INTERCOVID

A prospective cohort study
in pregnancy and the neonatal period

International Fetal and Newborn Growth
Consortium for the 21st Century
(INTERGROWTH-21st)

DATA COLLECTION FORMS

May 2020

(version 2.0)

UNIVERSITY OF
OXFORD

Contents

1. Frequently asked questions

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.

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

   Please report your interest and details to adele.winsey@wrh.ox.ac.uk
   Your institution will be sent a set of forms, a unique site identifier and access to the database (see Q.23).

3. **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.

4. **Who is an 'exposed' woman or case?**

   Any **pregnant** woman >18 years old who has any of the following:
   - Laboratory confirmed COVID-19 based on local protocols and methods
   - The presence of symptoms compatible with COVID-19 according to the predefined list of symptoms
   - Absence of symptoms, but reporting a close interaction with a person(s), who has laboratory confirmed COVID-19
   - 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 an 'exposed' woman or case.

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

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

   The medical records are likely to contain a radiological diagnosis that is "consistent with 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.

6. **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.

7. **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.

8. For an (index) 'exposed' case who is admitted to hospital but <u>not</u> 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.

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

On same day the index 'exposed' case is identified, you need to recruit <u>two</u> '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 <u>two</u> 'non-exposed' controls who deliver immediately after the index case delivers.

10. What forms do I need to complete?

Form name	**When to complete**
Study Entry Form	Whenever a pregnant woman is screened.
Maternal Admission/Referral (A&R) Form	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 (P&D) Form	When an 'exposed' case or 'non-exposed' control delivers.
Intensive Care Form	Whenever a woman is admitted to intensive care at any point during the study.
Infant Follow-up Form	When a baby is discharged from hospital, and weekly if the baby remains admitted.
Neonatal Abnormality Form	If the baby has conditions specified on the Pregnancy and Delivery (P&D) Form.

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

Recruitment is to be 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.

12. Are twins/multiple births eligible?

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

13. 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

(P&D) Form and tick any other relevant questions (e.g. Q54 and Q55 in Section 5, and Q81 in Section 7).

14. 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. Regardless of the test result she remains a case.

15. If a PCR test is done but the result is negative then what should be entered in the study entry form?

Enter the actual result. If the woman has been recruited as an 'exposed' case – she will remain as such.

16. Is it mandatory for 'unexposed' women to test negative for SARS-CoV-2?

No, they only need to have answered 

to question 7 on the Study Entry Form.

17. 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.

18. 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 to complete the Pregnancy and Delivery (P&D) and Infant Follow-up Forms.

19. 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 to complete the Pregnancy and Delivery (P&D) 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.

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

No.

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

No.

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

The limit of 50 cases (and 100 controls) is **per study site, not per country**

23. Can the database be accessed direct from mobile phone?

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

24. What if I don't have access to a computer?

Most people fill in the forms on papers 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 inputted here. Please contact us if computer access is a big issue.

25. 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.

26. 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.

27. 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.

Study Entry Form (COV)

Participant Number [ ][ ] - [ ][ ][ ][ ] **Hospital/Clinic Code** [ ][ ] - [ ][ ]

Maternal Hospital Record No. [ ][ ][ ][ ][ ][ ][ ][ ][ ] **Visit Date** D D M M Y Y

Please answer all yes/no questions by placing a 'X' in the corresponding box

Section 1

1. Has virological antigen testing for COVID-19 been carried out (e.g. PCR)? yes no

   If yes, was the result positive? yes no Date of test D D M M Y Y

2. Has antibody testing for COVID-19 been carried out (e.g. serology)? yes no

   If yes, was the result positive? yes no Date of test D D M M Y Y

3. Does the woman have radiological signs consistent with COVID-19 infection? yes no

4. Place an X next to any of the symptoms that the woman has presented with and record the number of days for each symptom.

