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

1. Study Entry Form (COV)
2. Covid Related Form (CRF)
3. Maternal Referral/Admission Form (MRA)
4. Pregnancy and Delivery Form (PAD)
5. Intensive Care Form (ICU)
6. Neonatal Follow-up Form (NFU)
7. Neonatal Abnormality Form (NAB)
8. Baby Care Form (BCU)
9. Adverse Event (AE)
COVID Study Entry Form
Participant Number

Hospital/Clinic Code

Maternal Hospital Record No.

Visit Date

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?  
   
   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?  
   Date of test  
   Type of test used:  
   Rapid antigen test

   Test 2: was there a positive result?  
   Date of test  
   Type of test used:  
   Rapid antigen test

   Test 3: was there a positive result?  
   Date of test  
   Type of test used:  
   Rapid antigen test

   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?  
   
   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?  
   Date of test  
   Type of test used:  
   Rapid antigen test

   Test 2: was there a negative result?  
   Date of test  
   Type of test used:  
   Rapid antigen test

   Test 3: was there a negative result?  
   Date of test  
   Type of test used:  
   Rapid antigen test

   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)
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.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td></td>
</tr>
<tr>
<td>Tiredness/lethargy</td>
<td></td>
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<tr>
<td>Loss of taste</td>
<td></td>
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<tr>
<td>Cough</td>
<td></td>
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<tr>
<td>Limb or joint pain</td>
<td></td>
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<tr>
<td>Loss of smell</td>
<td></td>
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<tr>
<td>Sore throat</td>
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<tr>
<td>Diarrhoea/vomiting</td>
<td></td>
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<tr>
<td>Runny nose</td>
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<tr>
<td>Headache</td>
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<tr>
<td>Breathlessness</td>
<td></td>
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<tr>
<td>Flu-like symptoms</td>
<td></td>
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<tr>
<td>Chest pain</td>
<td></td>
</tr>
</tbody>
</table>

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:

   - Oxford-AstraZeneca
   - Covishield/Serum Institute of India
   - Janssen/Johnson&Johnson
   - Sputnik V
   - Pfizer-BioNTech
   - Moderna
   - Coronovac/SinoVac

   Other, please specify: ____________________________

5. Record the date that each vaccine was given:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>Y Y</td>
<td>M M</td>
<td>D D</td>
<td></td>
<td></td>
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<tr>
<td>Second</td>
<td>Y Y</td>
<td>M M</td>
<td>D D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Third</td>
<td>Y Y</td>
<td>M M</td>
<td>D D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fourth</td>
<td>Y Y</td>
<td>M M</td>
<td>D D</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
   Method of testing: [ ] PCR [ ] Lateral flow/rapid test [ ] LAMP
   Date of test D D M M Y Y

   Test 2: was there a positive result? [ ] yes [ ] no
   Method of testing: [ ] PCR [ ] Lateral flow/rapid test [ ] LAMP
   Date of test D D M M Y Y

   Test 3: was there a positive result? [ ] yes [ ] no
   Method of testing: [ ] PCR [ ] Lateral flow/rapid test [ ] LAMP
   Date of test D D M M Y Y

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)
### 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/
   - Trauma/
   - High-risk clinic
   - 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
   - +
   - ++
   - +++

   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?

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

Section 5: Medications and treatment

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

63. Aspirin
64. Antibiotics/Antivirals
65. Antihypertensives
66. Prophylactic steroids for preterm labour
67. Treatments for asthma
68. Antipsychotics
69. Antidepressants
70. Magnesium sulphate
71. Blood transfusion
72. Just bed rest/observation
73. Any other treatment

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)

75. Date of discharge from hospital: 

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:

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

Name of Researcher/Midwife
Signature
Researcher Code
Pregnancy and Delivery Form (DEV)
### Section 1: Demographic, socioeconomic and nutritional characteristics

1. Maternal age
2. Maternal height
3. 1st trimester or pre-pregnancy weight
4. Has she smoked/chewed tobacco during this pregnancy?
5. If she smoked cigarettes, how many per day?
6. Has she used any recreational drugs during this pregnancy?
7. On average, how many units of alcohol per week has she had during this pregnancy?
   
