INTERCOVID 2022

A prospective cohort study in pregnancy and the neonatal period

International Fetal and Newborn Growth Consortium for the 21st Century

DATA COLLECTION FORMS

January 2022
Version 1.0

Data collection forms

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COVID Study Entry Form

UNIVERSITY OF OXFORD

INTERCOVID 2022

Study Entry Form

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: During this pregnancy

1. Has the woman had a positive COVID-19 test at any point during this pregnancy? yes ☐ no ☐

If yes, the woman is eligible as a diagnosed COVID-19 case. Go to section 2

If no, the woman is eligible as a non-diagnosed COVID-19 control. Go to section 3

Section 2: Diagnosed with COVID-19: eligible case

2. Record all the **positive** tests during this pregnancy, starting with the first positive test:

Test 1: was there a positive result? yes ☐ no ☐ Date of test D D M M Y Y

Type of test used: PCR ☐ RT-LAMP *(loop-mediated isothermal amplification)* ☐ Rapid antigen test *(e.g. lateral flow)* ☐

Test 2: was there a positive result? yes ☐ no ☐ Date of test D D M M Y Y

Type of test used: PCR ☐ RT-LAMP *(loop-mediated isothermal amplification)* ☐ Rapid antigen test *(e.g. lateral flow)* ☐

Test 3: was there a positive result? yes ☐ no ☐ Date of test D D M M Y Y

Type of test used: PCR ☐ RT-LAMP *(loop-mediated isothermal amplification)* ☐ Rapid antigen test *(e.g. lateral flow)* ☐

If you have more than 3 positive tests, record the total number: ☐☐

For all recruited cases, complete the COVID Related Form and the Pregnancy & Delivery Form. Complete the Infant Follow-up Form, and the Baby Care Form at newborn hospital discharge.

Section 3: Non-diagnosed with COVID-19: eligible controls - *remember two controls are required for each case*

3. Has the woman had a **negative** COVID-19 test during this pregnancy? yes ☐ no ☐
The woman is eligible as a control even if she has not been tested during this pregnancy.

If the woman had a negative test, record these starting with first negative test:

Test 1: was there a negative result? yes ☐ no ☐ Date of test D D M M Y Y

Type of test used: PCR ☐ RT-LAMP *(loop-mediated isothermal amplification)* ☐ Rapid antigen test *(e.g. lateral flow)* ☐

Test 2: was there a negative result? yes ☐ no ☐ Date of test D D M M Y Y

Type of test used: PCR ☐ RT-LAMP *(loop-mediated isothermal amplification)* ☐ Rapid antigen test *(e.g. lateral flow)* ☐

Test 3: was there a negative result? yes ☐ no ☐ Date of test D D M M Y Y

Type of test used: PCR ☐ RT-LAMP *(loop-mediated isothermal amplification)* ☐ Rapid antigen test *(e.g. lateral flow)* ☐

If you have more than 3 negative tests, record the total number: ☐☐

For all recruited controls, complete the COVID Related Form and the Pregnancy & Delivery Form. Complete the Infant Follow-up Form and the Baby Care Form at newborn hospital discharge.

Name of researcher ☐

Signature ☐ Researcher code ☐☐

COVID Related Form (CRQ)

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: During this pregnancy

1. Place a 'X' next to any of the symptoms that the woman has presented with and record the number of days for each symptom. If she has had COVID-19 twice, record these for her most recent episode.