Fever	[ ]	[ ][ ] days	Diarrhoea / vomiting	[ ]	[ ][ ] days
Cough	[ ]	[ ][ ] days	Breathlessness	[ ]	[ ][ ] days
Sore throat	[ ]	[ ][ ] days	Loss of smell	[ ]	[ ][ ] days
Headache	[ ]	[ ][ ] days	Runny nose	[ ]	[ ][ ] days
Tiredness/lethargy	[ ]	[ ][ ] days	Flu-like symptoms	[ ]	[ ][ ] days
Limb or joint pain	[ ]	[ ][ ] days	Chest pain	[ ]	[ ][ ] days

5. Does the woman have at least two of the symptoms listed above? yes no

6. Has the woman been in close contact with someone who was COVID-19 positive? yes no

Section 2: Eligibility

7. Are any of the shaded (yes) boxes above marked with a 'X'? yes no

If the answer is yes, the woman is an 'exposed' case.

If the answer is no, the woman is a 'non-exposed' control.

Remember to recruit TWO 'non-exposed' controls per 'exposed' case (who deliver immediately after the 'exposed' case).

When either a case or control delivers, complete the Pregnancy & Delivery Form, Infant Follow-up Form and Section 3 below.

If an 'exposed' case is admitted to hospital but delivery is not expected during this admission, also complete the Maternal Admission/Referral Form.

If an 'exposed' case is recruited but not admitted to hospital (i.e. advised to self-isolate at home), recruit two 'non-exposed' controls that day of similar gestational age (i.e. ± 2 weeks) who are receiving standard antenatal care, and follow them up to delivery. If that is not possible or the controls are lost to follow-up, then recruit two other 'non-exposed' controls instead who deliver immediately after the index case, and complete their Pregnancy & Delivery Form, Infant Follow-up Form and Section 3 below.

Section 3: Neonate **Infant hospital number** (if the woman delivers twins, complete one form for each baby) [ ][ ][ ][ ][ ][ ][ ][ ][ ]

8. Has the neonate had virological antigen testing for COVID-19 (e.g. PCR)? yes no

   If yes, was the result positive? yes no Date of test D D M M Y Y

9. Has the neonate had antibody testing for COVID-19 (e.g. serology)? yes no

   If yes, was the result positive? yes no Date of test D D M M Y Y

Name of researcher

Signature Researcher code

Maternal Referral/Admission (MRA)

UNIVERSITY OF OXFORD

INTERCOVID Study
Maternal Referral/Admission Form

MRA

Participant number ☐☐ - ☐☐☐☐ **Hospital/Clinic Code** ☐☐☐☐

LABEL SPACE

Antenatal Record No. ☐☐☐☐☐☐☐☐☐

Maternal Date of Birth D D M M Y Y

Visit Date D D M M Y Y

Please answer all yes/no questions by placing a 'X' in the corresponding box

Section 1: Pregnancy status

1. Is this a referral to another level of outpatient care or admission to hospital? (cross one box only)
   Referral ☐ Admission ☐
2. To which department/unit/service has she been referred or admitted? (cross one box only)
   Gynaecology ☐ Surgery ☐
   Obstetric/ High-risk clinic ☐ Trauma/ Orthopaedics ☐
   Nephrology ☐ Emergency room ☐
   Nutritional ☐ Internal medicine ☐
   Physiotherapy ☐ Other ☐
   Psychiatry ☐

If she has been referred or admitted for a nutritional problem, please indicate the diagnosis: (cross all that apply)

3. Gestational diabetes ☐
4. Overweight ☐
5. Underweight ☐
6. Anaemia ☐
7. Food allergy ☐
8. Heartburn ☐
9. Malabsorption syndrome ☐
10. Specific dietary requirement ☐

Section 2: Lab information (if requested during admission/referral)

11. Proteinuria (by dipstick): (cross one box only)
    0 / trace ☐ + ☐ ++ ☐
    +++ ☐ ++++ ☐ No urine test performed at this referral/ admission ☐
    and/or actual result (from urine sample) received from laboratory: ☐☐☐ mg/dl
12. Urine culture: (cross one box only)
    Positive ☐
    Negative ☐
    No urine culture available ☐
13. If positive, was antibiotic treatment given? yes ☐ no ☐
14. Lowest haemoglobin level: OR Lowest haematocrit:
    ☐☐.☐ g/dl ☐☐.☐ %
15. Lowest blood glucose level: ☐☐☐ mmol/l
16. Highest blood glucose level: ☐☐☐ mmol/l
17. Highest serum creatinine level: ☐.☐ µmol/l

Section 3: Clinical diagnosis for this admission or referral

Please provide the main diagnosis by referring to the medical records:

18. Diabetes yes ☐ no ☐
    If yes, was there any evidence of diabetic ketoacidosis? yes ☐ no ☐
19. Thyroid disease or any other endocrinological condition yes ☐ no ☐
20. Any type of malignancy/cancer (if yes, please complete an **Adverse Event Form**) yes ☐ no ☐
21. Cardiac disease yes ☐ no ☐
22. Epilepsy yes ☐ no ☐
23. Mental illness e.g. Clinical depression yes ☐ no ☐
24. Symptomatic malaria yes ☐ no ☐
25. Symptomatic malaria with parasite count yes ☐ no ☐
26. Respiratory disease (including asthma) yes ☐ no ☐
27. Pyelonephritis or kidney disease yes ☐ no ☐
28. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition yes ☐ no ☐
29. Lower urinary tract infection requiring antibiotic treatment yes ☐ no ☐
30. Respiratory tract infection requiring antibiotic/antiviral treatment yes ☐ no ☐
31. Any other infection requiring antibiotic/antiviral treatment yes ☐ no ☐
32. Non-septic shock requiring fluid replacement or pressor agents yes ☐ no ☐
33. Maternal trauma yes ☐ no ☐
34. Deep vein thrombosis yes ☐ no ☐
35. Systemic lupus erythematosus yes ☐ no ☐
36. HIV or AIDS yes ☐ no ☐
37. Any genital tract or sexually transmitted infection yes ☐ no ☐
38. Sickle-cell anaemia yes ☐ no ☐
39. Cholestasis yes ☐ no ☐
40. Any other medical/surgical condition requiring treatment or surgery (if yes, please complete an **Adverse Event Form**) yes ☐ no ☐

Participant number ☐☐ - ☐☐☐☐ **Hospital/Clinic Code** ☐☐☐☐

LABEL SPACE

Antenatal Record No. ☐☐☐☐☐☐☐☐☐

Maternal Date of Birth D D M M Y Y

Visit Date D D M M Y Y

Section 4: Pregnancy-related diagnosis for this admission or referral

Please provide the main diagnosis by referring to the medical records:

41. Severe vomiting requiring hospitalisation — yes / no
42. Gestational diabetes — yes / no
43. Vaginal bleeding — yes / no
44. Pregnancy-induced hypertension (BP>140/90, no proteinuria) — yes / no
45. Preeclampsia (BP>140/90 and proteinuria) — yes / no
46. Severe preeclampsia/Eclampsia/ HELLP syndrome — yes / no
47. Fetal maternal haemhorrage — yes / no
48. Rhesus disease or anti-Kell antibodies — yes / no
49. Uterine rupture — yes / no
50. Prelabour premature rupture of membranes (PPROM) or Preterm labour without delivery — yes / no
51. PPROM or Preterm labour and delivery (if yes, please complete the **Pregnancy and Delivery Form**) — yes / no
52. Miscarriage or fetal death (if yes, please complete the **Pregnancy and Delivery Form**) — yes / no
53. Fetal anaemia — yes / no
54. Fetal distress (abnormal fetal heart rate [FHR] or biophysical profile [BPP]) — yes / no
55. Suspected impaired fetal growth — yes / no
56. Pelvic mass — yes / no
57. Oligohydramnios — yes / no
58. Polyhydramnios — yes / no
59. A condition requiring amniocentesis or fetal blood sampling (FBS) — yes / no
60. Abruptio placentae — yes / no
61. Clinical chorioamnionitis — yes / no
62. Any other pregnancy-related infection or condition (if yes, please complete an **Adverse Event Form**) — yes / no

Section 5: Medications and treatment

Has she been prescribed any of the following medications or treatments?

63. Aspirin — yes / no
64. Antibiotics/Antivirals — yes / no
65. Antihypertensives — yes / no
66. Prophylactic steroids for preterm labour — yes / no
67. Treatments for asthma — yes / no
68. Antipsychotics — yes / no
69. Antidepressants — yes / no
70. Magnesium sulphate — yes / no
71. Blood transfusion — yes / no
72. Just bed rest/observation — yes / no
73. Any other treatment — yes / no

Section 6: Final outcome

74. Final outcome of the admission: (cross one box only)
    - ☐ Discharged
    - ☐ Transferred to another level of care or hospital (inform study coordinator)
    - ☐ Delivered/Miscarried (complete the **Pregnancy and Delivery Form**)
    - ☐ **Maternal death** (complete the **Pregnancy and Delivery** and **Adverse Event Forms**)
    - ☐ Left hospital or treatment against medical advice (inform study coordinator)
75. Date of discharge from hospital: D D M M Y Y

Section 7: Next appointment

If the woman is still pregnant (even if she is still in hospital) check the date of the next ultrasound appointment.

