

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

Instructions: If at any point during the completion of this CRF, the child is determined to be not eligible, go to Q23 and answer No.

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

Thailand only:

Check one: 1 – Initial Screening 2 – Re-screening

If Re-screening, initial PERCH ID:

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1. Time of screening:

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 (24 hour clock)

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 - NO

a. If Yes:

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 days

b. If No:

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 months

5. Where was the child evaluated?

<input type="checkbox"/>	01 - ER			
<input type="checkbox"/>	02 - Main ICU			
<input type="checkbox"/>	03 - High care area			
<input type="checkbox"/>	04 - Ward			
<input type="checkbox"/>	05 - Outpatient department			
<input type="checkbox"/>	06 - Clinic (for Dhaka and Gambia only)			
<input type="checkbox"/>	99 - Other, specify: _____ Code: <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 10px;"></td></tr></table>			

Please answer YES or NO to EVERY question.

Inclusion criteria: To be eligible for PERCH, answers to ALL 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. Ill with cough or difficulty breathing?	<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: 100px; height: 20px;"><tr><td style="width: 25px;"></td><td style="width: 25px;"></td><td style="width: 25px;"></td><td style="width: 25px;"></td></tr></table> (enter coded geographic area) 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"/> Continue if all above are checked Yes	<input type="checkbox"/> If any above are No, go to Q23 and tick No

*=Question does not appear in AdvantageEDCSM

SITE LOGO

**CRF 01:
CASE SCREENING AND ELIGIBILITY**

Participant ID input fields

PARTICIPANT ID

DATE OF SCREENING:

Day input fields

DAY

Month input fields

MONTH

Year input fields

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> Q9 or Q10 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:**

*=Question does not appear in AdvantageEDCSM

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DAY

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MONTH

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YEAR

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:

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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"><tr><td> </td><td> </td><td> </td></tr></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: | <input type="checkbox"/> 1 - YES | <input type="checkbox"/> 0 - NO |
| a. Lower chest wall indrawing..... | | <input type="checkbox"/> | <input type="checkbox"/> |
| | Very Severe: | <input type="checkbox"/> 1 - YES | <input type="checkbox"/> 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)?*

<input type="checkbox"/>	<input type="checkbox"/>	1 - YES	0 - NO
		<input type="checkbox"/>	<input type="checkbox"/>
Continue			Answer Q15-18, then skip to Q23 and tick NO

*=Question does not appear in AdvantageEDCSM

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DAY

MONTH

YEAR

(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

<input type="checkbox"/>	<input type="checkbox"/>
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17. Oxygen saturation by pulse oximetry (on room air whenever possible):

			%
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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

8 - UNK 9 - NR

<input type="checkbox"/>	<input type="checkbox"/>
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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):

			%
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8 - UNK 9 - N/A

<input type="checkbox"/>	<input type="checkbox"/>
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18. Respiratory rate (# of breaths counted in 60 seconds):
(only if not on assisted ventilation)

			per minute
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8 - UNK 9 - NR 7 - N/A

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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*=Question does not appear in AdvantageEDCSM

CRF 01: CASE SCREENING AND ELIGIBILITY

PARTICIPANT ID

DATE OF SCREENING:

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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

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 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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DAY

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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

SITE LOGO

**CRF 01:
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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: continued)

Eligibility for PERCH	1 - YES	0 - NO
<p>23. Is this child eligible for PERCH?</p> <p>Check Yes, if answers to all shaded sections of eligibility inclusion and exclusion criteria boxes are checked.</p> <p>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 type="checkbox"/> Continue to Section C	<input 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

SITE LOGO

**CRF 01:
CASE SCREENING AND ELIGIBILITY**

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PARTICIPANT ID

DATE OF SCREENING:

[][]

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

25. Has consent been obtained? 9- N/A (not eligible)

*Must be Yes to continue enrollment.
If No, skip to Q25c below.*

**Answer
25a and
25b**

**Answer
25c**

a. If Yes, child's date of birth: (when date of birth is uncertain, always estimate the date and check "date uncertain" box)

[][]

DAY

[][][][]

MONTH

[][][][][][]

YEAR

Date uncertain

b. If Yes, Date and time enrolled in PERCH:

[][]

DAY

[][][][]

MONTH

[][][][][][]

YEAR

[][][][]

TIME (24 hour clock)

c. If Q25 is No, indicate reason why consent was not obtained:

01 - Refused consent

02 - Died

03 - N/A (e.g. met quota or not during the hours of enrollment)

99 - Other, specify: _____

Code:

[][][]

26. Section C Comments: _____

Section C completed by: _____

STAFF CODE:

[][][][]

Supervisor Signature: _____

STAFF CODE:

[][][][]

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Day

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Month

[][][][][][]

Year

*=Question does not appear in AdvantageEDCSM

SITE LOGO

CRF 01A: COMMUNITY CONTROL SCREENING AND ELIGIBILITY

PARTICIPANT ID

DATE OF SCREENING:

DAY

MONTH

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: <input type="text"/> <input type="text"/> <input type="text"/>

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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MONTH

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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? a. If Yes, where does the child live? <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr></table> (enter coded geographic area) 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"/> Continue if BOTH above are checked YES	<input type="checkbox"/> If either above are checked NO , go to Q13 and tick NO then stop

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:

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Continue to Section B on next page...

*=Question does not appear in AdvantageEDCSm

SITE LOGO

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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MONTH

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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:

Exclusion criteria: <i>Please answer YES or NO to EVERY question.</i> To be eligible for PERCH, Q11 and Q12i below must be NO .	1 - YES	0 - NO																																																																
11. 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 Q13 and tick NO	<input type="checkbox"/> Continue																																																																
12. Assess symptoms of severe and very severe pneumonia: <table style="width: 100%; margin-left: 20px;"> <tr> <td style="width: 60%;"></td> <td style="text-align: center;">1 – YES</td> <td style="text-align: center;">0 – NO</td> </tr> <tr> <td>a. Is child ill with cough or difficulty breathing?.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td colspan="3" style="padding-left: 20px;"><i>(if No, answer all Q12b-h below, then tick No to Q12i.)</i></td> </tr> <tr> <td></td> <td style="text-align: center;">1 – YES</td> <td style="text-align: center;">0 – NO</td> </tr> <tr> <td>b. Lower chest wall indrawing.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>c. Head nodding.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>d. Central cyanosis.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>e. Unable to feed <i>(must be observed by examiner)</i>.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>f. Vomiting everything <i>(must be observed by examiner)</i>.....</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td colspan="3" style="padding-left: 20px;">g. Lethargy or impaired consciousness <i>(assess below)</i></td> </tr> <tr> <td colspan="3" style="padding-left: 20px;"><i>NOTE: Wait for >30 minutes after any convulsion before carrying out assessment of consciousness.</i></td> </tr> <tr> <td style="padding-left: 20px;"><input type="checkbox"/> A: alert & awake</td> <td colspan="2" style="padding-left: 20px;"><input type="checkbox"/> V: responds to voice</td> </tr> <tr> <td style="padding-left: 20px;"><input type="checkbox"/> P: responds to pain</td> <td colspan="2" style="padding-left: 20px;"><input type="checkbox"/> U: unresponsive</td> </tr> <tr> <td style="padding-left: 20px;"><input type="checkbox"/> 9 - Pharmacologically sedated</td> <td colspan="2"></td> </tr> <tr> <td colspan="3" style="padding-left: 20px;">+i. If 'A' or '9' is ticked above, tick 'No'. If V, P or U is ticked, tick 'Yes'.</td> </tr> <tr> <td colspan="3" style="padding-left: 20px;">h. Multiple or prolonged convulsions during this illness ...<i>(assess below)</i></td> </tr> <tr> <td colspan="3" style="padding-left: 20px;">Did child have convulsions? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(If no, tick Q12h.ii 'No')</i></td> </tr> <tr> <td colspan="3" style="padding-left: 20px;">i. If Yes, what kind? <i>(check all that apply):</i></td> </tr> <tr> <td style="padding-left: 40px;"><input type="checkbox"/> M: multiple (≥ 2 episodes)</td> <td colspan="2" style="padding-left: 40px;"><input type="checkbox"/> P: prolonged (≥ 15 min)</td> </tr> <tr> <td style="padding-left: 40px;"><input type="checkbox"/> S: single brief (<15 min)</td> <td colspan="2"></td> </tr> <tr> <td colspan="3" style="padding-left: 20px;">+ ii. If only S is ticked in Q12h.i above, then tick 'No.' If M or P is ticked, then tick 'Yes.'</td> </tr> <tr> <td style="padding: 5px;"> i. Does the child have <u>severe</u> or <u>very severe</u> pneumonia (defined as having cough or difficulty breathing (i.e. item12a above is YES) AND ONE or MORE of items 12b-h above are checked YES? </td> <td style="text-align: center; vertical-align: middle; padding: 5px;"> 1 – YES <input type="checkbox"/> <input type="checkbox"/> Go to Q13 and tick 'No' </td> <td style="text-align: center; vertical-align: middle; padding: 5px;"> 0 - NO <input type="checkbox"/> <input type="checkbox"/> Continue </td> </tr> </table>		1 – YES	0 – NO	a. Is child ill with cough or difficulty breathing?.....	<input type="checkbox"/>	<input type="checkbox"/>	<i>(if No, answer all Q12b-h below, then tick No to Q12i.)</i>				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 <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>			<i>NOTE: Wait for >30 minutes after any convulsion before carrying out assessment of consciousness.</i>			<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 ... <i>(assess below)</i>			Did child have convulsions? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(If no, tick Q12h.ii 'No')</i>			i. 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<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. item12a above is YES) AND ONE or MORE of items 12b-h above are checked YES?	1 – YES <input type="checkbox"/> <input type="checkbox"/> Go to Q13 and tick 'No'	0 - NO <input type="checkbox"/> <input type="checkbox"/> Continue																																																																

*=Question does not appear in AdvantageEDCSm

SITE LOGO

**CRF 01A:
COMMUNITY CONTROL SCREENING AND ELIGIBILITY**

Participant ID grid: 6 empty boxes

PARTICIPANT ID

DATE OF SCREENING:

Day grid: 2 empty boxes

DAY

Month grid: 3 empty boxes

MONTH

Year grid: 4 empty boxes

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.e., answers to Q6-7 are YES, and Q8-9, Q11, and Q12i are NO, and 15b is not blank)</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>	<p><input type="checkbox"/></p> <p>Continue</p>	<p><input type="checkbox"/></p> <p>STOP</p>

14. Section B Comments:

Two horizontal lines for comments

Section B completed by: _____

STAFF CODE:

Staff code grid: 4 empty boxes

Continue to Section C on next page...

*=Question does not appear in AdvantageEDCSm

SITE LOGO

**CRF 01A:
COMMUNITY CONTROL SCREENING AND ELIGIBILITY**

Participant ID input boxes

PARTICIPANT ID

DATE OF SCREENING:

Day input boxes

DAY

Month input boxes

MONTH

Year input boxes

YEAR

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

CONSENT AND ENROLLMENT for PERCH

YES

NO

15. Has consent been obtained? 9- N/A (not eligible)

Must be Yes to continue enrollment.

If No, skip Q15a and Q15b and mark the reason why not in Q15c below.

**Answer
15a and
15b**

**Answer
15c**

a. If Yes, child's date of birth: *(when date of birth is uncertain, always estimate the date and check the "date uncertain" box)*

Day input boxes

DAY

Month input boxes

MONTH

Year input boxes

YEAR

Date uncertain

b. If Yes, Date and time enrolled in PERCH:

Day input boxes

DAY

Month input boxes

MONTH

Year input boxes

YEAR

Time input boxes

TIME (24 hour clock)

c. If No, mark the reason why not:

01 - Refused consent

99 - Other, specify: _____

Code:

Code input boxes

16. Section C Comments:

Section C Comments input lines

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

Participant ID input boxes

CRF/Section C completed by: _____ STAFF CODE:

Staff code input boxes

Supervisor Signature: _____ STAFF CODE:

Staff code input boxes

Day input boxes

Day

Month input boxes

Month

Year input boxes

Year

*=Question does not appear in AdvantageEDCSm

SITE LOGO

**CRF 01B:
HIV+ CONTROL SCREENING AND ELIGIBILITY**

Participant ID grid: 6 empty boxes

PARTICIPANT ID

DATE OF SCREENING:

Day grid: 2 empty boxes

DAY

Month grid: 2 empty boxes

MONTH

Year grid: 4 empty boxes

YEAR

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) [] [] [] []

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 recruited from? HIV Clinic number: [] []

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: [] [] []

Continued on next page...

