

CRF 01: CASE SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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MONTH

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YEAR

(Section A: continued)

Exclusion criteria: To be eligible for PERCH, answers to BOTH <u>questions 9 and 10</u> must be No .	1 - YES	0 - NO	8 - UNK
9. Has the child been hospitalized overnight in the past 14 days (other than hospitalization at a referring hospital for this pneumonia episode <24 hours before screening)?	<input type="checkbox"/>	<input type="checkbox"/>	
a. Was this child admitted overnight at a referral hospital in the previous 24 hours for this pneumonia episode?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Has the child been discharged from the hospital in the past 30 days having been enrolled as a PERCH case?	<input type="checkbox"/> If <u>either</u> <u>Q9 or Q10</u> above are checked Yes, go to Q23 and tick No	<input type="checkbox"/> Continue if <u>both</u> Q9 and Q10 above are checked	

11. Section A Comments: _____

Section A completed by: _____ **STAFF CODE:**

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*=Question does not appear in AdvantageEDCSM

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Section B: Clinical Exam *(to be completed by a trained examiner only)*

 12. Was a clinical exam performed on this child by a PERCH trained examiner? ☐ 1 – YES ☐ 0 – NO

 a. If No, why not? ☐ 01 - Died ☐ 02 – Refused ☐ 03 - Not referred for hospital admission

☐ 04 - No trained examiner

☐ 99 – Other, specify: _____ Code:

13. Where was the clinical exam conducted?

<input type="checkbox"/> 01 - ER	<input type="checkbox"/> 04 - Ward
<input type="checkbox"/> 02 - Main ICU	<input type="checkbox"/> 05 – Outpatient department
<input type="checkbox"/> 03 - High care area	<input type="checkbox"/> 06 - Clinic <i>(for Dhaka and Gambia only)</i>
<input type="checkbox"/> Other, specify: _____ code: <table border="1" style="display: inline-table; width: 60px; height: 20px;"></table>	

Inclusion criteria:

Please answer YES or NO to EVERY question.

 To be eligible for PERCH, answer to Q14h below must be **YES**.

14. Assess the following symptoms of severe and very severe pneumonia:

	Severe:	1 - YES	0 - NO
a. Lower chest wall indrawing.....		<input type="checkbox"/>	<input type="checkbox"/>

	Very Severe:	1 - YES	0 - NO
b. Head nodding.....		<input type="checkbox"/>	<input type="checkbox"/>
c. Central cyanosis.....		<input type="checkbox"/>	<input type="checkbox"/>
d. Unable to feed <i>(must be observed by examiner)</i>		<input type="checkbox"/>	<input type="checkbox"/>
e. Vomiting everything <i>(must be observed by examiner)</i>		<input type="checkbox"/>	<input type="checkbox"/>
f. Lethargy or impaired consciousness <i>(assess below)</i>			

NOTE: Wait for >30 minutes after any convulsion before carrying out assessment of consciousness.

<input type="checkbox"/> 0 - A: Alert and awake
<input type="checkbox"/> 1 - V: Responds to voice
<input type="checkbox"/> 2 - P: Responds to pain
<input type="checkbox"/> 3 - U: Unresponsive

 9 –
Pharmacologically
sedated
☐

+i. If 'A' or '9' is ticked above, tick 'No.' If V, P or U is ticked, tick 'Yes.'

 g. Multiple or prolonged convulsions during this illness ... *(assess below)*

 Did child have convulsions? ☐ Yes ☐ No *(If no, tick 14g.ii 'No')*

 i. If Yes, what kind? *(check all that apply).*
☐ **M:** multiple (≥ 2 episodes) ☐ **P:** prolonged (≥ 15 min)

☐ **S:** single brief (<15 min)

 +ii. If **only S** is ticked in 14g.i above, tick 'No.' If M or P is ticked, tick 'Yes.'

 h. Does the child have severe or very severe pneumonia *(defined as having **ONE** or **MORE** items in grey outlined boxes above Q14a-g checked **YES**)?*

1 - YES 0 - NO

☐ ☐

1 - YES

☐

0 - NO

☐

Answer Q15-18, then skip to Q23 and tick NO

Continue

* = Question does not appear in AdvantageEDCSM

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(Section B: continued)

15. Did a PERCH study physician verify the signs/symptoms of severe/
very severe pneumonia?

1 - YES 0 - NO

<input type="checkbox"/>	<input type="checkbox"/>
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Oxygen Saturation and Respiratory Rate

16. Is the child on O₂? (Assess only if >30 min after seizure)

1 - Yes 0 - No 8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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a. If Yes, record route of administration (check one):

<input type="checkbox"/>	1 - Nasal prongs
<input type="checkbox"/>	2 - Nasal catheter
<input type="checkbox"/>	3 - Mechanical ventilation
<input type="checkbox"/>	4 - Face mask without reservoir
<input type="checkbox"/>	5 - Non-rebreathing mask with reservoir
<input type="checkbox"/>	6 - Head box
<input type="checkbox"/>	8 - UNK
<input type="checkbox"/>	9 - NR

b. If Yes, oxygen delivery flow rate:

			L/min
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8 - UNK 9 - NR
☐ ☐

17. Oxygen saturation by pulse oximetry (on room air whenever possible): %

8 - UNK 9 - NR
☐ ☐

a. Measured when child was on:

<input type="checkbox"/>	1 - Oxygen
<input type="checkbox"/>	2 - Room air
<input type="checkbox"/>	8 - UNK
<input type="checkbox"/>	9 - NR

For South Africa and Thailand only:

b. If oxygen saturation measured when child was on oxygen (Q17a='1- Oxygen'), record oxygen saturation measurement on room air (if available from chart): %

8 - UNK 9 - N/A
☐ ☐

18. Respiratory rate (# of breaths counted in 60 seconds): per minute

(only if not on assisted ventilation)

8 - UNK 9 - NR 7 - N/A
☐ ☐ ☐

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➔ If Q14h on previous page is checked Yes, please continue. If Q14h is checked No, skip to Q23.

19. Does this child have very severe pneumonia (i.e., any of Q14b-g checked YES)?

☐ 1 - YES → Skip to Q22

☐ 2 - NO → Answer Q20 (i.e. child has lower chest wall indrawing but no 'very severe' signs)

BRONCHODILATOR CHALLENGE

Inclusion criteria:

To be eligible, Q21c must be **Yes** if the child has severe pneumonia.

If the child has very severe pneumonia (i.e., any of Q14b-g is Yes), skip to Q22.

20. Does the child have lower chest wall indrawing and auscultatory wheeze?

☐ 1 - YES

☐ 0 - NO

21. Were all required doses of bronchodilators administered before consent?

☐ 1 - YES (complete Q21a-c below)

☐ 8 - N/A (e.g. met quota or not during the hours of enrollment) (skip to Q22)

☐ 9 - NO, Pending (complete Q21a-c when information is available)

a. Number of bronchodilators given: doses

b. Does child have wheeze on auscultation after bronchodilator challenge? 1 - YES ☐ 0 - NO ☐

c. Is the lower chest wall indrawing still present after bronchodilator challenge?

1 - YES ☐

0 - NO ☐

Go to Q23
and tick
NO

If both Q21 and Q21c are checked No (i.e., child is ineligible), stop here and follow the **Modified Protocol**.

*=Question does not appear in AdvantageEDCSM

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(Section B: continued)

Admission eligibility:

To be eligible for PERCH, the answer to Q22b below must be **YES**.

22. a. What is the hospital admission status of this child? (*check one*)

☐

Admitted to study hospital if Yes, record the Date / Time admitted:

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MONTH

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YEAR

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(24 hour clock)

☐

Recommended for admission to study hospital, but not admitted

i. Will the child be available to study staff for sufficient time to complete all study procedures?

☐
1- YES**0 - NO**

☐ (if No, check No to Q22b below)

ii. Specify reason not admitted:

☐

01 - Parent refused admission

☐

02 - Died

☐
99 - Other, specify : _____ Code:

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☐

Not referred for admission to study hospital → (*if checked, tick No to Q22b*)

iii. Specify reason:

☐

01 - Physician deemed not severe enough

☐

02 - Parent refused admission

☐

03 - Referred to another facility

☐

04 - Died

☐
99 - Other, specify: _____ Code:

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b. Does the child meet hospital admission criteria?

(*Check Yes if a shaded box in Q22a or Q22ai is checked*)

1 - YES
☐
Continue**0 - NO**
☐

**Tick Q23
NO**

*=Question does not appear in AdvantageEDCSM

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(Section B: continued)

Eligibility for PERCH	1 - YES	0 - NO
<p>23. Is this child eligible for PERCH?</p> <p style="margin-left: 40px;">Check Yes, if answers to all shaded sections of eligibility inclusion and exclusion criteria boxes are checked.</p> <p style="margin-left: 40px;">i.e. If Q6-8, Q14h, Q22b, Q25 are Yes, Q21 is Yes or No, pending (as applicable), answers to Q9-10 are 'No', and Q25b is not blank, then child is eligible for PERCH.</p>	<input style="width: 30px; height: 20px;" type="checkbox"/> Continue to Section C	<input style="width: 30px; height: 20px;" type="checkbox"/> Stop

24. Section B Comments: _____

Clinical Exam/Eligibility Status completed by: _____

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STAFF CODE

For Q23 to be Yes (child is eligible) after saving the form, ensure Section C is completed. If child is not eligible, answer N/A to Q25.

*=Question does not appear in AdvantageEDCSM

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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YEAR

Section C: *(to be completed by a screener or a trained examiner)*

CONSENT AND ENROLLMENT for PERCH	1 - YES	0 - NO
<p>25. Has consent been obtained? <input type="checkbox"/> 9- N/A (not eligible) <i>Must be Yes to continue enrollment. If No, skip to Q25c below.</i></p> <p>a. If Yes, child's date of birth: <i>(when date of birth is uncertain, <u>always</u> estimate the date and check "date uncertain" box)</i></p> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="text-align: center; margin-right: 10px;"> <table border="1" style="width: 40px; height: 25px;"></table> DAY </div> <div style="text-align: center; margin-right: 10px;"> <table border="1" style="width: 60px; height: 25px;"></table> MONTH </div> <div style="text-align: center; margin-right: 10px;"> <table border="1" style="width: 80px; height: 25px;"></table> YEAR </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Date uncertain </div> </div> <p>b. If Yes, Date and time enrolled in PERCH:</p> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="text-align: center; margin-right: 10px;"> <table border="1" style="width: 40px; height: 25px;"></table> DAY </div> <div style="text-align: center; margin-right: 10px;"> <table border="1" style="width: 60px; height: 25px;"></table> MONTH </div> <div style="text-align: center; margin-right: 10px;"> <table border="1" style="width: 80px; height: 25px;"></table> YEAR </div> <div style="text-align: center; margin-right: 10px;"> <table border="1" style="width: 60px; height: 25px;"></table> TIME (24 hour clock) </div> </div> <p>c. If Q25 is No, indicate reason why consent was not obtained:</p> <div style="margin-left: 20px;"> <input type="checkbox"/> 01 - Refused consent <input type="checkbox"/> 02 - Died <input type="checkbox"/> 03 - N/A (e.g. met quota or not during the hours of enrollment) <input type="checkbox"/> 99 - Other, specify: _____ </div> <div style="text-align: right; margin-top: 10px;"> Code: <table border="1" style="width: 60px; height: 25px;"></table> </div>	<input type="checkbox"/> Answer 25a and 25b	<input type="checkbox"/> Answer 25c

26. Section C Comments: _____

Section C completed by: _____ **STAFF CODE:**

Supervisor Signature: _____ **STAFF CODE:**

<table border="1" style="width: 40px; height: 25px;"></table> Day	<table border="1" style="width: 60px; height: 25px;"></table> Month	<table border="1" style="width: 80px; height: 25px;"></table> Year
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*=Question does not appear in AdvantageEDCSM

CRF 01A: COMMUNITY CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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YEAR

Instructions: If at any point during the completion of this CRF, the child is determined to be not eligible, skip to Q13, answer NO and sign the form.

Section A: (to be completed by a screener or a trained examiner)

 1. TIME OF SCREENING:

 (24 hour clock)

 2. Optional local site Participant ID number(s): a.

 b.

 c.

 3. Sex of the child: ☐ 0 - Male ☐ 1 - Female

4. Age of the child:

 Is the child < 1 month old? ☐ 1 – YES ☐ 0 - NO

 a. If Yes:

 days

 b. If No:

 months

5. Where was the child evaluated?

<input type="checkbox"/>	01 - Home
<input type="checkbox"/>	02 - Study facility
<input type="checkbox"/>	03 - Health center/clinic
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

Continue Section A on next page...

*=Question does not appear in AdvantageEDCsm

CRF 01A: COMMUNITY CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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YEAR

(Section A: Continued)

Inclusion criteria: To be eligible, BOTH of the following must be YES .	1 - YES	0 - NO
6. Age 28 days to 59 months inclusive?	<input type="checkbox"/>	<input type="checkbox"/>
7. Lives in catchment area?	<input type="checkbox"/>	<input type="checkbox"/>
a. If Yes, where does the child live? <table border="1" style="display: inline-table; width: 150px; height: 20px; vertical-align: middle;"></table> <i>(enter coded geographic area)</i>	Continue if BOTH above are checked YES	If either above are checked NO, go to Q13 and tick NO then stop
b. Was the child born in Bara? <input type="checkbox"/> 1 – YES <input type="checkbox"/> 0 - NO <input type="checkbox"/> 8 -UNK		

Exclusion criteria: To be eligible, ALL of the following must be NO	1 - YES	0 - NO
8. Has the child been hospitalized in the past 14 days?	<input type="checkbox"/>	<input type="checkbox"/>
9. Has the child been discharged from the hospital in the past 30 days having been enrolled as a PERCH case?	<input type="checkbox"/> If either above are checked YES, go to Q13 and tick NO then stop	<input type="checkbox"/> Continue if both above are checked NO

Section A completed by: _____ STAFF CODE:

Continue to Section B on next page...

*=Question does not appear in AdvantageEDCsm

CRF 01A:

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PARTICIPANT ID

DATE OF SCREENING:

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YEAR

Section B: *(to be completed by a PERCH trained examiner only)*

10. Was child examined by a trained examiner for completion of this Section? ☐ 1 – YES ☐ 0 – NO

a. If No, why not? ☐ 01 – Refused ☐ 02 - No trainer examiner ☐ 03 - Unable to contact after initial screen

☐ 99 – Other, specify: _____ Code:

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Exclusion criteria: To be eligible for PERCH, Q11 and Q12i below must be NO .	Please answer YES or NO to EVERY question.	1 - YES	0 - NO
11. Does this child appear very sick requiring urgent medical attention? If Yes, child is ineligible; prompt evaluation and treatment should be sought.		<input type="checkbox"/>	<input type="checkbox"/>
		Skip to Q13 and tick NO	Continue
12. Assess symptoms of severe and very severe pneumonia:			
	1 - YES 0 - NO		
a. Is child ill with cough or difficulty breathing?..... (if No, answer all Q12b-h below, then tick No to Q12i.)	<input type="checkbox"/> <input type="checkbox"/>		
	1 - YES 0 - NO		
b. Lower chest wall indrawing.....	<input type="checkbox"/> <input type="checkbox"/>		
c. Head nodding.....	<input type="checkbox"/> <input type="checkbox"/>		
d. Central cyanosis.....	<input type="checkbox"/> <input type="checkbox"/>		
e. Unable to feed (must be observed by examiner).....	<input type="checkbox"/> <input type="checkbox"/>		
f. Vomiting everything (must be observed by examiner).....	<input type="checkbox"/> <input type="checkbox"/>		
g. Lethargy or impaired consciousness (assess below) NOTE: Wait for >30 minutes after any convulsion before carrying out assessment of consciousness. <input type="checkbox"/> A: alert & awake <input type="checkbox"/> V: responds to voice <input type="checkbox"/> P: responds to pain <input type="checkbox"/> U: unresponsive <input type="checkbox"/> 9 - Pharmacologically sedated +i. If 'A' or '9' is ticked above, tick 'No'. If V, P or U is ticked, tick 'Yes'. h. Multiple or prolonged convulsions during this illness ...(assess below) Did child have convulsions? <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, tick Q12h.ii 'No') i. If Yes, what kind? (check all that apply): <input type="checkbox"/> M: multiple (≥2 episodes) <input type="checkbox"/> P: prolonged (≥15 min) <input type="checkbox"/> S: single brief (<15 min) + ii. If only S is ticked in Q12h.i above, then tick 'No.' If M or P is ticked, then tick 'Yes'. i. Does the child have <u>severe</u> or <u>very severe</u> pneumonia (defined as having cough or difficulty breathing (i.e. item 12a above is YES) AND ONE or MORE of items 12b-h above are checked YES?		1 - YES 0 - NO	1 - YES 0 - NO
		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
		<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
		Go to Q13 and tick 'No'	Continue

⁺=Question does not appear in AdvantageEDC_{SM}

CRF 01A: COMMUNITY CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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YEAR

(Section B: continued)

Eligibility for PERCH	1 - YES	0 - NO
<p>13. Is this child eligible for PERCH?</p> <p>If all shaded responses are checked, then the child is eligible for PERCH. <i>(i.e., answers to Q6-7 are YES, and Q8-9, Q11, and Q12i are NO, and 15b is not blank)</i></p> <p><i>For Q13 to be Yes (child is eligible) after saving the form, ensure Section C is completed. If child is not eligible, answer N/A to Q15.</i></p>	<input style="width: 30px; height: 20px;" type="checkbox"/> <div style="background-color: #cccccc; padding: 5px; text-align: center;">Continue</div>	<input style="width: 30px; height: 20px;" type="checkbox"/> <div style="padding: 5px; text-align: center;">STOP</div>

14. Section B Comments:

Section B completed by: _____

STAFF CODE:

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Continue to Section C on next page...* = Question does not appear in AdvantageEDC_{SM}

CRF 01A: COMMUNITY CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

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YEAR

Section C: (to be completed by a screener or trained examiner)

CONSENT AND ENROLLMENT for PERCH	YES	NO
<p>15. Has consent been obtained? <input type="checkbox"/> 9- N/A (not eligible) <i>Must be Yes to continue enrollment.</i> <i>If No, skip Q15a and Q15b and mark the reason why not in Q15c below.</i></p> <p>a. If Yes, child's date of birth: (<i>when date of birth is uncertain, <u>always</u> estimate the date and check the "date uncertain" box</i>)</p> <div style="display: flex; align-items: center; margin-bottom: 10px;"> <div style="margin-right: 10px;"> <table border="1" style="width: 30px; height: 20px;"></table> <div style="text-align: center; font-size: 8px;">DAY</div> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <div style="text-align: center; font-size: 8px;">MONTH</div> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 50px; height: 20px;"></table> <div style="text-align: center; font-size: 8px;">YEAR</div> </div> <div style="margin-left: 10px;"> <input type="checkbox"/> Date uncertain </div> </div> <p>b. If Yes, Date and time enrolled in PERCH:</p> <div style="display: flex; align-items: center; margin-bottom: 10px;"> <div style="margin-right: 10px;"> <table border="1" style="width: 30px; height: 20px;"></table> <div style="text-align: center; font-size: 8px;">DAY</div> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <div style="text-align: center; font-size: 8px;">MONTH</div> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 50px; height: 20px;"></table> <div style="text-align: center; font-size: 8px;">YEAR</div> </div> <div style="margin-left: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <div style="text-align: center; font-size: 8px;">TIME (24 hour clock)</div> </div> </div> <p>c. If No, mark the reason why not:</p> <div style="margin-left: 20px; margin-bottom: 10px;"> <input type="checkbox"/> 01 - Refused consent </div> <div style="margin-left: 20px;"> <input type="checkbox"/> 99 - Other, specify: _____ </div> <div style="text-align: right; margin-top: 10px;"> Code: <table border="1" style="width: 30px; height: 20px;"></table> </div>	<input type="checkbox"/> Answer 15a and 15b	<input type="checkbox"/> Answer 15c

16. Section C Comments:

17. Re-enter optional local site Participant ID number:

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CRF/Section C completed by: _____

STAFF CODE:

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Supervisor Signature: _____

STAFF CODE:

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Day

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Month

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Year

* = Question does not appear in AdvantageEDCsm

CRF 01B: HIV+ CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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Instructions: If at any point during the completion of this CRF, the child is determined to be not eligible, skip to Q15, answer NO and sign the form.

Section A: to be completed by a screener or a trained examiner

1. Time of Screening:

(24 hour clock)

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2. Optional local site Participant ID number(s): a.

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b.

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c.

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3. Sex of the child:

☐ 0 - Male☐ 1 - Female

4. Age of the child:

Is the child < 1 month old? ☐ 1 - YES ☐ 0 - NOa. If Yes:

 daysb. If No:

 months

5. Where was the child recruited from?

HIV Clinic number:

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6. Where was the child evaluated?

<input type="checkbox"/>	01 - Home
<input type="checkbox"/>	02 - Study facility
<input type="checkbox"/>	03 - Health center/clinic
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table>

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CRF 01B: HIV+ CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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YEAR

(Section A: continued)

Inclusion criteria: <i>Please answer YES or NO to EVERY question.</i> To be eligible for PERCH, ALL of the following must be YES	1 - YES	0 - NO
7. Age 28 days to 59 months inclusive?	<input type="checkbox"/>	<input type="checkbox"/>
8. Lives in catchment area? a. If Yes, where does the child live? <table border="1" style="display: inline-table; width: 150px; height: 20px; vertical-align: middle;"></table> <i>(enter coded geographic area)</i> b. Was the child born in Bara? <input type="checkbox"/> 1 – YES <input type="checkbox"/> 0 - NO <input type="checkbox"/> 8 - UNK	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the child confirmed as HIV positive? <i>If Yes,</i> a. Source of confirmation of HIV status: <input type="checkbox"/> 01 - Hospital outpatient folder <input type="checkbox"/> 02 - HIV Clinic folder <input type="checkbox"/> 03 - Laboratory database <input type="checkbox"/> 99 - Other _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table> b. If Yes, has the child had <3 months of ART treatment? <input type="checkbox"/> 1 – YES <input type="checkbox"/> 0 – NO <input type="checkbox"/> 8 - UNK	<input type="checkbox"/> Continue if <u>all</u> above are ticked	<input type="checkbox"/> If <u>any</u> above are ticked, go to Q17 and tick NO

If ALL shaded boxes in Q7-9 are checked YES and Q9b is checked either YES or NO, continue to next page. If any of Q7-9 is checked NO or Q9b is checked UNK, sign Section A then check Q17 NO and stop.

*=Question does not appear in AdvantageEDCsm

CRF 01B: HIV+ CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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MONTH

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YEAR

(Section A: continued)

Exclusion criteria: To be eligible for PERCH, answers to ALL of the following must be NO .	1 - YES	0 - NO
10. Has the child been hospitalized in the past 14 days?	<input type="checkbox"/>	<input type="checkbox"/>
11. Has the child been discharged from the hospital in the past 30 days having been enrolled as a PERCH case?	<input type="checkbox"/>	<input type="checkbox"/>
12. Has the child been admitted to the hospital in the past 30 days for an acute illness?	<input type="checkbox"/> If <u>any</u> above are ticked, go to Q17 and tick NO	<input type="checkbox"/> Continue if <u>all</u> above are ticked

13. Section A Comments: _____

Section A completed by: _____ **STAFF CODE:**

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Continue to Section B on next page if responses to Q8-10 above are all NO...

*=Question does not appear in AdvantageEDCSM

CRF 01B: HIV+ CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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MONTH

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YEAR

Section B: to be completed by a trained examiner

14. Was child examined by a trained examiner for the completion of this Section? ☐ 1 – YES ☐ 0 – NO

a. If No, why not? ☐ 01 – Refused ☐ 02 – Admin error

☐ 99 – Other, specify: _____ Code:

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Exclusion criteria: <i>Please answer YES or NO to EVERY question.</i> To be eligible for PERCH, Q15 and Q16i below must be NO .	1 - YES	0 - NO
15. Does this child appear very sick requiring urgent medical attention? <i>If Yes, child is ineligible; prompt evaluation and treatment should be sought.</i>	<input type="checkbox"/> Skip to Q17 and tick NO	<input type="checkbox"/> Continue
16. Assess the following symptoms of severe and very severe pneumonia:		
<div style="display: flex; justify-content: flex-end; margin-bottom: 5px;"> <div style="margin-right: 20px;">1 - YES</div> <div>0 - NO</div> </div> a. Is child ill with cough or difficulty breathing?..... <i>(if No, answer all Q16b-h below, then tick No to Q16i.)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<div style="display: flex; justify-content: flex-end; margin-bottom: 5px;"> <div style="margin-right: 20px;">1 - YES</div> <div>0 - NO</div> </div> b. Lower chest wall indrawing.....	<input type="checkbox"/>	<input type="checkbox"/>
c. Head nodding.....	<input type="checkbox"/>	<input type="checkbox"/>
d. Central cyanosis.....	<input type="checkbox"/>	<input type="checkbox"/>
e. Unable to feed <i>(must be observed by examiner)</i>	<input type="checkbox"/>	<input type="checkbox"/>
f. Vomiting everything <i>(must be observed by examiner)</i>	<input type="checkbox"/>	<input type="checkbox"/>
g. Lethargy or impaired consciousness ... <i>(assess below)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>NOTE: Wait for >30 minutes after any convulsion before carrying out assessment of consciousness.</i></p> <div style="display: flex; justify-content: space-between;"> <div><input type="checkbox"/> A: alert & awake</div> <div><input type="checkbox"/> V: responds to voice</div> </div> <div style="display: flex; justify-content: space-between;"> <div><input type="checkbox"/> P: responds to pain</div> <div><input type="checkbox"/> U: unresponsive</div> </div> <div style="text-align: center;"><input type="checkbox"/> 9 - Pharmacologically sedated</div>	1 – YES <input type="checkbox"/>	0 - NO <input type="checkbox"/>
+ii. If 'A' or '9' is ticked above, tick 'No'. If V, P or U is ticked, tick 'Yes'		
h. Multiple or prolonged convulsions during this illness ... <i>(assess below)</i> Did child have convulsions? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(If no, tick Q16h.ii 'No')</i>		
i. If Yes, what kind? <i>(check all that apply):</i>		
<input type="checkbox"/> M: multiple (≥ 2 episodes) <input type="checkbox"/> P: prolonged (≥ 15 min)		
<input type="checkbox"/> S: single brief (<15 min)		
+ii. If only S is ticked in Q16h.i above, then tick 'No.' If M or P is ticked, then tick 'Yes.'		
i. Does the child have <u>severe</u> or <u>very severe</u> pneumonia (defined as having cough or difficulty breathing (i.e. item16a above is YES) AND ONE or MORE of items 16b-h above are checked YES)?	1 – YES <input type="checkbox"/> <input type="checkbox"/> Go to Q17 and tick 'No'	0 - NO <input type="checkbox"/> <input type="checkbox"/> Continue

* = Question does not appear in AdvantageEDCSm

CRF 01B: HIV+ CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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YEAR

(Section B: continued)

Eligibility for PERCH	1 - YES	0 - NO
17. Is this child eligible for PERCH? If all shaded responses are checked, then the child is eligible for PERCH. <i>(i.e., answers to Q7-9 and Q19 are YES, and Q10-12, Q15 and Q16i are NO, and Q9b is not UNK, and Q19b is not blank)</i>	<input style="width: 30px; height: 20px;" type="checkbox"/> Continue	<input style="width: 30px; height: 20px;" type="checkbox"/> Stop

18. Section B Comments: _____

Section B completed by: _____ **STAFF CODE:**

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For Q17 to be Yes (child is eligible) after saving the form, ensure Section C is completed. If child is not eligible, answer N/A to Q19.