   (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?
9. Has she followed any special diets during this pregnancy?
   (e.g. vegetarian with no animal products, weight loss programme, malabsorption treatment, gluten-free)
10. Current marital status
    
    (cross one box only)
    - Single
    - Widowed
    - Married/Cohabiting
    - Separated/Divorced
11. Total number of years of formal education
    
    years
12. Highest level of education she attended
    
    (cross one box only)
    - Primary
    - Professional/technical training
    - Secondary
    - University
13. Which of the following best describes her occupational status?
    
    (cross one box only)
    - Housework
    - Skilled manual work
    - Manager/professional/technical
    - Unskilled manual work
    - Clerical support, service or sales
    - 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
### 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?  
34. First day of the last menstrual period (LMP)  
   - DD-MM-YY
35. Was she certain of her date of LMP?  
   - Yes: No
36. Date of the first ultrasound scan during this pregnancy  
   - DD-MM-YY
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?

### 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  
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
### Section 6: Pregnancy related complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe vomiting requiring hospitalisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational diabetes</td>
<td></td>
<td></td>
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<tr>
<td>Vaginal bleeding before 15 weeks</td>
<td></td>
<td></td>
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<tr>
<td>Vaginal bleeding between 15-27 weeks</td>
<td></td>
<td></td>
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<tr>
<td>Vaginal bleeding after 27 weeks</td>
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<td></td>
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<tr>
<td>Pregnancy-induced hypertension</td>
<td></td>
<td></td>
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<tr>
<td>Preeclampsia</td>
<td></td>
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<tr>
<td>Severe preeclampsia/Eclampsia/HELLP</td>
<td></td>
<td></td>
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<tr>
<td>Rhesus disease</td>
<td></td>
<td></td>
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<tr>
<td>Preterm labour</td>
<td></td>
<td></td>
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<tr>
<td>Fetal distress</td>
<td></td>
<td></td>
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<tr>
<td>Suspected impaired fetal growth or SGA</td>
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<tr>
<td>Any other pregnancy related condition</td>
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</tr>
</tbody>
</table>

#### Section 6: Pregnancy related complications (cont.)

<table>
<thead>
<tr>
<th>Condition</th>
<th>&lt;15 weeks</th>
<th>15-27 weeks</th>
<th>&gt;27 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest haemoglobin level (if available)</td>
<td>. g/dl</td>
<td>. g/dl</td>
<td>. g/dl</td>
</tr>
</tbody>
</table>

### Section 7: Nutritional supplements / Medications

<table>
<thead>
<tr>
<th>Supplement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron</td>
<td></td>
<td></td>
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<tr>
<td>Folic acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td></td>
<td></td>
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<tr>
<td>Food supplements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multi-vitamins/minerals</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Section 7: Nutritional supplements / Medications (cont.)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine aspirin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any antibiotics or antivirals (except those used for PROM)</td>
<td></td>
<td></td>
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<tr>
<td>Antibiotics used for PROM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-steroidal anti-inflammatories</td>
<td></td>
<td></td>
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<tr>
<td>Insulin</td>
<td></td>
<td></td>
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<tr>
<td>Prophylactic steroids for preterm labour</td>
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<tr>
<td>Any other treatment</td>
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</tbody>
</table>

### Section 8: Delivery

<table>
<thead>
<tr>
<th>Event</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of labour (cross one box only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Induced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Labour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mode of delivery (cross one box only)</td>
<td></td>
<td></td>
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<tr>
<td>Vaginal spontaneous</td>
<td></td>
<td></td>
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<tr>
<td>Assisted breech</td>
<td></td>
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<tr>
<td>Vaginal assisted</td>
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<tr>
<td>(e.g. forceps, vacuum)</td>
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<tr>
<td>Caesarean section</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Event</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal bleeding</td>
<td></td>
<td></td>
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<tr>
<td>Fetal death</td>
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<td></td>
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<tr>
<td>Pregnancy-induced hypertension</td>
<td></td>
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<tr>
<td>Preeclampsia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe preeclampsia/Eclampsia/HELLP</td>
<td></td>
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<tr>
<td>Breech presentation</td>
<td></td>
<td></td>
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<tr>
<td>Fetal distress</td>
<td></td>
<td></td>
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<tr>
<td>Failure to progress</td>
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<tr>
<td>Cephalo-pelvic disproportion</td>
<td></td>
<td></td>
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<tr>
<td>Prelabour rupture of membranes (PROM)</td>
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<td></td>
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<tr>
<td>Suspected impaired fetal growth or SGA</td>
<td></td>
<td></td>
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<tr>
<td>Post term (&gt;42 weeks gestation)</td>
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<tr>
<td>Rhesus disease</td>
<td></td>
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<tr>
<td>HIV or AIDS</td>
<td></td>
<td></td>
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<tr>
<td>Any sexually transmitted infections</td>
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<td></td>
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<tr>
<td>Any infections requiring antibiotics/antivirals</td>
<td></td>
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<tr>
<td>Maternal request</td>
<td></td>
<td></td>
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<tr>
<td>Any other maternal reason</td>
<td></td>
<td></td>
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<tr>
<td>Any other fetal reason</td>
<td></td>
<td></td>
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<tr>
<td>Previous Caesarean section</td>
<td></td>
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</tr>
</tbody>
</table>
### Section 9: Newborn outcome and care