*=Question does not appear in AdvantageEDCSm

SITE LOGO

**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)

Inclusion criteria: <i>Please answer YES or NO to EVERY question.</i>	1 - YES	0 - NO						
To be eligible for PERCH, ALL of the following must be YES								
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; vertical-align: middle;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr></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; vertical-align: middle;"><tr><td> </td><td> </td></tr></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 all above are ticked	<input type="checkbox"/> If any 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

SITE LOGO

**CRF 01B:
HIV+ CONTROL SCREENING AND ELIGIBILITY**

Participant ID input fields

PARTICIPANT ID

DATE OF SCREENING:

Day input fields

DAY

Month input fields

MONTH

Year input fields

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:**

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>	1 - YES	0 - NO
To be eligible for PERCH, Q15 and Q16i below must be 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:		
a. Is child ill with cough or difficulty breathing?..... <i>(if No, answer all Q16b-h below, then tick No to Q16i.)</i>	1 - YES <input type="checkbox"/>	0 - NO <input type="checkbox"/>
b. Lower chest wall indrawing.....	1 - YES <input type="checkbox"/>	0 - NO <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"/>
<i>NOTE: Wait for >30 minutes after any convulsion before carrying out assessment of consciousness.</i>		
<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	1 – YES	0 - NO
<input type="checkbox"/> 9 - Pharmacologically sedated	<input type="checkbox"/>	<input type="checkbox"/>
+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 ... <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)	1 – YES	0 - NO
<input type="checkbox"/> S: single brief (<15 min)	<input type="checkbox"/>	<input type="checkbox"/>
+ii. If only S is ticked in Q16h.i above, then tick 'No.' If M or P is ticked, then tick 'Yes.'	<input type="checkbox"/>	<input type="checkbox"/>
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)?	Go to Q17 and tick 'No'	Continue

*=Question does not appear in AdvantageEDCSm

SITE LOGO

**CRF 01B:
HIV+ CONTROL SCREENING AND ELIGIBILITY**

Participant ID input fields (6 boxes)

PARTICIPANT ID

DATE OF SCREENING:

Day input fields (2 boxes)

DAY

Month input fields (2 boxes)

MONTH

Year input fields (4 boxes)

YEAR

(Section B: continued)

Eligibility for PERCH	1 - YES	0 - NO
<p>17. Is this child eligible for PERCH?</p> <p>If all shaded responses are checked, then the child is eligible for PERCH. (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)</p>	<input type="checkbox"/> Continue	<input type="checkbox"/> Stop

18. Section B Comments: _____

Section B completed by: _____ STAFF CODE:

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 AdvantageEDCSm

SITE LOGO

**CRF 01B:
HIV+ CONTROL SCREENING AND ELIGIBILITY**

Participant ID grid

PARTICIPANT ID

DATE OF SCREENING:

Day grid

DAY

Month grid

MONTH

Year grid

YEAR

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

CONSENT AND ENROLLMENT for PERCH

1 - YES

0 - NO

19. Has consent been obtained? 9- N/A (not eligible)

Must be Yes to continue enrollment.

If No, skip Q19a and Q19b and mark the reason why not in Q19c below.

a. If Yes, child's date of birth: *(when date of birth is uncertain, always estimate the date and check the date uncertain box)*

Day grid

DAY

Month grid

MONTH

Year grid

YEAR

Date uncertain checkbox

Date uncertain

b. If Yes, Date and time enrolled in PERCH:

Day grid

DAY

Month grid

MONTH

Year grid

YEAR

Time grid

TIME (24 hour clock)

c. If No, reason why not:

01 - Refused consent

99 - Other, specify: _____

Code:

Code grid

Yes checkbox

Answer 19a and 19b

No checkbox

Answer 19c

20. Section C Comments: _____

Section C completed by: _____

Staff code grid

STAFF CODE

Supervisor Signature: _____

Staff code grid

STAFF CODE

Day grid

Day

Month grid

Month

Year grid

Year

*=Question does not appear in AdvantageEDCSm

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="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
b. Cough:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
c. Difficulty breathing:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
d. Wheeze:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
e. Unable to feed:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
f. Runny nose:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
g. Ear discharge:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
h. Vomiting:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
i. Diarrhea (≥3 abnormally loose or watery stools per day)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
i) If Yes, was there blood in the stool?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></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="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>					
k. Other: _____ Code: <table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 10px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>		
l. Other: _____ Code: <table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 10px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></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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DAY

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MONTH

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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)

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?

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

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
	Other, specify: _____ Code: <input type="text"/>

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

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

PAST MEDICAL HISTORY

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

1 - YES 0 - NO 8 - UNK # of admissions

If YES,

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

1 - YES 0 - NO 8 - UNK # of admissions

If YES,

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

1 - YES 0 - NO 8 - UNK

a. If Yes, are wheezing medications regularly taken at home?

6. Has child had measles in the past month?

1 - YES 0 - NO 8 - UNK

CRF 03: CLINICAL HISTORY

Participant ID grid

DATE OF CLINICAL HISTORY: DAY MONTH 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

7a.iii. Does the child receive prophylactic nevirapine (NVP)? 1-YES 0-NO 8-UNK

If Yes, indicate duration: (xx)
Weeks Months

7a.iv. Does the child receive prophylactic Cotrimoxazole (Bactrim, Septrim)? 1-YES 0-NO 8-UNK

If Yes, indicate duration: (xx)
Weeks Months

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?: (xx)
Days Months Years

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

SITE LOGO

CRF 03: CLINICAL HISTORY

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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DAY

MONTH

YEAR

Child HIV

8. Is the child known to be HIV positive? 1-YES 0-NO 8-UNK

(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

i. If Yes, date HAART initiated:

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8-UNK
Day *Month* *Year*

b. Has the child attended a HAART clinic in the past 3 months? 1-YES 0-NO 8-UNK

c. Has the child had CD4 cell counts measured in the past 3 months? 1-YES 0-NO 8-UNK

If Yes, record the most recent CD4 results:

i. Date of CD4 test:

--	--

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8-UNK
Day *Month* *Year*

ii. CD4 number:

--	--	--	--

 / mm³ 8-UNK

iii. CD4 percent:

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 % 8-UNK

**CRF 03:
CLINICAL HISTORY**

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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DAY

MONTH

YEAR

TUBERCULOSIS

9. Is the child living in the same household with someone on TB treatment? 1 - YES 0 - NO 8 - UNK
 (If NO or UNK, go to Q10)

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 (if close contact is another child)			
<input type="checkbox"/>	08 - UNK			
<input type="checkbox"/>	99 - Other			
	Other, specify: _____ Code: <table border="1"><tr><td> </td><td> </td><td> </td></tr></table>			

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

10. Has this child ever been diagnosed with TB? 1 - YES 0 - NO 8 - UNK

a. If Yes, has this child ever received TB treatment? 1 - YES 0 - NO 8 - UNK
 (If No or UNK, go to Q11.)