 * = Question does not appear in AdvantageEDC_{SM}

CRF 01B: HIV+ CONTROL SCREENING AND ELIGIBILITY

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PARTICIPANT ID

DATE OF SCREENING:

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DAY

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YEAR

Section C: (to be completed by a screener or a trained examiner)

CONSENT AND ENROLLMENT for PERCH	1 - YES	0 - NO
<p>19. Has consent been obtained? <input type="checkbox"/> 9- N/A (not eligible) <i>Must be Yes to continue enrollment.</i> <i>If No, skip Q19a and Q19b and mark the reason why not in Q19c below.</i></p> <p>a. If Yes, child's date of birth: (when date of birth is uncertain, <u>always</u> estimate the date and check the date uncertain box)</p> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div> <div style="margin-right: 10px;"> <input type="checkbox"/> Date uncertain </div> <div style="margin-left: 10px;"> <div style="display: flex; justify-content: space-around; width: 100%;"> DAY MONTH YEAR </div> </div> </div> <p>b. If Yes, Date and time enrolled in PERCH:</p> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div> <div style="margin-right: 10px;"> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div> <div style="margin-left: 10px;"> <div style="display: flex; justify-content: space-around; width: 100%;"> DAY MONTH YEAR TIME (24 hour clock) </div> </div> </div> <p>c. If No, reason why not:</p> <div style="margin-left: 20px; margin-top: 5px;"> <input type="checkbox"/> 01 - Refused consent <input type="checkbox"/> 99 - Other, specify: _____ </div> <div style="margin-left: 400px; margin-top: 10px;"> Code: <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> <table border="1" style="width: 40px; height: 20px;"></table> </div>	<input type="checkbox"/> Answer 19a and 19b	<input type="checkbox"/> Answer 19c

20. Section C Comments: _____

Section C completed by: _____

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STAFF CODE

Supervisor Signature: _____

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STAFF CODE

Day

Month
Year

* = Question does not appear in AdvantageEDCs_{SM}

CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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DAY

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MONTH

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YEAR

CURRENT HEALTH STATUS

1. Has the child had any of the following symptoms (*by parent/caregiver report or observed by physician*)?

Symptom	Symptom present?	If YES, duration in days (xx) (1=today)
	1 - YES 0 - NO 9 - NR	
a. Fever:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
b. Cough:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
c. Difficulty breathing:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
d. Wheeze:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
e. Unable to feed:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
f. Runny nose:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
g. Ear discharge:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
h. Vomiting:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
i. Diarrhea (≥3 abnormally loose or watery stools per day)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
i) If Yes, was there blood in the stool?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
j. Has the child had abnormal sleepiness or been difficult to wake?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
k. Other: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>
l. Other: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>

NOTE: If a control develops difficulty breathing, is unable to drink/breastfeed, or becomes very lethargic, child should be taken to hospital/clinic to be seen.

CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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YEAR

MEDICATIONS (*prior to hospital presentation*)

2. Was the child given any medication for this illness in the past 48 hours? *(If No or UNK, go to Q3.)* **1-YES 0-NO 8-UNK 9-N/A** (N/A for non-ill controls)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Medication	Given?
a. Anti-malarials?	1-YES 0-NO 8-UNK 9-NR <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
b. Antibiotics?	1-YES 0-NO 8-UNK 9-NR <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
c. Fever medication / Analgesics / Antipyretics?	1-YES 0-NO 8-UNK 9-NR <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
d. Bronchodilators	1-YES 0-NO 8-UNK 9-NR <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
e. Traditional medicine?	1-YES 0-NO 8-UNK 9-NR <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

3. Did the child get antibiotics at the referral hospital before being sent to study hospital?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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- a. If Yes, route of administration:

<input type="checkbox"/>	01 - IV
<input type="checkbox"/>	02 - IM
<input type="checkbox"/>	03 - PO
<input type="checkbox"/>	08 - UNK
<input type="checkbox"/>	09 - NR
<input type="checkbox"/>	99 - Other
<input type="checkbox"/>	Other, specify: _____ Code: <table style="display: inline-table; border: 1px solid black; width: 40px; height: 20px; vertical-align: middle;"></table>

- b. Did the child get steroids at the referral hospital before being sent to the study hospital?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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PAST MEDICAL HISTORY

4. Has the child been admitted to a hospital since birth? *(If No or UNK, go to Q5.)*

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							# of admissions
							If YES, <table style="display: inline-table; border: 1px solid black; width: 40px; height: 20px; vertical-align: middle;"></table>

- a. If Yes, was the child ever admitted for Pneumonia?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							# of admissions
							If YES, <table style="display: inline-table; border: 1px solid black; width: 40px; height: 20px; vertical-align: middle;"></table>

5. Has the child ever been diagnosed with wheezing or asthma?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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- a. If Yes, are wheezing medications regularly taken at home?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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6. Has child had measles in the past month?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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YEAR

HIV Exposure

Maternal HIV – History

During Pregnancy

7a. Was the mother known to be HIV positive *during* pregnancy with this child?
 1-YES 0-NO 8-UNK
☐ ☐ ☐
7ai. Source of HIV status during pregnancy (*check all that apply*):☐ Self-report☐ Documented test results

7a.ii. If HIV positive, does the mother receive HAART?

 1-YES 0-NO 8-UNK
☐ ☐ ☐

If Yes, for how long?:

 Days Months Years

 8-UNK
☐

7a.iii. Does the child receive prophylactic nevirapine (NVP)?

 1-YES 0-NO 8-UNK
☐ ☐ ☐

If Yes, indicate duration:

 Weeks Months (xx)

 8-UNK
☐

7a.iv. Does the child receive prophylactic Cotrimoxazole (Bactrim, Septrim)?

 1-YES 0-NO 8-UNK
☐ ☐ ☐

If Yes, indicate duration:

 Weeks Months (xx)

 8-UNK
☐

After Pregnancy

Only required if 7a is No or UNK

7b. Has the mother received a positive HIV result since the birth of this child?

 1-YES 0-NO 8-UNK
☐ ☐ ☐
7bi. Source of post-partum HIV status (*check all that apply*):☐ Self-report☐ Documented test results within the last 6 months

7b.ii. If HIV positive, does the mother receive ART?

 1-YES 0-NO 8-UNK
☐ ☐ ☐

If yes, for how long?:

 Days Months Years (xx)

 8-UNK
☐

Maternal HIV – Test Results

Only required if 7a and 7b are No or UNK

7c. Was the mother tested for HIV at the PERCH Clinic?

 1- YES 0-NO 2-REFUSED 9-N/A
☐ ☐ ☐ ☐

7ci. If yes, Maternal RVD test results:

 1- POS 2- NEG 3- IND
☐ ☐ ☐

CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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YEAR

Child HIV

8. Is the child known to be HIV positive?

1-YES 0-NO 8-UNK

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*(If No or UNK, go to Q9)**If Yes, child is HIV positive, answer the following questions:*

a. Does the child receive HAART?

1-YES 0-NO 8-UNK

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i. If Yes, date HAART initiated:

--	--

Day

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Month

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Year

8-UNK

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b. Has the child attended a HAART clinic in the past 3 months?

1-YES 0-NO 8-UNK

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c. Has the child had CD4 cell counts measured in the past 3 months?

--	--	--

If Yes, record the most recent CD4 results:

i. Date of CD4 test:

--	--

Day

--	--	--

Month

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Year

8-UNK

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ii. CD4 number:

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/ mm³

8-UNK

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iii. CD4 percent:

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%

8-UNK

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CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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YEAR

TUBERCULOSIS

9. Is the child living in the same household with someone on TB treatment?
(If NO or UNK, go to Q10)

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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- a. If Yes, how long has the TB contact been on treatment? months 8 - UNK ☐

- b. If Yes, how was the TB diagnosed?

<input type="checkbox"/>	01 - CXR
<input type="checkbox"/>	02 - AFB positive sputum
<input type="checkbox"/>	03 - Clinical
<input type="checkbox"/>	04 - TB skin test <i>(if close contact is another child)</i>
<input type="checkbox"/>	08 - UNK
<input type="checkbox"/>	99 - Other
Other, specify: _____ Code: 	

- c. If Yes, what regimen is the contact being treated with?

<input type="checkbox"/>	1 - Oral medication
<input type="checkbox"/>	2 - Oral and injectables
<input type="checkbox"/>	03 - UNK

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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10. Has this child ever been diagnosed with TB?

- a. If Yes, has this child ever received TB treatment?
(If No or UNK, go to Q11.)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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- i. If YES, current TB treatment status:

<input type="checkbox"/>	1 - On treatment
<input type="checkbox"/>	2 - Completed treatment
<input type="checkbox"/>	3 - Defaulted
<input type="checkbox"/>	8 - UNK

1 - YES 0 - NO 8 - UNK

11. Has the child had noticeable weight loss or failed to gain weight?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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OTHER UNDERLYING CONDITIONS

12. Did your child drink paraffin in the past 48 hours?

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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8 - UNK

- a. If Yes, how many days ago? *(1=today)* days 8 - UNK ☐

- b. If Yes, did someone see the child drink the paraffin?..... 1 - YES 0 - NO 8 - UNK

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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13. Thalassemia?.....

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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YEAR

IMMUNIZATION HISTORY

1 - YES 0 - NO 8 - UNK

14. Does the child have their immunization records with them?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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15. Has the child had Vitamin A supplements in the last 6 months?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------

8 - UNK

16. Has the child had any of the following vaccinations?

<input type="checkbox"/>	(for all vaccinations)
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(If Yes, list the date of each dose.)

	Dose	1- YES	0- NO	8- UNK	If Yes, Date Received			Date Estimated
					DAY	MONTH	YEAR	
a. BCG	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b. DTP-HiB (Combact-HiB)	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c. DTP only	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d. DTaP only	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. DTP-HepB	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. DTP-HiB-HepB (Penta)	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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DAY

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MONTH

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YEAR

	Dose	1- YES	0- NO	8- UNK	If Yes, Date Received			Date Estimated
					DAY	MONTH	YEAR	
g. DTaP-HiB-IPV (Pentaxim)	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. HepB	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
i. HIB	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
	4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
j. OPV (Date received field available for 01KEN site only)	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
k. PCV	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
l. Rotavirus	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="text"/>

CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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DAY

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MONTH

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YEAR

	Dose	1- YES	0- NO	8- UNK	If Yes, Date Received			Date Estimated
					DAY	MONTH	YEAR	
m. Japanese Encephalitis	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>
n. Measles	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
	3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
o. MMR	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>
p. Influenza (for the current season)	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
	2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
q. MR	1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

17. If child is <9 months of age, has the mother had any of the following vaccinations during her pregnancy with this child?

☐ 8 - UNK (for all vaccinations)

(If Yes, list the date of the last dose if more than one.)

☐ 9 - N/A (i.e., child > 9 months)

	1-YES	0-NO	8-UNK	If Yes, Date of Last Dose			Date Estimated
				DAY	MONTH	YEAR	
a. Influenza (for the current season)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
b. DTaP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
c. PCV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
d. PPS-23	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

Comments: _____

Interviewer's Name: _____

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STAFF CODE

Supervisor Signature: _____

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STAFF CODE

Supervisor Verification Date:

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CRF 04: CASE CLINICAL ASSESSMENT

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PARTICIPANT ID

Date of assessment:

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DAY

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MONTH

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YEAR

1. Time of assessment:

 (24 hour clock)

2. Where is child being assessed?

<input type="checkbox"/>	01 - Hospital
<input type="checkbox"/>	02 - Clinic
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table style="display: inline-table; border: 1px solid black; width: 40px; height: 20px; vertical-align: middle;"></table>

3. Was child referred from another health clinic/hospital?

<input type="checkbox"/>	1 - Yes	→	a. Clinic/hospital name: _____	Code: <table style="display: inline-table; border: 1px solid black; width: 40px; height: 20px; vertical-align: middle;"></table>
<input type="checkbox"/>	0 - No		_____	
<input type="checkbox"/>	8 - UNK			

NUTRITION / HYDRATION STATUS / VITAL SIGNS

4. Temperature (axillary):

 .

 °C

8 - UNK

☐

5. Height/length:

 .

 cm

8 - UNK

☐

6. Was the child weighed alone?

1 - Yes ☐ 0 - No ☐
If No, child's weight will be calculated in AdvantageEDCSM.

6a. Weight of child:

 .

 kg

8 - UNK

☐

7. Weight of mother and child:

 .

 kg

8 - UNK

☐

8. Weight of mother:

 .

 kg

8 - UNK

☐
9. Mid-Upper Arm Circumference (MUAC)
(N/A for children <3 months old):

 mm

8 - UNK 9 - N/A

☐
☐

10. Heart rate:

 beats per minute

8 - UNK

☐

14. Pedal edema:

<input type="checkbox"/>	1 - Yes
<input type="checkbox"/>	2 - No
<input type="checkbox"/>	8 - UNK
<input type="checkbox"/>	9 - NR

CRF 04: CASE CLINICAL ASSESSMENT

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PARTICIPANT ID

Date of assessment:

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DAY

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MONTH

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YEAR

15. Skin turgor:

<input type="checkbox"/>	1 - Normal
<input type="checkbox"/>	2 - Reduced
<input type="checkbox"/>	8 - UNK
<input type="checkbox"/>	9 - NR

16. Capillary refill time:

seconds

8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

1 - Yes 0 - No 8 - UNK 9 - NR

17. Cool peripheries (cool hands and feet):.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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18. Weak peripheral pulses (Radial/Dorsalis pedis pulse):.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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19. Gallop rhythm:.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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20. Tender liver mass (With/without hepatomegaly):.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

RESPIRATORY SIGNS (in addition to those recorded on CRF 01)

21. Observed cough:.....

1 - Yes 0 - No 8 - UNK 9 - NR

a. If Yes, is it a barking cough?.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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22. Stridor:.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

a. If Yes, is the stridor still present when the child is quiet (not crying?)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

23. Grunting:.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

24. Nasal flaring:.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

25. Deep breathing:.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

26. Is there an audible wheeze?.....

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

27. Does the child have any of the following findings on chest auscultation?

Findings:	Left side				Right side			
	1 - Yes	0 - No	8 - UNK	9 - NR	1 - Yes	0 - No	8 - UNK	9 - NR
a. Wheeze:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Crackles/Crepitations:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Decreased breath sounds:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Bronchial breath sounds:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>
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e. Auscultation findings were done by:

<input type="checkbox"/>	01 - Hospital staff
<input type="checkbox"/>	02 - PERCH staff
<input type="checkbox"/>	99 - Other, specify: _____ Code: <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/>

28. Clubbing:.....

1 - Yes 0 - No 8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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CRF 04: CASE CLINICAL ASSESSMENT

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PARTICIPANT ID

Date of assessment:

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DAY

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MONTH

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YEAR

29. Was a digital stethoscope recording taken?.....

1 - Yes 0 - No 8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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a. If Yes, enter the sound file record number:

--	--	--	--	--	--	--	--	--	--	--

(D D M M Y Y - x x x x x)

b. Time of recording:

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(24 hour clock)

c. Digital auscultation comments:

MISCELLANEOUS SIGNS

30. Jaundice:.....

1 - Yes 0 - No 8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

31. Bulging fontanelle (if < 18 months):

10 - N/A

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

32. Rash:.....

8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

a. If Yes, type of rash? (check one)

<input type="checkbox"/>	01 - Petechial (size of individual lesions < 3 mm)
<input type="checkbox"/>	02 - Purpurial (size of individual lesions ≥ 3 mm)
<input type="checkbox"/>	03 - Measles
<input type="checkbox"/>	04 - Chicken pox
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

33a. Clinical pneumonia diagnosis made by hospital staff on admission (check one):

- | | | |
|---|---|--|
| <input type="checkbox"/> 1 – Non-severe pneumonia/
Pneumonia not otherwise specified | <input type="checkbox"/> 2 – Severe pneumonia | <input type="checkbox"/> 3 – Very severe pneumonia |
| <input type="checkbox"/> 4 – No pneumonia diagnosis | <input type="checkbox"/> 9 – Not available/
Not done by hospital | |

33b. Other clinical diagnosis made by hospital staff on admission (check all that apply):

- | | |
|---|--|
| <input type="checkbox"/> Pulmonary TB
<input type="checkbox"/> Extrapulmonary TB
<input type="checkbox"/> Bronchiolitis/RSV
<input type="checkbox"/> Asthma / Reactive Airway Disease (RAD)
<input type="checkbox"/> Measles
<input type="checkbox"/> Malaria
<input type="checkbox"/> Meningitis
<input type="checkbox"/> Gastroenteritis
<input type="checkbox"/> HIV
<input type="checkbox"/> Presumptive septicaemia | <input type="checkbox"/> Paraffin ingestion
<input type="checkbox"/> Severe anaemia
<input type="checkbox"/> Sickle cell disease
<input type="checkbox"/> Severe malnutrition
<input type="checkbox"/> Bronchitis
<input type="checkbox"/> Developmental delay/Cerebral palsy
<input type="checkbox"/> Other: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>
<input type="checkbox"/> Other: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>
<input type="checkbox"/> Other: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>
<input type="checkbox"/> Not available/Not done by hospital
<input type="checkbox"/> Pneumonia diagnosis only |
|---|--|

**CRF 04:
CASE CLINICAL ASSESSMENT**

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PARTICIPANT ID

Date of assessment:

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DAY

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MONTH

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YEAR

Comments: _____

Form completed by: _____ **Staff Code:**

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Supervisor signature: _____ **Staff Code:**

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Day

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Month

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Year

CRF 04A: CONTROL CLINICAL ASSESSMENT

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PARTICIPANT ID

Date of
assessment:

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DAY

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MONTH

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YEAR

NUTRITION / HYDRATION STATUS / VITAL SIGNS

1. Were any signs or symptoms of illness in the last 48 hours reported?

(Question 1 on CRF03)

1 - Yes 0 - No 8 - UNK

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a. If Yes, temperature:

		.		°C
--	--	---	--	----

SOURCE:

1-Auxillary

2-Rectal

8 - UNK

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2. Height/length:

			.		cm
--	--	--	---	--	----

8 - UNK

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3. Was the child weighed alone?

1 - Yes 0 - No

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If No, child's weight will be calculated in AdvantageEDCSM.

3a. Weight of child:

		.		kg
--	--	---	--	----

8 - UNK

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4. Weight of mother and child:

			.		kg
--	--	--	---	--	----

8 - UNK

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5. Weight of mother:

			.		kg
--	--	--	---	--	----

8 - UNK

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6. Mid-upper arm circumference (MUAC)

(N/A for children <3 months old):

				mm
--	--	--	--	----

8 - UNK

--

9 - N/A

--

7. Respiratory rate (# of breaths counted in 60 seconds):

--	--	--

per min

8 - UNK

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RESPIRATORY SIGNS

8. Observed cough?

1 - Yes 0 - No 8 - UNK

--	--	--

9. Was a digital stethoscope recording taken?

1 - Yes 0 - No 8-UNK 9 - NR

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a. If Yes, enter the sound file record number:

						-					
D	D	M	M	Y	Y		x	x	x	x	x

b. Time of recording: (24 hour clock)

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c. Digital auscultation comments:

10. Clubbing:

1 - Yes 0 - No 8 - UNK 9 - NR

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MISCELLANEOUS SIGNS

11. Rash:

1 - Yes 0 - No 8 - UNK 9 - NR

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a. If Yes, type of rash? (check one)

<input type="checkbox"/>	01 - Petechial (size of individual lesions < 3 mm)			
<input type="checkbox"/>	02 - Purpurial (size of individual lesions ≥ 3 mm)			
<input type="checkbox"/>	03 - Measles			
<input type="checkbox"/>	04 - Chicken pox			
<input type="checkbox"/>	08 - UNK			
<input type="checkbox"/>	09 - NR			
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1"><tr><td></td><td></td><td></td></tr></table>			

SITE LOGO

CRF 04A:
CONTROL CLINICAL ASSESSMENT



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PARTICIPANT ID

Date of assessment:

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DAY

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MONTH

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YEAR

Comments: _____

Form completed by: _____ **Staff Code:**

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Supervisor Signature: _____ **Staff Code:**

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Day

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Month

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Year

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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DAY

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MONTH

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YEAR

1. Are you a primary caregiver for this child? 1-YES ☐ 0- NO ☐ 8-UNK ☐

2. What is your relationship to him or her (*choose one*)?

08 - UNK

- | | | | |
|---|--|--|---|
| <input type="checkbox"/> 01 - Mother | <input type="checkbox"/> 02 - Father | <input type="checkbox"/> 03 - Grandmother | <input type="checkbox"/> 04 - Grandfather |
| <input type="checkbox"/> 05 - Brother | <input type="checkbox"/> 06 - Sister | <input type="checkbox"/> 07 - Aunt | <input type="checkbox"/> 09 - Uncle |
| <input type="checkbox"/> 10 - Other relative | <input type="checkbox"/> 11 - Maid / Baby sitter | | |
| <input type="checkbox"/> 99 – Other, specify: _____ | | Code: <table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> | |

DEMOGRAPHICS

3. Mother's ethnic group (*choose one*):

98 - UNK

<input type="checkbox"/> 14 - Asian <input type="checkbox"/> 51 - Xhosa <input type="checkbox"/> 52 - Zulu <input type="checkbox"/> 53 - Coloured <input type="checkbox"/> 54 - Sotho <input type="checkbox"/> 55 - Bemba <input type="checkbox"/> 56 - Lozi <input type="checkbox"/> 57 - Chewa <input type="checkbox"/> 58 - Tonga <input type="checkbox"/> 59- Lunda <input type="checkbox"/> 60 - Luvale <input type="checkbox"/> 61 - Kaonde <input type="checkbox"/> 62 - Mandinka <input type="checkbox"/> 63 - Wollof <input type="checkbox"/> 64 - Fula <input type="checkbox"/> 65 - Serahule <input type="checkbox"/> 66 - Jola <input type="checkbox"/> 67 - Aku <input type="checkbox"/> 68 - Manjago <input type="checkbox"/> 69 - Serere <input type="checkbox"/> 70 - Ndebele <input type="checkbox"/> 99 - Other, specify: <div style="border-bottom: 1px solid black; width: 100%; margin-top: 5px;"></div> <div style="display: flex; align-items: center;"> Code: <table border="1" style="display: inline-table; width: 60px; height: 20px;"></table> </div>	<input type="checkbox"/> 71 - Vietnamese <input type="checkbox"/> 72 - Bambara <input type="checkbox"/> 73 - Malinké <input type="checkbox"/> 74 - Sarakolé <input type="checkbox"/> 75 - Peuhl <input type="checkbox"/> 76 - Bobo <input type="checkbox"/> 77 - Sénoufo <input type="checkbox"/> 78 - Minianka <input type="checkbox"/> 79 - Bozo <input type="checkbox"/> 80 - Somono <input type="checkbox"/> 81 - Dogon <input type="checkbox"/> 82 - Sonrhái <input type="checkbox"/> 83 - Maure <input type="checkbox"/> 84 - Tamachek <input type="checkbox"/> 85 - Samoko <input type="checkbox"/> 86 - Dafing <input type="checkbox"/> 87 - Thai <input type="checkbox"/> 88 - Lao <input type="checkbox"/> 89 - Cambodian <input type="checkbox"/> 90 -Bangladeshi <input type="checkbox"/> 91 - Soli
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CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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DAY

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MONTH

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YEAR

4. Father's ethnic group (mark only one):

98 - UNK

☐

<input type="checkbox"/>	14 - Asian	<input type="checkbox"/>	71 - Vietnamese
<input type="checkbox"/>	51 - Xhosa	<input type="checkbox"/>	72 - Bambara
<input type="checkbox"/>	52 - Zulu	<input type="checkbox"/>	73 - Malinké
<input type="checkbox"/>	53 - Coloured	<input type="checkbox"/>	74 - Sarakolé
<input type="checkbox"/>	54 - Sotho	<input type="checkbox"/>	75 - Peuhl
<input type="checkbox"/>	55 - Bemba	<input type="checkbox"/>	76 - Bobo
<input type="checkbox"/>	56 - Lozi	<input type="checkbox"/>	77 - Sénoufo
<input type="checkbox"/>	57 - Chewa	<input type="checkbox"/>	78 - Minianka
<input type="checkbox"/>	58 - Tonga	<input type="checkbox"/>	79 - Bozo
<input type="checkbox"/>	59 - Lunda	<input type="checkbox"/>	80 - Somono
<input type="checkbox"/>	60 - Luvale	<input type="checkbox"/>	81 - Dogon
<input type="checkbox"/>	61 - Kaonde	<input type="checkbox"/>	82 - Sonrhái
<input type="checkbox"/>	62 - Mandinka	<input type="checkbox"/>	83 - Maure
<input type="checkbox"/>	63 - Wollof	<input type="checkbox"/>	84 - Tamachek
<input type="checkbox"/>	64 - Fula	<input type="checkbox"/>	85 - Samoko
<input type="checkbox"/>	65 - Serahule	<input type="checkbox"/>	86 - Dafing
<input type="checkbox"/>	66 - Jola	<input type="checkbox"/>	87 - Thai
<input type="checkbox"/>	67 - Aku	<input type="checkbox"/>	88 - Lao
<input type="checkbox"/>	68 - Manjago	<input type="checkbox"/>	89 - Cambodian
<input type="checkbox"/>	69 - Serere	<input type="checkbox"/>	90 - Bangladeshi
<input type="checkbox"/>	70 - Ndebele	<input type="checkbox"/>	91 - Soli
<input type="checkbox"/>	99 - Other, specify: <div style="border-bottom: 1px solid black; height: 15px; margin: 5px 0;"></div> Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>		

5. Has the child been previously enrolled as a PERCH case or control?

 (check all that apply) ☐ 0 - No ☐ 8 - UNK ☐ Case ☐ Control

(If No or UNK, skip to Q6)

If previously enrolled:

a. 1st previous PERCH participant ID #:

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b. 2nd previous PERCH participant ID #:

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c. 3rd previous PERCH participant ID #:

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CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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DAY

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MONTH

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YEAR

6. Was the child enrolled in any intervention studies in the past year?
(i.e. has the child received medicines, vaccines, vitamins, etc. as part of a study?)
(If no or unknown, skip to Q7)

1-YES 0-NO 8-UNK
☐ ☐ ☐

If Yes, please provide the name of the other studies and the associated ID numbers:

Study name:

(or description of intervention if name UNK)

ID number in the other study:

	8 - UNK		8 - UNK
a1. _____ <input type="checkbox"/>		b1. <table border="1" style="display: inline-table; width: 100%; height: 20px;"></table>	<input type="checkbox"/>
a2. _____ <input type="checkbox"/>		b2. <table border="1" style="display: inline-table; width: 100%; height: 20px;"></table>	<input type="checkbox"/>
a3. _____ <input type="checkbox"/>		b3. <table border="1" style="display: inline-table; width: 100%; height: 20px;"></table>	<input type="checkbox"/>
a4. _____ <input type="checkbox"/>		b4. <table border="1" style="display: inline-table; width: 100%; height: 20px;"></table>	<input type="checkbox"/>

HOUSEHOLD INFORMATION

7. Is the biological mother of child still alive? ☐ 1- Yes ☐ 0- No

8-UNK
☐

If Yes, record the mother's age

 years

8-UNK
☐

If No, estimate the mother's age at the time of the child's birth
(Estimate using major events if needed.)

 years

8-UNK
☐

8. How many years of formal education has the mother / primary caregiver completed?

 years

8-UNK
☐

9. What type of school did the mother / primary caregiver attend? *(check all that apply)*

<input type="checkbox"/>	Unknown
<input type="checkbox"/>	No formal education
<input type="checkbox"/>	Formal education
<input type="checkbox"/>	Religious education
<input type="checkbox"/>	College (and beyond)

10. Does the mother / primary caregiver belong to any social group?

11. Is the father of child still alive? *(if no, skip to Q15)*

1-YES 0-NO 8-UNK
☐ ☐ ☐

12. How many years of formal education has the father completed?

 Years

8-UNK
☐

13. What type of school did the father attend? *(check all that apply)*

<input type="checkbox"/>	Unknown
<input type="checkbox"/>	No formal education
<input type="checkbox"/>	Formal education
<input type="checkbox"/>	Religious education
<input type="checkbox"/>	College (and beyond)

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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YEAR

14. How many current wives does the father have?.....

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8-UNK

☐

a. If more than one wife, what is the order number of the child's mother?