110. Date of delivery (DD-MM-YYYY)
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)
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?


### Section 10: Newborn anthropometry

147. Birthweight: ___ kg
148. Length at birth: ___ cm
149. Head Circumference at birth: ___ cm

### Date of measurement

150. Date of measurement (DD-MM-YYYY)
151. Time of measurement (HH-MM-YYYY)

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

Has the newborn been given any of the following:

- Corticosteroids postnatally [ ]
- Surfactant replacement therapy [ ]
- Diuretics [ ]
- Antibiotics [ ]
- Antipyrétics [ ]
- Methylxanthines [ ]

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

161. Intraventricular haemorrhage  
- Grade I [ ]  
- Grade II [ ]  
- Grade III [ ]  
- Grade IV [ ]

162. Necrotising enterocolitis  
- Stage I [ ]  
- Stage IIa [ ]  
- Stage IIb [ ]  
- Stage III [ ]

163. Retinopathy of prematurity  
- 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: [DD MM YY MM][DD MMM YYYY]

### 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 breastfeeding [ ]  
- Predominant breastfeeding [ ]  
- Partial breastfeeding [ ]  
- Exclusive formula (IV fluids only) [ ]  
- No oral feeds [ ]

### 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)
INTERCOVID Study
Intensive Care Form

Participant Number
Hospital/Clinic Code

Maternal Hospital Record No.

Date of admission to intensive care

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 positioning
   Oxygen treatment
   Positive airway pressure treatment (CPAP)
   Invasive mechanical ventilation
   Extracorporeal membrane oxygenation (ECMO)
   Antivirals
   Hydroxychloroquine
   Steroid treatment for maternal indication
   Tocilizumab
   Any other COVID related therapy

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)
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

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 M 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
   - [ ] Soy based formula
   - [ ] Breast milk with fortifiers
   - [ ] Hydrolysed formula
   - [ ] Standard infant formula
   - [ ] Any other special formula
   - [ ] Preterm formula
   - [ ] Animal milk
   - [ ] High energy formula
   - [ ] Water based drinks/fruit juice
   - [ ] Another special care unit
   - [ ] Oral feeding
   - [ ] Tube feeding
   - [ ] Parenteral nutrition including dextrose infusion

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 M Y

15. Time of measurement  
   - [ ] H H : M M

1\textsuperscript{st} set of anthropometric measurements

16. Weight  
   - [ ] kgs

17. Length  
   - [ ] cm

18. Head circumference  
   - [ ] cm
**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
25. Corticosteroids postnatally [____] yes [____] no
26. Surfactant replacement therapy [____] yes [____] no
27. Diuretics [____] yes [____] no
28. Antibiotics [____] yes [____] no
29. Antipyretics [____] yes [____] no
30. Intrauterine hemorrhage
   - Grade I [____] yes [____] no
   - Grade II [____] yes [____] no
   - Grade III [____] yes [____] no
   - Grade IV [____] yes [____] no
31. Necrotising enterocolitis
   - Stage I [____] yes [____] no
   - Stage IIa [____] yes [____] no
   - Stage IIb [____] yes [____] no
   - Stage III [____] yes [____] no
32. Retinopathy of prematurity
   - Stage I [____] yes [____] no
   - Stage II [____] yes [____] no
   - Stage III [____] yes [____] no
   - Stage IV [____] yes [____] no
   - Stage V [____] yes [____] no
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. Bronchopulmonary 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) [____] yes [____] no

**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]

**Participant Number**, **Newborn Hospital Record Number**, **Paediatric Outpatient Clinic Record Number**, **Delivery Hospital Code**, **Date of birth**, **Date of this visit**