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

2. Has the woman had COVID-19 before this pregnancy? ☐ yes ☐ no

   If, yes, when did she have COVID-19? *Record the month and year* M M Y Y

Section 2: Vaccination

3. Has the woman ever received a COVID-19 vaccine? ☐ yes ☐ no

4. Record which vaccine was administered:

	1st	2nd	3rd	4th		1st	2nd	3rd	4th
Oxford-AstraZeneca	☐	☐	☐	☐	Sinopharm	☐	☐	☐	☐
Covishield/Serum Institute of India	☐	☐	☐	☐	Covaxin (Bharat BioTech)	☐	☐	☐	☐
Janssen/Johnson&Johnson	☐	☐	☐	☐	Novavax	☐	☐	☐	☐
Sputnik V	☐	☐	☐	☐	Soberana 01	☐	☐	☐	☐
Pfizer-BioNTech	☐	☐	☐	☐	Soberana 02	☐	☐	☐	☐
Moderna	☐	☐	☐	☐	Soberana Plus	☐	☐	☐	☐
Coronovac/SinoVac	☐	☐	☐	☐	Abdala	☐	☐	☐	☐
Other, please specify:						☐	☐	☐	☐

5. Record the date that each vaccine was given:

   First D D M M Y Y Third D D M M Y Y

   Second D D M M Y Y Fourth D D M M Y Y

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

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

   Test 1: was there a positive result? ☐ yes ☐ no D D M M Y Y

   Method of testing: PCR ☐ Lateral flow/rapid test ☐ LAMP ☐

   Test 2: was there a positive result? ☐ yes ☐ no D D M M Y Y

   Method of testing: PCR ☐ Lateral flow/rapid test ☐ LAMP ☐

   Test 3: was there a positive result? ☐ yes ☐ no D D M M Y Y

   Method of testing: PCR ☐ Lateral flow/rapid test ☐ LAMP ☐

7. 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 Form (MRA)

UNIVERSITY OF OXFORD

INTERCOVID 2022
Maternal Referral/Admission

MRA

PTID Number ☐☐ - ☐☐☐☐☐ **Hospital/Clinic Code** ☐☐

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 <u>nutritional</u> 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: <u>OR</u> 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 ☐

INTERBIO-21st PTID Number 0 7 - 1 0 0 0 0 **Hospital/Clinic Code**

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 Form (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		**Newborn is part of the BC study**	yes no

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	–	**Delivery Hospital Code**	–
Maternal Hospital Number		**Infant date of birth**	D D – M M – Y Y
Infant Hospital Number		**Newborn is part of the BC study**	yes no

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		

	<15 weeks	15-27 weeks	>27 weeks
74. Lowest haemoglobin level (if available)	. g/dl	. g/dl	. 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	–	**Delivery Hospital Code**	–
Maternal Hospital Number		**Infant date of birth**	D D – M M – Y Y
Infant Hospital Number		**Newborn is part of the BC study**	yes no

Section 9: Newborn outcome and care

110. Date of delivery D D – M M – Y Y

111. Time of delivery (24h clock) H H : M M

112. Number of babies

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

112b. Was the baby born alive? yes no

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

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 D D – M M – Y Y

151. Time of measurement H H – M M

(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

Newborn is part of the BC study yes no

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

Neonatal Follow up Form (NFU)

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

Newborn Hospital Record Number | | | | | | | | | |

Paediatric Outpatient Clinic Record Number | | | | | | | | | |

Date of birth D D - M M - Y Y

Date of this visit D D - M M - Y Y

Delivery Hospital Code | | |

This form should be completed for neonates at 2, 4, 6 and 8 weeks after birth.

Section 1: Status of the neonate

1. Status of the neonate

☐ Alive ☐ Dead If dead, date of death D D — M M — Y Y

Since the last study examination, how many days has the neonate spent in any of the following:

2. High dependency unit/NICU | | days
3. Intermediate dependency unit | | days
4. Low dependency unit/Nursery | | days
5. Another special care unit | | days
6. Hospital with mother i.e. rooming-in | | days
7. At home | | days
8. TOTAL NUMBER OF DAYS since last study examination | | days
9. If the neonate has been discharged since the last visit, date of hospital discharge D D — M M — Y Y

