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|  | INTERCOVID STUDY  Frequently asked questions |

1. **Who is eligible?**

The study is open to all pregnant women >18 years old.

1. **What is an exposure / non-exposure**: **Who is an “exposure”?**

Any **pregnant** woman that has any of the following:

* laboratory confirmed COVID-19 infection based on local protocols and methods
* the presence of symptoms compatible with COVID-19 infection according to a predefined list of symptoms
* absence of symptoms, but reporting a close interaction with a person(s), who has laboratory confirmed COVID-19 infection
* radiological confirmation of COVID-19 symptoms

Any woman who is known to be exposed to COVID-19, for the sake of this study will be called a ‘case’.

**Who is a “non-exposure”?**

Any **pregnant** woman at least 18 years old, who is not known to be exposed to COVID-19 for this study will be called a ‘non-case’.

For each ‘case’ recruited, two ‘non-cases’ must be recruited

1. **What forms do I need to complete?**

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| Form name | When to complete |
| COVID Study Entry Form | Complete for every woman screened to participate in the study. |
| Maternal Referral/Admission | If the woman is not delivering at the time of recruitment, fill this in, but keep her in the study and fill in the Pregnancy and Delivery form when she does deliver. |
| Pregnancy and Delivery form | At delivery for each case and non-case. |
| Intensive Care form | If the woman is admitted to intensive care at any point during the study. |
| Infant Follow-up form | Complete for each infant at discharge, and if the baby is admitted to hospital complete weekly until discharge. |
| Neonatal abnormality form | If the baby has conditions specified on the pregnancy and delivery form |

1. **Can I recruit a woman that is eligible but was seen in previous weeks?**

Recruitment is to be prospective, but in the first few weeks it is recognised that candidate women may have accumulated so retrospective recruitment is acceptable in the initial phase.

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

Yes – the database will allow you to fill in multiple forms for one woman.

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

Not at the moment however we are working to make this possible.

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

You can send pictures of the forms to [adele.winsey@nhs.net](mailto:adele.winsey@nhs.net), and they can be input in Oxford

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

These are not currently available.

1. **Q56 on the infant follow up forms** – **why does this ask the researcher to make another appointment?**

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

1. **Q76 on the Maternal Referral form**

Why does this ask for the date of the next ultrasound appointment - it is not relevant for this study, unless you wish to use it locally.

1. **What do the terms ‘exposed’ case and ‘non-exposed’ control mean ?**

A:  An ‘exposed’ case is a woman, at any stage of pregnancy, who has: a) had a positive COVID-19 test; b) symptoms suggestive of COVID-19, or c) been in close contact with someone with a positive COVID-19 test (see further explanations below).  A ‘non-exposed’ control is a woman, at any stage of pregnancy, who does not have any of these COVID-19 criteria.

1. **For an ‘exposed’ case who is admitted to hospital in labour or expected to give birth during the admission, who should the controls be?**

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

1. **For an ‘exposed’ case who is: a) admitted to hospital but not in labour or expected to give birth during the admission or b) identified during the antenatal period and quarantined at home, who should the controls be ?**

The controls should be two ‘non-exposed’ women attending antenatal clinic, whose gestational age matches the ‘exposed’ case within ±2 weeks.

1. **What is meant by radiological pulmonary findings consistent with COVID-19 ?**

The medical records are likely to contain a radiological diagnosis “suggestive of COVID-19”. COVID-19 causes a severe lower respiratory tract infection with bilateral, basal and peripheral predominant ground-glass opacity, consolidation or both, with reticulation/thickened interlobular septa, nodules etc. All these are features typical of an organising pneumonia pattern of lung injury, and lesion distribution can be left, right or bilateral lungs. These findings peak around 9–13 days and slowly begin to resolve thereafter.

1. **What does any close contact with someone who was COVID-19 positive mean?**

Close contact can occur at home or at work.  Examples include: a) sharing a house with someone (partner/other family member) who has tested positive for COVID-19 or b) looking after a COVID-19 positive person as a health professional or caregiver.

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

The woman will remain a control for the purposes of the study.  However, you should note the test result and/or new symptoms in the free text field (Q170) in the Pregnancy & Delivery Form and tick any other relevant questions (e.g. Q54 and Q55 in Section 5, and Q81 in Section 7).

1. **At study entry, what if the woman, enrolled as an ‘exposed’ case, has had a COVID-19 test but the result is not yet available?**

Please indicate in the Study Entry Form that a test has been done (Q1 or Q2), and complete the question “If yes, was the result positive?” as soon as the result is available.

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