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

11. Has the child had noticeable weight loss or failed to gain weight? 1 - YES 0 - NO 8 - UNK

OTHER UNDERLYING CONDITIONS

12. Did your child drink paraffin in the past 48 hours? 1 - YES 0 - NO 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

13. Thalassemia?..... 1 - YES 0 - NO 8 - UNK

**CRF 03:
CLINICAL HISTORY**

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PARTICIPANT ID

DATE OF CLINICAL HISTORY:

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DAY

MONTH

YEAR

IMMUNIZATION HISTORY

1 - YES 0 - NO 8 - UNK

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

15. Has the child had Vitamin A supplements in the last 6 months?

8 - UNK

16. Has the child had any of the following vaccinations?
(If Yes, list the date of each dose.) (for all vaccinations)

	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 <i>(Date received field available for 01KEN site only)</i>	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 MONTH 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: _____

STAFF CODE

Supervisor Signature: _____

STAFF CODE

Supervisor Verification Date:

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 border="1" style="display: inline-table; width: 60px; height: 25px;"></table>

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

<input type="checkbox"/>	1 - Yes	→	a. Clinic/hospital name: _____			Code: <table border="1" style="display: inline-table; width: 60px; height: 25px;"></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

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

	1 - Yes	0 - No	8 - UNK	9 - NR
21. Observed cough:.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. If Yes, is it a barking cough?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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/Creptitations:	<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"/>

e. Auscultation findings were done by: 8 - UNK 9 - NR

<input type="checkbox"/>	01 - Hospital staff	
<input type="checkbox"/>	02 - PERCH staff	
<input type="checkbox"/>	99 - Other, specify: _____	Code: <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>

28. Clubbing:..... 1 - Yes 0 - No 8 - UNK 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

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:

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(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

31. Bulging fontanelle (if < 18 months): 10 - N/A

32. Rash:..... 8 - UNK 9 - NR

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

<input type="checkbox"/>	01 - Petechial (size of individual lesions < 3 mm)			
<input type="checkbox"/>	02 - Purpural (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: 25px; vertical-align: middle;"> <tr> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> </tr> </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: 25px; vertical-align: middle;"> <tr> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> </tr> </table>
<input type="checkbox"/> Other: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 25px; vertical-align: middle;"> <tr> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> </tr> </table>
<input type="checkbox"/> Other: _____ Code: <table border="1" style="display: inline-table; width: 60px; height: 25px; vertical-align: middle;"> <tr> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> <td style="width: 20%;"> </td> </tr> </table>
<input type="checkbox"/> Not available/Not done by hospital
<input type="checkbox"/> Pneumonia diagnosis only | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

SITE LOGO



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

SITE LOGO

CRF 04A: CONTROL CLINICAL ASSESSMENT

PARTICIPANT ID

Date of assessment: DAY MONTH YEAR

NUTRITION / HYDRATION STATUS / VITAL SIGNS

1. Were any signs or symptoms of illness in the last 48 hours reported? (Question 1 on CRF03)

a. If Yes, temperature:

Temperature in degrees Celsius

SOURCE: 1-Auxillary 2-Rectal 8-UNK

2. Height/length:

Height/length in cm

3. Was the child weighed alone?

1-Yes 0-No

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

3a. Weight of child:

Weight of child in kg

4. Weight of mother and child:

Weight of mother and child in kg

5. Weight of mother:

Weight of mother in kg

6. Mid-upper arm circumference (MUAC)

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

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

Respiratory rate per min

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

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

Sound file record number format

b. Time of recording: (24 hour clock)

Time of recording

c. Digital auscultation comments:

10. Clubbing:

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

MISCELLANEOUS SIGNS

11. Rash:

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

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

Table with 2 columns: Rash type (01-09, 99-Other) and Code

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
- 01 - Mother 02 - Father 03 - Grandmother 04 - Grandfather
- 05 - Brother 06 - Sister 07 - Aunt 09 - Uncle
- 10 - Other relative 11 - Maid / Baby sitter
- 99 – Other, specify: _____ Code:

DEMOGRAPHICS

3. Mother's ethnic group (*choose 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: _____ Code: <table border="1" style="display: inline-table; width: 30px; height: 15px; vertical-align: middle;"></table> <table border="1" style="display: inline-table; width: 30px; height: 15px; vertical-align: middle;"></table> <table border="1" style="display: inline-table; width: 30px; height: 15px; vertical-align: middle;"></table>	

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: Code: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td><td style="width: 25px; height: 20px;"></td></tr></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: <i>(or description of intervention if name UNK)</i>	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: 24px;"></table> <input type="checkbox"/>
a2. _____ <input type="checkbox"/>	b2. <table border="1" style="display: inline-table; width: 100%; height: 24px;"></table> <input type="checkbox"/>
a3. _____ <input type="checkbox"/>	b3. <table border="1" style="display: inline-table; width: 100%; height: 24px;"></table> <input type="checkbox"/>
a4. _____ <input type="checkbox"/>	b4. <table border="1" style="display: inline-table; width: 100%; height: 24px;"></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)

SITE LOGO

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

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"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	<input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"><tr><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td><td style="width: 13.3px;"></td></tr></table>				<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)

--	--

8-UNK

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

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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*)

- | | | |
|---|---|---|
| <input type="checkbox"/> 01-Piped into house (indoor tap water) | <input type="checkbox"/> 06-Open well in house or yard | <input type="checkbox"/> 13-Protected spring |
| <input type="checkbox"/> 02-Piped into yard/compound/property | <input type="checkbox"/> 07-Covered well in house or yard | <input type="checkbox"/> 14-Unprotected spring |
| <input type="checkbox"/> 03-Bought (tank, bottles, etc) | <input type="checkbox"/> 09-Open public well | <input type="checkbox"/> 15-Dam or earth pan |
| <input type="checkbox"/> 04-Outdoor / Public tap | <input type="checkbox"/> 10-Covered public well | <input type="checkbox"/> 16-Rainwater |
| <input type="checkbox"/> 05- Borehole | <input type="checkbox"/> 11-Deep tube well | <input type="checkbox"/> 17-River, stream, pond or lake water |
| <input type="checkbox"/> 99-Other, specify: _____ | <input type="checkbox"/> 12-Shallow tube well | |

