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| C:\Users\awinsey\AppData\Local\Temp\Temp1_Intercovid.zip\Intercovid\Intercovid_green.png | INTERCOVID 22 STUDY  Frequently asked questions V1 19.1.22 |

1. **Who is eligible to be enrolled in the INTERCOVID Study?**

The study is open to all pregnant women >18 years old at any stage of pregnancy.

1. **How can my institution participate in the study?**

Please report your interest and details to [adele.winsey@wrh.ox.ac.uk](mailto:adele.winsey@wrh.ox.ac.uk)

Your institution will be sent a set of forms, a unique site identifier and access to the database.

1. **Does my institution need local ethical approval to participate?**

The answer depends on each country’s regulations. Some sites will need approval from their own local ethics committee in addition to that provided by the Oxford committee; others may have in place country-specific approval already for the use of routinely collected clinical data relating to COVID-19.

1. **Who is an ‘exposed’ woman or case?**

Any **pregnant** woman >18 years old who has:

* Confirmed positive COVID-19 test, via PCR, lateral flow or LAMP, **at any time during her current pregnancy**

1. **Who is a ‘non-exposed’ woman or control?**

Any **pregnant** woman >18 years old who is not an ‘exposed’ case, according to the definitions above, is a ‘non-exposed’ woman or control for the purposes of this study.

* Controls will either have tested negative for COVID-19 at each test during their pregnancy, or perhaps never have been tested at all

For each ‘exposed’ case recruited, two ‘non-exposed’ controls must be recruited.

1. **For an (index) ‘exposed’ case who is admitted to hospital in labour or expected to deliver during the admission, who should the two controls be?**

The controls should be the next two ‘non-exposed’ women admitted to hospital in labour or expected to deliver during the admission, whatever their gestational age.

1. **For an (index) ‘exposed’ case who is admitted to hospital but not in labour or expected to deliver during the admission, who should the controls be?**

You can wait and recruit the controls when the ‘exposed’ case delivers. The controls should be the next two ‘non-exposed’ women admitted to hospital in labour or expected to deliver during the admission, whatever their gestational age.

1. **For an (index) ‘exposed’ case who is identified during the antenatal period and quarantined at home, who should the controls be?**

On the same day the index ‘exposed’ case is identified, you need to recruit two ‘non-exposed’ controls of similar gestational age (± 2 weeks) who are receiving standard antenatal care. Each woman needs to be followed up until delivery. If that is not possible, or women are lost to follow-up before delivery, then, recruit two ‘non-exposed’ controls who deliver immediately after the index case delivers.

1. **What forms do I need to complete? 5 of the forms must be filled in for every case/control, the other 4 are only needed in specific circumstances:**

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| **Form name** | **Fill in for every case/control** | **When to complete** |
| Study Entry Form (COV) | YES | Whenever a pregnant woman is screened. |
| Covid related symptoms (CRQ) form | YES | For both cases and controls as this form takes important vaccination details |
| Maternal Referral/ Admission (MRA) Form | Only if relevant | Whenever an ‘exposed’ case is admitted to hospital for any reason, **but not expected to deliver during the admission**. When she does deliver, complete the Pregnancy and Delivery (P&D) Form and the Infant Follow-up Form (at discharge and weekly if the baby remains admitted). |
| Pregnancy and Delivery (DEV) Form | YES | When an ‘exposed’ case or ‘non-exposed’ control delivers. |
| Intensive Care Form (ICU) | Only if relevant | Whenever a woman is admitted to intensive care at any point during the study. |
| Neonatal Follow-up Form (NFU) | YES | When a baby is discharged from hospital, and weekly if the baby remains admitted. |
| Neonatal Abnormality Form (NAB) | Only if relevant | If the baby has conditions specified on the Pregnancy and Delivery (P&D) Form. |
| Baby Care Form (BCF) | YES | When the baby is discharged |
| Adverse Event Form (AE) | Only if relevant | In the case that the woman has a health condition which needs further explanation please complete an adverse event form. This includes if:   1. She has been diagnosed with any type of malignancy/cancer 2. She had a medical condition requiring treatment or surgery during her pregnancy 3. If she died during her pregnancy |

1. **Can I recruit a woman who was exposed a few weeks ago?**

Yes, retrospective recruitment back to 1st December 2021 is acceptable. Recruitment is to be mainly prospective, but in the first few weeks it is recognised that eligible cases may have accumulated so retrospective recruitment is acceptable in the initial phase.

