destroyed after testing.

However, should you wish, you have the opportunity to anonymously donate your and your baby's samples to SGUL for storage in our Institute of Infection and Immunity Research Tissue bank, to help with future research. If you do not want to donate your samples, this decision will not prevent you from taking part in the periCOVID study. Any samples that are stored long-term at SGUL will not contain any personal data (such as

name and address) of you or your baby, and the study code will be removed so it will not be possible for researchers to identify you or your baby.

Your personal data will be stored in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018.

Will any genetic tests be done?

No.

What will happen to the results of the research study?

Your local care team will be able to let you know the results of your tests, and of your baby's tests.

The results of this research study will be analysed by the research team, and will be made publicly available. This may be via our website, publication in scientific journals, and presentation of the results at scientific conferences.

We will not use your name or any other information that can be used to identify you when we publish the results of this study.

Who is organising and funding the research?

St George's University of London is organizing and overseeing this study. Funding has been secured from Action Medical Research. Your doctor or midwife will not be paid for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favorable opinion by the North East – Newcastle & North Tyneside 1 Research Ethics Committee.

Further Information and Contact Details

If you have questions about the study, you can contact your local research team:

[INSERT CONTACT DETAILS FOR LOCAL TEAM]

If you are unhappy with something that has happened during the study, please contact your local PALS team:

[INSERT CONTACT DETAILS FOR LOCAL PALS TEAM]

You will be asked whether you have understood the instructions for the study before it starts, and you will be asked to sign a short form to say that you agree to take part. You will be provided with a written copy of both the participant information sheet and informed consent form.

Thank you for agreeing to take part in this study.