Code:

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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; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> 8-UNK <input type="checkbox"/>			
<input type="checkbox"/>	99-Other, specify: _____ Code: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></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; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></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; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>			

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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PARTICIPANT ID

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24. How long does it take to reach the water source used for washing hands? Mins 8-UNK

25. In the last 24 hours, have you used soap and water to wash your hands? 1-YES 0-NO 8-UNK

26. Does your household have a shared basin with standing water for washing hands? 1-YES 0-NO 8-UNK
 a. If yes, how many times per day is the water changed? (if <1 time per day, put 0) 8-UNK

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: <input type="text"/> <input type="text"/> <input type="text"/>

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: <input type="text"/> <input type="text"/> <input type="text"/>

SITE LOGO

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"><tr><td></td><td></td><td></td></tr></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"><tr><td></td><td></td><td></td></tr></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"/>	<input type="checkbox"/>
	Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>	Code: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>

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)

<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

8-UNK

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)

<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)

8-UNK

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

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

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?

1-YES 0-NO 8-UNK

CRF 05: DEMOGRAPHICS & ENVIRONMENTAL RISK FACTORS

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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 style="width: 100%;"> <tr> <td style="width: 70%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%; text-align: center;">8-UNK <input type="checkbox"/></td> <td style="width: 20%;"></td> </tr> </table>	<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>		<table style="width: 100%;"> <tr> <td style="width: 70%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%; text-align: center;">8-UNK <input type="checkbox"/></td> <td style="width: 20%; text-align: center;">9-N/A <input type="checkbox"/></td> </tr> </table>	<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>
<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>							
<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>						
b. Study hospital	<table style="width: 100%;"> <tr> <td style="width: 70%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%; text-align: center;">8-UNK <input type="checkbox"/></td> <td style="width: 20%;"></td> </tr> </table>	<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>		<table style="width: 100%;"> <tr> <td style="width: 70%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%; text-align: center;">8-UNK <input type="checkbox"/></td> <td style="width: 20%; text-align: center;">9-N/A <input type="checkbox"/></td> </tr> </table>	<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>
<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>							
<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>						
c. Is the study hospital the nearest hospital? 1-YES <input type="checkbox"/> 0-NO <input type="checkbox"/> 8-UNK <input type="checkbox"/>								
d. Nearest hospital <i>(If nearest hospital is the study hospital, answer N/A.)</i>	<table style="width: 100%;"> <tr> <td style="width: 70%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%; text-align: center;">8-UNK <input type="checkbox"/></td> <td style="width: 20%; text-align: center;">9-N/A <input type="checkbox"/></td> </tr> </table>	<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>	<table style="width: 100%;"> <tr> <td style="width: 70%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%; text-align: center;">8-UNK <input type="checkbox"/></td> <td style="width: 20%; text-align: center;">9-N/A <input type="checkbox"/></td> </tr> </table>	<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>
<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>						
<input style="width: 100%;" type="text"/>	8-UNK <input type="checkbox"/>	9-N/A <input type="checkbox"/>						

*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:

--	--	--

If Other, specify: _____ Other code:

--	--	--

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

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If Other, specify: _____ Other code:

--	--	--

08-UNK

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"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/>
b. Sheep	<input type="checkbox"/>	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/>
c. Goats	<input type="checkbox"/>	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/>
d. Horses	<input type="checkbox"/>	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/>
e. Donkeys	<input type="checkbox"/>	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/>
f. Pigs	<input type="checkbox"/>	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<input type="checkbox"/>
g. Chickens	<input type="checkbox"/>	<table border="1"><tr><td></td><td></td><td></td><td></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

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
8-UNK

a. If yes, specify how many acres?

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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: 30px; height: 15px; 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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></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: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></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: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></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: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 8-UNK <input type="checkbox"/>	<table border="1" style="display: inline-table; width: 30px; height: 15px;"></table> 9- N/A <input type="checkbox"/>

SITE LOGO

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 0-NO 8-UNK

a. For how many months was the child exclusively breastfed?

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 8-UNK

b. For how many months was the child breastfed?

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 8-UNK

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:**

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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

<p>In instances of limited blood volume, the following guidance applies in decreasing order of priority:</p> <ol style="list-style-type: none"> 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 <p><small>*Volume may vary based on local requirements for CBC and risk factor tests.</small></p>	<p>When < 3mL of blood is collected from a patient, the following guidelines may be used:</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 15%;">Total Volume Available</th> <th style="width: 15%;">Blood Culture Bottle Volume</th> <th style="width: 15%;">EDTA Tube #1 (CBC*) Volume</th> <th style="width: 15%;">EDTA Tube #2 (PCR) Volume</th> <th style="width: 15%;">Plain/ Red Top Tube Volume</th> </tr> </thead> <tbody> <tr> <td>< 1 mL</td> <td>all</td> <td>0 mL</td> <td>0 mL</td> <td>0 mL</td> </tr> <tr> <td>1 to < 2 mL</td> <td>1 mL</td> <td>0.5* mL</td> <td>0 - 0.5 mL</td> <td>0 mL</td> </tr> <tr> <td>2 to < 3 mL</td> <td>1 mL</td> <td>0.5* mL</td> <td>0.5 – 1 mL</td> <td>Any remaining volume</td> </tr> </tbody> </table>	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
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.

SITE LOGO

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="checkbox"/> Other: _____ Other specify code: <input style="width: 30px; height: 20px;" type="text"/>	DAY: <input style="width: 30px; height: 20px;" type="text"/> MONTH: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/> YEAR: <input style="width: 30px; height: 20px;" type="text"/> TIME: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Initials: _____ Staff code: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input style="width: 100%; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/>
b. EDTA tube #1 (CBC) <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="checkbox"/> Other: _____ Other specify code: <input style="width: 30px; height: 20px;" type="text"/>	DAY: <input style="width: 30px; height: 20px;" type="text"/> MONTH: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/> YEAR: <input style="width: 30px; height: 20px;" type="text"/> TIME: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Initials: _____ Staff code: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input style="width: 100%; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/>
c. EDTA tube #2 (PCR) <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="checkbox"/> Other: _____ Other specify code: <input style="width: 30px; height: 20px;" type="text"/>	DAY: <input style="width: 30px; height: 20px;" type="text"/> MONTH: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/> YEAR: <input style="width: 30px; height: 20px;" type="text"/> TIME: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Initials: _____ Staff code: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input style="width: 100%; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/>
d. Plain/ red top tube <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input type="checkbox"/> Other: _____ Other specify code: <input style="width: 30px; height: 20px;" type="text"/>	DAY: <input style="width: 30px; height: 20px;" type="text"/> MONTH: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/> YEAR: <input style="width: 30px; height: 20px;" type="text"/> TIME: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Initials: _____ Staff code: <input style="width: 30px; height: 20px;" type="text"/> 8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input style="width: 100%; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" 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)