Section 2: Status of the mother

10. Where is the mother? (cross one box only)

Still in hospital ☐ At home/ with family ☐ Dead ☐

Section 3: Feeding Practices

11. Which of the following liquids has the neonate been given since the last study examination (cross as many as apply)

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

12. Which method(s) were used? (cross as many as apply)

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

13. Number of days exclusive TPN (total parenteral nutrition) since last study examination ☐

Section 4: Neonate anthropometry

14. Date of measurement D D — M M — Y Y

15. Time of measurement H H : M M

1st set of anthropometric measurements

16. Weight | . | | | | kgs
17. Length | | . | | cm
18. Head circumference | | . | | cm

Participant Number ☐☐ – ☐☐☐☐☐☐☐ **Date of birth** D D - M M - Y Y

Newborn Hospital Record Number ☐☐☐☐☐☐☐☐☐ **Date of this visit** D D - M M - Y Y

Paediatric Outpatient Clinic Record Number ☐☐☐☐☐☐☐☐☐ **Delivery Hospital Code** ☐☐☐

Section 4: Neonate anthropometry continued - 2nd set of anthropometric measurements

19. Weight ☐.☐☐☐ kgs
20. Length ☐☐.☐ cm
21. Head circumference ☐☐.☐ cm

Section 5: Morbidities/treatments

22. Since the last study examination, has the neonate received respiratory support? yes ☐ no ☐
23. If yes, number of days on respiratory support, since the last examination (if part of a day round up to the next whole day) ☐ days
24. If on respiratory support, type of respiratory support.

Mechanical ventilation ☐ Nasal C-PAP/ High flow nasal cannula ☐

Oxygen Hood ☐

Since the last study examination has the neonate been given the following:

25. Corticosteroids postnatally yes ☐ no ☐
26. Surfactant replacement therapy yes ☐ no ☐
27. Diuretics yes ☐ no ☐
28. Antibiotics yes ☐ no ☐
29. Antipyretics yes ☐ no ☐

Since the last study examination, has the neonate been diagnosed with/treated for any of the following conditions?

30. Intraventricular hemorrhage yes ☐ no ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐
31. Necrotising enterocolitis yes ☐ no ☐ Stage I ☐ Stage IIa ☐ Stage IIb ☐ Stage III ☐
32. Retinopathy of prematurity yes ☐ no ☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV ☐ Stage V ☐
33. Respiratory distress syndrome yes ☐ no ☐
34. Pneumonia/Bronchiolitis yes ☐ no ☐
35. Meconium aspiration with respiratory distress yes ☐ no ☐
36. Hypoxic-ischaemic encephalopathy yes ☐ no ☐
37. Apnea of prematurity yes ☐ no ☐
38. Stoppage of enteral feeding for more than 3 consecutive days yes ☐ no ☐
39. Broncopulmonary dysplasia/chronic lung disease yes ☐ no ☐
40. Any gastro-intestinal condition requiring surgery (complete an **adverse event** form) yes ☐ no ☐
41. Patent ductus arteriosus requiring surgery (complete an **adverse event** form) yes ☐ no ☐
42. Any other condition requiring surgery (complete an **adverse event** form) yes ☐ no ☐
43. Short bowel syndrome yes ☐ no ☐
44. Severe Diarrhoea yes ☐ no ☐
45. Hyperbilirubinemia requiring exchange transfusion yes ☐ no ☐
46. Kernicterus yes ☐ no ☐
47. Chronic renal failure yes ☐ no ☐
48. Major neurological impairment yes ☐ no ☐
49. Seizures yes ☐ no ☐
50. Periventricular leukomalacia yes ☐ no ☐
51. Hypoglycaemia yes ☐ no ☐
52. Hypotension requiring inotropic treatment or steroids yes ☐ no ☐
53. Anaemia (requiring transfusion) yes ☐ no ☐
54. Sepsis yes ☐ no ☐
55. Endocrine abnormalities yes ☐ no ☐
56. Inborn errors of metabolism yes ☐ no ☐
57. Any other serious condition yes ☐ no ☐
58. Any congenital abnormality (complete a **Neonatal abnormality** form)