76. Date of the next ultrasound appointment: D D M M Y Y

If the woman is still in hospital please inform the study coordinator.

Name of Researcher/Midwife			
Signature		Researcher Code	

Pregnancy and Delivery (DEV)

Participant study number | | | – | | | | |

Maternal Hospital Number | | | | | | | | |

Infant Hospital Number | | | | | | | | |

Delivery Hospital Code | | – | |

Infant date of birth D D – M M – Y Y

Section 1: Demographic, socioeconomic and nutritional characteristics

1. Maternal age | | years
2. Maternal height | | . | cm
3. 1st trimester or pre-pregnancy weight | | . | kg
4. Has she smoked/chewed tobacco during this pregnancy? yes no
5. If she smoked cigarettes, how many per day? | |
6. Has she used any recreational drugs during this pregnancy? yes no
7. On average, how many units of alcohol per week has she had during this pregnancy? | | units
   (1 unit = small glass (125ml) of wine or one bottle/can (330ml) of beer; see table)
8. Has she been involved in any high risk occupation and/or vigorous sport during this pregnancy? yes no see table
9. Has she followed any special diets during this pregnancy? yes no see table
   (e.g. vegetarian with no animal products, weight loss programme, malabsorption treatment, gluten-free)
10. Current marital status (cross one box only)
    Single ☐ Married/Cohabiting ☐ Widowed ☐ Separated/Divorced ☐
11. Total number of years of formal education | | years
12. Highest level of education she attended (cross one box only)
    Primary ☐ Secondary ☐ Professional/ technical training ☐ University ☐
13. Which of the following best describes her occupational status? (cross one box only)
    Housework ☐ Manager/professional/technical ☐ Clerical support, service or sales ☐ Skilled manual work ☐ Unskilled manual work ☐ Other ☐

Section 2: Medical history

14. Diabetes yes no
15. Thyroid disease yes no
16. Other endocrinological conditions yes no
17. Cardiac disease yes no
18. Hypertension/chronic hypertension yes no
19. Chronic respiratory disease (including asthma) yes no
20. Proteinuria, kidney disease or chronic renal disease yes no
21. Any type of malignancy/cancer yes no
22. Lupus erythematosus yes no
23. Any hematologic condition including sickle-cell anaemia or leukaemia yes no
24. Epilepsy yes no
25. HIV or AIDS yes no
26. Malaria yes no
27. Tuberculosis yes no
28. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption yes no
29. Any congenital abnormality yes no
30. Any other clinically relevant condition yes no

Participant study number		**Delivery Hospital Code**	
Maternal Hospital Number		**Infant date of birth**	D D – M M – Y Y
Infant Hospital Number			

Section 3: Gynaecological history

31. Did she have regular (24-32 day) menstrual cycles in the 3 months prior to this pregnancy? yes / no
32. Has she used hormonal contraceptives or been breastfeeding in the 2 months prior to this pregnancy? yes / no
33. Was this pregnancy conceived with fertility treatment? yes / no
34. First day of the last menstrual period (LMP) D D – M M – Y Y
35. Was she certain of her date of LMP? yes / no
36. Date of the first ultrasound scan during this pregnancy D D – M M – Y Y
37. What was the CRL (crown rump length) measurement at the first ultrasound scan? . mm
38. What was the BPD (biparietal diameter) measurement at the first ultrasound scan? . mm
39. Estimated gestational age at the first ultrasound scan wks days

Section 4: Obstetric history

40. Number of previous pregnancies, excluding the present pregnancy (if 0, skip to Section 5)
41. Number of previous miscarriages
42. Number of previous births, excluding this birth (if 0, skip to Section 5)?
43. Have ANY of her other babies weighed less than 2.5kg or more than 4.5kg? yes / no
44. Have ANY of her other babies been born preterm (<37 weeks' gestation)? yes / no
45. Has she had ANY previous stillbirths or neonatal deaths? yes / no