**Any congenital abnormality (complete a Neonatal abnormality form)**

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

- Corticosteroids postnatally [____] yes [____] no
- Surfactant replacement therapy [____] yes [____] no
- Diuretics [____] yes [____] no
- Antibiotics [____] yes [____] no
- Antipyretics [____] yes [____] no

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

- Intraventricular hemorrhage [____] yes [____] no
- Necrotising enterocolitis
  - Stage I [____] yes [____] no
  - Stage IIa [____] yes [____] no
  - Stage IIb [____] yes [____] no
  - Stage III [____] yes [____] no
- Retinopathy of prematurity
  - Stage I [____] yes [____] no
  - Stage II [____] yes [____] no
  - Stage III [____] yes [____] no
  - Stage IV [____] yes [____] no
  - Stage V [____] yes [____] no
- Respiratory distress syndrome [____] yes [____] no
- Pneumonia/Bronchiolitis [____] yes [____] no
- Meconium aspiration with respiratory distress [____] yes [____] no
- Hypoxic-ischaemic encephalopathy [____] yes [____] no
- Apnea of prematurity [____] yes [____] no
- Stoppage of enteral feeding for more than 3 consecutive days [____] yes [____] no
- Bronchopulmonary dysplasia/chronic lung disease [____] yes [____] no
- Any gastro-intestinal condition requiring surgery (complete an adverse event form) [____] yes [____] no
- Patent ductus arteriosus requiring surgery (complete an adverse event form) [____] yes [____] no
- Any other condition requiring surgery (complete an adverse event form) [____] yes [____] no
- Short bowel syndrome [____] yes [____] no
- Severe Diarrhoea [____] yes [____] no
- Hyperbilirubinemia requiring exchange transfusion [____] yes [____] no
- Kernicterus [____] yes [____] no
- Chronic renal failure [____] yes [____] no
- Major neurological impairment [____] yes [____] no
- Seizures [____] yes [____] no
- Periventricular leukomalacia [____] yes [____] no
- Hypoglycaemia [____] yes [____] no
- Hypotension requiring inotropic treatment or steroids [____] yes [____] no
- Anaemia (requiring transfusion) [____] yes [____] no
- Sepsis [____] yes [____] no
- Endocrine abnormalities [____] yes [____] no
- Inborn errors of metabolism [____] yes [____] no
- Any other serious condition [____] yes [____] no
- Any congenital abnormality (complete a Neonatal abnormality form) [____] yes [____] no
Neonatal Abnormality Form (NAB)
### 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.

<table>
<thead>
<tr>
<th>Area</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Head</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Brain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Face</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Neck</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Spine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Heart</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Anterior abdominal wall</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Gastro-intestinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Bladder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Limbs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Lungs/Pleura</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Kidneys</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Genitalia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Chromosomal abnormality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e.g. Down's syndrome)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Indeterminate sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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)
Participant Number - Hospital/Clinic Code
Maternal Hospital Record No.
Date of delivery

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?  no
2. Was the baby ever isolated from the mother?  no
2b. When did the mother and baby start rooming-in?  D D M M Y Y
3. Did the mother always wear a mask when near the baby?  no
4. Did the mother always wash her hands properly before touching the baby?  no
5. Was it hospital policy at this time for staff to always wear masks and gloves?  no
6. Did any close relatives also test positive for COVID-19? (mothers should not be considered)  no

If yes, give details:

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

Section 2: Additional information

Name of researcher
Signature

Researcher code
Adverse Event (AE)
### INTERCOVID Study Adverse Event Form

**INTERCOVID Patient Identifier**

**Hospital/Clinic Code**

**Maternal Hospital Record No.**

**Maternal Date of Birth**

### Final diagnosis (provide all details)

<table>
<thead>
<tr>
<th>Timing of event</th>
<th>Actions</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Start date:</strong></td>
<td>Measures taken: (cross all that apply)</td>
<td>What was the outcome of the event? (cross one box only)</td>
</tr>
<tr>
<td><strong>End date:</strong></td>
<td>Treatment given</td>
<td>Complete recovery</td>
</tr>
<tr>
<td><strong>or cross here if continuing:</strong></td>
<td>No treatment given</td>
<td>Partial recovery</td>
</tr>
<tr>
<td></td>
<td>Delivery (please complete Pregnancy and Delivery Form)</td>
<td>Not yet resolved</td>
</tr>
</tbody>
</table>

### Final diagnosis (provide all details)

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