(1=first wife, 2=second wife, etc.)

--	--

8-UNK

☐

For Qs 15-17, respond for the most common living situations of the child during the past 12 months.

15. How many (total) people usually live in the same household as this child? (Defined as sharing a cooking pot/area.)

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8-UNK

☐

16. How many children aged 0-10 years (including study child) live in the same household?

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☐

17. How many people usually slept in the same room as this child in the last month (including the study child)?

--	--

☐

8-UNK

☐

18. For people usually sleeping in the same room as this child, record the following details:

Person #	a. Relationship to child: (1-Mother, 2-Father, 3-Sibling, 4-Other child, 5-Other adult)	b. Age (nearest year) (If UNK, request a missing value in EDC)	c. Sleep in same bed?			d. Had a cough in the last month?		
			1-Yes	0- No	8-UNK	1-Yes	0-No	8-UNK
1	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19. How many live deliveries has mother had? (including the study child; twins counts as one.)

(If 1 or more, answer Q19a; otherwise skip to Q20)

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8-UNK

☐

a. Of the live deliveries reported in Q19, how many of her children have died?

--	--

8-UNK

☐

20. Does this child attend out of home care (nursery/preschool/family care/crèche)?

(Must include at least 2 other children for at least 4 hours per day, 3 days a week)

1-YES	0-NO	8-UNK
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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YEAR

ENVIRONMENT & SANITATION

08-UNK

☐
21. What is the **main** source of drinking water for child's household? (*check only one response*)☐ 01-Piped into house (indoor tap water)☐ 06-Open well in house or yard☐ 13-Protected spring☐ 02-Piped into yard/compound/property☐ 07-Covered well in house or yard☐ 14-Unprotected spring☐ 03-Bought (tank, bottles, etc)☐ 09-Open public well☐ 15-Dam or earth pan☐ 04-Outdoor / Public tap☐ 10-Covered public well☐ 16-Rainwater☐ 05- Borehole☐ 11-Deep tube well☐ 17-River, stream, pond or lake water☐ 99-Other, specify: _____☐ 12-Shallow tube wellCode:

08-UNK

☐
22. Where is the nearest drinking water source? (*check one*)

<input type="checkbox"/>	01-Inside house
<input type="checkbox"/>	02-Inside compound ≤5m of house
<input type="checkbox"/>	03-Inside compound >5m of house
<input type="checkbox"/>	04-Outside compound → <i>if checked</i> , record time to reach in minutes: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table> 8-UNK <input type="checkbox"/>
<input type="checkbox"/>	99-Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

08-UNK

23. What is the **main** source of water for washing hands in your household? (*check one*) ☐

<input type="checkbox"/>	01-Piped into house (indoor tap water) (<i>If checked, skip Q24 and go to Q25</i>)
<input type="checkbox"/>	a. If piped into house, how many working taps/sinks with running water are located inside your house? <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table> 8-UNK <input type="checkbox"/>
<input type="checkbox"/>	02-Piped into yard / property
<input type="checkbox"/>	03-Outdoor / public tap
<input type="checkbox"/>	04-Public well
<input type="checkbox"/>	05-Rainwater
<input type="checkbox"/>	06-River, stream, pond, or lake water
<input type="checkbox"/>	07-Pumped from ground through bore hole
<input type="checkbox"/>	09-Protected spring
<input type="checkbox"/>	10-Unprotected spring
<input type="checkbox"/>	11-Tube well
<input type="checkbox"/>	12-Covered well in house or yard
<input type="checkbox"/>	99-Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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YEAR

24. How long does it take to reach the water source used for washing hands?

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Mins

8-UNK

25. In the last 24 hours, have you used soap and water to wash your hands?

1-YES <input type="checkbox"/>	0-NO <input type="checkbox"/>	8-UNK <input type="checkbox"/>
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26. Does your household have a shared basin with standing water for washing hands?

1-YES <input type="checkbox"/>	0-NO <input type="checkbox"/>	8-UNK <input type="checkbox"/>
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a. If yes, how many times per day is the water changed? (if <1 time per day, put 0)

1-YES <input type="checkbox"/>	0-NO <input type="checkbox"/>	8-UNK <input type="checkbox"/>
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27. How often does your household run out of water for washing hands? (check one)

8-UNK

<input type="checkbox"/>	1- More than 10 days every month
<input type="checkbox"/>	2- 5-10 days every month
<input type="checkbox"/>	3- 1-4 days per month
<input type="checkbox"/>	4- Occasionally but not every month
<input type="checkbox"/>	5- Never

28. How concerned are you about the cost of water used for washing hands? (check one)

8-UNK

<input type="checkbox"/>	1-Not at all concerned
<input type="checkbox"/>	2-Somewhat concerned
<input type="checkbox"/>	3-Very concerned

29. What are the floors in the child's house primarily made of? (check one)

08-UNK

<input type="checkbox"/>	01 - Natural floor (sand/earth/dung)				
<input type="checkbox"/>	02 - Rudimentary floor (wood/palm/bamboo)				
<input type="checkbox"/>	03 - Finished floor (wood/tiles/cement/carpet)				
<input type="checkbox"/>	99 - Other, specify: _____	Code: <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>			

30. What are the walls in the child's house primarily made of? (check one)

08-UNK

<input type="checkbox"/>	01 - Bricks				
<input type="checkbox"/>	02 - Tin / iron sheeting				
<input type="checkbox"/>	03 - Mud / mud stick / bamboo / traditional				
<input type="checkbox"/>	04 - Cement / concrete / coral				
<input type="checkbox"/>	05 - Wood				
<input type="checkbox"/>	06 - Plaster				
<input type="checkbox"/>	07 - Stone				
<input type="checkbox"/>	99-Other, specify: _____	Code: <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>			

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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31. What is the roof in the child's house primarily made of? (*check one*)

08-UNK

☐

<input type="checkbox"/>	01 - Thatch
<input type="checkbox"/>	02 - Tin / iron sheeting / metal / corrugated
<input type="checkbox"/>	03 - Cement / concrete
<input type="checkbox"/>	04 - Wood
<input type="checkbox"/>	05 - Tiled
<input type="checkbox"/>	06 - Asbestos
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

32. What type of toilet does child's house have? (*check one*)

08-UNK

☐

<input type="checkbox"/>	01 - Flush toilet
<input type="checkbox"/>	02 - Modern toilet without flush
<input type="checkbox"/>	03 - Ventilated, well-kept pit latrine
<input type="checkbox"/>	04 - Open pit latrine
<input type="checkbox"/>	05 - Bucket system
<input type="checkbox"/>	06 - None / outdoors
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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For Q33-39, respond for the most common situation for the child. For controls, ask about **during the past month**. For cases, ask about the month **before** the child became ill with pneumonia symptoms since the period when they were ill might have been atypical for the family.

33. Describe the type of cooking fuel you used *in the past month*:

08- UNK 9- N/A

☐ ☐

Fuel type	a. What was the <u>main</u> cooking fuel? (check one)	b. What <u>other</u> fuel types did you use? (check all that apply)
01-Animal dung	<input type="checkbox"/>	<input type="checkbox"/>
02 - Crop wastes	<input type="checkbox"/>	<input type="checkbox"/>
03 - Wood	<input type="checkbox"/>	<input type="checkbox"/>
04 - Straw/shrubs/grass	<input type="checkbox"/>	<input type="checkbox"/>
05 - Charcoal	<input type="checkbox"/>	<input type="checkbox"/>
06 - Coal / ignite	<input type="checkbox"/>	<input type="checkbox"/>
07 - Kerosene/Paraffin	<input type="checkbox"/>	<input type="checkbox"/>
09- Gas	<input type="checkbox"/>	<input type="checkbox"/>
10 - Electricity	<input type="checkbox"/>	<input type="checkbox"/>
99 - Other (specify)	<input type="checkbox"/> <div style="text-align: right; margin-top: 5px;">Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table></div>	<input type="checkbox"/> <div style="text-align: right; margin-top: 5px;">Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table></div>

If animal dung, crop wastes, wood, straw/shrubs/grass, charcoal, coal/ignite, kerosene/paraffin was checked as the main fuel source in Q33 above, please answer Q34. Otherwise, skip to Q38.

34. What was the main stove type that you used for cooking? (check one)

8-UNK

☐

<input type="checkbox"/>	01 - Stove: Traditional open	
<input type="checkbox"/>	02 - Stove: Enclosed	
<input type="checkbox"/>	03 - Stove: Advanced type (modern design, may have a fan to improve combustion)	
<input type="checkbox"/>	04 - 3-stone fire (if checked, skip to Q35)	
<input type="checkbox"/>	05 - Kerosene wick (if checked, skip to Q35)	
<input type="checkbox"/>	06 - Pressurized kerosene (if checked, skip to Q35)	
<input type="checkbox"/>	99 - Other, specify: _____	Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

a. If you used a stove or open fire, does it have a functioning chimney or hood?

1-YES 0-NO 8-UNK 9- N/A

☐ ☐ ☐ ☐

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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35. Where did you usually cook with fuel *in the past month?* (check one)

8-UNK

<input type="checkbox"/>	1 - In the house, but in a room separate from living/sleeping area
<input type="checkbox"/>	2 - In the house, part of the living / sleeping area
<input type="checkbox"/>	3 - Outside the house or in a separate building

☐

36. How many open windows does the room have where the cooking is done?

☐

8-UNK 9-N/A

☐
☐

37. Typically, where was the study child when the mother / caretaker was cooking with fuel *in the past month (before the child became ill)?* (check one)

8-UNK

<input type="checkbox"/>	1 - On her back
<input type="checkbox"/>	2 - In the cooking area, but not on her back
<input type="checkbox"/>	3 - Not in the cooking area (e.g. outside, in another room, etc)

☐

38. What was the main method used to light your home when it was dark *in the past month?* (check one)

8-UNK

☐

<input type="checkbox"/>	01 - None (did not light home)
<input type="checkbox"/>	02 - Used light from cooking stove
<input type="checkbox"/>	03 - Candles
<input type="checkbox"/>	04 - Kerosene (paraffin) wick lamp
<input type="checkbox"/>	05 - Kerosene (paraffin) pressure lamp
<input type="checkbox"/>	06 - Gas
<input type="checkbox"/>	07 - Electricity
<input type="checkbox"/>	09 - Battery powered lamp
<input type="checkbox"/>	10 - Solar
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table> <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table> <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table>

39. Did you use a fire to heat your home *in the past month?*

8-UNK

☐

a. If Yes, how often?

<input type="checkbox"/>	1 - Everyday
<input type="checkbox"/>	2 - Most days (16-29 days)
<input type="checkbox"/>	3 - Many days (5-15 days)
<input type="checkbox"/>	4 - Few days (<5 days)

40. Does anyone who lives in the same household as the child smoke cigarettes?

1-YES 0-NO 8-UNK

☐
☐
☐

41. Does your household have any mosquito nets that can be used while sleeping?
If Yes, answer Q41a-b. If No or UNK, skip to Q42.

1-YES 0-NO 8-UNK

☐
☐
☐

1-YES 0-NO 8-UNK

☐
☐
☐

a. Did this child sleep under the mosquito net last night?

1-YES 0-NO 8-UNK

☐
☐
☐

b. Does this child usually sleep under a mosquito net?

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☐
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CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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YEAR

HEALTHCARE UTILIZATION

Minute guidelines:

1 hour = 60 minutes

2 hours = 120 minutes

3 hours = 180 minutes

42. Record the *usual* travel time to the following locations by the *usual* mode of transport and the *usual* costs associated with this travel.

Location:	i. How long does it usually take (<i>minutes</i>)?	ii. How much does transportation usually cost? (<i>in local currency, one way</i>)									
a. Nearest health post / clinic	<table border="1" style="display: inline-table; width: 100%;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="display: inline-block; text-align: right;">8-UNK <input style="width: 20px; height: 20px;" type="checkbox"/></div>				<table border="1" style="display: inline-table; width: 100%;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="display: inline-block; text-align: right;">8-UNK <input style="width: 20px; height: 20px;" type="checkbox"/> 9-N/A <input style="width: 20px; height: 20px;" type="checkbox"/></div>						
b. Study hospital	<table border="1" style="display: inline-table; width: 100%;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="display: inline-block; text-align: right;">8-UNK <input style="width: 20px; height: 20px;" type="checkbox"/></div>				<table border="1" style="display: inline-table; width: 100%;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="display: inline-block; text-align: right;">8-UNK <input style="width: 20px; height: 20px;" type="checkbox"/> 9-N/A <input style="width: 20px; height: 20px;" type="checkbox"/></div>						
c. Is the study hospital the nearest hospital? 1-YES <input style="width: 20px; height: 20px;" type="checkbox"/> 0-NO <input style="width: 20px; height: 20px;" type="checkbox"/> 8-UNK <input style="width: 20px; height: 20px;" type="checkbox"/>											
d. Nearest hospital (If nearest hospital is the study hospital, answer N/A.)	<table border="1" style="display: inline-table; width: 100%;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="display: inline-block; text-align: right;">8-UNK <input style="width: 20px; height: 20px;" type="checkbox"/> 9-N/A <input style="width: 20px; height: 20px;" type="checkbox"/></div>				<table border="1" style="display: inline-table; width: 100%;"> <tr> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="display: inline-block; text-align: right;">8-UNK <input style="width: 20px; height: 20px;" type="checkbox"/> 9-N/A <input style="width: 20px; height: 20px;" type="checkbox"/></div>						

For **Cases** only, ask Q43-44. For **Controls**, skip to Q45.

43. How long did it take to get to the study hospital for this admission (*minutes*)?

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8-UNK

☐

44. How much was the cost of transportation for this hospital admission (*one way*)?

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8-UNK

☐

9-N/A

☐

HOUSEHOLD INCOME & ASSETS

For Q45-47, reference site-specific codelist.

45. What is the occupation of the head of household? Site-specific code:

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If Other, specify: _____ Other code:

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46. Father's occupation (*if not head of household*): Site-specific code:

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If Other, specify: _____ Other code:

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47. Mother's/primary care giver's occupation: Site-specific code:

--	--	--

If Other, specify: _____ Other code:

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08-UNK

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CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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YEAR

48. What was the weekly/monthly cash income of the household last month?

<input type="checkbox"/>	01 - 0 – 500 Rand	<input type="checkbox"/>	07 - 0-1,000 baht
<input type="checkbox"/>	02 - 501 – 1,000 Rand	<input type="checkbox"/>	09 - 1,001-2000 baht
<input type="checkbox"/>	03 - 1,001 – 3,000 Rand	<input type="checkbox"/>	10 - 2,001-4,000 baht
<input type="checkbox"/>	04 - 3,001 – 5,000 Rand	<input type="checkbox"/>	11 - 4,001-7,000 baht
<input type="checkbox"/>	05 - 5,001 – 15,000 Rand	<input type="checkbox"/>	12 - >7,000 baht
<input type="checkbox"/>	06 - >15,000 Rand		

49. Ask mother / primary caregiver: Do you regularly earn any income yourself?

1-YES 0-NO 8-UNK
☐ ☐ ☐

50. Is the child receiving a “child grant”?

1-YES 0-NO 8-UNK
☐ ☐ ☐

51. Does your household have any of the following which are in working order?

8-UNK
☐

(check all that apply)

- | | | |
|--|---|---|
| <input type="checkbox"/> Electricity | <input type="checkbox"/> Television | <input type="checkbox"/> Bicycle / rickshaw |
| <input type="checkbox"/> Generator | <input type="checkbox"/> Satellite TV/DS TV | <input type="checkbox"/> Boat with a motor |
| <input type="checkbox"/> Air conditioner | <input type="checkbox"/> Radio | <input type="checkbox"/> Canoe |
| <input type="checkbox"/> Electric Fan | <input type="checkbox"/> Mobile phone | <input type="checkbox"/> Sewing machine |
| <input type="checkbox"/> Computer | <input type="checkbox"/> Electric Iron | <input type="checkbox"/> Water heater |
| <input type="checkbox"/> Refrigerator | <input type="checkbox"/> Watch | <input type="checkbox"/> Washing machine |
| <input type="checkbox"/> Animal-drawn cart | <input type="checkbox"/> Camera | <input type="checkbox"/> None of these |
| <input type="checkbox"/> Clock | <input type="checkbox"/> Car / truck | |
| <input type="checkbox"/> DVD/Video Player | <input type="checkbox"/> Motorcycle / scooter | |

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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DAY

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MONTH

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YEAR

52. Does anyone in the household own any of the following livestock? *(For all that apply, check and enter how many are owned. Confirm by observation where possible and appropriate.)*

Livestock	Check all that apply	i. If checked, how many owned?	8 - UNK				
a. Cattle	<input type="checkbox"/>	<table border="1" style="display: inline-table;"><tr><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td></tr></table>					<input type="checkbox"/>
b. Sheep	<input type="checkbox"/>	<table border="1" style="display: inline-table;"><tr><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td></tr></table>					<input type="checkbox"/>
c. Goats	<input type="checkbox"/>	<table border="1" style="display: inline-table;"><tr><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td></tr></table>					<input type="checkbox"/>
d. Horses	<input type="checkbox"/>	<table border="1" style="display: inline-table;"><tr><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td></tr></table>					<input type="checkbox"/>
e. Donkeys	<input type="checkbox"/>	<table border="1" style="display: inline-table;"><tr><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td></tr></table>					<input type="checkbox"/>
f. Pigs	<input type="checkbox"/>	<table border="1" style="display: inline-table;"><tr><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td></tr></table>					<input type="checkbox"/>
g. Chickens	<input type="checkbox"/>	<table border="1" style="display: inline-table;"><tr><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td><td style="width: 25px; height: 25px;"></td></tr></table>					<input type="checkbox"/>
h. None of these	<input type="checkbox"/>						

53. Does your household own at least five items of furniture?

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Furniture	Check all that apply
a. Table	<input type="checkbox"/>
b. Chair	<input type="checkbox"/>
c. Sofa	<input type="checkbox"/>
d. Bed	<input type="checkbox"/>
e. Armoire	<input type="checkbox"/>
f. Cabinet	<input type="checkbox"/>

54. Does any member of this household own agricultural land?

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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a. If yes, specify how many acres?

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8-UNK

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CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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DAY

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MONTH

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YEAR

BIRTH AND DELIVERY MILESTONES

08- UNK

55. Place of birth:

☐

<input type="checkbox"/>	01 - Hospital
<input type="checkbox"/>	02 - Clinic
<input type="checkbox"/>	03 - Home
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table>

56. Mode of delivery:

8-UNK

<input type="checkbox"/>	1 - Vaginal
<input type="checkbox"/>	2 - C-section

☐
57. Gestational age.....

 weeks

8-UNK

☐

58. Was this child premature (<37 weeks recorded) at birth?

1-YES ☐ 0-NO ☐ 8-UNK ☐
59. How much did the child weigh at birth?

 .

 kg

8-UNK

☐

a. If exact weight is unknown, what was the child's size at birth?

8-UNK

☐

<input type="checkbox"/>	1 – Small
<input type="checkbox"/>	2 – Medium
<input type="checkbox"/>	3 – Large

60. How was this child fed since s/he was born?

	Given at any stage?			i. If Yes, age first started (Enter "00" if from birth)		ii. If stopped, age stopped (check N/A if still continuing)		
	1-Yes	0-No	8-UNK	Age (months)		Age (months)		
a. Breast feeding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 9-N/A <input type="checkbox"/>
b. Infant formula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 9-N/A <input type="checkbox"/>
c. Any liquids other than breast milk (e.g. water, tea) or semi-solid food (e.g. pap)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 9-N/A <input type="checkbox"/>
d. Solid food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 40px; height: 20px;"></table> 9- N/A <input type="checkbox"/>

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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DAY

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MONTH

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YEAR

61. Was the child breastfed?

1-YES <input type="checkbox"/>	0-NO <input type="checkbox"/>	8-UNK <input type="checkbox"/>
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a. For how many months was the child exclusively breastfed?

		8-UNK <input type="checkbox"/>
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b. For how many months was the child breastfed?

		8-UNK <input type="checkbox"/>
--	--	-----------------------------------

c. Was the child breastfed in the week before illness
(or the week before enrollment for controls)?
 8-UNK
☐

<input type="checkbox"/>	1 - Exclusive
<input type="checkbox"/>	2 - Mixed
<input type="checkbox"/>	3 - None

Comments: _____

Form Completed by: _____ Staff Code:

Supervisor Signature: _____ Staff Code:

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Day

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Month

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Year

CRF 06: CASE SPECIMEN COLLECTION: BLOOD, NP/OP, URINE

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PARTICIPANT ID

1. Child's weight category (*check one*): ☐ 1: ≤ 1 kg ☐ 2: > 1 kg to < 3 kg ☐ 3: ≥ 3 kg

Child's Weight	Total Volume	Blood Culture Bottle Volume	EDTA Tube #1 (CBC) Volume	EDTA Tube #2 (PCR) Volume	Plain/Red Top Tube Volume
≤ 1 kg	3 mL	1 mL	0.5 mL	1 mL	0.5 mL
> 1 kg to < 3 kg	4.5 mL	2 mL	0.5 mL	1 mL	1 mL
≥ 3 kg	5 mL	2 mL	0.5 mL	1.5 mL	1 mL

In instances of limited blood volume, the following guidance applies in decreasing order of priority: 1) Blood cultures CBC malaria slides (for endemic sites) HIV serology (for high prevalence sites) 2) Purple top tube for PCR, etc., (up to 1 mL max.) 3) If there is sufficient volume, any remaining blood should be placed in the red top tube *Volume may vary based on local requirements for CBC and risk factor tests.	When < 3 mL of blood is collected from a patient, the following guidelines may be used:				
	Total Volume Available	Blood Culture Bottle Volume	EDTA Tube #1 (CBC*) Volume	EDTA Tube #2 (PCR) Volume	Plain/ Red Top Tube Volume
	< 1 mL	all	0 mL	0 mL	0 mL
	1 to < 2 mL	1 mL	0.5* mL	0 - 0.5 mL	0 mL
	2 to < 3 mL	1 mL	0.5* mL	0.5 – 1 mL	Any remaining volume

2. Enrollment category (*check one*):

<input type="checkbox"/>	Child had wheeze at admission AND the case defining signs of severe pneumonia resolved after 1 dose of bronchodilator treatment (< 2 yrs old) or after 1 - 3 doses (≥ 2 to < 5 yrs old).	→	Modified protocol: Collect blood and swabs only. Do not collect other specimens.
<input type="checkbox"/>	Either (a) child did not have wheeze, (b) child had very severe pneumonia, or (c) signs of severe pneumonia persisted after complete course of bronchodilator therapy.	→	Proceed with standard protocol.