Section 5: Clinical conditions

During this pregnancy was she diagnosed with, or treated for, any of the following conditions (cross all that apply)

46. Cardiac disease yes / no
47. Chronic respiratory disease (including asthma) yes / no
48. Malaria yes / no
49. Mental illness e.g. depression yes / no
50. Epilepsy yes / no
51. Thyroid disease or any other endocrinological condition yes / no
52. Lower urinary tract infection requiring antibiotic treatment yes / no
53. Pyelonephritis yes / no
54. Respiratory tract infection requiring antibiotic/antiviral treatment yes / no
55. Any infection requiring antibiotics/antivirals yes / no
56. Positive syphilis test yes / no
57. HIV or AIDS yes / no
58. Any sexually transmitted infection yes / no
59. Any type of malignancy or cancer yes / no
60. Any other medical/surgical condition requiring treatment or referral yes / no

Participant study number | | | – | | | | |

Maternal Hospital Number | | | | | | | |

Infant Hospital Number | | | | | | | |

Delivery Hospital Code | | – | |

Infant date of birth D D – M M – Y Y

Section 6: Pregnancy related complications

During this pregnancy was she diagnosed with, or treated for, any of the following conditions (cross all that apply)

61. Severe vomiting requiring hospitalisation	yes	no	68. Severe preeclampsia/ Eclampsia/HELLP	yes	no
62. Gestational diabetes	yes	no	69. Rhesus disease	yes	no
63. Vaginal bleeding before 15 weeks	yes	no	70. Preterm labour	yes	no
64. Vaginal bleeding between 15-27 weeks	yes	no	71. Fetal distress	yes	no
65. Vaginal bleeding after 27 weeks	yes	no	72. Suspected impaired fetal growth or SGA	yes	no
66. Pregnancy-induced hypertension	yes	no	73. Any other pregnancy related condition requiring treatment or referral	yes	no
67. Preeclampsia	yes	no			

74. Lowest haemoglobin level (if available) — <15 weeks ..g/dl; 15-27 weeks ..g/dl; >27 weeks ..g/dl

Section 7: Nutritional supplements / Medications

During this pregnancy, has she routinely taken any of the following supplements? (cross all that apply)

75. Iron	yes	no	78. Food supplements	yes	no
76. Folic acid	yes	no	79. Multi-vitamins/minerals	yes	no
77. Calcium	yes	no			

During this pregnancy, has she taken any of the following medications? (cross all that apply)

80. Routine aspirin	yes	no	83. Non-steroidal anti-inflammatories	yes	no
81. Any antibiotics or antivirals (except those used for PROM)	yes	no	84. Insulin	yes	no
			85. Prophylactic steroids for preterm labour	yes	no
82. Antibiotics used for PROM	yes	no	86. Any other treatment	yes	no

Section 8: Delivery

87. Onset of labour (cross one box only)

Spontaneous ☐ Induced ☐ No Labour ☐

88. Did she have pre-labour rupture of membranes yes no

89. Mode of delivery (cross one box only)

Vaginal spontaneous ☐ Assisted breech ☐

Vaginal assisted (e.g. forceps, vacuum) ☐ Caesarean section ☐

If labour was induced or a Caesarean section was performed, please cross all indications that apply

90. Vaginal bleeding	yes	no	100. Suspected impaired fetal growth or SGA	yes	no
91. Fetal death	yes	no	101. Post term (>42 weeks gestation)	yes	no
92. Pregnancy-induced hypertension	yes	no	102. Rhesus disease	yes	no
93. Preeclampsia	yes	no	103. HIV or AIDS	yes	no
94. Severe preeclampsia/ Eclampsia/HELLP	yes	no	104. Any sexually transmitted infections	yes	no
95. Breech presentation	yes	no	105. Any infections requiring antibiotics/antivirals	yes	no
96. Fetal distress	yes	no	106. Maternal request	yes	no
97. Failure to progress	yes	no	107. Any other maternal reason	yes	no
98. Cephalo-pelvic disproportion	yes	no	108. Any other fetal reason	yes	no
99. Prelabour rupture of membranes (PROM)	yes	no	109. Previous Caesarean section	yes	no