1. **Are twins/multiple births eligible?**

Yes – the database will allow you to enter for twins.

1. **What if a ‘non-exposed’ woman is enrolled as a control in the antenatal period but tests positive for COVID-19 later in pregnancy?**

The woman will can no longer be a control for the purposes of the study, you will need to recruit a new control to replace her, however she could now be considered as a case (providing you can get 2 more consecutive controls).

1. **At study entry, what if the woman, has had a COVID-19 test but the result is not yet available?**

The woman can only be recruited as a case if the result is positive. If the test is negative and she has never had a positive result in this pregnancy, then she is eligible as a control.

1. **Is it mandatory for ‘unexposed’ women to test negative for SARS-CoV-2?**

No, they only need to have answered ‘NO’ to 

1. **In a tertiary referral obstetric centre it’s likely that controls may have other comorbidities such as lupus, does this affect the study?**

The cases and controls from your hospital will be equally likely to have comorbidities so this will not affect the study.

1. **What if we recruit an ‘exposed’ woman in the antenatal period and she does not deliver at our hospital?**

Do your best to contact her/the other hospital in which she delivered to complete the Pregnancy and Delivery (DEV) and Infant Follow-up Forms.

1. **What if we recruit a ‘non-exposed’ woman in the antenatal period and she does not deliver at our hospital?**

Do your best to contact her/the other hospital in which she delivered to complete the Pregnancy and Delivery (DEV) and Infant Follow-up Forms. If she is lost to follow-up, recruit another ‘non-exposed’ control who delivers immediately after the index ‘exposed’ case.

1. **Are there any specifics for matching controls? Have we got some specific variables to match other than timings meaning antenatal/perinatal?**

No.

1. **Are we expected to follow up the neonate after hospital discharge**?

No.

1. **Is there an enrolment limit if there is more than one study site in a country?**

No, the target of 50 cases (and 100 controls) is **per study site, not per country,** if sites have more than 50 cases, that’s good news as it will help those where the disease is less prevalent, with fewer cases.

1. **Can the database be accessed direct from mobile phone?**

Unfortunately not.

1. **What if I don’t have access to a computer**?

Most people fill in the forms on paper initially, as it gives you a good record to refer back to. Having the paper in front of you also makes it easier to fill in the online database. If you don’t have access to a computer, you can send pictures of the forms to Oxford, and they can be input here. Please contact us if computer access is an issue.

1. **Are the forms available in in other languages**?

The original forms are in English. Some centres are translating the forms, so please ask us and we may be able to direct you towards a centre that has already translated them.

1. **Q56 on the Infant Follow-up Forms** **asks the researcher to make another appointment. Why?**

This is only relevant if the local hospital decides they want to arrange a follow-up.

1. **Q76 on the Maternal Admission/Referral (A&R) Form asks for the date of the next ultrasound appointment. Why?**

This question is not relevant, unless you wish to use it locally.

1. **Maternal hospital record number: Can we omit it if it’s too long to fit within the 9 boxes or if our hospital has asked that we don’t include it?**

This information is for the local site for when you need to go back to the medical record to respond to a query. Hence, you should have a method to match the study number with the hospital number, locally from a booklet or similar. If the number is too long for the database, add as many digits as you can. If your hospital really will not allow you to include the number in the database, you can include it on the paper form, which you keep locally, but put 00 in the database.

1. **Why have you asked us to take pictures of the birth registry to demonstrate that we are recruiting consecutive births as controls? Do we send you these?**

We are going to ask for a random sample per site, to show the controls are consecutive cases. Do not send the pictures to us unless you are asked to, just keep them locally.

1. **Q17 of the Maternal referral/admission form-highest creatinine level what units should this be in.**

Please report it in mg/Dl

1. **What if a woman recruited as a control tests positive for COVID-19 after the delivery?**

If the swab was taken prior to delivery, then she cannot be a control, as she was exposed whilst still pregnant. If she was negative before delivery then tests positive after delivery she can remain as a control as we assume she was exposed after delivery.