CRF 06:
CASE SPECIMEN COLLECTION: BLOOD, NP/OP, URINE

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PARTICIPANT ID

3. Were the following samples collected?		Reason, if not collected*	Date (ddMMMyyyy& Time (24hr clock)	Collected by	Specimen ID/Barcode
a. Blood culture	<input type="checkbox"/> Yes, at study facility <input type="checkbox"/> Yes, at referring facility <input type="checkbox"/> Not collected	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/> <input type="text"/> <input type="text"/>	DAY: <input type="text"/> <input type="text"/> MONTH: <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/> YEAR: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Initials: _____ Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
b. EDTA tube #1 (CBC)	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/> <input type="text"/> <input type="text"/>	DAY: <input type="text"/> <input type="text"/> MONTH: <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/> YEAR: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Initials: _____ Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
c. EDTA tube #2 (PCR)	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/> <input type="text"/> <input type="text"/>	DAY: <input type="text"/> <input type="text"/> MONTH: <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/> YEAR: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Initials: _____ Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
d. Plain/ red top tube	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/> <input type="text"/> <input type="text"/>	DAY: <input type="text"/> <input type="text"/> MONTH: <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/> YEAR: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Initials: _____ Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="text"/>	Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>

*Reason Codes: 01 = Parent/Guardian refused; 02 = Child died prior to specimen collection; 03 = Insufficient blood volume; 04 = All EDTA being collected in one tube; 05=Child discharged; 07 = Child could not produce specimen; 08 = Unknown; 09 = Not applicable; 99 = Other (give reason and enter other specify code)

CRF 06: CASE SPECIMEN COLLECTION: BLOOD, NP/OP, URINE

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PARTICIPANT ID

4. Were the following samples collected?	Reason, if not collected*	Date (ddMMyyyy) & Time (24hr clock)	Collected by	Specimen ID/Barcode
a. NPS-VTM <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input style="width: 30px;" type="text"/> Other: _____ Other specify code: <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div>	DAY: <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div> MONTH: <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/> YEAR: <div style="border: 1px solid black; display: inline-block; width: 50px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/> TIME: <div style="border: 1px solid black; display: inline-block; width: 50px; height: 20px;"></div> <input style="width: 20px; height: 20px;" type="checkbox"/>	Initials: _____ Staff code: <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/>	Flocked NP swab and OP swab should be put together in one VTM vial (one barcode label only). <div style="border: 1px solid black; padding: 5px; text-align: center;"> Scan or affix barcode label: <div style="border: 1px solid black; display: inline-block; width: 100px; height: 20px;"></div> - <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div> </div>
b. OPS <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input style="width: 30px;" type="text"/> Other: _____ Other specify code: <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div>	DAY: <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div> MONTH: <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/> YEAR: <div style="border: 1px solid black; display: inline-block; width: 50px; height: 20px;"></div> UNK <input style="width: 20px; height: 20px;" type="checkbox"/> TIME: <div style="border: 1px solid black; display: inline-block; width: 50px; height: 20px;"></div> <input style="width: 20px; height: 20px;" type="checkbox"/>	Initials: _____ Staff code: <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/>	<div style="border: 1px solid black; height: 100px;"></div>
c. NPS-STGG <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input style="width: 30px;" type="text"/> Other: _____ Other specify code: <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div>	DAY: <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div> MONTH: <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/> YEAR: <div style="border: 1px solid black; display: inline-block; width: 50px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/> TIME: <div style="border: 1px solid black; display: inline-block; width: 50px; height: 20px;"></div> <input style="width: 20px; height: 20px;" type="checkbox"/>	Initials: _____ Staff code: <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/>	Rayon NP swab should be put in STGG vial. <div style="border: 1px solid black; padding: 5px; text-align: center;"> Scan or affix barcode label: <div style="border: 1px solid black; display: inline-block; width: 100px; height: 20px;"></div> - <div style="border: 1px solid black; display: inline-block; width: 30px; height: 20px;"></div> </div>

*Reason Codes: 01 = Parent/Guardian refused; 02 = Child died prior to specimen collection; 03 = Insufficient blood volume; 04 = All EDTA being collected in one tube; 05=Child discharged; 07 = Child could not produce specimen; 08 = Unknown; 09 = Not applicable; 99 = Other (give reason and enter other specify code)

SITE LOGO



CRF 06:
CASE SPECIMEN COLLECTION: BLOOD, NP/OP, URINE

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PARTICIPANT ID

5. Was the following sample collected?		Reason, if not collected*	Date (ddMMMyyyy) & Time (24hr clock)	Collected by	Specimen ID/Barcode
a. Urine	<input type="checkbox"/> Yes, sterile cup	Reason code: <input type="text"/>	DAY: <input type="text"/> <input type="text"/>	Initials: _____	<div>Scan or affix barcode label:</div> <div> <input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/> - <input type="text"/><input type="text"/> </div>
	<input type="checkbox"/> Yes, urine bag or catheter	Other: _____	MONTH: <input type="text"/> <input type="text"/> <input type="text"/> 8 -UNK <input type="text"/>	Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	<input type="checkbox"/> NO	Other specify code: <input type="text"/> <input type="text"/> <input type="text"/>	YEAR: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 -UNK <input type="text"/>	

*Reason Codes: 01 = Parent/Guardian refused; 02 = Child died prior to specimen collection; 03 = Insufficient blood volume; 04 = All EDTA being collected in one tube; 05=Child discharged; 07 = Child could not produce specimen; 08 = Unknown; 09 = Not applicable; 99 = Other (give reason and enter other specify code)

Comments:

Supervisor Signature: _____ **Staff code:**

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Supervisor Verification Date:

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DayMonthYear

SITE LOGO

CRF 06A: CONTROL SPECIMEN COLLECTION: BLOOD, NP/OP, URINE



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PARTICIPANT ID

Date specimens
collected:

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DAY

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MONTH

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YEAR

Volume of Blood Collection Guidelines:

EDTA Volume	Plain/Red Top Volume	Total Volume
2 mL	2 mL	4 mL

In instances where less than the minimum volume is obtained, at least 1mL should be collected in the EDTA tube.

1. Specimens collected by: _____

Staff code:

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2. Were the following samples collected?		Reason, if not collected*	Time of specimen collection (24hr clock)	Specimen ID (barcode label)																	
a. EDTA tube	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <table border="1"><tr><td></td></tr></table> Other: _____ Other specify code: <table border="1"><tr><td></td><td></td><td></td></tr></table>					TIME: <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> <div>8 - UNK <input type="checkbox"/></div>					Scan or affix barcode label: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> <td>-</td> <td></td><td></td> </tr> </table>							-		
						-															
b. Plain/ red top tube	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <table border="1"><tr><td></td></tr></table> Other: _____ Other specify code: <table border="1"><tr><td></td><td></td><td></td></tr></table>					TIME: <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> <div>8 - UNK <input type="checkbox"/></div>					Scan or affix barcode label: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> <td>-</td> <td></td><td></td> </tr> </table>							-		
						-															
c. Dried blood spot <i>Collect only for HIV PCR testing</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Reason code: <table border="1"><tr><td></td></tr></table> Other: _____ Other specify code: <table border="1"><tr><td></td><td></td><td></td></tr></table>					TIME: <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> <div>8 - UNK <input type="checkbox"/></div>					Scan or affix barcode label: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> <td>-</td> <td></td><td></td> </tr> </table>							-		
						-															

* Reason codes: 01 = Parent/Guardian refused; 02 = Phlebotomist unable to collect blood; 05 = Child discharged; 07 = Child could not produce specimen; 08 = Unknown; 99 = Other (give other reason or enter the other specify code if available)

SITE LOGO

CRF 06A: CONTROL SPECIMEN COLLECTION: BLOOD, NP/OP, URINE



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PARTICIPANT ID

Date specimens
collected:

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DAY

MONTH

YEAR

3. Were the following samples collected?		Reason, if not collected*	Time of specimen collection (24hr clock)		Specimen ID (barcode label)
a. NPS-VTM	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/>	TIME: <input type="text"/>	8 - UNK <input type="checkbox"/>	Flocked NP swab and OP swab should be put together in one VTM vial (one barcode label only). Scan or affix barcode label: <input type="text"/> - <input type="text"/>
b. OPS	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/>	TIME: <input type="text"/>	8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input type="text"/> - <input type="text"/>
c. NPS-STGG	<input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/>	TIME: <input type="text"/>	8 - UNK <input type="checkbox"/>	Rayon NP swab should be put in STGG vial. Scan or affix barcode label: <input type="text"/> - <input type="text"/>
d. Urine	<input type="checkbox"/> YES, sterile cup <input type="checkbox"/> YES, urine bag <input type="checkbox"/> NO	Reason code: <input type="text"/> Other: _____ Other specify code: <input type="text"/>	TIME: <input type="text"/>	8 - UNK <input type="checkbox"/> Date of urine collection if different from date above: <input type="text"/> Day <input type="text"/> Month <input type="text"/> Year	Scan or affix barcode label: <input type="text"/> - <input type="text"/>

Comments: _____

Supervisor Signature: _____ Staff code: Supervisor Verification Date: Day Month Year

* Reason codes: 01 = Parent/Guardian refused; 02 = Phlebotomist unable to collect blood; 05 = Child discharged; 07 = Child could not produce specimen; 08 = Unknown; 99 = Other (give other reason or enter the other specify code if available)

CRF 07: CASE SPECIMEN COLLECTION: INDUCED SPUTUM

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PARTICIPANT ID

Date form
completed:

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DAY

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YEAR

Do not complete this form if case is in the “modified protocol” category.

- Induced sputum should be collected within 24 hours of admission whenever possible.
- If induced sputum is not collected within 24 hours, a gastric aspirate specimen should be obtained. Attempts should still be made to obtain induced sputum after 24 hours post-admission.

SECTION A – FIRST INDUCED SPUTUM (IS)

1. Was an endotracheal tube (ETT) aspirate collected from an intubated patient? 1 - Yes ☐ 0 - No ☐

[Note: If an endotracheal tube (ETT) aspirate was collected from an intubated patient, skip to question 3]

2. At the initial assessment, does the child have any of the following contraindications to IS collection? 9 - N/A ☐

(N/A should only be selected if the subject died before contraindications could be assessed for specimen collection)

- | | 1 - Yes | 0 - No |
|--|--------------------------|--------------------------|
| a. Oxygen saturation < 92% on supplemental oxygen: | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Inability to protect airways: | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Severe bronchospasm: | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Seizure within the past 24 hours: | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Deemed inappropriate by the clinician for another reason: | <input type="checkbox"/> | <input type="checkbox"/> |

If the answer to any of the above is Yes, do not collect induced sputum at this time. Wait and evaluate the child again at a later point.

	1 - Yes	0 - No	If <u>No</u> , reason not collected (check all that apply):
3. Was IS or ETT aspirate collected <u>within 24 hrs</u> of admission? (If Yes, skip to Q5)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Child met one or more clinical contraindications <input type="checkbox"/> Parent/guardian refused <input type="checkbox"/> Child died prior to collection of specimen <input type="checkbox"/> Other, specify: _____ <input type="checkbox"/> Unknown Code: <table border="1" style="display: inline-table; width: 60px; height: 20px;"></table>
4. Was IS or ETT aspirate collected <u>more than 24 hrs</u> after admission?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Child met one or more clinical contraindications <input type="checkbox"/> Parent/guardian refused <input type="checkbox"/> Child died prior to collection of specimen <input type="checkbox"/> Other, specify: _____ <input type="checkbox"/> Unknown Code: <table border="1" style="display: inline-table; width: 60px; height: 20px;"></table>

CRF 07:

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PARTICIPANT ID

Date form completed:

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YEAR

	1 - Yes	0 - No	If <u>No</u> , reason not collected <i>(check all that apply)</i> :			
5. Was a gastric aspirate specimen collected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Not applicable induced sputum was collected before gastric aspirate was considered <i>(If Not applicable is selected, skip remainder of reasons)</i> <input type="checkbox"/> Child met one or more clinical contraindications <input type="checkbox"/> Parent/guardian refused <input type="checkbox"/> Child died prior to collection of specimen <input type="checkbox"/> Other, specify: _____ <input type="checkbox"/> Unknown <div style="text-align: right;">Code: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td></tr></table></div>			

If no specimen was collected (Q3-5 are 'NO'), this form is complete. Sign and date at end.

- If an ETT aspirate was collected (Q1='Yes'), complete CRF 07ETT.
- If an IS was collected, continue with completion of this form.
- If a Gastric Aspirate was collected (Q5='Yes'), complete CRF 07GA.

6. Was an IS sample collected? ☐ 1 – Yes ☐ 0 - No

First IS collection:

a. Date/time of first IS collection:

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Day

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Month

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Year

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(24 hr clock)

b. IS collection performed by: _____

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Staff Code:

Scan or affix barcode label here:

c. Enter IS specimen ID (barcode label):

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SAFETY MONITORING

7. List any clinical findings that are relevant to this procedure:

8. Was the induced sputum procedure stopped because oxygen saturation levels dropped below 88%?

☐ 1 – Yes ☐ 0 – No ☐ 8 – UNK

CRF 07: CASE SPECIMEN COLLECTION: INDUCED SPUTUM

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PARTICIPANT ID

Date form
completed:

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DAY

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YEAR

9. Record the following clinical measures:

Time point	i. Oxygen requirement (XX.X, L/min) (N/A if not on O ₂)	ii. Oxygen saturation (%)	iii. Respiratory Rate (per minute)	iv. Conscious Level* (check one) A=Alert and awake V= Responds to voice P=Responds to pain U= Unresponsive PS= Pharmacologically sedated										
A. Immediately prior to IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												
B. Immediately following IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												
C. 30 minutes after IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												
D. 2 hours after IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												
E. 4 hours after IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												

*A: Alert & awake
U: Unresponsive

V: Responds to voice
PS: Pharmacologically sedated

P: Responds to pain

CRF 07: CASE SPECIMEN COLLECTION: INDUCED SPUTUM

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PARTICIPANT ID

Date form
completed:

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10. Were any of the following observed <u>within four hours</u> following the induced sputum procedure?	1 - Yes	0 - No	8 - UNK
a. Drop in oxygen saturation below 92%, resulting in increased supply of supplemental oxygen for 10 minutes or more	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. New onset of unconsciousness or prostration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. New requirement for bronchodilator or increased frequency of bronchodilator treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



If any response above is marked Yes, notify the local safety monitor and complete CRF 16 (Case SAE).

CRF 07:PARTICIPANT ID

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YEAR

SECTION B – ADDITIONAL INDUCED SPUTUM

1- Yes

0 -No

(If No, sign and end form.)

a. If Yes, specify reason (check all that apply):

☐ Suspected TB ☐ Treatment failure ☐ Routine

b. Date/time of additional IS collection:

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Year

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(24 hr clock)

c. IS collection performed by:

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Staff Code:

d. Enter IS specimen ID (barcode label):

Scan or affix barcode label:

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SAFETY MONITORING

12. List any clinical findings that are relevant to this procedure:

13. Was the induced sputum procedure stopped because oxygen saturation levels dropped below 88%?

☐ 1 – Yes ☐ 0 – No ☐ 8 - UNK

14. Record the following clinical measures:

Time point	i. Oxygen requirement (XX.X, L/min) (N/A if not on O ₂)	ii. Oxygen saturation (%)	iii. Respiratory Rate (per minute)	iv. Conscious Level* (check one)
A. Immediately prior to IS procedure	<div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div>.</div> <div><div></div></div> </div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – N/A <input type="checkbox"/></div>	<div> <div><div></div><div></div><div></div></div> </div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – NR <input type="checkbox"/></div>	<div> <div><div></div><div></div><div></div></div> </div> <div>8 – UNK <input type="checkbox"/></div> <div>9 - N/A <input type="checkbox"/></div>	<div>0 – A <input type="checkbox"/></div> <div>1 – V <input type="checkbox"/></div> <div>2 – P <input type="checkbox"/></div> <div>3 – U <input type="checkbox"/></div> <div>8 – UNK <input type="checkbox"/></div> <div>9 - PS <input type="checkbox"/></div>

CRF 07: CASE SPECIMEN COLLECTION: INDUCED SPUTUM

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PARTICIPANT ID

Date form
completed:

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Time point	i. Oxygen requirement (XX.X, L/min) (N/A if not on O ₂)	ii. Oxygen saturation (%)	iii. Respiratory Rate (per minute)	iv. Conscious Level* (check one)										
B. Immediately following IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												
C. 30 minutes after IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												
D. 2 hours after IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												
E. 4 hours after IS procedure	<table border="1"> <tr> <td></td> <td></td> <td>.</td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>			.		<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – NR <input type="checkbox"/>				<table border="1"> <tr> <td></td> <td></td> <td></td> </tr> </table> 8 – UNK <input type="checkbox"/> 9 – N/A <input type="checkbox"/>				0 – A <input type="checkbox"/> 1 – V <input type="checkbox"/> 2 – P <input type="checkbox"/> 3 – U <input type="checkbox"/> 8 – UNK <input type="checkbox"/> 9 – PS <input type="checkbox"/>
		.												

*A: Alert & awake
U: Unresponsive

V: Responds to voice
PS: Pharmacologically sedated

P: Responds to pain

CRF 07: CASE SPECIMEN COLLECTION: INDUCED SPUTUM

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PARTICIPANT ID

Date form
completed:

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15. Were any of the following observed <u>within four hours</u> following the second induced sputum procedure?	1 - Yes	0 - No	8 - UNK
a. Drop in oxygen saturation to below 92%, resulting in increased supply of supplemental oxygen for 10 minutes or more	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. New onset of unconsciousness or prostration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. New requirement for bronchodilator or increased frequency of bronchodilator treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



If any response above is marked Yes, notify the local safety monitor and complete CRF 16 (Case SAE).

Comments:

SECTION A:
Form Completed by: _____ **Staff Code:**

Supervisor Signature: _____ **Staff Code:**

Supervisor Verification Date:

DAY
MONTH
YEAR

SECTION B:
Supervisor Signature: _____ **Staff Code:**

Supervisor Verification Date:

DAY
MONTH
YEAR

CRF 07ETT:
CASE SPECIMEN COLLECTION: Endotracheal (ETT) Aspirate

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PARTICIPANT ID

Specimen number:

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Date specimen collected:

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DAY

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MONTH

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YEAR

1. Time of ETT aspirate collection:

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TIME (24 hour clock)

8 - UNK

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2. Specimen collected by Staff Code::

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3. ETT aspirate specimen ID (barcode label):

Scan or affix barcode label:

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Comments: _____

Supervisor Signature: _____

STAFF CODE:

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Day

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Month

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Year

CRF 07GA:
CASE SPECIMEN COLLECTION: GASTRIC ASPIRATE

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PARTICIPANT ID

DATE SPECIMEN
COLLECTED:

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DAY

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MONTH

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YEAR

1. Time of gastric aspirate collection:

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TIME (24 hour clock)

8 - UNK

□

2. Specimen collected by Staff Code:

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3. Gastric aspirate specimen ID (barcode label):

Scan or affix barcode label

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Comments: _____

Supervisor Signature: _____

STAFF CODE:

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Day

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Month

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Year

CRF 08: CASE CXR

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PARTICIPANT ID

Date of CXR:

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MONTH

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YEAR

1. Time of CXR:

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 (24 hour clock) ☐ 9 - N/A (if no CXR taken, skip all questions and sign form at end)
2. Is this the initial or a follow-up CXR? ☐ 1 – Initial ☐ 2 - Follow-up
3. Was an antero-posterior or postero-anterior view image taken? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK
(If NO or UNK, go to Q4)

If Yes, insert specimen ID (barcode label):

Scan or affix barcode label:

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- a. Indicate which view: ☐ 1 – AP ☐ 2 – PA ☐ 8 – UNK
- b. Indicate position: ☐ 1 – Supine ☐ 2 – Upright ☐ 8 – UNK
- c. Captured on inspiration? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK
- d. Quality of image: ☐ 1 – Good ☐ 2 – Fair ☐ 3 – Poor / Uninterpretable ☐ 8 – UNK
4. Was a lateral view image taken? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK
(If No or UNK, go to Q5)

Scan or affix barcode label:

If Yes, insert specimen ID (barcode label):

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- a. Indicate position: ☐ 1 – Supine ☐ 2 – Upright ☐ 8 – UNK
- b. Captured on inspiration? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK
- c. Quality of image: ☐ 1 – Good ☐ 2 – Fair ☐ 3 – Poor / Uninterpretable ☐ 8 – UNK
5. Was a decubitus image taken? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK
(If No or UNK, go to Q6)

Scan or affix barcode label:

If Yes, insert specimen ID (barcode label):

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- a. Captured on inspiration? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK
- b. Quality of image: ☐ 1 – Good ☐ 2 – Fair ☐ 3 – Poor / Uninterpretable ☐ 8 – UNK

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PARTICIPANT ID

Date of CXR:

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YEAR

6. CXR interpretation (*mark all that apply*):

- ☐ a. Normal
☐ b. Abscess
☐ c. Air bronchogram
☐ d. Alveolar infiltrate
☐ e. Atelectasis
☐ f. Bronchial thickening/peribronchial cuffing
☐ g. Cardiomegaly
☐ h. Consolidation

→ i. If checked, do the findings indicate eligibility for lung tap? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

1. If child is eligible for a lung tap, was the procedure done? ☐ 1 – YES ☐ 0 – NO

If No, reason not collected (*check all that apply*):

- ☐ Unknown
☐ Child met one or more clinical contraindications
☐ Parent/guardian refused
☐ Child died prior to collection of specimen
☐ Other, specify: _____

Other code:

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- ☐ i. Hyperinflation
☐ j. Interstitial infiltrate
☐ k. Lymphadenopathy or mass
☐ l. Other abnormalities
☐ m. Pleural effusion
☐ n. Pneumatocoeles
☐ o. Pneumothorax
☐ p. Pulmonary edema
☐ q. Reticulonodular infiltrate
☐ r. Unknown / uninterpretable

CRF 08: CASE CXR

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PARTICIPANT ID

Date of CXR:

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DAY

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MONTH

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YEAR

Optional (For Sites Comparing Site Readings with PERCH Radiology Panel):

7. Is the film quality adequate: ☐ 1 – Adequate ☐ 2 – Suboptimal ☐ 3 – Poor / Uninterpretable ☐ 8 – UNK

8. Does the film contain significant pathology? ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

9. Primary end-point consolidation? Right: ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

Left: ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

10. Other consolidation/infiltrate? Right: ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

Left: ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

11. Pleural fluid? Right: ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

Left: ☐ 1 – YES ☐ 0 – NO ☐ 8 – UNK

12. Conclusion (*check one*):

☐ 1 – Primary end-point consolidation or pleural effusion

☐ 2 – Other consolidation/infiltrate

☐ 3 – No consolidation/infiltrate/effusion

☐ 4 – Uninterpretable

Comments: _____

Form Completed By: _____ **Staff Code:**

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Supervisor Signature: _____ **Supervisor Staff Code:**

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Supervisor Verification Date:

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Day Month Year

CRF 09:

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PARTICIPANT ID

DATE LUNG
ASPIRATE COLLECTED:

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DAY

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MONTH

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YEAR

- 1 - YES

- a. Presence of pneumatocoeles on CXR: ☐
- b. Post measles pneumonia: ☐
- c. Patient determined clinically unstable by a clinician..... ☐
- d. CPR performed within the last 24 hours..... ☐

0 - NO

If the answer to any of the above is Yes, do not collect a lung aspirate at this time.

Wait and evaluate the child again at a later point.

LUNG ASPIRATE

2. Time of lung aspirate collection:

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(24 hour clock)

(24 hour clock)

- | | | | | |
|-----------------------------------|-------------|--|--|--|
| 3. Collection performed by: _____ | STAFF CODE: | | | |
|-----------------------------------|-------------|--|--|--|

STAFF CODE:

Scan or affix barcode label: **9A**

4. Lung aspirate specimen ID (barcode label):

						-		
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Record the following clinical measures:

Record the following clinical measures:				
Time point	i. Oxygen requirement (XX.X, L/min) (N/A if not on O ₂)	ii. Oxygen saturation (%)	iii. Respiratory Rate (per minute) and Haemoptysis	iv. Conscious Level (check one) A=Alert and awake V= Responds to voice P=Responds to pain U= Unresponsive PS= Pharmacologically sedated
A. Immediately prior to LA procedure ____:____	<div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div></div> </div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – N/A <input type="checkbox"/></div>	<div> <div><div></div><div></div><div></div></div> </div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – NR <input type="checkbox"/></div>	<div> <div><div></div><div></div><div></div></div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – N/A <input type="checkbox"/></div> <div>Haemoptysis: Y <input type="checkbox"/></div> <div>N <input type="checkbox"/></div> </div>	<div>0 – A <input type="checkbox"/></div> <div>1 – V <input type="checkbox"/></div> <div>2 – P <input type="checkbox"/></div> <div>3 – U <input type="checkbox"/></div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – PS <input type="checkbox"/></div>
B. Immediately following LA procedure ____:____	<div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div></div> </div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – N/A <input type="checkbox"/></div>	<div> <div><div></div><div></div><div></div></div> </div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – NR <input type="checkbox"/></div>	<div> <div><div></div><div></div><div></div></div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – N/A <input type="checkbox"/></div> <div>Haemoptysis: Y <input type="checkbox"/></div> <div>N <input type="checkbox"/></div> </div>	<div>0 – A <input type="checkbox"/></div> <div>1 – V <input type="checkbox"/></div> <div>2 – P <input type="checkbox"/></div> <div>3 – U <input type="checkbox"/></div> <div>8 – UNK <input type="checkbox"/></div> <div>9 – PS <input type="checkbox"/></div>

CRF 09: CASE SPECIMEN COLLECTION: LUNG ASPIRATE

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PARTICIPANT ID

DATE LUNG
ASPIRATE COLLECTED:

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DAY

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MONTH

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YEAR

Time point	i. Oxygen requirement (XX.X, L/min) (N/A if not on O ₂)	ii. Oxygen saturation (%)	iii. Respiratory Rate (per minute) and <u>Haemoptysis</u>	iv. Conscious Level (check one) A=Alert and awake V= Responds to voice P=Responds to pain U= Unresponsive PS= Pharmacologically sedated												
C. 15 minutes following LA procedure ____:____	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/> Haemoptysis: Y <input type="checkbox"/> N <input type="checkbox"/>					0 - A <input type="checkbox"/> 1 - V <input type="checkbox"/> 2 - P <input type="checkbox"/> 3 - U <input type="checkbox"/> 8 - UNK <input type="checkbox"/> 9 - PS <input type="checkbox"/>
D. 30 minutes following LA procedure ____:____	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/> Haemoptysis: Y <input type="checkbox"/> N <input type="checkbox"/>					0 - A <input type="checkbox"/> 1 - V <input type="checkbox"/> 2 - P <input type="checkbox"/> 3 - U <input type="checkbox"/> 8 - UNK <input type="checkbox"/> 9 - PS <input type="checkbox"/>
E. 2 hours after LA procedure ____:____	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/> Haemoptysis: Y <input type="checkbox"/> N <input type="checkbox"/>					0 - A <input type="checkbox"/> 1 - V <input type="checkbox"/> 2 - P <input type="checkbox"/> 3 - U <input type="checkbox"/> 8 - UNK <input type="checkbox"/> 9 - PS <input type="checkbox"/>
F. 4 hours after LA procedure ____:____	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/> Haemoptysis: Y <input type="checkbox"/> N <input type="checkbox"/>					0 - A <input type="checkbox"/> 1 - V <input type="checkbox"/> 2 - P <input type="checkbox"/> 3 - U <input type="checkbox"/> 8 - UNK <input type="checkbox"/> 9 - PS <input type="checkbox"/>

CRF 09: CASE SPECIMEN COLLECTION: LUNG ASPIRATE

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PARTICIPANT ID

DATE LUNG
ASPIRATE COLLECTED:

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DAY

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MONTH

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YEAR

5. Safety Monitoring: Where any of the following observed <u>within four hours</u> following the lung aspirate procedure?	1 - Yes	0 - No	8 - Unk
a. Drop in oxygen saturation to below 92%, resulting in increased supply of supplemental oxygen for 10 minutes or more	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. New onset of unconsciousness or prostration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. New requirement for bronchodilator or increased frequency of bronchodilator treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Pneumothorax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Significant haemoptysis (>5mls) at any time following lung aspirate, during the hospitalization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Death during hospitalization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



If any response above is marked YES, notify the local safety monitor and complete CRF 16 (Case SAE).

Note: Beyond the first four hours of surveillance, if the child develops a pneumothorax or dies at any time during hospitalization, the event must be reported to the local safety monitor and CRF 16 (Case SAE) must be completed.

Comments: _____

Supervisor Signature: _____

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STAFF CODE

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Day

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Month

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Year

CRF 10:
CASE SPECIMEN COLLECTION: PLEURAL FLUID

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PARTICIPANT ID

Specimen number:

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Date specimen collected:

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DAY

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MONTH

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YEAR

1. Time of pleural fluid collection:

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TIME (24 hour clock)

8 - UNK

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2. Specimen collected by Staff Code:

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3. Pleural fluid specimen ID (*barcode label*):

Scan or affix barcode label:

								-		
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Comments: __________
_____**Supervisor Signature:** _____ **STAFF CODE:**

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Day

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Month

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Year

CRF 11: CASE ADMISSION MEDICATIONS

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PARTICIPANT ID

DATE FORM
COMPLETED:

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DAY

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MONTH

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YEAR

1. Were antibiotics administered at the study hospital on the day of admission? 1-YES 0-NO 8-UNK

If Yes, check all that apply:

	Administered		Mode of Administration		
			1-ORAL	2-PARENTERAL	8-UNK
a. Penicillin	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Amoxicillin (Ampicillin)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Amoxicillin/Clavulanate (Augmentin)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Cotrimoxazole (Bactrim, Septrin)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Cefuroxime (2 nd gen. Cephalosporin)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Ceftriaxone (3 rd gen. Cephalosporin)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Ganciclovir	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Macrolide (Azithromycin, Erythromycin)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Aminoglycoside (Gentamicin)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Chloramphenicol	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Ciprofloxacin (Quinolone)	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Cloxacillin	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. Other antibiotic: _____	<input type="checkbox"/>	If checked →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other code:

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n. Date and time first antibiotic was administered in the study hospital:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DAY	MONTH	YEAR	8-UNK	(24 hour clock)	8-UNK				

Was antibiotic administered before collection of each of the following specimens?