SITE LOGO



**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	Reason code: <input type="checkbox"/>	DAY: <input type="text"/> <input type="text"/>	Initials: _____	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"/> <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="checkbox"/> NO	Other: _____	MONTH: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="checkbox"/>	Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
		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"/> 8 - UNK <input type="checkbox"/>	TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> UNK <input type="checkbox"/>	
b. OPS	<input type="checkbox"/> YES	Reason code: <input type="checkbox"/>	DAY: <input type="text"/> <input type="text"/>	Initials: _____	Rayon NP swab should be put in STGG vial. 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"/> - <input type="text"/> <input type="text"/>
	<input type="checkbox"/> NO	Other: _____	MONTH: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="checkbox"/>	Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
		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"/> UNK <input type="checkbox"/>	TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> UNK <input type="checkbox"/>	
c. NPS-STGG	<input type="checkbox"/> YES	Reason code: <input type="checkbox"/>	DAY: <input type="text"/> <input type="text"/>	Initials: _____	Rayon NP swab should be put in STGG vial. 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"/> - <input type="text"/> <input type="text"/>
	<input type="checkbox"/> NO	Other: _____	MONTH: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 8 - UNK <input type="checkbox"/>	Staff code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
		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"/> 8 - UNK <input type="checkbox"/>	TIME: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> UNK <input type="checkbox"/>	

*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 <input type="checkbox"/> Yes, urine bag or catheter <input type="checkbox"/> NO	Reason code: <input style="width: 30px;" type="text"/> Other: _____ Other specify code: <input style="width: 30px; height: 20px;" type="text"/>	DAY: <input style="width: 30px; height: 20px;" type="text"/> MONTH: <input style="width: 60px; height: 20px;" type="text"/> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/> YEAR: <input style="width: 80px; height: 20px;" type="text"/> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/> TIME: <input style="width: 60px; height: 20px;" type="text"/> 8 - UNK <input style="width: 20px; height: 20px;" type="checkbox"/>	Initials: _____ Staff code: <input style="width: 40px; height: 20px;" type="text"/>	Scan or affix barcode label: <input style="width: 60px; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" 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:**

Supervisor Verification Date:
Day Month Year

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: <input style="width: 40px;" type="text"/> Other: _____ Other specify code: <input style="width: 40px;" type="text"/>	TIME: <input style="width: 100px;" type="text"/> 8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input style="width: 100px;" type="text"/> - <input style="width: 40px;" type="text"/>
b. Plain/ red top tube <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input style="width: 40px;" type="text"/> Other: _____ Other specify code: <input style="width: 40px;" type="text"/>	TIME: <input style="width: 100px;" type="text"/> 8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input style="width: 100px;" type="text"/> - <input style="width: 40px;" type="text"/>
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: <input style="width: 40px;" type="text"/> Other: _____ Other specify code: <input style="width: 40px;" type="text"/>	TIME: <input style="width: 100px;" type="text"/> 8 - UNK <input type="checkbox"/>	Scan or affix barcode label: <input style="width: 100px;" type="text"/> - <input style="width: 40px;" type="text"/>

* 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 style="width: 30px;" type="text"/> Other: _____ Other specify code: <input style="width: 30px;" type="text"/>	TIME: <input style="width: 40px;" type="text"/> <input style="width: 20px;" 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). <div style="border: 1px solid black; padding: 5px; text-align: center;"> Scan or affix barcode label: <input style="width: 100px;" type="text"/> - <input style="width: 30px;" type="text"/> </div>
b. OPS <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input style="width: 30px;" type="text"/> Other: _____ Other specify code: <input style="width: 30px;" type="text"/>	TIME: <input style="width: 40px;" type="text"/> <input style="width: 20px;" type="text"/> 8 - UNK <input 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: <input style="width: 100px;" type="text"/> - <input style="width: 30px;" type="text"/> </div>
c. NPS-STGG <input type="checkbox"/> YES <input type="checkbox"/> NO	Reason code: <input style="width: 30px;" type="text"/> Other: _____ Other specify code: <input style="width: 30px;" type="text"/>	TIME: <input style="width: 40px;" type="text"/> <input style="width: 20px;" type="text"/> 8 - UNK <input 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: <input style="width: 100px;" type="text"/> - <input style="width: 30px;" type="text"/> </div>
d. Urine <input type="checkbox"/> YES, sterile cup <input type="checkbox"/> YES, urine bag <input type="checkbox"/> NO	Reason code: <input style="width: 30px;" type="text"/> Other: _____ Other specify code: <input style="width: 30px;" type="text"/>	TIME: <input style="width: 40px;" type="text"/> <input style="width: 20px;" type="text"/> 8 - UNK <input type="checkbox"/> Date of urine collection if different from date above: <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <i style="font-size: small;">Day Month Year</i>	Scan or affix barcode label: <div style="border: 1px solid black; padding: 5px; text-align: center;"> <input style="width: 100px;" type="text"/> - <input style="width: 30px;" type="text"/> </div>

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)

SITE LOGO

**CRF 07:
CASE SPECIMEN COLLECTION: INDUCED SPUTUM**

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PARTICIPANT ID

Date form completed:

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DAY MONTH 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	<u>If No</u> , reason not collected <i>(check all that apply)</i> :			
<p>3. Was IS or ETT aspirate collected <u>within 24 hrs</u> of admission? <i>(If Yes, skip to Q5)</i></p>	<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;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>			
<p>4. Was IS or ETT aspirate collected more than <u>24 hrs</u> after admission?</p>	<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;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>			

**CRF 07:
CASE SPECIMEN COLLECTION: INDUCED SPUTUM**

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PARTICIPANT ID

Date form completed:

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DAY MONTH 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 Code: <table border="1" style="display: inline-table;"><tr><td> </td><td> </td><td> </td></tr></table>			

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 Month Year (24 hr clock)

b. IS collection performed by: _____

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Staff Code:

Scan or affix barcode label here:

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c. Enter IS specimen ID (barcode label):

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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MONTH