Section 6: Next Examination. Please now arrange the next follow-up examination (2 weeks from today)

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

Name of Researcher				Signature	
Researcher Code	☐☐	Code of 1st anthropometrist	☐☐	Code of 2nd anthropometrist	☐☐

Neonatal Abnormality Form (NAB)

UNIVERSITY OF OXFORD

INTERCOVID Study
Neonatal Abnormality Form

NAB

Participant Number 0 7 - _____ **Hospital/Clinic Code** _____

LABEL SPACE

Maternal Hospital 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: 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. Gastro-intestinal	yes	no	16. Other	yes	no

17. Detailed information _____

18. Final diagnosis _____

Once completed, please fax - or scan and email - a copy of this form to the Coordinating Unit in Oxford.

Name of Researcher/Midwife			
Signature		Researcher Code	

Baby Care Form (BCF)

UNIVERSITY OF OXFORD

INTERCOVID 2022

Baby Care Form

BCF

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

Maternal Hospital Record No. [ ][ ][ ][ ][ ][ ][ ][ ][ ]

Date of delivery D D M M Y Y

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

Section 1: Actions

1. Did the mother immediately give the baby skin-to-skin contact? yes no
2. Was the baby ever isolated from the mother? yes no

2b. When did the mother and baby start rooming-in? D D M M Y Y H H : M M

3. Did the mother always wear a mask when near the baby? yes no
4. Did the mother always wash her hands properly before touching the baby? yes no
5. Was it hospital policy at this time for staff to always wear masks and gloves? yes no
6. Did any close relatives also test positive for COVID-19?*(mothers should not be considered)* yes no

   If yes, give details:

7. Did the baby have any cultures taken? yes no If yes, please provide details in the box below
8. Was the placenta examined for pathology? yes no If yes, please provide details in the box below
9. Did the baby have a chest x-ray? yes no If yes, please provide details in the box below

Section 2: Additional information

Name of researcher

Signature

Researcher code

Adverse Event (AE)

UNIVERSITY OF OXFORD

INTERCOVID Study
Adverse Event Form

AE

Page

AFFIX PTID LABEL HERE

INTERCOVID Patient Identifier | | | - | | | | |

Hospital/Clinic Code | | | - | |

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

Maternal Date of Birth D D M M Y Y

Final diagnosis (provide all details)	Timing of event	Actions	Outcomes
1.	Start date: D D M M Y Y End date: D D M M Y Y or cross here if continuing: ☐	Measures taken: (cross all that apply) Treatment given ☐ No treatment given ☐ Delivery (please complete **Pregnancy and Delivery Form**) ☐	What was the outcome of the event? (cross one box only) Complete recovery ☐ Chronic condition ☐ Partial recovery ☐ Death ☐ Not yet resolved ☐ Unknown ☐
Final diagnosis (provide all details)	**Timing of event**	**Actions**	**Outcomes**
2.	Start date: D D M M Y Y End date: D D M M Y Y or cross here if continuing: ☐	Measures taken: (cross all that apply) Treatment given ☐ No treatment given ☐ Delivery (please complete **Pregnancy and Delivery Form**) ☐	What was the outcome of the event? (cross one box only) Complete recovery ☐ Chronic condition ☐ Partial recovery ☐ Death ☐ Not yet resolved ☐ Unknown ☐
Final diagnosis (provide all details)	**Timing of event**	**Actions**	**Outcomes**
3.	Start date: D D M M Y Y End date: D D M M Y Y or cross here if continuing: ☐	Measures taken: (cross all that apply) Treatment given ☐ No treatment given ☐ Delivery (please complete **Pregnancy and Delivery Form**) ☐	What was the outcome of the event? (cross one box only) Complete recovery ☐ Chronic condition ☐ Partial recovery ☐ Death ☐ Not yet resolved ☐ Unknown ☐