Participant study number ☐☐ – ☐☐☐☐

Maternal Hospital Number ☐☐☐☐☐☐☐

Infant Hospital Number ☐☐☐☐☐☐☐

Delivery Hospital Code ☐☐ – ☐☐

Infant date of birth DD – MM – YY

Section 9: Newborn outcome and care

110. Date of delivery DD – MM – YY

111. Time of delivery (24h clock) HH : MM

112. Number of babies ☐☐

If more than 1 baby, complete another Pregnancy and delivery form (sections 9 to 13 only)

113. Gestational age at birth ☐☐ wks ☐ days (best obstetric estimate)

114. Apgar score at 5 minutes ☐☐

115. Newborn sex Male ☐ Female ☐

116. Fetal presentation at delivery (cross one box only)

Cephalic ☐ Breech ☐ Other ☐

117. Was the newborn admitted to intensive care or any special care unit? yes no

118. Total number of days spent in intensive/special care unit (if <24h, enter 1 day) ☐☐☐ days

119. Age at gavage onset ☐☐☐ days

120. Age at full oral feeding onset ☐☐☐ days

121. Enteral feeding was suspended/reintroduced yes no

Has the newborn been diagnosed with/treated for any of the following conditions?

122.	Respiratory distress syndrome	yes no	135.	Seizures	yes no
123.	Transient tachypnea of the newborn	yes no	136.	Hypoglycaemia	yes no
124.	Pneumonia/Bronchiolitis	yes no	137.	Periventricular haemorrhage/leukomalacia	yes no
125.	Apnea of prematurity	yes no	138.	Hypotension requiring inotropics/steroids	yes no
126.	Bronchopulmonary dysplasia	yes no	139.	Anaemia (requiring transfusion)	yes no
127.	Meconium aspiration with respiratory distress	yes no	140.	Patent ductus arteriosus (requiring pharmacological treatment or surgery)	yes no
128.	No enteral feeding for more than 24 hours	yes no			
129.	Hypoxic-ischaemic encephalopathy	yes no	141.	Any gastro-intestinal surgery	yes no
130.	Polycythaemia	yes no	142.	Any other condition requiring surgery	yes no
131.	Hyperbilirubinemia requiring transfusion	yes no	143.	Endocrine abnormalities	yes no
132.	Kernicterus	yes no	144.	Inborn errors of metabolism	yes no
133.	TORCH or any other intrauterine infections	yes no	145.	Any other serious condition	yes no
134.	Sepsis	yes no	146.	Congenital abnormality	yes no

Section 10: Newborn anthropometry

147. Birthweight ☐.☐☐☐ kg

148. Length at birth ☐☐.☐ cm

149. Head Circumference at birth ☐☐.☐ cm

150. Date of measurement DD – MM – YY

151. Time of measurement HH – MM

(please obtain the anthropometry preferably within 12 hours, and no later than 24 hours, after birth)

Participant study number ☐☐ – ☐☐☐☐

Maternal Hospital Number ☐☐☐☐☐☐☐

Infant Hospital Number ☐☐☐☐☐☐☐

Delivery Hospital Code ☐☐ – ☐☐

Infant date of birth D D – M M – Y Y

Section 11: Morbidities/treatments during hospitalisation

152. Has the newborn received respiratory support? yes no

153. If yes, number of days in respiratory support until discharge (round up to the next whole day) ☐☐☐ days

154. If on respiratory support, type of respiratory support.

Mechanical ventilation ☐ Nasal C-PCP/high flow nasal cannula ☐

Oxygen hood ☐

Has the newborn been given any of the following:

155. Corticosteroids postnatally yes no

156. Surfactant replacement therapy yes no

157. Diuretics yes no

158. Antibiotics yes no

159. Antipyretics yes no

160. Methylxanthines yes no

Has the newborn been diagnosed with/treated for any of the following conditions?