	1-YES	0-NO	8-UNK	9-N/A
o. Blood culture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. NPS-VTM, OPS, NPS-STGG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. Urine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r. Induced sputum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Was a medication to treat influenza administered on the day of admission?

1-YES ☐ 0-NO ☐ 8-UNK ☐

*If Yes, check all that apply:*a. ☐ Oseltamivirb. ☐ Zanamivirc. ☐ Other: *Specify:* _____ Code:

d. Date and time first influenza medication was administered:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DAY	MONTH	YEAR	8-UNK	(24 hour clock)	8-UNK				

CRF 11: CASE ADMISSION MEDICATIONS

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PARTICIPANT ID

DATE FORM
COMPLETED:

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DAY

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MONTH

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YEAR

3. Were steroids administered on the day of admission? 1-YES ☐ 0-NO ☐ 8-UNK ☐
- a. If Yes, specify type: ☐ 1-Oral ☐ 2-Inhaled ☐ 3-Intramuscular ☐ 4-Intravenous 8-UNK ☐

b. Date first dose of steroids was administered:

DAY		MONTH		YEAR			

4. Have bronchodilators been administered on the day of admission? 1-YES ☐ 0-NO ☐ 8-UNK ☐
(as part of bronchodilator challenge or otherwise)

5. Were medications to treat TB administered on the day of admission? 1-YES ☐ 0-NO ☐ 8-UNK ☐

If Yes, check all that apply:

Administered

Mode of Administration?

1-ORAL 2-PARENTERAL 8-UNK

- | | | | | | |
|----------------------------|--------------------------|--------------|--------------------------|--------------------------|--------------------------|
| a. Fixed Drug Combinations | <input type="checkbox"/> | If checked → | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. INH | <input type="checkbox"/> | If checked → | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Ethambutol | <input type="checkbox"/> | If checked → | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Rifampin | <input type="checkbox"/> | If checked → | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Pyrazinamide | <input type="checkbox"/> | If checked → | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f. Other medication: _____ | <input type="checkbox"/> | If checked → | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Other code:

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g. Date first TB medication was administered:

DAY		MONTH		YEAR			

Comments: _____

Form completed by: _____

STAFF CODE:

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Supervisor Signature: _____

STAFF CODE:

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Day		Month		Year			

CRF 12: CASE 24/48-HOUR FOLLOW-UP

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PARTICIPANT ID

DATE FORM
COMPLETED:

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DAY

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MONTH

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YEAR

Complete this form on each of the two days following admission.

1. Check which post-admission assessment is being performed: ☐ 1 - 24 hours ☐ 2 - 48 hours
2. Time of assessment:

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 (24 hour clock)
3. Location of assessment:
☐ 1 - Hospital ☐ 2 - Clinic ☐ 3 - Home
4. Temperature.....

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 °C ☐ 1- Axillary ☐ 2- Rectal ☐ 8-UNK
5. Respiratory rate (# of breaths counted in 60 seconds):

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 per minute ☐ 8-UNK ☐ 9 - N/A
6. Is child on O₂? (if No or UNK, skip to Q7)..... 1-YES ☐ 0-NO ☐ 8-UNK ☐
 a. If Yes, oxygen delivery flow rate:.....

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 L/min ☐ 8-UNK
7. Is child receiving mechanical ventilation?..... 1-YES ☐ 0-NO ☐ 8-UNK ☐
8. Pulse oximetry (on room air whenever possible):

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 % ☐ 8-UNK ☐
 b. Measured when child was on:

<input type="checkbox"/>	1 - O ₂
<input type="checkbox"/>	2 - Room air
<input type="checkbox"/>	8 - UNK

CRF 12: CASE 24/48-HOUR FOLLOW-UP

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PARTICIPANT ID

DATE FORM
COMPLETED:

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DAY

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MONTH

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YEAR

CLINICAL STATUS

9. On exam today, does the child have any of the following signs?

Signs:	1-YES	0-NO	8-UNK
a. Lower chest wall indrawing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Head nodding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Central cyanosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Unable to feed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Vomiting everything	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Lethargy, or unconsciousness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Assessment of consciousness level: If V, P or U are ticked, the child has lethargy or impaired consciousness.

NOTE: wait for >30 minutes after any convulsion before carrying out assessment of consciousness level.

- ☐ 0-A: Alert & awake
☐ 1-V: responds to Voice
☐ 2-P: responds to Pain
☐ 3-U: Unresponsive
☐ 8-UNK
☐ 9 - Pharmacologically sedated

10. Did the child have convulsions since the last assessment?.....1-YES 0-NO 8-UNK
☐ ☐ ☐

a. If Yes, what kind (*check all that apply*)

☐ Multiple (≥ 2 episodes)
 ☐ Prolonged (≥ 15 minutes)
 ☐ Single brief (< 15 minutes)

11. What is the WHO pneumonia severity classification?

<input type="checkbox"/>	1 - Very severe
<input type="checkbox"/>	2 - Severe
<input type="checkbox"/>	3 - Neither
<input type="checkbox"/>	8 - UNK

CRF 12: CASE 24/48-HOUR FOLLOW-UP

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PARTICIPANT ID

DATE FORM
COMPLETED:

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DAY

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MONTH

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YEAR

MEDICATION

12. Has any additional medication for treatment of wheeze been administered since enrollment (other than any bronchodilator challenge doses administered at enrollment)? (If No or UNK, skip to Q13)..... 1-YES ☐ 0-NO ☐ 8-UNK ☐

13. Which antibiotics is the child currently on, including medication added during this assessment? (check all that apply)

Antibiotic:		Mode of administration?		
		1-ORAL	2-PARENTERAL	8-UNK
a.	<input type="checkbox"/> Penicillin	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	<input type="checkbox"/> Amoxicillin (ampicillin)	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c.	<input type="checkbox"/> Amoxicillin & Clavulonate (Augmentin)	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.	<input type="checkbox"/> Cotrimoxizole (Bactrim, Septrin)	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e.	<input type="checkbox"/> Cefuroxime (2 nd gen. Cephalosporin)	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f.	<input type="checkbox"/> Ceftriaxone (3 rd gen. Cephalosporin)	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g.	<input type="checkbox"/> Macrolide (Azithromycin, Erythromycin)	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h.	<input type="checkbox"/> Aminoglycoside (Gentamicin)	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i.	<input type="checkbox"/> Cloxacillin	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j.	<input type="checkbox"/> Chloramphenicol	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k.	<input type="checkbox"/> Ganciclovir	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l.	<input type="checkbox"/> Any Quinolone (specify: _____) <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m.	<input type="checkbox"/> Other antibiotic: _____	If checked, <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>				

14. If antibiotics were changed since last assessment, specify why:

<input type="checkbox"/>	01 - New findings on CXR
<input type="checkbox"/>	02 - Changed to oral antibiotics
<input type="checkbox"/>	03 - Changed because of diagnostic test result
<input type="checkbox"/>	04 - Allergic reaction to medication
<input type="checkbox"/>	05 - Not responding to initial therapy
<input type="checkbox"/>	06 - Stock (out of initial antibiotics)
<input type="checkbox"/>	08 - Unknown
<input type="checkbox"/>	09-N/A
<input type="checkbox"/>	99-Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

CRF 12: CASE 24/48-HOUR FOLLOW-UP

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PARTICIPANT ID

DATE FORM
COMPLETED:

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DAY

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MONTH

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YEAR

15. Was a medication to treat influenza (e.g. oseltamavir) added since the last assessment?

1-YES 0-NO 8-UNK
☐ ☐ ☐

16. Since admission (or last assessment) has the child been started on medication to treat or prevent PCP?

1-YES 0-NO 8-UNK
☐ ☐ ☐

(If Yes, answer questions below ; if No or UNK, skip to Q17)

Why started?

a. Why started? ☐ 1 - PCP preventive therapy (if checked, answer Q16b, skip Q16c and proceed to Q17)

☐ 2 - PCP treatment (if checked, answer both Q16b and Q16c)

b. ☐ Cotrimoxazole (Septrin, Bactrim)

If checked, →

- ☐ 01-Clinical suspicion of PCP
☐ 02-Lab test results suggest PCP
☐ 03-Newly recognized risk factor, e.g. HIV
☐ 04-Prevention of PCP
☐ 08-UNK
☐ 99-Other

Other specify: _____ Code: _____

c. ☐ Corticosteroids

If checked, →

- ☐ 01-Clinical suspicion of PCP
☐ 02-Lab test results suggest PCP
☐ 03-Newly recognized risk factor, e.g. HIV
☐ 08-UNK
☐ 99-Other

Other specify: _____ Code: _____

17. Have any TB meds been started since the last assessment?.....

1-YES 0-NO 8-UNK
☐ ☐ ☐

a. If Yes, why started? (check all that apply)

☐ UNK

☐ Contact history

☐ CXR

☐ Clinical suspicion

☐ TB skin test → i. What is the TST result?

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 mm

☐ Diagnostic test

☐ Other specify: _____ Code:

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Comments: _____

Form completed by: _____

STAFF CODE:

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Supervisor Signature: _____

STAFF CODE:

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Day

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Month

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Year

CRF 13: CASE DISCHARGE

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PARTICIPANT ID

Date form
completed:

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DAY

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MONTH

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YEAR

1. Date of discharge:

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DAY

MONTH

YEAR

2. Discharge status (*check one*):

- ☐ 1 - Discharged home: not moribund
- ☐ 2 - Discharged home: moribund
- ☐ 3 - Left against medical advice: not moribund
- ☐ 4 - Left against medical advice: moribund
- ☐ 5 - Died (skip to Q5 and complete CRF 17 Case Mortality)
- ☐ 6 - Transferred (if transferred, complete Q2a)

a. Reason for transfer?

- ☐ 01 - For higher level facility
- ☐ 02 - To be closer to home
- ☐ 03 - Convalescent care for patient in moribund state (i.e, lower level facility)
- ☐ 08 - UNK
- ☐ 99 - Other, specify: _____ Code:

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3. Respiratory rate (*# of breaths counted in 60 seconds*):

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 per minute 8 - UNK ☐ 9 - N/A ☐

4. Pulse oximetry (*on room air whenever possible - record from digit*):

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 % 8 - UNK ☐

5. Were antibiotics changed since last assessment?

1 - YES ☐ 0 - NO ☐ 8 - UNK ☐

- a. If Yes, why? ☐ New findings on CXR ☐ Not responding to initial therapy ☐ Change from IV to PO medication
- (*Check all that apply*) ☐ Allergic reaction to med ☐ Stock-out of initial antibiotics
- ☐ Other, specify: _____ Code:

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6. Was medication to treat influenza (e.g., oseltamavir) added since last assessment?

1 - YES ☐ 0 - NO ☐ 8 - UNK ☐

7. Were any TB meds started since last assessment?

1 - YES ☐ 0 - NO ☐ 8 - UNK ☐

- a. If Yes, why? ☐ Contact history 8 - UNK ☐
- (*Check all that apply*) ☐ CXR finding

☐ Clinical suspicion

☐ TB skin test If checked → i. What is the TST result?

☐ Diagnostic test

☐ Other, specify: _____ Code:

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 mm 8 - UNK ☐

CRF 13: CASE DISCHARGE

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PARTICIPANT ID

Date form
completed:

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DAY

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MONTH

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YEAR

8. Since last assessment has the child been started on medication to treat or prevent PCP?

1-YES 0-NO 8-UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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If Yes, answer questions below; if No or UNK, skip to Q9)

- a. Why started? ☐ 1 - PCP preventive therapy *(if checked, answer Q8b, skip Q8c and proceed to Q9)*
☐ 2 - PCP treatment *(if checked, answer both Q8b and Q8c)*

- b. ☐ Cotrimoxazole (Septrin, Bactrim)

If checked, →

Why started?

- ☐ 01-Clinical suspicion of PCP
☐ 02-Lab test results suggest PCP
☐ 03-Newly recognized risk factor, e.g. HIV
☐ 04-Prevention of PCP
☐ 08-UNK
☐ 99-Other

Other specify: _____ Code:

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- c. ☐ Corticosteroids

If checked, →

- ☐ 01-Clinical suspicion of PCP
☐ 02-Lab test results suggest PCP
☐ 03-Newly recognized risk factor, e.g. HIV
☐ 08-UNK
☐ 99-Other

Other specify: _____ Code:

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CRF 13: CASE DISCHARGE

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PARTICIPANT ID

Date form
completed:

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DAY

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YEAR

8 - UNK

9. Discharge diagnoses (*check all that apply*):
☐

- | | |
|---|---|
| <input type="checkbox"/> Pneumonia | <input type="checkbox"/> Malaria |
| <input type="checkbox"/> Bronchiolitis (Acute) | <input type="checkbox"/> Malnutrition |
| <input type="checkbox"/> Lower respiratory tract infection | <input type="checkbox"/> Meningitis |
| <input type="checkbox"/> Afebrile seizure disorder | <input type="checkbox"/> Mucocutaneous candidiasis |
| <input type="checkbox"/> Anaemia – cause unknown | <input type="checkbox"/> Neonatal sepsis |
| <input type="checkbox"/> Anaemic heart failure | <input type="checkbox"/> Osteomyelitis (Acute) |
| <input type="checkbox"/> Asthma (Acute) | <input type="checkbox"/> Otitis media |
| <input type="checkbox"/> Birth asphyxia | <input type="checkbox"/> PCP Pneumonia |
| <input type="checkbox"/> Cellulitis | <input type="checkbox"/> Pneumothorax - primary and secondary |
| <input type="checkbox"/> Cerebral palsy | <input type="checkbox"/> Poisoning |
| <input type="checkbox"/> Congenital heart disease (<i>clinically suspected or echo-diagnosed</i>) | |
| <input type="checkbox"/> Congenital abnormality (<i>excluding congenital heart disease</i>) | |
| <input type="checkbox"/> Diarrhoeal disease (Acute) | <input type="checkbox"/> Prematurity |
| <input type="checkbox"/> Dysentery | <input type="checkbox"/> Protein energy malnutrition |
| <input type="checkbox"/> Empyema thoracis | <input type="checkbox"/> Pulmonary TB |
| <input type="checkbox"/> Epilepsy | <input type="checkbox"/> Septic arthritis |
| <input type="checkbox"/> Failure to thrive | <input type="checkbox"/> Septicaemia |
| <input type="checkbox"/> Febrile convulsion (Acute) | <input type="checkbox"/> Sickle cell anaemia |
| <input type="checkbox"/> Gastroenteritis | <input type="checkbox"/> Sickle cell disease |
| <input type="checkbox"/> Helminthiasis | <input type="checkbox"/> Skin sepsis |
| <input type="checkbox"/> HIV | <input type="checkbox"/> Urinary tract infection |
| <input type="checkbox"/> Immunosuppression | <input type="checkbox"/> Upper respiratory tract infection |

☐ Other: _____ Code:

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☐ Other: _____ Code:

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☐ Other: _____ Code:

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CRF 13: CASE DISCHARGE

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PARTICIPANT ID

Date form
completed:

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DAY

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MONTH

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YEAR

10. All other concurrent conditions (*check all that apply*):

- ☐ Pneumonia
☐ Bronchiolitis (Acute)
☐ Lower respiratory tract infection
☐ Afebrile seizure disorder
☐ Anaemia – cause unknown
☐ Anaemic heart failure
☐ Asthma (Acute)
☐ Birth asphyxia
☐ Cellulitis
☐ Cerebral palsy
☐ Congenital heart disease (*clinically suspected or echo-diagnosed*)
☐ Congenital abnormality (*excluding congenital heart disease*)
☐ Diarrhoeal disease (Acute)
☐ Dysentery
☐ Empyema thoracis
☐ Epilepsy
☐ Failure to thrive
☐ Febrile convulsion (Acute)
☐ Gastroenteritis
☐ Helminthiasis
☐ HIV
☐ Immunosuppression

8 - UNK

9 - NONE

☐
☐

- ☐ Malaria
☐ Malnutrition
☐ Meningitis
☐ Mucocutaneous candidiasis
☐ Neonatal sepsis
☐ Osteomyelitis (Acute)
☐ Otitis media
☐ PCP Pneumonia
☐ Pneumothorax - primary and secondary
☐ Poisoning
☐ Prematurity
☐ Protein energy malnutrition
☐ Pulmonary TB
☐ Septic arthritis
☐ Septicaemia
☐ Sickle cell anaemia
☐ Sickle cell disease
☐ Skin sepsis
☐ Urinary tract infection
☐ Upper respiratory tract infection

☐ Other: _____ Code:

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☐ Other: _____ Code:

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☐ Other: _____ Code:

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Comments: _____

Form Completed by: _____ STAFF CODE:

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Supervisor Signature: _____ STAFF CODE:

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Supervisor Verification Date:

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Day

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Month

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Year

CRF 14: CASE 30-DAY FOLLOW-UP AND CONVALESCENT BLOOD

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PARTICIPANT ID

Date of
follow-up:

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DAY

MONTH

YEAR

NOTE: This form does not need to be completed if the child died prior to discharge.

1. Was a follow-up interview conducted? ☐ 1 – Yes ☐ 0 – No

At least two attempts must be made to contact the patient. A phone interview is only acceptable if an in person visit is not possible.

- a. If Yes, location of follow-up:

<input type="checkbox"/>	01 - Facility			
<input type="checkbox"/>	02 - By phone			
<input type="checkbox"/>	03 - At child's home			
<input type="checkbox"/>	08 - UNK			
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1"><tr><td></td><td></td><td></td></tr></table>			

- b. If No, provide reason for no follow-up interview:

<input type="checkbox"/>	01 - Child out-migrated or moved to unknown address			
<input type="checkbox"/>	02 - Child travelled out of study area			
<input type="checkbox"/>	03 - Parent refused			
<input type="checkbox"/>	04 - Unable to locate child during follow-up period			
<input type="checkbox"/>	05 - Child died after discharge			
<input type="checkbox"/>	08 - UNK			
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1"><tr><td></td><td></td><td></td></tr></table>			

2. Who was interviewed? (check all that apply)

<input type="checkbox"/>	Unknown			
<input type="checkbox"/>	Mother			
<input type="checkbox"/>	Father			
<input type="checkbox"/>	Caregiver (non-parent)			
<input type="checkbox"/>	Other relative or household member (non-caregiver)			
<input type="checkbox"/>	Neighbor			
<input type="checkbox"/>	Other, specify: _____ Code: <table border="1"><tr><td></td><td></td><td></td></tr></table>			

3. Child's vital status:

<input type="checkbox"/>	1 - Living
<input type="checkbox"/>	2 - Deceased
<input type="checkbox"/>	8 - UNK

4. Was child observed? (If No, skip to end and sign form) ☐ 1 – Yes ☐ 0 – No ☐ 8 - UNK

CASE 30-DAY FOLLOW-UP AND CONVALESCENT BLOOD

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PARTICIPANT ID

Date of follow-up:

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DAY

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MONTH

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YEAR

- | | | |
|--|---|---|
| 5. Height/length: | <div><div></div><div></div><div></div> . <div></div> cm</div> | 8 - UNK
<div></div> |
| 6. Weight: | <div><div></div><div></div> . <div></div> kg</div> | 8 - UNK
<div></div> |
| 7. Mid upper arm circumference (MUAC) (<i>N/A for children <3 months old</i>): | <div><div></div><div></div><div></div> mm</div> | 8 - UNK <div></div> 9 - N/A <div></div> |
| 8. Respiratory rate (<i># of breaths counted in 60 seconds</i>): | <div><div></div><div></div><div></div> per minute</div> | 8 - UNK <div></div> 9 - N/A <div></div> |
| 9. If in facility, pulse oximetry (<i>on room air whenever possible; record from digit</i>): | <div><div></div><div></div><div></div> %</div> | 8 - UNK <div></div> 9 - N/A <div></div> |

10. Was convalescent blood collected? (plain/red top tube - collect 4mL; minimum 2mL)

☐ 1 – Yes ☐ 0 – No ☐ 8 - UNK

If Yes, complete Q10 a-c and fill out CRF 19

If No, complete Q10d

- a. Date of blood collection:

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*Day**Month**Year*

- | | | | | | |
|------------------------------|--|--|--|--|-----------------|
| b. Time of blood collection: | | | | | (24 hour clock) |
|------------------------------|--|--|--|--|-----------------|

Scan or affix barcode label:

- c. Blood specimen ID (barcode label):

- d. Reason why not?

- ☐ 01 - Parent refused
- ☐ 02 - Phlebotomist unable to collect blood
- ☐ 08 - UNK
- ☐ 99 - Other, specify: _____

Code:

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Question 11 is For HIV-positive cases only: (i.e., HIV-negative)

11. Was EDTA blood obtained for CD4 testing? 1 – YES 0 – NO 8 – UNK 9 – N/A

If Yes, complete Q11a and fill out CRF 19.

If No, complete Q11 b.

Scan or affix barcode label:

- a. EDTA blood specimen ID
(barcode label):

- b. Reason why not?

- ☐ 01 - Parent refused
☐ 02 - CD4 count obtained from Patient Support Center/ART Treatment Clinic
☐ 08 - UNK
☐ 99 - Other, specify: _____ Code:

CRF 15: CASE SPECIMEN COLLECTION: POST-MORTEM LUNG BIOPSY

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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MONTH

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YEAR

☐ Please check this box which confirms that a consent form was signed for the lung biopsy

PERCUTANEOUS NEEDLE BIOPSY

1. Time of postmortem lung biopsy
or pleural aspiration:

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(24 hour clock)

8 - UNK

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2. Death-biopsy (or aspiration) interval in hours:

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8 - UNK

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3. Procedure performed by Staff Code:

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4. Was at least one lung biopsy successfully collected? ☐ 1 -Yes ☐ 0 - No
(If Yes, skip to Q 6 If No, complete questions 5 a-b below and then end form.)

5. Only if unable to take any core biopsies (Q4 is No), attempt pleural aspiration. If antemortem chest x-ray was done, target aspiration from any effusion if present, or area of consolidation.

Was pleural fluid/aspirate taken from:

- a. Right Lung: ☐ 1 - Yes
☐ 0 - No

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- b. Left Lung: ☐ 1 - Yes
☐ 0 - No

Insert barcode number or label:									

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6. What was the site of disease as diagnosed by clinical exam and chest x-ray?

<input type="checkbox"/>	1 - Localised (lobar pneumonia)
<input type="checkbox"/>	2 - Diffuse disease
<input type="checkbox"/>	8 - Unknown

(If 1 – Localised is selected complete Q7. If 2 – Diffuse disease or 8 – Unknown is selected, skip to Q8.)