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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 style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td>.</td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>				.		<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>				<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></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 style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td>.</td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>				.		<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>				<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></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 style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td>.</td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>				.		<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>				<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></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 style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td>.</td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>				.		<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>				<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></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 style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td>.</td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - N/A <input type="checkbox"/>				.		<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> 8 - UNK <input type="checkbox"/> 9 - NR <input type="checkbox"/>				<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></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

SITE LOGO

**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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MONTH

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YEAR

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:
CASE SPECIMEN COLLECTION: INDUCED SPUTUM**

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PARTICIPANT ID

Date form completed:

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DAY

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MONTH

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YEAR

Time point	i. Oxygen requirement (XX.X, L/min) <i>(N/A if not on O₂)</i>	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

SITE LOGO

**CRF 07:
CASE SPECIMEN COLLECTION: INDUCED SPUTUM**

Participant ID input boxes

PARTICIPANT ID

Date form completed:

Day input boxes

DAY

Month input boxes

MONTH

Year input boxes

YEAR

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:

Horizontal lines for 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

SITE LOGO

**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 MONTH YEAR

1. Time of ETT aspirate collection:

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8 - UNK
TIME (24 hour clock)

2. Specimen collected by Staff Code:

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3. ETT aspirate specimen ID (barcode label):

Scan or affix barcode label:												
										-		

Comments: _____

Supervisor Signature: _____ **STAFF CODE:**

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Day Month Year

SITE LOGO

CRF 07GA: CASE SPECIMEN COLLECTION: GASTRIC ASPIRATE

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PARTICIPANT ID

DATE SPECIMEN COLLECTED:

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DAY

MONTH

YEAR

1. Time of gastric aspirate collection:

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8 - UNK

TIME (24 hour clock)

2. Specimen collected by Staff Code:

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3. Gastric aspirate specimen ID (barcode label):

Scan or affix barcode label												
										-		

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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DAY

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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)

Scan or affix barcode label:

If Yes, insert specimen ID (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):

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

- 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

**CRF 08:
CASE CXR**

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PARTICIPANT ID

Date of CXR:

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DAY

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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? <input type="checkbox"/> 1 – YES <input type="checkbox"/> 0 – NO			
If No, reason not collected (<i>check all that apply</i>):			
<input type="checkbox"/> Unknown			
<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: _____ Other code: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td></tr></table>			

- 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

MONTH

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:
CASE SPECIMEN COLLECTION: LUNG ASPIRATE**

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PARTICIPANT ID

DATE LUNG ASPIRATE COLLECTED:

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DAY

MONTH

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"> <tr><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"/> 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"> <tr><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"/> 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"> <tr><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"/> 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"> <tr><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"/> 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"/>

SITE LOGO

**CRF 09:
CASE SPECIMEN COLLECTION: LUNG ASPIRATE**

Participant ID input boxes

PARTICIPANT ID

DATE LUNG
ASPIRATE COLLECTED:

Day input boxes

DAY

Month input boxes

MONTH

Year input boxes

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: _____

Staff code input boxes

STAFF CODE

Day input boxes

Day

Month input boxes

Month

Year input boxes

Year

SITE LOGO

**CRF 10:
CASE SPECIMEN COLLECTION: PLEURAL FLUID**

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PARTICIPANT ID

Specimen number:

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Date specimen collected:

DAY		MONTH		YEAR					

1. Time of pleural fluid collection:

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

2. Specimen collected by Staff Code:

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

Scan or affix barcode label:												
										-		

Comments: _____

Supervisor Signature: _____ **STAFF CODE:**

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Day		Month		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:

<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>	8-UNK <input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"> </table>	8-UNK <input type="checkbox"/>
DAY	MONTH	YEAR		(24 hour clock)	

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. Oseltamivir
- b. Zanamivir
- c. Other: *Specify:* _____ *Code:*

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d. Date and time first influenza medication was administered:

<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>	8-UNK <input type="checkbox"/>	<table border="1" style="width: 40px; height: 20px;"> </table>	8-UNK <input type="checkbox"/>
DAY	MONTH	YEAR		(24 hour clock)	

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?
(as part of bronchodilator challenge or otherwise) 1-YES 0-NO 8-UNK

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					

SITE LOGO



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

PARTICIPANT ID

DATE FORM
COMPLETED:

DAY

MONTH

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: (24 hour clock)

3. Location of assessment:

1 - Hospital 2 - Clinic 3 - Home

4. Temperature..... . °C 1- Axillary 2- Rectal 8-UNK

5. Respiratory rate (# of breaths counted in 60 seconds): 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:..... . L/min 8-UNK

7. Is child receiving mechanical ventilation?..... 1-YES 0-NO 8-UNK

8. Pulse oximetry (on room air whenever possible): % 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

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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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. <input type="checkbox"/> Amoxicillin (ampicillin)	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. <input type="checkbox"/> Amoxicillin & Clavulonate (Augmentin)	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. <input type="checkbox"/> Cotrimoxizole (Bactrim, Septrin)	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. <input type="checkbox"/> Cefuroxime (2 nd gen. Cephalosporin)	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. <input type="checkbox"/> Ceftriaxone (3 rd gen. Cephalosporin)	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. <input type="checkbox"/> Macrolide (Azithromycin, Erythromycin)	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. <input type="checkbox"/> Aminoglycoside (Gentamicin)	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. <input type="checkbox"/> Cloxacillin	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. <input type="checkbox"/> Chloramphenicol	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. <input type="checkbox"/> Ganciclvir	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. <input type="checkbox"/> Any Quinolone (specify: _____) <input type="text"/>	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. <input type="checkbox"/> Other antibiotic: _____	If checked, <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other code: <input type="text"/>			

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: <input type="text"/>

**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:

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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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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 Month 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:

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:

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

 per minute

8 - UNK 9 - N/A

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

 %

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:

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?

 mm 8 - UNK

Diagnostic test

Other, specify: _____ Code:

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

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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MONTH

