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**INTERGROWTH-21st Project**

**INTERCOVID STUDY**

PATIENT INFORMATION SHEET

We would like to invite you to take part in the INTERCOVID Study,

which aims to investigate the effects of COVID-19 infection on pregnancy outcomes.

Before you decide, we would like you to understand why the research is being done

and what it would involve for you and your baby.

Please read this information sheet carefully.

One of our team will go through it with you and answer any questions you have.

We suggest this should take about 15 minutes.

Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if anything is not clear.

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| --- | --- |
| Oxford Maternal & Perinatal Health Institute  Green Templeton College  Woodstock Road  Oxford OX2 6HG | Nuffield Department of  Women’s & Reproductive Health  University of Oxford  Women’s Centre, John Radcliffe Hospital  Oxford OX3 9DU |

**PART 1: The purpose of the study and what will happen to you if you take part**

**What is the purpose of the study?**

We wish to investigate the effects of COVID-19 infection in pregnancy on mothers and babies. To do so, we would like to collect information about newborn and pregnancy outcomes.

It is believed that pregnancy is not affected by COVID-19 infection. So, the overall purpose of our study is to use the information we collect to confirm whether or not this is the case.

**Why have I been invited?**

We are inviting women, over 18 years old, who aim to deliver at the ……………………..……. Hospital with confirmed or suspected COVID-19 infection. We are also inviting women without confirmed or suspected COVID-19 infection so that we can compare their outcomes.

**Do I have to take part?**

It is up to you to decide whether or not you wish to take part. Your decision will not affect the care you receive in any way. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. If you have any questions or concerns after reading this leaflet, our research midwife will be happy to answer them. You can also call her on the number on the back of this information leaflet.

**What will happen if I don’t want to carry on with the study?**

You are free to withdraw from the study at any time, without giving a reason. This would not affect the care you or your baby receives in any way. If you decide to withdraw from the study, we would ask your permission to retain any data already collected. If you are not happy with this, all the data that identify you and your baby will be destroyed.

**What will happen to me if I take part?**

We would like to obtain from your medical records routinely collected information about your pregnancy, including measurements taken of your baby and the answers to questions about your exposure to COVID-19.

**What are the possible disadvantages and risks in taking part?**

We do not believe there are any disadvantages or risks in taking part.

**What are the possible benefits of taking part?**

Taking part in this study would not usually benefit you or your baby directly. However, if you do take part you will be helping us to learn more about pregnancy and newborn outcomes, which will benefit others in the future.

**What if there is a problem?**

Any complaint about your involvement in the study 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 (next pages) before making any decision.

**PART 2: More detailed information about the conduct of the study**

**What will happen if I don’t want to carry on with the study?**

You may withdraw from the study at any time. It would not affect the care you or your baby receives in any way. If you decide to withdraw from the study, we would ask your permission to retain any data already collected. If you are not happy with this, all the data that identify you and your baby will be destroyed.

**What if there is a problem?**

If you have concerns or complaints about the way you have been approached or treated during the course of the study, you can contact …………………………………………………………………………

………………………………………………………………………………………………………………………………….

**Will my taking part in this study be kept confidential?**

Any information that is collected about you during the course of the research will be kept strictly confidential. Our data manager, who has a duty of confidentiality to you and your baby as research participants, is the only person able to identify you and your baby. If you choose to continue with the study, your and your baby’s results will be held anonymously in a secure database. We would like your permission to share your totally anonymised data, which include ultrasound images, your and your baby’s clinical and laboratory results, and your baby’s measurements, with academic collaborators around the world, including the Bill & Melinda Gates Foundation, and possibly commercial companies.

Authorised representatives of the University of Oxford may look at the anonymised results to check that the study is being performed correctly. No individual participants will be identified when the results of the study are published. Any information that leaves the hospital will have your name removed so that you cannot be identified.

**How will my data be protected?**

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above.  Research is a task that is performed in the public interest.

The data will be retained for 21 years after the end of the study in the event that future discussions about pregnancy and newborn outcomes require the data to be reanalysed. After 21 years, the data will be disposed of securely. You have the right to check the accuracy of data held about you and your baby, and to correct any errors.

Further information about your rights with respect to your personal data is available from <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>.

**What will happen to the results of the research study?**

The results will be prepared for publication in scientific journals and presentation at international meetings. We can provide you with a copy of the papers after publication if you wish. Your name will not appear in any report or publication. Some of the data from the study may be included in a PhD thesis of one or more of researchers. Your identity will be protected at all times.

**Who is organising the research?**

The research is being carried out by the Nuffield Department of Women’s & Reproductive Health at the University of Oxford in collaboration with …………………………………………………….. The doctors involved in the research are not being paid to include you in the study and have no conflicts of interest with regards to the study.

**Who has reviewed the study?**

Research is reviewed by an independent group of people called a Research Ethics Committee to protect your interests, safety, rights, well-being and dignity. This study has been reviewed and given favourable opinion by the Oxford Tropical Research Ethics Committee.

This completes Part 2.

You may keep this information leaflet for your records.

If you have any questions, please contact us as above.

If you wish to take part in the study we will ask you to sign a consent form.

We will give you a signed copy to keep for your records

**Further information and contact details**

If you have any questions, please do not hesitate to contact (local Research Midwife and details):

Telephone:

Email:

Post:

You can find our website at <https://intergrowth21.tghn.org/>