CRF 15: CASE SPECIMEN COLLECTION: POST-MORTEM LUNG BIOPSY

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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MONTH

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YEAR

7. Sampling Protocol for **Localised (Lobar) Pneumonia**: (To minimize contamination, please collect the samples in the order specified below)

Note: if collection difficult, prioritise 1 sample for microbiology, 1 sample for histology and 1 sample to be stored in RNA later as indicated by underlining below (Sample types b,e,g):

a) Site(s) of Disease (check all that apply)	<input type="checkbox"/> Right Upper Lobe (RUL)	<input type="checkbox"/> Right Middle Lower (RML)	<input type="checkbox"/> Right Lower Lobe (RLL)	<input type="checkbox"/> Left Upper Lobe (LUL)	<input type="checkbox"/> Left Lower Lobe (LLL)
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Sample Type	Tube	Specimen ID (scan barcode label):
<u>b) Microbiology core from a diseased lobe</u> Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M1	Insert barcode number or label: <div style="border: 1px solid black; padding: 5px; display: flex; align-items: center;"> <div style="border: 1px solid black; width: 100px; height: 20px; display: flex;"> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> </div> <div style="margin: 0 10px;">–</div> <div style="border: 1px solid black; padding: 2px 5px;">M</div> <div style="border: 1px solid black; padding: 2px 5px;">1</div> </div>
c) Microbiology core from a diseased lobe Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M2	Insert barcode number or label: <div style="border: 1px solid black; padding: 5px; display: flex; align-items: center;"> <div style="border: 1px solid black; width: 100px; height: 20px; display: flex;"> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> </div> <div style="margin: 0 10px;">–</div> <div style="border: 1px solid black; padding: 2px 5px;">M</div> <div style="border: 1px solid black; padding: 2px 5px;">2</div> </div>
d) Microbiology core from a diseased lobe Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M3	Insert barcode number or label: <div style="border: 1px solid black; padding: 5px; display: flex; align-items: center;"> <div style="border: 1px solid black; width: 100px; height: 20px; display: flex;"> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> </div> <div style="margin: 0 10px;">–</div> <div style="border: 1px solid black; padding: 2px 5px;">M</div> <div style="border: 1px solid black; padding: 2px 5px;">3</div> </div>
<u>e) RNA later sample from a diseased lobe</u> Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube R7	Insert barcode number or label: <div style="border: 1px solid black; padding: 5px; display: flex; align-items: center;"> <div style="border: 1px solid black; width: 100px; height: 20px; display: flex;"> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> </div> <div style="margin: 0 10px;">–</div> <div style="border: 1px solid black; padding: 2px 5px;">R</div> <div style="border: 1px solid black; padding: 2px 5px;">7</div> </div>
f) RNA later sample from a diseased lobe Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube R8	Insert barcode number or label: <div style="border: 1px solid black; padding: 5px; display: flex; align-items: center;"> <div style="border: 1px solid black; width: 100px; height: 20px; display: flex;"> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> <div style="flex: 1;"></div> </div> <div style="margin: 0 10px;">–</div> <div style="border: 1px solid black; padding: 2px 5px;">R</div> <div style="border: 1px solid black; padding: 2px 5px;">8</div> </div>

CRF 15: CASE SPECIMEN COLLECTION: POST-MORTEM LUNG BIOPSY

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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MONTH

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YEAR

Sample Type	Tube	Specimen ID (scan barcode label):										
g) Histology core from a diseased lobe Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube H11	<div style="border: 1px solid black; padding: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">H</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> </tr> </table> </div>							–	H	1	1
						–	H	1	1			
h) Histology core from a diseased lobe Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube H12	<div style="border: 1px solid black; padding: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">H</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">2</td> </tr> </table> </div>							–	H	1	2
						–	H	1	2			
i) Histology core from non-diseased lobe of diseased lung Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube H13	<div style="border: 1px solid black; padding: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">H</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">3</td> </tr> </table> </div>							–	H	1	3
						–	H	1	3			
j) Frozen tissue core from a diseased lobe Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube F16	<div style="border: 1px solid black; padding: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">F</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">6</td> </tr> </table> </div>							–	F	1	6
						–	F	1	6			
k) Microbiology core from non-diseased lung (If right lung is diseased, take core from LUL; if left lung is diseased, take core from RUL) Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M4	<div style="border: 1px solid black; padding: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">4</td> </tr> </table> </div>							–	M	4	
						–	M	4				
l) Microbiology core from non-diseased lung (If right lung is diseased, take core from LUL; if left lung is diseased, take core from RUL) Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M5	<div style="border: 1px solid black; padding: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">5</td> </tr> </table> </div>							–	M	5	
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CRF 15: CASE SPECIMEN COLLECTION: POST-MORTEM LUNG BIOPSY

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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YEAR

Sample Type	Tube	Specimen ID (scan barcode label):										
<p>m) Microbiology core from non-diseased lung (If right lung is diseased, take core from LUL; if left lung is diseased, take core from RUL) Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube M6	<div style="border: 1px solid black; padding: 10px; margin: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">6</td> </tr> </table> </div>							–	M	6	
						–	M	6				
<p>n) RNAlater sample from non-diseased lung (If right lung is diseased, take core from LUL; if left lung is diseased, take core from RUL) Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube R9	<div style="border: 1px solid black; padding: 10px; margin: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">R</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">9</td> </tr> </table> </div>							–	R	9	
						–	R	9				
<p>o) RNAlater sample from non-diseased lung (If right lung is diseased, take core from LUL; if left lung is diseased, take core from RUL) Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube R10	<div style="border: 1px solid black; padding: 10px; margin: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">R</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">0</td> </tr> </table> </div>							–	R	1	0
						–	R	1	0			
<p>p) Histology core from non-diseased lung (If right lung is diseased, take core from LUL; if left lung is diseased, take core from RUL) Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube H14	<div style="border: 1px solid black; padding: 10px; margin: 5px;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">H</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">4</td> </tr> </table> </div>							–	H	1	4
						–	H	1	4			

CRF 15: CASE SPECIMEN COLLECTION: POST-MORTEM LUNG BIOPSY

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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MONTH

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YEAR

Sample Type	Tube	Specimen ID (scan barcode label):										
q) Histology core from non-diseased lung (If right lung is diseased, take core from LUL; if left lung is diseased, take core from RUL) Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube H15	<div style="border: 1px solid black; padding: 10px; margin: 10px auto; width: 80%;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">H</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">5</td> </tr> </table> </div>							–	H	1	5
						–	H	1	5			

8. Sampling protocol for **Diffuse Disease** OR if the site of disease (Q6) is **Unknown**: (To minimize contamination, please collect the samples in the order specified below)

Note: if collection difficult, prioritise 1 sample for microbiology, 1 sample for histology and 1 sample to be stored in RNA later as indicated by underlining below (Sample types a,d,f):

<u>Sample Type</u>	<u>Tube</u>	<u>Specimen ID (scan barcode label):</u>									
<u>a) Microbiology core from RUL</u> Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M1	<div style="border: 1px solid black; padding: 10px; margin: 10px auto; width: 80%;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> </tr> </table> </div>							–	M	1
						–	M	1			
b) Microbiology core from RLL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M2	<div style="border: 1px solid black; padding: 10px; margin: 10px auto; width: 80%;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">2</td> </tr> </table> </div>							–	M	2
						–	M	2			
c) Microbiology core from RUL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M3	<div style="border: 1px solid black; padding: 10px; margin: 10px auto; width: 80%;"> Insert barcode number or label: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">3</td> </tr> </table> </div>							–	M	3
						–	M	3			

CRF 15:

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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MONTH

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YEAR

<u>Sample Type</u>	<u>Tube</u>	<u>Specimen ID (scan barcode label):</u>
<p>d) <u>RNAlater sample from RUL</u></p> <p>Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube R7	<div> <p>Insert barcode number or label:</p> <div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>–</div> <div> <div>R</div> <div>7</div> </div> </div> </div>
<p>e) <u>RNAlater sample from RLL</u></p> <p>Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube R8	<div> <p>Insert barcode number or label:</p> <div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>–</div> <div> <div>R</div> <div>8</div> </div> </div> </div>
<p>f) <u>Histology core from RUL</u></p> <p>Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube H11	<div> <p>Insert barcode number or label:</p> <div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>–</div> <div> <div>H</div> <div>1</div> <div>1</div> </div> </div> </div>
<p>g) <u>Histology core from RML</u></p> <p>Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube H12	<div> <p>Insert barcode number or label:</p> <div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>–</div> <div> <div>H</div> <div>1</div> <div>2</div> </div> </div> </div>
<p>h) <u>Histology core from RLL</u></p> <p>Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube H13	<div> <p>Insert barcode number or label:</p> <div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>–</div> <div> <div>H</div> <div>1</div> <div>3</div> </div> </div> </div>
<p>i) <u>Frozen tissue core from RUL</u></p> <p>Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube F16	<div> <p>Insert barcode number or label:</p> <div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>–</div> <div> <div>F</div> <div>1</div> <div>6</div> </div> </div> </div>

CRF 15: CASE SPECIMEN COLLECTION: POST-MORTEM LUNG BIOPSY

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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MONTH

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YEAR

<u>Sample Type</u>	<u>Tube</u>	<u>Specimen ID (scan barcode label):</u>										
j) Microbiology core from LUL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M4	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Insert barcode number or label: <table style="margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">4</td> </tr> </table> </div>							–	M	4	
						–	M	4				
k) Microbiology core from LLL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M5	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Insert barcode number or label: <table style="margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">5</td> </tr> </table> </div>							–	M	5	
						–	M	5				
l) Microbiology core from LUL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M6	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Insert barcode number or label: <table style="margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">M</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">6</td> </tr> </table> </div>							–	M	6	
						–	M	6				
m) RNAlater core from LUL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube R9	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Insert barcode number or label: <table style="margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">R</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">9</td> </tr> </table> </div>							–	R	9	
						–	R	9				
n) RNAlater core from LLL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube R10	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Insert barcode number or label: <table style="margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">R</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">0</td> </tr> </table> </div>							–	R	1	0
						–	R	1	0			
o) Histology core from LUL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube H14	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Insert barcode number or label: <table style="margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">H</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">4</td> </tr> </table> </div>							–	H	1	4
						–	H	1	4			
p) Histology core from LLL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube H15	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Insert barcode number or label: <table style="margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="width: 10px; text-align: center;">–</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">H</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">1</td> <td style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">5</td> </tr> </table> </div>							–	H	1	5
						–	H	1	5			

SITE LOGO



CRF 15:
CASE SPECIMEN COLLECTION: POST-MORTEM LUNG BIOPSY

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PARTICIPANT ID

DATE OF
LUNG BIOPSY:

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DAY

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MONTH

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YEAR

Comments: _____

Supervisor Signature: _____

STAFF CODE:

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Day

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Month

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Year

CRF 16: CASE SERIOUS ADVERSE EVENT

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PARTICIPANT ID

SAE event number for this child:

 (xx)

1. Date of SAE:

<small>DAY</small>		<small>MONTH</small>		<small>YEAR</small>					

2. Date of birth:

<small>DAY</small>		<small>MONTH</small>		<small>YEAR</small>					

 3. Is this the initial or final report of this SAE? ☐ 1 – Initial ☐ 2 – Final
 (The final report must have "Final" selected.)

8 - UNK

4. Time of SAE onset:

<small>(24 HR)</small>				

5. Did the child have a lung aspirate or was there an attempt to collect this specimen?

☐ 1 - Yes ☐ 0 - No

a. If Yes, date/time:

<small>DAY</small>		<small>MONTH</small>		<small>YEAR</small>				<small>TIME (24 HR)</small>	

6. Did the child have induced sputum collected or was there an attempt to collect this specimen?

☐ 1 - Yes ☐ 0 - No

a. If Yes, date/time:

<small>DAY</small>		<small>MONTH</small>		<small>YEAR</small>				<small>TIME (24 HR)</small>	

7. Specify event and any complications (check all that apply):

Event Description	During the severe pneumonia episode:	Within 4 hrs after lung aspirate:	Within 4 hrs after induced sputum:
a. Death related to PERCH procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Drop in oxygen saturation below 92%, resulting in increased supply of supplemental oxygen for 10 minutes or more	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. New onset of unconsciousness or prostration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. New requirement for bronchodilators or increased frequency of bronchodilator treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Pneumothorax at any time following lung aspirate, during the hospitalization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Significant haemoptysis (> 5 mLs) at any time following lung aspirate, during the hospitalization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Code: <table style="display: inline-table; width: 40px; height: 20px;"></table> <table style="display: inline-table; width: 40px; height: 20px;"></table> <table style="display: inline-table; width: 40px; height: 20px;"></table> <table style="display: inline-table; width: 40px; height: 20px;"></table>			

CRF 16: CASE SERIOUS ADVERSE EVENT

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PARTICIPANT ID

SAE event number for this child:

 (xx)

8. Relatedness to study procedure:
(N/A if study procedure not done)

a. SAE relatedness to lung aspirate:

<input type="checkbox"/>	1 - Definitely related
<input type="checkbox"/>	2 - Probably related
<input type="checkbox"/>	3 - Possibly related
<input type="checkbox"/>	4 - Probably not related/unlikely
<input type="checkbox"/>	5 - Definitely not related

☐ 9 - N/A

b. SAE relatedness to induced sputum:

<input type="checkbox"/>	1 - Definitely related
<input type="checkbox"/>	2 - Probably related
<input type="checkbox"/>	3 - Possibly related
<input type="checkbox"/>	4 - Probably not related/unlikely
<input type="checkbox"/>	5 - Definitely not related

☐ 9 - N/A

c. SAE relatedness to other study procedure:

<input type="checkbox"/>	1 - Definitely related
<input type="checkbox"/>	2 - Probably related
<input type="checkbox"/>	3 - Possibly related
<input type="checkbox"/>	4 - Probably not related/unlikely
<input type="checkbox"/>	5 - Definitely not related

☐ 9 - N/A

i. Specify other study procedure: _____

Code:

d. If Definitely not related, specify probable cause: _____

Code:

9. SAE Severity:

<input type="checkbox"/>	1 - Mild
<input type="checkbox"/>	2 - Moderate
<input type="checkbox"/>	3 - Severe

CRF 16:
CASE SERIOUS ADVERSE EVENT

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PARTICIPANT ID

SAE event number for this child:

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 (xx)

10. SAE outcome at initial reporting: *(check one)*

- ☐ 1 - Resolved
- ☐ 2 - Resolved with sequelae (*explain in comments*)
- ☐ 3 - Continuing (*explain in comments*)
- ☐ 4 - Death
- ☐ 8 – Unknown

Date of death/ Date resolved:

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DAY

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MONTH

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YEAR

11. Is the child continuing to participate in the PERCH study? ☐ 1 - Yes ☐ 0 - No

12. Clinical narrative of SAE: _____

[illegible]

CRF 16:
CASE SERIOUS ADVERSE EVENT

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PARTICIPANT ID

SAE event number for this child:		(xx)
----------------------------------	--	------

ALL SAEs MUST BE FOLLOWED TO RESOLUTION. IF NOT RESOLVED, REASSESS THE SAE UNTIL FINAL RESOLUTION.

13. Final SAE outcome (if different from the initial SAE outcome in Q10): *(check one)*

- ☐ 1 - Resolved
- ☐ 2 - Resolved with sequelae (*explain in comments*)
- ☐ 3 - Continuing (*explain in comments*)
- ☐ 4 – Death
- ☐ 8 - Unknown

Date of death/ Date resolved:

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DAY

MONTH

YEAR

14. SAE final comments: _____

[illegible]

Form Completed By: _____

--	--	--	--

Staffcode

Local Safety Monitor: _____

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Staffcode

Supervisor Signature: _____

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Staffcode

Verification Date:

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DAY

MONTH

YEAR

CRF 17: CASE MORTALITY

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PARTICIPANT ID

DATE OF
DEATH:

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DAY

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MONTH

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YEAR

1 - YES 0 - NO 8 - UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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1. Did the child die at the **study facility**?*If Yes, complete Section A. If No or UNK, skip to Section B.*a. If Yes, where did the child die? ☐ 1 – Kamalapur ☐ 2 – Dhaka Hospital
Section A. Complete this section for deaths that occurred at the study facility.

2. Time of death:

 (24 hour clock) Time 8-UNK ☐ 8 - UNK ☐
3. Indicate the immediate cause of death from the medical record (*check one*):

- | | |
|---|---|
| <input type="checkbox"/> 01 - Pneumonia
<input type="checkbox"/> 02 - Gastorenteritis
<input type="checkbox"/> 03 - Malaria
<input type="checkbox"/> 04 - Dehydration/shock
<input type="checkbox"/> 99 - Other, specify: _____ | <input type="checkbox"/> 05 - Meningitis
<input type="checkbox"/> 06 - Malnutrition
<input type="checkbox"/> 07 - HIV
<input type="checkbox"/> 09 - Sepsis (any cause)
Code: <table border="1" style="display: inline-table; width: 80px; height: 20px; vertical-align: middle;"></table> |
|---|---|

4. Indicate other causes of death listed on the medical record (*check all that apply*): 8 - UNK 9 - NONE

- | | |
|---|---|
| <input type="checkbox"/> Pneumonia
<input type="checkbox"/> Gastorenteritis
<input type="checkbox"/> Malaria
<input type="checkbox"/> Dehydration/shock
<input type="checkbox"/> Other, specify _____ | <input type="checkbox"/> Meningitis
<input type="checkbox"/> Malnutrition
<input type="checkbox"/> HIV
<input type="checkbox"/> Sepsis (any cause)
Code: <table border="1" style="display: inline-table; width: 80px; height: 20px; vertical-align: middle;"></table> |
|---|---|

PERCUTANEOUS LUNG BIOPSY CONSENT

5. Did parent/caregiver give consent for a post-mortem lung biopsy?

8 - UNK

- ☐ 1 - Yes → *If Yes, complete CRF 15 CASE SPECIMEN COLLECTION: LUNG BIOPSY.*
- ☐ 0 - No → *If No, what is parent/caregiver's reason for refusing consent?*

- ☐ 2 - Consent not sought

CRF 17: CASE MORTALITY

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PARTICIPANT ID

DATE OF
DEATH:

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DAY

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MONTH

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YEAR

Section B. Complete this section for deaths that were not known to occur at the study facility.

6. Where did the child die?

8-UNK

☐

<input type="checkbox"/>	01 - Other facility, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>
<input type="checkbox"/>	02 - Home
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

7. Is a death certificate available?

1-YES

0-NO

8-UNK

☐
☐
☐

If Yes, answer Q7a and Q7b, then skip to end. If No or Unk, skip to Q8.

a. Immediate cause of death (check one):

8-UNK

☐
☐ 01 - Pneumonia

☐ 05 - Meningitis

☐ 02 - Gastroenteritis

☐ 06 - Malnutrition

☐ 03 - Malaria

☐ 07 - HIV

☐ 04 - Dehydration/shock

☐ 09 - Sepsis (any cause)

☐ 99 - Other, specify: _____

Code:

b. Other causes of death (check all that apply):

8 - UNK

9 - NONE

☐
☐
☐ Pneumonia

☐ Meningitis

☐ Gastroenteritis

☐ Malnutrition

☐ Malaria

☐ HIV

☐ Dehydration/shock

☐ Sepsis (any cause)

☐ Other, specify: _____

Code:

CRF 17: CASE MORTALITY

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PARTICIPANT ID

DATE OF
DEATH:

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DAY

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MONTH

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YEAR

(Section B continued. Post-discharge Deaths.)
If No death certificate is available (or UNK), answer Q8.

8. Was the family interviewed regarding the cause of death?

1-YES 0-NO 8-UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------

If Yes, ask the parent/caregiver Q8a and Q8b. If No or Unk, skip to Q9.

a. What did the doctor or nurse say was the cause of death? (check all that apply)

9-N/A 8-UNK

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

- | | |
|--|---|
| <input type="checkbox"/> Pneumonia
<input type="checkbox"/> Gastorenteritis
<input type="checkbox"/> Malaria
<input type="checkbox"/> Dehydration/shock | <input type="checkbox"/> Meningitis
<input type="checkbox"/> Malnutrition
<input type="checkbox"/> HIV
<input type="checkbox"/> Sepsis (any cause) |
|--|---|

☐ Other, specify: _____ Code:

☐ Other, specify: _____ Code:

☐ Other, specify: _____ Code:

b. What do you think is the cause of death? (check all that apply)

8-UNK

☐

- | | |
|--|---|
| <input type="checkbox"/> Pneumonia
<input type="checkbox"/> Gastorenteritis
<input type="checkbox"/> Malaria
<input type="checkbox"/> Dehydration/shock | <input type="checkbox"/> Meningitis
<input type="checkbox"/> Malnutrition
<input type="checkbox"/> HIV
<input type="checkbox"/> Sepsis (any cause) |
|--|---|

☐ Other, specify: _____ Code:

☐ Other, specify: _____ Code:

☐ Other, specify: _____ Code:

CRF 17: CASE MORTALITY

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PARTICIPANT ID

DATE OF
DEATH:

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DAY

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MONTH

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YEAR

(Section B continued. Post-discharge Deaths.)

 If No death certificate is available (or UNK), answer Q9.

9. Is cause of death available from another source?

1-YES 0-NO 8-UNK

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------

If Yes, answer Q9a-c. If No or UNK, skip to end.

a. Source (check one) :

08-UNK

☐ 01 - Medical record (from other non-study facility)

☐
☐ 02 - Verbal autopsy

☐ 99 - Other, specify _____ Code:

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b. Immediate cause of death (check one) :

08-UNK

☐ 01 - Pneumonia

☐ 05 - Meningitis

☐ 02 - Gastroenteritis

☐ 06 - Malnutrition

☐ 03 - Malaria

☐ 07 - HIV

☐ 04 - Dehydration/shock

☐ 09 - Sepsis (any cause)

☐ 99 - Other, specify: _____ Code:

--	--	--	--

c. Other causes of death (check all that apply):

8 - UNK

9 - NONE

☐ Pneumonia

☐ Meningitis

☐ Gastroenteritis

☐ Malnutrition

☐ Malaria

☐ HIV

☐ Dehydration/shock

☐ Sepsis (any cause)

☐ Other, specify _____ Code:

--	--	--	--

Comments:

Interviewer's Name: _____

STAFF CODE:

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Supervisor Signature: _____

STAFF CODE:

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--	--

Day

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Month

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Year

CRF 18: STUDY TERMINATION

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PARTICIPANT ID

Date of
termination

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DAY

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MONTH

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YEAR

This form should be completed for all children who terminate the PERCH study early. Complete this form when their participation has ended. This form should be completed only once for each child.

1. Did the child complete all applicable study protocol assessments? ☐ 1 – YES ☐ 0 - NO

a. If No, indicate the reason(s) the child terminated the study early: *(check all that apply)*

<input type="checkbox"/>	Primary caregiver withdrew consent
<input type="checkbox"/>	Died
<input type="checkbox"/>	Failure to comply with study regulations
<input type="checkbox"/>	Moved from the area
<input type="checkbox"/>	Could not locate for follow up
<input type="checkbox"/>	Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table>
<input type="checkbox"/>	8 - UNK

Comments: _____

Form completed by: _____ Staff code:

Supervisor signature: _____ Staff code:

Supervisor verification date:

Day

Month

Year

CRF 19:
LAB: SPECIMEN RECEPTION

DATE
SPECIMEN
RECEIVED

DAY

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MONTH

YEAR			

1. Specimen ID (barcode label):

Scan or Affix Barcode Label

						-		
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2. Specimen Type (check **one**):

<input type="checkbox"/>	1A - Blood Culture Bottle	<input type="checkbox"/>	2A - 30 Day Follow up Plain Tube	<input type="checkbox"/>	6A - Gastric Aspirate
<input type="checkbox"/>	1B - Plain/ Red Top Tube	<input type="checkbox"/>	2B - 30 Day Follow up EDTA (CD4)	<input type="checkbox"/>	6B - Second Gastric Aspirate
<input type="checkbox"/>	1C - EDTA <i>case</i> tube #1	<input type="checkbox"/>	3A - NP STGG Swab	<input type="checkbox"/>	6C - Third Gastric Aspirate
<input type="checkbox"/>	1D - EDTA <i>case</i> tube #2	<input type="checkbox"/>	3B - NP VTM and OP Swab	<input type="checkbox"/>	7A - Urine
<input type="checkbox"/>	1E - EDTA <i>control</i> tube #1	<input type="checkbox"/>	3B - NP VTM Swab ONLY	<input type="checkbox"/>	7B - 30 Day Follow up Urine
<input type="checkbox"/>	1F - EDTA <i>control</i> tube #2	<input type="checkbox"/>	3B - OP Swab ONLY	<input type="checkbox"/>	8A - Pleural Fluid
<input type="checkbox"/>		<input type="checkbox"/>	4A - Induced Sputum	<input type="checkbox"/>	8B - Second Pleural Fluid
<input type="checkbox"/>	1H - Malaria Slide	<input type="checkbox"/>	4B - Second Induced Sputum	<input type="checkbox"/>	9A - Lung Aspirate
<input type="checkbox"/>	1I - HIV Rapid Test	<input type="checkbox"/>	5A - ETT Specimen	<input type="checkbox"/>	6D - Fourth Gastric Aspirate
<input type="checkbox"/>	1J - Dried Blood Spot	<input type="checkbox"/>	5B - Second ETT Specimen	<input type="checkbox"/>	6E - Fifth Gastric Aspirate

3. Time received in laboratory:

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TIME (24 hour clock)

4. Specimen volume:

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 μ l ☐ N/A (for blood culture, dried blood spot, NP/OP swabs, and slides only)

**CRF 19:
LAB: SPECIMEN RECEPTION**DATE
SPECIMEN
RECEIVED

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DAY

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MONTH

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YEAR

5. Status: ☐ Accepted for processing☐ Rejected – specify reason below (check all that apply):Contact clinic
immediately if
any apply.☐

a. Specimen unlabeled

☐

b. Specimen ID does not match ID on requisition form

☐

c. Blood is hemolyzed or anti-coagulated specimen contains clots

☐

d. Specimen container is leaking

☐

e. Other, specify: _____

--	--	--

CODE

6. Was specimen transported under appropriate conditions and time frame?

☐ Yes☐ No☐ UNK

7. Person Receiving Specimen Staff Code:

--	--	--	--

Comments: _____

Supervisor Staff Code:

--	--	--	--

Supervisor Verification Date:

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Day

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Month

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Year

CRF 19PM:

LAB: SPECIMEN RECEPTION – POST-MORTEM SPECIMENS

DATE
SPECIMEN
RECEIVED

DAY

DAY

MONTH		

MONTH

YEAR			

YEAR

1. Specimen ID (barcode label):

Scan or Affix Barcode Label

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-

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2. Specimen Type (check **one**):

<input type="checkbox"/>	M1 – Microbiology Core 1	<input type="checkbox"/>	H11 – Histology Core 1
<input type="checkbox"/>	M2 – Microbiology Core 2	<input type="checkbox"/>	H12 – Histology Core 2
<input type="checkbox"/>	M3 – Microbiology Core 3	<input type="checkbox"/>	H13 – Histology Core 3
<input type="checkbox"/>	M4 – Microbiology Core 4	<input type="checkbox"/>	H14 – Histology Core 4
<input type="checkbox"/>	M5 – Microbiology Core 5	<input type="checkbox"/>	H15 – Histology Core 5
<input type="checkbox"/>	M6 – Microbiology Core 6	<input type="checkbox"/>	F16 – Frozen Tissue Sample
<input type="checkbox"/>	R7 – RNAlater Sample 1	<input type="checkbox"/>	PR – Pleural Aspirate – Right Lung
<input type="checkbox"/>	R8 – RNAlater Sample 2	<input type="checkbox"/>	PL – Pleural Apsirate – Left Lung
<input type="checkbox"/>	R9– RNAlater Sample 3		
<input type="checkbox"/>	R10 – RNAlater Sample 4		

3. Time received in laboratory:

--	--	--	--

TIME (24 hour clock)

4. Specimen volume:

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 μl

Volume should be recorded for the pleural aspirates only.

**CRF 19PM:
LAB: SPECIMEN RECEPTION – POST-MORTEM SPECIMENS**DATE
SPECIMEN
RECEIVED

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DAY

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MONTH

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YEAR5. Status: ☐ 1 - Accepted for processing☐ 2 - Rejected – specify reason below (check all that apply):*Contact study
personnel
immediately if
any apply*

- a. Specimen unlabeled
- b. Specimen ID does not match ID on requisition form
- c. Specimen container is leaking
- d. Other, specify:

--	--	--

CODE

6. Was specimen transported under appropriate conditions and time frame?

☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

7. Person Receiving Specimen Staff Code:

--	--	--	--

Comments: _____

Supervisor Staff Code:

--	--	--	--

Supervisor Verification Date:

--	--

Day

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Month

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Year

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

Scan / Affix barcode label:

						-		
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NOT DONE:
Stop here and end form

1. Specimen ID (barcode label):

2. a. Date/time the blood culture bottle was placed in BACTEC / BacT/ALERT:

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DAY

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MONTH

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YEAR

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TIME (24 hour clock)

- b. Technician's Staff Code:

--	--	--	--

3. Sample volume:

- a. Weight of bottle prior to specimen collection:

--	--	--

 .