161. Intraventricular haemorrhage no yes → Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐

162. Necrotising enterocolitis no yes → Stage I ☐ Stage IIa ☐ Stage IIb ☐ Stage III ☐

163. Retinopathy of prematurity no yes → Stage I ☐ Stage II ☐ Stage III ☐ Stage IV ☐ Stage V ☐

Section 12: Newborn outcomes

164. Newborn status at hospital discharge

Alive ☐ Alive but referred to another hospital ☐ Dead ☐

165. Date of hospital discharge or date of neonatal death

D D – M M – Y Y

Section 13: Newborn nutritional practices at hospital discharge

166. What was the main mode of feeding in the 24 hours prior to hospital discharge? (cross one box only)

Exclusive breastmilk ☐

Combination feeding: Predominant breastmilk ☐ Partial breastmilk ☐

Exclusive formula ☐

No oral feeds (IV fluids only) ☐

Section 14: Maternal outcomes

167. Was the mother admitted to intensive care or any special care unit after delivery? yes no

168. If yes, total number of days: (if less than 24 hours, please enter as 1 day) ☐☐☐

169. Maternal status at hospital discharge: (cross one box only) Alive ☐ Alive but referred to another hospital ☐ Dead ☐

170. Comments (please identify the question that the comment refers to with a *q* followed by the question number; example: "*q146. head circumference at birth not taken and not available in medical records*")

_____

_____

_____

Name of researcher _____

Signature _____ Researcher code ☐☐

Intensive Care Form (ICU)

UNIVERSITY OF OXFORD

INTERCOVID Study

Intensive Care Form

ICU

Participant Number | | | - | | | | |

Hospital/Clinic Code | | | - | | |

AFFIX LABEL

Maternal Hospital Record No. | | | | | | | | | |

Date of admission to intensive care D D M M Y Y

Please answer all yes/no questions by placing a 'X' in the corresponding box

Section 1: Actions

1. Indicate any measures taken: (Cross all the apply):

Treatment given	☐
No treatment given	☐
Delivery (please complete **Pregnancy and Delivery form**)	☐

2. If she had treatment, please record what treatment and for how many days:

Prone postioning	yes ☐	no ☐	☐☐ days
Oxygen treatment	yes ☐	no ☐	☐☐ days
Positive airway pressure treatment (CPAP)	yes ☐	no ☐	☐☐ days
Invasive mechanical ventilation	yes ☐	no ☐	☐☐ days
Extracorporeal membrane oxygenation (ECMO)	yes ☐	no ☐	☐☐ days
Antivirals	yes ☐	no ☐	☐☐ days
Hydroxychloroquine	yes ☐	no ☐	☐☐ days
Steroid treatment for maternal indication	yes ☐	no ☐	☐☐ days
Tocilizumab	yes ☐	no ☐	☐☐ days
Any other COVID related therapy	yes ☐	no ☐	☐☐ days

Section 2: Maternal outcome

3. What was the outcome of the intensive care admission?

Alive	☐
Died in intensive care	☐

Section 3: Additional information

Name of researcher

Signature

Researcher code

Infant Follow-up Form

Participant Study Number ☐☐ – ☐☐☐☐ **Delivery Hospital Code** ☐☐ – ☐☐

Maternal Hospital Number ☐☐☐☐☐☐☐ **Infant date of birth** DD – MM – YY

Infant Hospital Number ☐☐☐☐☐☐☐ **Date of this visit** DD – MM – YY

This form should be completed at discharge and at least once a week if the baby remains in hospital.

Section 1: Status of the infant

1. Status of the infant Alive ☐ Dead ☐ → If dead, date of death DD – MM – YY

Since the last study examination, how many days has the infant spent in any of the following;

2. High dependency unit/NICU (any hospital) ☐☐ days
3. Intermediate dependency unit ☐☐ days
4. Low dependency unit/Nursery ☐☐ days
5. Another special care unit ☐☐ days
6. At home ☐☐ days
7. TOTAL NUMBER OF DAYS since last study examination ☐☐ days

8. If the infant has been discharged since the last visit, date of hospital discharge DD – MM – YY

Section 2: Status of the mother

9. Where is the mother? (cross one box only) Still in hospital ☐ At home/with family ☐ Dead ☐

Section 3: Feeding Practices

10. Which of the following liquids has the infant been given since the last study examination (cross all that apply)

- Breast milk ☐
- Breast milk with fortifiers ☐
- Standard infant formula ☐
- Preterm/post-discharge formula ☐
- High energy formula ☐
- Soy based formula ☐
- Hydrolysed formula ☐
- Any other special formula ☐
- Animal milk ☐
- Water based drinks/fruit juice ☐