--	--

 grams

--	--	--

[illegible]

- b. Weight of bottle after collection / at time of reception in lab:

 .

 grams

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- #### 4. Results reporting:

- a. Alarm positive? ☐ 1 - YES ☐ 0 – NO, negative at 5 days (stop here and end form)

5. Time to positive (from blood culture machine):

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 hrs

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hrs

6. Description of any organism by Gram stain of blood culture broth (*check all that apply*):

Gram stain performed: ☐ 1 - YES. ☐ 0 - NO

☐ 1 - YES.☐ 0 - NO

a.	No organisms seen	<input type="checkbox"/>
b.	Gram-negative rods (GNR)	<input type="checkbox"/>
c.	Gram-positive cocci in clusters (GPC clusters)	<input type="checkbox"/>
d.	Gram-negative coccobacilli (GNCB)	<input type="checkbox"/>
e.	Gram-positive cocci in chains (GPC chains)	<input type="checkbox"/>
f.	Gram-negative diplococci (GNDC)	<input type="checkbox"/>
g.	Gram-positive cocci single cells (GPC singles)	<input type="checkbox"/>
h.	Gram-negative cocci (GNC)	<input type="checkbox"/>
i.	Gram-positive rods (GPR)	<input type="checkbox"/>
j.	Gram-positive diplococci (GPDC)	<input type="checkbox"/>
k.	Yeasts or other fungal elements	<input type="checkbox"/>

CRF 20: LAB RESULT: BLOOD CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

Reminder: Binax result should be performed only on samples that are:

- *BACTEC or BacT/ALERT alarm positive, gram stain negative, and sub-culture negative (no growth on 24 hour plates)*

-or-

- *BACTEC or BacT/ALERT alarm positive, streptococci positive on gram stain, and sub-culture negative (no growth on 24 hour plates)*

7. Binax result (check one): ☐ 1- Positive ☐ 2 – Negative ☐ 3 – Indeterminate ☐ 9 - Not done

8. Description of sub-culture growth results: ☐ 1 - Growth ☐ 2 - No growth
(If no growth, stop here and end form.)

9. Organism identification:

Organism Code	Isolate ID (barcode label) N/A <u>ONLY</u> if organism is a contaminant	Organism Confirmation C - Confirmed U - Updated NC - Not Confirmed												
a. Organism 1 <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td></tr></table>					<div style="border: 1px solid black; padding: 5px; text-align: center;">Scan/Affix Barcode Label</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="text-align: right; margin-top: 5px;">9 – N/A <input type="checkbox"/></div>									<input type="checkbox"/> 1 - C <input type="checkbox"/> 2 - U <input type="checkbox"/> 3 - NC
b. Organism 2 <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td></tr></table>					<div style="border: 1px solid black; padding: 5px; text-align: center;">Scan/Affix Barcode Label</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="text-align: right; margin-top: 5px;">9 – N/A <input type="checkbox"/></div>									<input type="checkbox"/> 1 - C <input type="checkbox"/> 2 - U <input type="checkbox"/> 3 - NC
c. Organism 3 <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td></tr></table>					<div style="border: 1px solid black; padding: 5px; text-align: center;">Scan/Affix Barcode Label</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td> <td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td> </tr> </table> <div style="text-align: right; margin-top: 5px;">9 – N/A <input type="checkbox"/></div>									<input type="checkbox"/> 1 - C <input type="checkbox"/> 2 - U <input type="checkbox"/> 3 - NC

CRF 20: LAB RESULT: BLOOD CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

10. Antibiotic Susceptibility Testing:Note: 1: **S** = Susceptible; 2: **I** = Intermediate; 3: **R** = Resistant

	Organism 1		Organism 2		Organism 3	
Antibiotic code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:
a. AMC (Amoxicillin / Clavulanic acid)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
b. AMP (Ampicillin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
c. CAZ (Ceftazidime)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
d. CH (Chloramphenicol)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
e. CIP (Ciprofloxacin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
f. CN (Gentamicin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
g. CRO (Ceftriaxone)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
h. CTX (Cefotaxime)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
i. DA (Clindamycin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
j. ERY (Erythromycin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
k. FOX (Cefoxitin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
l. IPM (Imipenem)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
m. OX (Oxacillin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
n. P (Penicillin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
o. SXT (Cotrimoxazole)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
p. TET (Tetracycline)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
q. VA (Vancomycin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
r. Other: _____ Code: <table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
s. Other: _____ Code: <table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
t. Other: _____ Code: <table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
u. Beta lactamase	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative	

CRF 20: LAB RESULT: BLOOD CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

11. MIC Etest® results for *S. pneumoniae* isolates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

MIC Etest® performed? ☐ 1 - YES ☐ 0 - No ☐ 9 - N/A (If No or N/A, skip to Question 12)

a. Penicillin Etest® results ☐ < ☐ >

 .

 $\mu\text{g/mL}$

b. ☐ Ceftriaxone or ☐ Cefotaxime (choose one) ☐ < ☐ >

 .

 $\mu\text{g/mL}$

c. Clindamycin Dtest® results ☐ 1- Positive ☐ 2 - Negative

12. Screening for Extended Spectrum β -Lactamase (ESBL) Production done?

☐ 1 - YES ☐ 0 - NO

- a. If Yes, results of additional phenotypic testing:

☐ 1 - ESBL confirmed ☐ 2 - ESBL not confirmed

13. MIC Etest® results for *S. aureus* isolates that are resistant (R) or intermediate (I) to cefoxitin disk diffusion testing.

MIC Etest® performed? ☐ 1 - YES ☐ 0 - No ☐ 9 - N/A

a. Vancomycin Etest® results ☐ < ☐ >

 .

 $\mu\text{g/mL}$

b. Clindamycin Dtest® results ☐ 1- Positive ☐ 2 - Negative

14. Was *S. pneumoniae* isolated?

☐ 1 - YES ☐ 0 - NO

If Yes, what serotypes were identified:

a.

b.

c.

d.

**CRF 20:
LAB RESULT: BLOOD CULTURE**

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

15. Was *H. influenza* isolated?☐ 1 – YES ☐ 0 – NO

If Yes, what serotype was identified:

a.

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Comments:

Technician Reporting Final Results Staff Code:

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Supervisor Staff Code:

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Supervisor Verification Date:

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Day Month Year

CRF 21:

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Year

CRF 22:
LAB RESULT: ANTIBIOTIC ACTIVITY

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Page 1 of 1

CRF 23: LAB RESULT: CORE BLOOD TESTS

CBC

South Africa only - Date and time received in laboratory:

<i>DAY</i>		<i>MONTH</i>		<i>YEAR</i>				<i>TIME (24 hour clock)</i>			

NOT DONE:
Skip to next section

1. Date of test:

<i>DAY</i>		<i>MONTH</i>		<i>YEAR</i>			

2. Specimen ID (barcode label):

Scan or Affix Barcode Label

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3. Technician's Staff Code:

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4. CBC Results

Controls:					
Variable:	Result:	Units:	Result:	Units:	
a. Hemoglobin	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	g/dL	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	g/dL	N/A <div style="border: 1px solid black; width: 20px; height: 20px;"></div>
b. Hematocrit	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			
c. MCV	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	fL			
d. MCH	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	Pg			
e. MPV	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	fL			
f. Platelets	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	x10 ³ /μL			
g. WBC	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	x10 ³ /μL			
h. Neutrophils	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			
i. Lymphocytes	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			
j. Monocytes	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			
k. Eosinophils	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			
l. Basophils	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			
m. Band Cells	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			
n. RBC	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	x10 ⁶ /μL			
o. MCHC	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	g/dL			
p. Reticulocytes	<div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> . <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	%			

CRF 23: LAB RESULT: CORE BLOOD TESTS

HIV ANTIBODY TEST

If HIV antibody test not done, indicate the reason why:

- ☐ 1 – Child known to be positive
 ☐ 2 – Testing was refused
 ☐ 9 – Other

Other, specify: _____ Other code:

5. Date of test:

DAY

MONTH

YEAR

6. Specimen ID (barcode label):

Scan or Affix Barcode Label:

–

Same as Above

7. Technician's name: _____ Staff Code:

8. HIV antibody test final result:
 ☐ 1 - Positive ☐ 2 - Negative

 ☐ 3 – Indeterminate ☐ 4 - Invalid

- a. If positive, is the child <18 months old? ☐ 1 - Yes ☐ 0 - No
(If Yes, HIV PCR test should be done.)

HIV PCR TEST

(for HIV antibody-positive children less than 18 months old)

9. Date of test:

DAY

MONTH

YEAR

10. PCR test result: ☐ 1 - Positive ☐ 2 - Negative

11. Technician's Staff Code:

CD4 TEST

12. Date of test:

DAY

MONTH

YEAR

13. CD4 test result:

a. Absolute count: cells/μL ☐ 9 - Not done

b. CD4 percent: . % ☐ 9 - Not done

14. Technician's Staff Code:

NOT DONE:
If applicable, indicate
reason not done and
then skip to next section

NOT DONE:
Skip to next section

NOT DONE:
Skip to Q15

SICKLE CELL TEST [THALASSEMIA TESTING for Thailand]

<i>DAY</i>	<i>MONTH</i>	<i>YEAR</i>	

Scan or Affix Barcode Label:

7

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☐ 1 – Positive ☐ 2 - Negative ☐ 9 - N/A

☐ 01 - AA ☐ 02 - AF ☐ 03 - AS ☐ 04 - EA ☐ 05 - EF ☐ 06 - SC

☐ 07 - SS ☐ 08 - A₂A ☐ 10 - EE ☐ 11 - EFA ☐ 12 - C A₂A H ☐ 13 - A₂F☐ 14 -A₂FA ☐ 15 - A₂A H ☐ 16- AE Barts ☐ 17- AC ☐ 99 – Other, specify _____Other code:

--	--	--

A	<input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="text"/> 9 – N/A	F	<input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="text"/> 9 – N/A
A2	<input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="text"/> 9 – N/A	Cs	<input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="text"/> 9 – N/A
E	<input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="text"/> 9 – N/A	H	<input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="text"/> 9 – N/A

MALARIA TESTING

<i>DAY</i>		<i>MONTH</i>		<i>YEAR</i>	

7

Scan or Affix Barcode Label

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CRF 23: LAB RESULT: CORE BLOOD TESTS

22. Type of Test (check one. If both tests were done, check the one that was done first.):

☐ 1 – Rapid Antigen Detection ☐ 2 - Microscopy

a. Test result: ☐ 1 – Positive ☐ 2 - Negative

23. a: If Positive, species ☐ Speciation not done, skip to next section

1 - Yes 0 - No

i. *P. falciparum* ☐ ☐

ii. *P. vivax* ☐ ☐

iii. *P. ovale* ☐ ☐

iv. *P. malariae* ☐ ☐

b: Quantification ☐ 9 – Not done

i. Parasitaemia

☐ 1 - per 200 WBC

☐ 2 - per 500 WBC

ii. Density / μ L

☐ 1 - using white cell count

☐ 2 - using red blood cell count

CRP TESTING

24. Date of test:

DAY

MONTH

YEAR

**NOT DONE:
End Form**

☐

25. Specimen ID (barcode label):

Scan or Affix Barcode Label

 -

Same as Above

☐

26. Technician's Staff Code:

27. Test result: . mg/L

30 DAY FOLLOW-UP CD4 TEST

28. Date of test:

DAY

MONTH

YEAR

29. CD4 test result:

a. Absolute count: cells/ μ L ☐ 9 - Not done

b. CD4 percent: . % ☐ 9 - Not done

**CRF 23:
LAB RESULT: CORE BLOOD TESTS**30. Technician's Staff Code:

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Comments: _____

_____**Supervisor Staff Code:**

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Day

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Month

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Year

CRF 24: LAB RESULT: NP CULTURE

DATE FORM
INITIATED:

DAY

MONTH

YEAR

Scan or affix barcode label:

 -

1. Specimen ID:

2. Date / time put up for culture:

DAY

MONTH

YEAR

TIME (24 hour clock)

Identification of pneumococcal colonies	a. If yes, optochin zone diameter (mm):	b. Bile soluble? (only do if optochin zone is 9-13mm)	Serotype (skip if not yet available)	c. Isolate ID (barcode label):
3. Was a pneumococcal colony identified? (if no, end form) <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
4. Was a second pneumococcal colony identified? (if no, end form) <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
5. Was a third pneumococcal colony identified? (if no, end form) <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
6. Was a fourth pneumococcal colony identified? (if no, end form) <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>

Comments:

Supervisor STAFF CODE:

DAY

MONTH

YEAR

CRF 25: LAB RESULT: MULTIPLEX PCR

DATE FORM
INITIATED:

DAY

MONTH

YEAR

Specimen number:

**NOT DONE:
Stop here and end form**

1. Date of nucleic acid extraction:

DAY

MONTH

YEAR

Scan or affix barcode label:

2. Nucleic acid extract aliquot ID:

 -

3. Technician who performed extraction:

STAFF CODE

4. Specimen type (check one):

- ☐ 01 - NP flocked swab/OP swab
 ☐ 02 - Induced sputum
 ☐ 03 - Lung aspirate
☐ 04 - NP flocked swab only
 ☐ 05 - ETT aspirate
 ☐ 07 - OP swab only
☐ 08 - Pleural fluid
 ☐ 09 - M2: Microbiology Core 2
 ☐ 10 - M5: Microbiology Core 5
☐ 11 - PR: Pleural Aspirate Right Lung
☐ 12 - PL: Pleural Aspirate Left Lung

5. Date of PCR Run:

DAY

MONTH

YEAR

**NOT DONE:
Stop here and end form**

6. Technician who performed run Staff Code:

Comments: _____

Supervisor Staff Code:

Day

Month

Year

CRF 26:

LAB RESULT: INDUCED SPUTUM MICRO-CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

Quality Assessment and Gram Stain

1. a. Date:

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 b. Time:

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DAY

MONTH

YEAR

TIME (24 HR)

2. Specimen ID (barcode label):

Scan or affix barcode label:

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NOT DONE:

Stop here and end form

--

3. Specimen type:

☐ 1 - Induced sputum ☐ 2 - ETT aspirate
4. Technician's Staff Code:

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5. Number of neutrophils per representative low powered field (x10 objective)? (check one)

1 - <10 ☐2 - 10-25 ☐3 - >25 ☐

6. Mucus seen? (check one)

1 - Yes ☐0 - No ☐

7. Number of epithelial cells per representative low powered field (x10 objective)? (check one)

1 - <10 ☐2 - 10-25 ☐3 - >25 ☐

Induced Sputum Gram Stain

8. Description of any organism by Gram stain:

Check the appropriate quantification box for Q8a-j below.

If no organisms were seen, check here and skip to Q9: ☐ No organisms seen (NOS)

	Organism	Not Seen	Scanty	1+	2+	3+
a.	Gram-negative rods (GNR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	Gram-positive cocci in clusters (GPC clusters)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c.	Gram-negative coccobacilli (GNCB)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.	Gram-positive cocci in chains (GPC chains)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e.	Gram-negative diplococci (GNDC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f.	Gram-positive cocci single cells (GPC singles)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g.	Gram-negative cocci (GNC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h.	Gram-positive rods (GPR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i.	Gram-positive diplococci (GPDC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j.	Yeasts or other fungal elements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CRF 26:

LAB RESULT: INDUCED SPUTUM MICRO-CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

Culture of Induced Sputum

9. Date/time put up for culture:

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DAY

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MONTH

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YEAR

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(24 hour clock)

10. Technician's Staff Code:

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11. Final culture result: ☐ 1 - Growth (proceed) ☐ 2 - No growth (Stop here and end form)

12. Organism identification and quantification:

Organism Code	Quantity (Select One)	Isolate ID (barcode label):	Organism Confirmation (Check one): C – Confirmed U – Updated NC – Not Confirmed													
a. Oropharyngeal flora	<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1+ <input type="checkbox"/> 2+ <input type="checkbox"/> 3+ <input type="checkbox"/> 0 - None	N/A														
b. Organism 1 <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1+ <input type="checkbox"/> 2+ <input type="checkbox"/> 3+	Scan or affix barcode label: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> <td>–</td> <td></td><td></td> </tr> </table>							–			<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
						–										
c. Organism 2 <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1+ <input type="checkbox"/> 2+ <input type="checkbox"/> 3+	Scan or affix barcode label: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> <td>–</td> <td></td><td></td> </tr> </table>							–			<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
						–										
d. Organism 3 <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1+ <input type="checkbox"/> 2+ <input type="checkbox"/> 3+	Scan or affix barcode label: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> <td>–</td> <td></td><td></td> </tr> </table>							–			<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
						–										
e. Organism 4 <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1+ <input type="checkbox"/> 2+ <input type="checkbox"/> 3+	Scan or affix barcode label: <table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> <td>–</td> <td></td><td></td> </tr> </table>							–			<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
						–										

CRF 26:

LAB RESULT: INDUCED SPUTUM MICRO-CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

13. Antibiotic Susceptibility Testing:

Note: 1: S = Susceptible; 2: I = Intermediate; 3: R = Resistant

	Organism 1		Organism 2		Organism 3		Organism 4					
Antibiotic Code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:				
a. AMC (Amoxicillin / Clavulanic acid)												
b. AMP (Ampicillin)												
c. CAZ (Ceftazidime)												
d. CH (Chloramphenicol)												
e. CIP (Ciprofloxacin)												
f. CN (Gentamicin)												
g. CRO (Ceftriaxone)												
h. CTX (Cefotaxime)												
i. DA (Clindamycin)												
j. ERY (Erythromycin)												
k. FOX (Cefoxitin)												
l. IPM (Imipenem)												
m. OX (Oxacillin)												
n. P (Penicillin)												
o. SXT (Cotrimoxazole)												
p. TET (Tetracycline)												
q. VA (Vancomycin)												
r. Other: _____ Code: <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>												
s. Other: _____ Code: <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>												
t. Other: _____ Code: <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>												
u. Beta lactamase	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative					

CRF 26:

LAB RESULT: INDUCED SPUTUM MICRO-CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

14. MIC Etest® results for *S. pneumoniae* isolates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

MIC Etest® performed? ☐ 1 - Yes ☐ 0 - No ☐ 9 - N/A (If No or N/A, skip to Question 15)

a. Penicillin Etest® results: ☐ < ☐ >

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 µg/mL

b. Ceftriaxone ☐ or Cefotaxime ☐ (choose one) ☐ < ☐ >

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 .

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 µg/mL

15. Screening for Extended Spectrum β-Lactamase (ESBL) Production done?

☐ 1 - Yes ☐ 0 - No

a. If Yes, results of additional phenotypic testing:

☐ 1 - ESBL confirmed ☐ 2 - ESBL not confirmed

16. Was *S. pneumoniae* isolated?

☐ 1 - Yes ☐ 0 - No

If Yes, what serotypes were identified:

a.

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b.

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c.

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d.

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17. Was *H. influenza* isolated?

☐ 1 - Yes ☐ 0 - No

If Yes, what serotype was identified:

a.

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SITE LOGO

CRF 26:
LAB RESULT: INDUCED SPUTUM MICRO-CULTURE

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PARTICIPANT ID

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

Comments:

Technician Reporting Final Results Staff Code:

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Supervisor Staff Code:

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Supervisor Verification Date:

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Day Month Year

CRF 27:
LAB RESULT: TB TESTING

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DAY	MONTH	YEAR	

Specimen type *(select one)*:

- ☐ 01 - Initial induced sputum ☐ 02- Pleural fluid ☐ 03 - Gastric aspirate
☐ 04 - ETT specimen ☐ 05 - Lung aspirate ☐ 07 - Second induced sputum
☐ 08 - Second pleural fluid ☐ 09 - Second gastric aspirate ☐ 10 - Second ETT specimen
☐ 11 - Third gastric aspirate ☐ 12 - Fourth gastric aspirate ☐ 13 - Fifth gastric aspirate
☐ 14 - M3: Microbiology Core 3 ☐ 15 - M6: Microbiology Core 6
☐ 16 - PR: Pleural Aspirate Right Lung
☐ 17 - PL: Pleural Aspirate Left Lung

1. Date tested or sent to reference lab:

Day		Month		Year			

2. Specimen ID (scan barcode label):

Scan or affix barcode label:

						-		
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3. Technician's staff code:

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4. Volume of specimen sent for TB staining and culture:						μL
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ACID-FAST BACILLI SMEAR

5. Results (select one):

<input type="checkbox"/>	1 – Negative	No AFB per 100 oil immersion fields
<input type="checkbox"/>	2 – Scanty	1-9 AFB per 100 oil immersion fields --- If Scanty, enter # of AFB <input type="text"/>
<input type="checkbox"/>	3 – Positive 1+	10-99 AFB per 100 oil immersion fields
<input type="checkbox"/>	4 – Positive 2+	1-10 AFB per oil immersion field
<input type="checkbox"/>	5 – Positive 3+	>10 AFB per oil immersion field
<input type="checkbox"/>	6 – Not Done	Microscopy not done

CULTURE

☐ Culture not done (*skip to end*)

6. *Mycobacterium tuberculosis* isolated? ☐ 1 - Yes ☐ 0 – No ☐ 2 –Contaminated specimen

7. Other mycobacterium isolated? ☐ 1 - Yes ☐ 0 - No ☐ 2 –Contaminated specimen

a - b. If Yes, enter the following information:

Organism Code	
a.	<div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; align-items: center;"> <div style="flex: 1;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="margin-left: 20px;">Specimen ID (scan or affix barcode label):</div> </div> <div style="margin-top: 10px;"> <div style="display: flex; align-items: center;"> <div style="flex: 1;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="margin: 0 10px;">-</div> <div style="flex: 0.5;"> <input type="text"/> <input type="text"/> </div> </div> </div> </div>

b.		Specimen ID (scan or affix barcode label): <div style="border: 1px solid black; display: inline-block; width: 100%; height: 30px; margin-top: 5px;"></div>
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CRF 27: LAB RESULT: TB TESTING

Date form
initiated:

DAY

MONTH

YEAR

8. Susceptibility testing:

Note: 1: S = Susceptible; 2: I = Intermediate; 3: R = Resistant

	Mycobacterium tuberculosis	Organism A	Organism B
		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Antibiotic	S / I / R Code:	S / I / R Code:	S / I / R Code:
a. Isoniazid:	<input type="text"/>	<input type="text"/>	<input type="text"/>
b. Pyrazinamide:	<input type="text"/>	<input type="text"/>	<input type="text"/>
c. Ethambutol:	<input type="text"/>	<input type="text"/>	<input type="text"/>
d. Amikacin:	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. Capreomycin:	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. Ethionamide:	<input type="text"/>	<input type="text"/>	<input type="text"/>
g. Rifampicin:	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. Streptomycin:	<input type="text"/>	<input type="text"/>	<input type="text"/>
i. Ofloxacin:	<input type="text"/>	<input type="text"/>	<input type="text"/>
j. Kanamycin:	<input type="text"/>	<input type="text"/>	<input type="text"/>
k. Cycloserine:	<input type="text"/>	<input type="text"/>	<input type="text"/>
l. PAS:	<input type="text"/>	<input type="text"/>	<input type="text"/>
m. Other: Code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
n. Other: Code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
o. Other: Code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comments: _____

Supervisor Staff Code:

Supervisor Verification Date:

Day

Month

Year

CRF 28:
LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

Specimen number:

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NOT DONE:

Stop here and end form

7

1. Date/time put up for culture:

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DAY

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MONTH

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YEAR

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TIME (24 hour clock)

2. Specimen ID (barcode label):

Scan or affix barcode label:

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3. Specimen type (*check one*):

☐ 1 - Pleural fluid

☐ 2 - Lung aspirate

3a. If pleural fluid, select all that apply:

☐

purulent

☐

bloody

1

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] clear
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4. Technician's Staff Code:

Gram Stain

5. Description of any organism by Gram stain:

Check the appropriate quantification box for Q5a-j below.

If no organisms were seen, check here and skip to Q6:

☐

No organisms seen (NOS)

CRF 28: LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM
INITIATED:

DAY

MONTH

YEAR

	Organism	Not Seen	Scanty	1+	2+	3+
a.	Gram-negative rods (GNR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	Gram-positive cocci in clusters (GPC clusters)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c.	Gram-negative coccobacilli (GNCB)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.	Gram-positive cocci in chains (GPC chains)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e.	Gram-negative diplococci (GNDC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f.	Gram-positive cocci single cells (GPC singles)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g.	Gram-negative cocci (GNC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h.	Gram-positive rods (GPR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i.	Gram-positive diplococci (GPDC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j.	Yeasts or other fungal elements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k.	Leukocytes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Bacterial Culture

6. Aerobic Plate: Was growth observed up to 96 hours? ☐ 1 - Yes ☐ 0 - No
7. Anerobic Plate: Was growth observed at 48 hours? ☐ 1 - Yes ☐ 0 - No
8. Was broth positive? ☐ 1 - Yes ☐ 0 - No

If the answer to Q6, Q7 AND Q8 are No, please skip to Q13.

CRF 28:
LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

9. Organism identification and quantification:

Organism Code	Found In		Organism Quantity		Isolate ID (barcode label)	Organism Confirmation
	1 - Solid Media	2 - Broth				3 - Both
a. Mixed skin flora	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 9-N/A		
b. Organism 1 <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 4: Scanty <input type="checkbox"/> 1: 1+ <input type="checkbox"/> 2: 2+ <input type="checkbox"/> 3: 3+	<div>Insert barcode number or label: <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>–<div><input type="text"/><input type="text"/></div></div>	<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
c. Organism 2 <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<div>Insert barcode number or label: <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>–<div><input type="text"/><input type="text"/></div></div>	<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
d. Organism 3 <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<div>Insert barcode number or label: <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>–<div><input type="text"/><input type="text"/></div></div>	<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
e. Organism 4 <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<div>Insert barcode number or label: <div><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/><input type="text"/></div>–<div><input type="text"/><input type="text"/></div></div>	<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC

CRF 28: LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM
INITIATED:

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YEAR

10. Antibiotic Susceptibility Testing:

Note: 1: **S** = Susceptible; 2: **I** = Intermediate; 3: **R** = Resistant

	Organism 1		Organism 2		Organism 3		Organism 4	
Antibiotic code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:	Zone of inhibition in mm (xx):	S / I / R Code:
a. AMC (Amoxicillin / Clavulanic acid)								
b. AMP (Ampicillin)								
c. CAZ (Ceftazidime)								
d. CH (Chloramphenicol)								
e. CIP (Ciprofloxacin)								
f. CN (Gentamicin)								
g. CRO (Ceftriaxone)								
h. CTX (Cefotaxime)								
i. DA (Clindamycin)								
j. ERY (Erythromycin)								
k. FOX (Cefoxitin)								
l. IPM (Imipenem)								
m. OX (Oxacillin)								
n. P (Penicillin)								

CRF 28:
LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM INITIATED:

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DAY MONTH YEAR

	Organism 1		Organism 2		Organism 3		Organism 4	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. SXT (Cotrimoxazole)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. TET (Tetracycline)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. VA (Vancomycin)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r. Other: _____ Code: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
s. Other: _____ Code: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
t. Other: _____ Code: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
u. Beta lactamase	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative	

11. MIC Etest® results for *S. pneumoniae* isolates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

MIC Etest® performed? ☐ 1 – Yes ☐ 0 – No ☐ 9 – N/A (If No or N/A, skip to Question 12)

a. Penicillin Etest® results: < > . $\mu\text{g/mL}$

b. Ceftriaxone or Cefotaxime (choose one) < > . $\mu\text{g/mL}$

c. Clindamycin Dtest® results ☐ 1- Positive ☐ 2 – Negative

CRF 28: LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM
INITIATED:

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DAY

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MONTH

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YEAR

12. Screening for Extended Spectrum β -Lactamase (ESBL) Production done?
☐ 1 – Yes ☐ 0 - No

a. If Yes, results of additional phenotypic testing:

☐ 1 - ESBL confirmed ☐ 2 - ESBL not confirmed

Chemistry – Pleural Fluid Only

13. Results:

Variable:	Result:			
a. Protein	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> . <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> </table> g/dL			
b. Glucose	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> . <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> </table> mmol/L			
c. Not Done	<input type="checkbox"/>			

14. Technician's Staff Code:

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BinaxNOW Pneumococcal Antigen Testing – Pleural Fluid Only

15. Technician's Staff Code:

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16. Test result: ☐ 1 – Positive ☐ 2 – Negative ☐ 3 – Indeterminate ☐ 9 - Not done17. MIC Etest® results for *S. aureus* isolates that are resistant (R) or intermediate (I) to cefoxitin disk diffusion testing.MIC Etest® performed? ☐ 1 - Yes ☐ 0 – No ☐ 9 – N/A

CRF 28:
LAB RESULT: PLEURAL FLUID - LUNG ASPIRATEDATE FORM
INITIATED:

--	--

DAY

--	--	--

MONTH

--	--	--	--

YEAR

a. Vancomycin Etest® results < > . $\mu\text{g/mL}$ b. Clindamycin Dtest® results ☐ 1- Positive ☐ 2 – Negative18. Was *S. pneumoniae* isolated?☐ 1 – YES ☐ 0 – NO

If Yes, what serotypes were identified:

a.