11. Which method(s) were used? (cross all that apply)

- Breastfeeding ☐
- Oral feeding ☐
- Tube feeding ☐
- Parenteral nutrition including dextrose infusion ☐

12. Number of days of parenteral nutrition since birth or the last study examination ☐☐ days

Section 4: Infant Anthropometry

13. Date of measurement DD – MM – YY
14. Time of measurement HH : MM
15. Weight ☐☐ . ☐☐☐ kg
16. Length ☐☐ . ☐ cm
17. Head Circumference ☐☐ . ☐ cm

Participant Study Number | | | – | | | | |

Delivery Hospital Code | | | – | |

Maternal Hospital Number | | | | | | | | |

Infant date of birth D D – M M – Y Y

Infant Hospital Number | | | | | | | | |

Date of this visit D D – M M – Y Y

Section 5: Morbidities/treatments

Since the last study examination, has the infant started or continued treatment for any of the conditions which required appointment(s) with a health care provider?

18.	Pneumonia/Acute respiratory infection/ Bronchiolitis	yes / no	30.	Febrile episodes	yes / no
19.	Blindness	yes / no	31.	Sepsis/meningitis	yes / no
20.	Otitis media	yes / no	32.	Infectious disease (e.g. measles, malaria)	yes / no
21.	Hearing problems	yes / no	33.	Metabolic disorders	yes / no
22.	Cardiovascular problems	yes / no	34.	Seizures	yes / no
23.	Skin problems	yes / no	35.	Chronic renal failure	yes / no
24.	Stoppage of enteral feeding for more than 3 consecutive days	yes / no	36.	Neurological disorders	yes / no
25.	Gastro-esophago-pharyngeal reflux	yes / no	37.	Hydrocephalus	yes / no
26.	Other feeding problems	yes / no	38.	Endocrine abnormalities	yes / no
27.	Persistent vomiting	yes / no	39.	Malignancy	yes / no
28.	Diarrhoea	yes / no	40.	Injury/trauma	yes / no
29.	Short bowel syndrome	yes / no	41.	Any other serious condition	yes / no
				(please specify)	

Since the last study examination which treatments have been given?

42.	Analgesics	yes / no	49.	Antipyretics	yes / no
43.	Antacids	yes / no	50.	Antitussive or expectorant drugs	yes / no
44.	Haematinics	yes / no	51.	Blood transfusions	yes / no
45.	Anticonvulsants	yes / no	52.	Bronchodilators	yes / no
46.	Antiemetics	yes / no	53.	Diuretics	yes / no
47.	Anti-inflammatory agents	yes / no	54.	Glucocorticoids	yes / no
48.	Antibiotics	yes / no	55.	Oxygen	yes / no

Section 6: Next examination

Please now arrange the next follow-up examination

56. Date of the next study appointment or hospital examination D D – M M – Y Y

Name of the researcher

Signature

Researcher code

Neonatal Abnormality Form

UNIVERSITY OF OXFORD

INTERCOVID Study

Neonatal Abnormality Form

Participant Number | | | - | | | | | **Hospital/Clinic Code** | | | - | |

Maternal Hospital Record No. | | | | | | | | | |

Infant Hospital no. | | | | | | | | | |

Please answer all yes/no questions by placing a 'X' in the corresponding box

Section 1: Abnormalities observed at birth

In which of the following areas were the abnormalities seen?

Please provide detailed information in the text box for any abnormality where 'yes' is crossed.

1. Head	yes	no	9. Bladder	yes	no
2. Brain	yes	no	10. Limbs	yes	no
3. Face	yes	no	11. Lungs/Pleura	yes	no
4. Neck	yes	no	12. Kidneys	yes	no
5. Spine	yes	no	13. Genitalia	yes	no
6. Heart	yes	no	14. Chromosomal abnormality (e.g. Down's syndrome)	yes	no
7. Anterior abdominal wall	yes	no	15. Indeterminate sex	yes	no
8. Gasto-intestinal	yes	no	16. Other	yes	no

17. Detailed information

18. Final diagnosis

Once completed please scan and email a copy of this form to the Coordinating Unit in Oxford

Name of researcher

Signature

Researcher code