--	--	--	--	--	--	--	--	--	--

b.

--	--	--	--	--	--	--	--	--	--

c.

--	--	--	--	--	--	--	--	--	--

d.

--	--	--	--	--	--	--	--	--	--

19. Was *H. influenza* isolated?☐ 1-YES ☐ 0-NO

If Yes, what serotype was identified:

a.

--	--	--	--

Comments: _____

Supervisor Staff Code:

--	--	--	--

Supervisor Verification Date:

--	--

Day

--	--	--

Month

--	--	--	--

Year

CRF 29: LAB RESULT: PCP STAINING / FLUORESCENCE RESULTS

DATE FORM
INITIATED:

--	--

DAY

--	--	--

MONTH

--	--	--	--

YEAR

- Specimen type (*check one*):
- ☐ 1 - Induced sputum
- ☐ 2 - Pleural fluid
- ☐ 3 - Lung aspirate
- ☐ 4 - ETT aspirate

Scan or affix barcode label:

1. Specimen ID (*Scan or affix barcode label*):

--	--	--	--	--	--	--	--	--	--	--	--

2. Date / time test performed:

--	--

DAY

--	--	--

MONTH

--	--	--	--

YEAR

--	--	--	--

TIME (24 hour clock)

3. Technician's Staff Code:

--	--	--	--

4. Type of test (*check one*):

- ☐ 1 - Immunofluorescence
- ☐ 2 - Toluidine blue staining

5. Test result (*check one*):

- ☐ 1 - Positive
- ☐ 2 - Negative

If Positive, check one:

- ☐ 1+ (<10 cysts per field)
- ☐ 2+ (11-100 cysts per field)
- ☐ 3+ (101-1000 cysts per field)
- ☐ 4+ (>1000 cysts per field)

Comments: _____

Supervisor Signature: _____ STAFF CODE:

--	--	--	--

--	--

Day

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Month

--	--	--	--

Year

CRF 30: PARTICIPANT EVENT FORM

--	--	--	--	--	--

PARTICIPANT ID

 Event number:

Indicate which best categorizes the study participant event:

1. Category (*check one*):

<input type="checkbox"/>	01 - Safety
<input type="checkbox"/>	02 - Informed consent
<input type="checkbox"/>	03 - Protocol implementation
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table> <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table> <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table> <table border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"></table>

2. Description of event:

 Code:

3. Corrective action taken:

☐ 9 - N/A

 Code:

4. Event start date:

Day		Month		Year			

5. Event end date:

Day		Month		Year			

6. Date reported to local ERC,
if required:

Day		Month		Year				<input type="checkbox"/> 9 - N/A	

Comments:

Form Completed by: _____ Staff Code:

Supervisor Signature: _____ Staff Code:

Supervisor Verification Date:

Day

Month

Year

CRF 30A: SITE EVENT FORM

XX

SITE ID

Event number:

1. Description of event:

Code:

2. Data that may be affected:

Code:

3. Corrective action taken:

☐ 9 – N/A

Code:

4. Event start date:

Day

Month

Year

5. Event end date:

Day

Month

Year

6. Date reported to local ERC,
if required:

Day

Month

Year

☐ 9 - N/A

Comments:

Form Completed by: _____

Staff Code:

Supervisor Signature: _____

Staff Code:

Supervisor Verification Date:

Day

Month

Year

CRF 31: CASE PRE-SCREENING

--	--

SITE ID

Reporting Period:

--	--	--	--

Month

--	--	--	--

Year

To be completed once a month

1. If reporting period start and end dates are not the first and last day of the month, record them here:

9- NA

☐

a. Start date:

--	--

Day

--	--	--

Month

--	--	--	--

Year

b. End date:

--	--

Day

--	--	--

Month

--	--	--	--

Year

PART A: Pre-screening

2. Total under-five admissions (all days, all hours):

--	--	--	--

8- UNK

☐

a. Provide a brief description of the source of the above data:

- 2i. Total under-five admissions that are admitted to the hospital:

--	--	--	--

8- UNK

☐

a. Provide a brief description of the source of the above data:

3. Total under-five admissions who met the clinical screening trigger:

--	--	--	--

8- UNK

☐

a. Provide a brief description of the source of the above data:

4. Total under-five admissions during hours of screening:

--	--	--	--

8- UNK

☐

9- NA

☐

a. Provide a brief description of the source of the above data:

CRF 31: CASE PRE-SCREENING

--	--

SITE ID

Reporting Period:

--	--	--	--

Month

--	--	--	--

Year

5. Total under-five admissions during the hours of screening who met the clinical screening trigger:

--	--	--	--

8- UNK

--

9- NA

--

- a. Provide a brief description of the source of the above data:

6. Number of all patient screened (all ages): *(check NA if all screened are entered in EDC)*

--	--	--	--

8- UNK

--

9- NA

--

7. Number of admitted patient screened (all ages): *(check NA if all screened are entered in EDC)*

--	--	--	--

8- UNK

--

9- NA

--

- a. If applicable, please provide additional information to describe why Q3 or Q5, as applicable, does not equal Q7 (i.e. explain why some hospitalized age-eligible children who met the clinical screening trigger were not screened).

PART B – For sites that do not submit CRF 01 for INELIGIBLE or NON-ENROLLED subjects

8. Of Q7 (screened and admitted), how many were eligible?

--	--	--	--

8- UNK

--

- a. Of Q7 (screened and admitted), for how many was eligibility unknown?

--	--	--	--

8- UNK

--

9. Of Q8 (screened and eligible), how many were not enrolled for each of the reasons below:

- a. Refused consent

--	--	--	--

8- UNK

--

- b. Died

--	--	--	--

8- UNK

--

- c. Met quota

--	--	--	--

8- UNK

--

- d. Other

--	--	--	--

8- UNK

--

Other, specify: _____ Code:

--	--	--	--

CRF 31: CASE PRE-SCREENING

--	--

SITE ID

Reporting Period:

--	--	--

Month

--	--	--	--

Year

10. Of Q6 (all patients screened) who were ineligible, how many were excluded for each of the reasons below:

a. Not from catchment area

--	--	--

8- UNK

--

b. Not age-eligible

--	--	--

8- UNK

--

c. No cough or difficulty breathing

--	--	--

8- UNK

--

d. No signs of severe or very severe pneumonia

--	--	--

8- UNK

--

e. Not admitted to hospital

--	--	--

8- UNK

--

f. Hospitalized within the past 14 days

--	--	--

8- UNK

--

g. PERCH case within past 30 days

--	--	--

8- UNK

--

h. LCWI resolved after BD challenge (severe cases only)

--	--	--

8- UNK

--

i. Other

--	--	--

8- UNK

--

Other, specify: _____ Code:

--	--	--

Comments: _____

Form Completed by: _____ Staff Code:

--	--	--

Supervisor Signature: _____ Staff Code:

--	--	--

Supervisor Verification Date:

--	--

Day

--	--

Month

--	--	--

Year

CRF 31Ai: EPI CONTROL PRE-SCREENING

SITE ID

Reporting period:

Month

Year

To be completed once a month

1. If reporting period start and end dates are not the first and last day of the month, record them here:

a. Start date:

Day

Month

Year

9- NA

b. End date:

Day

Month

Year

PART A: Pre-Screening

2. Number of households visited with an age-eligible child for screening:

8- UNK

3. Of Q2 above (i.e., households with an age-eligible child), record the number of controls that were not screened (i.e., Screening Form CRF 01A was not completed) because:

a. Guardian could not be located:

8- UNK

9- N/A

b. Child out of town:

8- UNK

9- N/A

c. They declined to be screened for PERCH:

8- UNK

9- N/A

d. They did not appear at the clinic/hospital for enrollment:

8- UNK

9- N/A

e. Other :

8- UNK

9- N/A

Other, specify: _____

Code:

PART B – for sites that do not submit CRF 01A for INELIGIBLE or NON-ENROLLED screened subjects

4. Record the number of children screened:

8- UNK

9- N/A

5. Of Q4 (screened), how many were eligible but did not have CRF 01A entered into EDC?

8- UNK

9- N/A

Of Q5, record how many were not enrolled for each of the reasons below:

a. Refused consent:

8- UNK

b. Met quota:

8- UNK

c. Other:

8- UNK

CRF 31Ai: EPI CONTROL PRE-SCREENING

--	--

SITE ID

Reporting period:

--	--	--

Month

--	--	--	--

Year

Other, specify: _____ Code:

8- UNK 9- N/A

6. Of Q4 (screened), how many were ineligible and did not have CRF 01A entered into EDC?

--	--	--	--

--

--

Of Q6, record how many were ineligible for each of the reasons below:

a. Not from catchment area:

--	--	--	--

8- UNK

--

b. Not age-eligible:

--	--	--	--

8- UNK

--

c. Hospitalized within the past 14 days:

--	--	--	--

8- UNK

--

d. PERCH case within past 30 days:

--	--	--	--

8- UNK

--

e. Too sick (requires hospitalization):

--	--	--	--

8- UNK

--

f. Other:

--	--	--	--

8- UNK

--

Other, specify: _____ Code:

--	--	--	--

Comments: _____

Form Completed by: _____ Staff Code:

--	--	--	--

Supervisor Signature: _____ Staff Code:

--	--	--	--

Supervisor Verification Date:

--	--

Day

--	--

Month

--	--	--	--

Year

CRF 31Aii: DSS CONTROL PRE-SCREENING

SITE ID

Reporting period:

Month

Year

To be completed once a month

1. If reporting period start and end dates are not the first and last day of the month, record them here:

a. Start date:

Day

Month

Year

9- NA

b. End date:

Day

Month

Year

PART A: Pre-Screening

2. Number of controls approached or attempted to enroll in PERCH:

8- UNK 9- N/A

a. Number of controls approached from birth registry (SA only)

8- UNK 9- N/A

3. Of Q2, record the number of controls that were not screened (i.e., Screening Form CRF 01A was not completed/entered into the EDC) because:

a. Could not be located (moved or not found at home after repeated visits)

8- UNK 9- N/A

b. Declined to be screened

8- UNK 9- N/A

c. Did not appear at the clinic/hospital for enrollment

8- UNK 9- N/A

d. Died

8- UNK 9- N/A

e. Incorrect DSS records (e.g. wrong age or address)

8- UNK 9- N/A

f. Withdrew from surveillance (Bangladesh only)

8- UNK 9- N/A

g. Recently provided specimens for surveillance or other studies (Bangladesh only)

8- UNK 9- N/A

h. Enrolled in another study that prevents PERCH enrollment

8- UNK 9- N/A

i. Other:

Other, specify: _____

8- UNK 9- N/A

Code:

PART B: For sites that do not submit CRF 01A for INELIGIBLE or NON-ENROLLED subjects

4. Record the number of children screened:

8- UNK 9- N/A

CRF 31Aii: DSS CONTROL PRE-SCREENING

SITE ID

Reporting period:

Month

Year

5. Of Q4 (screened), how many were eligible but did not have CRF 01A entered into EDC?

8- UNK

9- N/A

Of Q5, record how many were not enrolled for each of the reasons below:

- a. Refused consent

8- UNK

- b. Met quota

8- UNK

- c. Other

8- UNK

Other, specify: _____

Code:

6. Of Q4 (screened) how many were ineligible and did not have CRF 01A entered into EDC?

8- UNK

9- N/A

Of Q6, record how many were ineligible for each of the reasons below:

- a. Not from catchment area

8- UNK

- b. Not age-eligible

8- UNK

- c. Hospitalized within the past 14 days

8- UNK

- d. PERCH case within past 30 days

8- UNK

- e. Too sick (requires hospitalization)

8- UNK

- f. Other

8- UNK

Other, specify: _____

Code:

Comments: _____

Form Completed by: _____

Staff Code:

Supervisor Signature: _____

Staff Code:

Supervisor Verification Date:

Day

Month

Year

CRF 31B: HIV+ CONTROL PRE-SCREENING

--	--

SITE ID

Reporting period:

--	--	--

Month

--	--	--	--

Year

To be completed once a month to describe HIV-Infected Control Recruitment

1. If reporting period start and end dates are not the first and last day of the month, record them here:

a. Start date:

--	--

Day

--	--

Month

--	--	--

Year

9- NA

--

b. End date:

--	--

Day

--	--

Month

--	--	--

Year

PART A: Pre-Screening

2. Number of potentially eligible (i.e., in target age group) HIV-infected controls that were identified for screening:

--	--	--	--

8- UNK

--

3. Of Q2, record the number of controls that were not screened (i.e., Screening Form CRF 01B was not completed/entered into the EDC) because:

a. Declined to be screened:

--	--	--

8- UNK

--

9- N/A

--

b. Guardian could not be located:

--	--	--

8- UNK

--

9- N/A

--

c. Enrolled in another study that prevents PERCH enrollment:

--	--	--

8- UNK

--

9- N/A

--

d. Enrolled as PERCH control within past 3 months:

--	--	--

8- UNK

--

9- N/A

--

e. Other:

--	--	--

8- UNK

--

9- N/A

--

Other, specify: _____ Code:

--	--

PART B: For sites that do not submit CRF 01B for INELIGIBLE or NON-ENROLLED screened subjects

4. Record the number of children screened:

--	--	--

8- UNK

--

9- N/A

--

5. Of Q4 (screened), how many were eligible but did not have CRF 01B entered into EDC?

--	--	--

8- UNK

--

9- N/A

--

Of Q5, record how many were not enrolled for each of the reasons below:

a. Refused consent:

--	--	--

8- UNK

--

b. Met quota:

--	--	--

8- UNK

--

c. Other:

--	--	--

8- UNK

--

Other, specify: _____ Code:

--	--

CRF 31B: HIV+ CONTROL PRE-SCREENING

--	--

SITE ID

Reporting period:

--	--	--

Month

--	--	--	--

Year

6. Of Q4 (screened), how many were ineligible and did not have CRF 01B entered into EDC? 8- UNK ☐ 9- N/A ☐

Of Q6, record how many were ineligible for each of the reasons below:

a. Not from catchment area:

--	--	--	--

8- UNK

☐

b. Not age-eligible:

--	--	--	--

8- UNK

☐

c. Hospitalized within the past 14 days:

--	--	--	--

8- UNK

☐

d. PERCH case within past 30 days:

--	--	--	--

8- UNK

☐

e. Too sick (requires hospitalization):

--	--	--	--

8- UNK

☐

f. Enrolled as PERCH control within past 3 months:

--	--	--	--

8- UNK

☐

g. Other:

--	--	--	--

8- UNK

☐
Other, specify: _____ Code:

--	--	--

Comments:

Form Completed by: _____ Staff Code:

--	--	--	--

Supervisor Signature: _____ Staff Code:

--	--	--	--

Supervisor Verification Date:

--	--

Day

--	--

Month

--	--	--

Year

CRF 32: MICROBIOLOGY REPORT: POST-MORTEM LUNG BIOPSY

DATE FORM INITIATED:
DAY MONTH YEAR

1. Date/time put up for culture:

DAY MONTH YEAR TIME (24 hour clock)

2. Specimen ID (scan barcode label):

Scan or affix barcode label:
 -

3. Technician's Staff Code:

NOT DONE:
 Stop here and end form if no
 lung biopsy specimen was
 taken.

☐

Gram Stain

4. Description of any organism found by Gram stain: ☐ No organisms seen (NOS - *skip to Q5*) ☐ N/A (Gram stain not done - *skip to Q5*)

Check the appropriate quantification box for Q4a-k below.

	Organism	Not Seen	Scanty	1+	2+	3+
a.	Gram-negative rods (GNR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.	Gram-positive cocci in clusters (GPC clusters)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c.	Gram-negative coccobacilli (GNCB)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.	Gram-positive cocci in chains (GPC chains)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e.	Gram-negative diplococci (GNDC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f.	Gram-positive cocci single cells (GPC singles)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g.	Gram-negative cocci (GNC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h.	Gram-positive rods (GPR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i.	Gram-positive diplococci (GPDC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j.	Yeasts or other fungal elements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k.	Leukocytes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Bacteria per representative HPF (×100 oil objective)

<1 = Scanty
 1-9 = 1+
 10-99 = 2+
 ≥100 = 3+

Number of leucocytes per representative LPF (×10 objective)

0 = nil
 1-9 = 1+
 10-24 = 2+
 ≥25 = 3+

CRF 32:
MICROBIOLOGY REPORT: POST-MORTEM LUNG BIOPSY

DATE FORM INITIATED:

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--	--	--

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DAY MONTH YEAR

Bacterial Culture

5. Aerobic Plate: Was growth observed up to 96 hours? ☐ 0 - No ☐ 1 - Yes ☐ 9 - Not done
6. Anerobic Plate: Was growth observed at 48 hours? ☐ 0 - No ☐ 1 - Yes ☐ 9 - Not done
7. Was broth positive? ☐ 0 - No ☐ 1 - Yes ☐ 9 - Not done

If the answers to Q5, Q6 AND Q7 are No or Not done, please end form.

CRF 32:
MICROBIOLOGY REPORT: POST-MORTEM LUNG BIOPSY

DATE FORM INITIATED:

--	--

--	--	--

--	--	--	--

DAY MONTH YEAR

8. Bacterial culture organism identification and quantification:

Organism Code	Found In	Organism Quantity	Isolate ID (barcode label)	Organism Confirmation
a. Mixed skin flora*	<div> <div>1 - Solid Media</div> <div>2 - Broth</div> <div>3 - Both</div> <div>9 – Not seen</div> </div> <div> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div>			
b. Organism 1	<input type="checkbox"/> 1 - Solid Media <input type="checkbox"/> 2 - Broth <input type="checkbox"/> 3 - Both	<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1 - 1+ <input type="checkbox"/> 2 - 2+ <input type="checkbox"/> 3 - 3+	<div>Insert barcode number or label:</div> <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div>	<input type="checkbox"/> 1: C - Confirmed <input type="checkbox"/> 2: U - Updated <input type="checkbox"/> 3: NC - Not Confirmed
c. Organism 2	<input type="checkbox"/> 1 - Solid Media <input type="checkbox"/> 2 - Broth <input type="checkbox"/> 3 - Both	<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1 - 1+ <input type="checkbox"/> 2 - 2+ <input type="checkbox"/> 3 - 3+	<div>Insert barcode number or label:</div> <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div>	<input type="checkbox"/> 1: C - Confirmed <input type="checkbox"/> 2: U - Updated <input type="checkbox"/> 3: NC - Not Confirmed
d. Organism 3	<input type="checkbox"/> 1 - Solid Media <input type="checkbox"/> 2 - Broth <input type="checkbox"/> 3 - Both	<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1 - 1+ <input type="checkbox"/> 2 - 2+ <input type="checkbox"/> 3 - 3+	<div>Insert barcode number or label:</div> <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div>	<input type="checkbox"/> 1: C - Confirmed <input type="checkbox"/> 2: U - Updated <input type="checkbox"/> 3: NC - Not Confirmed
e. Organism 4	<input type="checkbox"/> 1 - Solid Media <input type="checkbox"/> 2 - Broth <input type="checkbox"/> 3 - Both	<input type="checkbox"/> 4 - Scanty <input type="checkbox"/> 1 - 1+ <input type="checkbox"/> 2 - 2+ <input type="checkbox"/> 3 - 3+	<div>Insert barcode number or label:</div> <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div>	<input type="checkbox"/> 1: C - Confirmed <input type="checkbox"/> 2: U - Updated <input type="checkbox"/> 3: NC - Not Confirmed

*Includes *S. epidermidis* and many species of *Corynebacteria*, *Propionibacteria*, *Micrococci* and *Mycobacteria*. See SOP for complete list.

CRF 32: MICROBIOLOGY REPORT: POST-MORTEM LUNG BIOPSY

DATE FORM INITIATED:

--	--

--	--	--

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DAY MONTH YEAR

9. Bacterial culture organism antibiotic susceptibility testing: ☐ N/A (not done)

	Organism 1		Organism 2		Organism 3		Organism 4	
	<table border="1" style="width: 100%; height: 20px;"></table>		<table border="1" style="width: 100%; height: 20px;"></table>		<table border="1" style="width: 100%; height: 20px;"></table>		<table border="1" style="width: 100%; height: 20px;"></table>	
Antibiotic code:	Zone of inhibition in mm (xx):	S / I / R Code*:	Zone of inhibition in mm (xx):	S / I / R Code*:	Zone of inhibition in mm (xx):	S / I / R Code*:	Zone of inhibition in mm (xx):	S / I / R Code*:
a. AMC (Amoxicillin / Clavulanic acid)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
b. AMP (Ampicillin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
c. CAZ (Ceftazidime)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
d. CH (Chloramphenicol)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
e. CIP (Ciprofloxacin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
f. CN (Gentamicin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
g. CRO (Ceftriaxone)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
h. CTX (Cefotaxime)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
i. DA (Clindamycin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
j. ERY (Erythromycin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
k. FOX (Cefoxitin)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>
l. IPM (Imipenem)	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 30px; height: 20px;"></table>

***S / I / R code:**

1: S = Susceptible

2: I = Intermediate

3: R = Resistant

CRF 32: MICROBIOLOGY REPORT: POST-MORTEM LUNG BIOPSY

DATE FORM INITIATED:

DAY MONTH YEAR

	Organism 1		Organism 2		Organism 3		Organism 4	
	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
Antibiotic code:	Zone of inhibition in mm (xx):	S / I / R Code*:	Zone of inhibition in mm (xx):	S / I / R Code*:	Zone of inhibition in mm (xx):	S / I / R Code*:	Zone of inhibition in mm (xx):	S / I / R Code*:
m. OX (Oxacillin)	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
n. P (Penicillin)	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
o. SXT (Cotrimoxazole)	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
p. TET (Tetracycline)	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
q. VA (Vancomycin)	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
r. Other: _____ Code: <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
s. Other: _____ Code: <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
t. Other: _____ Code: <div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>
u. Beta lactamase	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative		<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative	

CRF 32:
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DATE FORM INITIATED:

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DAY MONTH YEAR

10. MIC Etest® results for *S. pneumoniae* isolates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

Was MIC Etest® performed? ☐ 1 – Yes ☐ 0 – No ☐ 9 – N/A (If No or N/A, skip to Question 11)

a. Penicillin Etest® results:

☐ >

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 $\mu\text{g/mL}$
☐ <

b. Ceftriaxone ☐ or Cefotaxime ☐ (choose one)

☐ <

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 $\mu\text{g/mL}$
☐ >

11. Screening for Extended Spectrum β -Lactamase (ESBL) Production done?

☐ 1 - Yes ☐ 0 - No

a. If Yes, results of additional phenotypic testing:

☐ 1 - ESBL confirmed ☐ 2 - ESBL not confirmed

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DAY MONTH YEAR12. Was *S. pneumoniae* isolated?☐ 1 – Yes ☐ 0 – No

If Yes, what serotypes were identified:

a.

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b.

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c.

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d.

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13. Was *H. influenzae* isolated?☐ 1-Yes ☐ 0-No

If Yes, what serotype was identified:

a.

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Technician Reporting Final Results:

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Initial QC By:

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Supervisor Staff Code:

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Supervisor Verification Date:

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Day Month Year

CRF 33:

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YEAR

1. Biopsy Information

Biopsy available?	Specimen ID (scan barcode label):	Specimen quality (check one):	Does biopsy show lung tissue?
a. H11? 1 - Yes. <input type="checkbox"/> 0 - No <input type="checkbox"/>	Scan or affix barcode label: <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> H <input type="text"/> 11 </div>	1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
b. H12? 1 - Yes. <input type="checkbox"/> 0 - No <input type="checkbox"/>	Scan or affix barcode label: <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> H <input type="text"/> 12 </div>	1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
c. H13? 1 - Yes. <input type="checkbox"/> 0 - No <input type="checkbox"/>	Scan or affix barcode label: <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> H <input type="text"/> 13 </div>	1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
d. H14? 1 - Yes. <input type="checkbox"/> 0 - No <input type="checkbox"/>	Scan or affix barcode label: <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> H <input type="text"/> 14 </div>	1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
e. H15? 1 - Yes. <input type="checkbox"/> 0 - No <input type="checkbox"/>	Scan or affix barcode label: <div> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> H <input type="text"/> 15 </div>	1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>

MICROSCOPY (GENERAL QUESTIONS FOR CASE)

2. Appearances: Do biopsies show abnormal / pathological features?

- ☐ 1 – No pathological appearances – Normal lung
- ☐ 2 – Pathology identified

7

3. Special Stains performed on biopsies

- ☐ 1 – None (H&E only)
- ☐ 2 – Yes: Specify _____

CRF 33: HISTOLOGY RESULT: POST-MORTEM LUNG BIOPSY

DATE FORM
INITIATED:

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4. Histological Findings

	Pathological Feature	Present or Not (tick box if present)
a.	Pulmonary Edema	<input type="checkbox"/>
b.	Pyogenic pneumonia (neutrophilic consolidation)	<input type="checkbox"/>
c.	Lymphocytic infiltration of alveolar walls	<input type="checkbox"/>
d.	Tuberculosis	<input type="checkbox"/>
e.	Granulomas	<input type="checkbox"/>
f.	Viral inclusion bodies	<input type="checkbox"/>
g.	Hyaline membrane formation	<input type="checkbox"/>
h.	Specific pathogen identified	<input type="checkbox"/>
	If identified, type/s of pathogen:	1.
	(e.g. Fungi / Pneumocystis jiroveci / Viral inclusions/TB)	2.
		3.
i.	Other pathological features	
	If identified, type of feature	1.
		2.
	Special Stains Positive? If positive state:	<input type="checkbox"/>
j.	Gram Stain	<input type="checkbox"/>
	If positive : Gram positive organisms	<input type="checkbox"/>
	Gram negative organisms	<input type="checkbox"/>
k.	Silver Stain	<input type="checkbox"/>
l.	ZN Stain	<input type="checkbox"/>
m.	Other (specify: _____)	<input type="checkbox"/>
		<input type="checkbox"/>

CRF 33:
HISTOLOGY RESULT: POST-MORTEM LUNG BIOPSYDATE FORM
INITIATED:

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MONTH

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YEAR

Written Histology Report: (Summary report of Case across all available biopsies)

5. Histology Report:

Please note: if a clinical report has been issued on this case, an anonymous copy of the report can also be appended here

6. Final diagnosis: _____

7. Signature of examining pathologist: _____ Staff Code:

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8. Date:

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Day Month Year

Comments: _____

Technician's Staff Code:

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Supervisor Staff Code:

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Supervisor Verification Date:

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Day Month Year