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YEAR

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

8 - UNK

- | | |
|--|--|
| <input type="checkbox"/> Pneumonia
<input type="checkbox"/> Bronchiolitis (Acute)
<input type="checkbox"/> Lower respiratory tract infection
<input type="checkbox"/> Afebrile seizure disorder
<input type="checkbox"/> Anaemia – cause unknown
<input type="checkbox"/> Anaemic heart failure
<input type="checkbox"/> Asthma (Acute)
<input type="checkbox"/> Birth asphyxia
<input type="checkbox"/> Cellulitis
<input type="checkbox"/> Cerebral palsy
<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"/> Dysentery
<input type="checkbox"/> Empyema thoracis
<input type="checkbox"/> Epilepsy
<input type="checkbox"/> Failure to thrive
<input type="checkbox"/> Febrile convulsion (Acute)
<input type="checkbox"/> Gastroenteritis
<input type="checkbox"/> Helminthiasis
<input type="checkbox"/> HIV
<input type="checkbox"/> Immunosuppression | <input type="checkbox"/> Malaria
<input type="checkbox"/> Malnutrition
<input type="checkbox"/> Meningitis
<input type="checkbox"/> Mucocutaneous candidiasis
<input type="checkbox"/> Neonatal sepsis
<input type="checkbox"/> Osteomyelitis (Acute)
<input type="checkbox"/> Otitis media
<input type="checkbox"/> PCP Pneumonia
<input type="checkbox"/> Pneumothorax - primary and secondary
<input type="checkbox"/> Poisoning

<input type="checkbox"/> Prematurity
<input type="checkbox"/> Protein energy malnutrition
<input type="checkbox"/> Pulmonary TB
<input type="checkbox"/> Septic arthritis
<input type="checkbox"/> Septicaemia
<input type="checkbox"/> Sickle cell anaemia
<input type="checkbox"/> Sickle cell disease
<input type="checkbox"/> Skin sepsis
<input type="checkbox"/> Urinary tract infection
<input type="checkbox"/> Upper respiratory tract infection |
|--|--|

Other: _____ Code:

Other: _____ Code:

Other: _____ Code:

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:

Other: _____ Code:

Other: _____ Code:

Comments: _____

Form Completed by: _____ **STAFF CODE:**

Supervisor Signature: _____ **STAFF CODE:**

Supervisor Verification Date:

Day Month 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" style="display: inline-table; width: 30px; height: 15px;"><tr><td style="width: 10px;"></td><td style="width: 10px;"></td><td style="width: 10px;"></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" style="display: inline-table; width: 30px; height: 15px;"><tr><td style="width: 10px;"></td><td style="width: 10px;"></td><td style="width: 10px;"></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" style="display: inline-table; width: 30px; height: 15px;"><tr><td style="width: 10px;"></td><td style="width: 10px;"></td><td style="width: 10px;"></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

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

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PARTICIPANT ID

DATE OF LUNG BIOPSY:

DAY		MONTH		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: (24 hour clock) 8 - UNK

2. Death-biopsy (or aspiration) interval in hours: 8 - UNK

3. Procedure performed by Staff Code:

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

								P	R
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b. Left Lung: 1 - Yes
 0 - No

Insert barcode number or label:									
								P	L

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

Sample Type	Tube	Specimen ID (scan barcode label):										
<p>g) Histology core from a diseased lobe Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube H11	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>-</td> <td>H</td><td>1</td><td>1</td> </tr> </table>							-	H	1	1
						-	H	1	1			
<p>h) Histology core from a diseased lobe Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube H12	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>-</td> <td>H</td><td>1</td><td>2</td> </tr> </table>							-	H	1	2
						-	H	1	2			
<p>i) Histology core from non-diseased lobe of diseased lung Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube H13	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>-</td> <td>H</td><td>1</td><td>3</td> </tr> </table>							-	H	1	3
						-	H	1	3			
<p>j) Frozen tissue core from a diseased lobe Core collected?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube F16	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>-</td> <td>F</td><td>1</td><td>6</td> </tr> </table>							-	F	1	6
						-	F	1	6			
<p>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?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube M4	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>-</td> <td>M</td><td>4</td> </tr> </table>							-	M	4	
						-	M	4				
<p>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?</p> <p><input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No</p>	Tube M5	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>-</td> <td>M</td><td>5</td> </tr> </table>							-	M	5	
						-	M	5				

**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):										
<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	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>–</td> <td>M</td><td>6</td> </tr> </table>							–	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	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>–</td> <td>R</td><td>9</td> </tr> </table>							–	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	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>–</td> <td>R</td><td>1</td><td>0</td> </tr> </table>							–	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	<p>Insert barcode number or label:</p> <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> <td>–</td> <td>H</td><td>1</td><td>4</td> </tr> </table>							–	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

<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	Insert barcode number or label: <table border="1" style="width: 100%; height: 40px; margin: 5px 0;"> <tr> <td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td> <td style="width: 10px; text-align: center;">-</td> <td style="width: 15px; text-align: center;">M</td> <td style="width: 15px; text-align: center;">4</td> </tr> </table>							-	M	4	
						-	M	4				
k) Microbiology core from LLL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M5	Insert barcode number or label: <table border="1" style="width: 100%; height: 40px; margin: 5px 0;"> <tr> <td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td> <td style="width: 10px; text-align: center;">-</td> <td style="width: 15px; text-align: center;">M</td> <td style="width: 15px; text-align: center;">5</td> </tr> </table>							-	M	5	
						-	M	5				
l) Microbiology core from LUL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube M6	Insert barcode number or label: <table border="1" style="width: 100%; height: 40px; margin: 5px 0;"> <tr> <td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td> <td style="width: 10px; text-align: center;">-</td> <td style="width: 15px; text-align: center;">M</td> <td style="width: 15px; text-align: center;">6</td> </tr> </table>							-	M	6	
						-	M	6				
m) RNAlater core from LUL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube R9	Insert barcode number or label: <table border="1" style="width: 100%; height: 40px; margin: 5px 0;"> <tr> <td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td> <td style="width: 10px; text-align: center;">-</td> <td style="width: 15px; text-align: center;">R</td> <td style="width: 15px; text-align: center;">9</td> </tr> </table>							-	R	9	
						-	R	9				
n) RNAlater core from LLL Core collected? <input type="checkbox"/> 1 – Yes <input type="checkbox"/> 0 - No	Tube R10	Insert barcode number or label: <table border="1" style="width: 100%; height: 40px; margin: 5px 0;"> <tr> <td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td> <td style="width: 10px; text-align: center;">-</td> <td style="width: 15px; text-align: center;">R</td> <td style="width: 15px; text-align: center;">1</td> <td style="width: 15px; text-align: center;">0</td> </tr> </table>							-	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	Insert barcode number or label: <table border="1" style="width: 100%; height: 40px; margin: 5px 0;"> <tr> <td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td> <td style="width: 10px; text-align: center;">-</td> <td style="width: 15px; text-align: center;">H</td> <td style="width: 15px; text-align: center;">1</td> <td style="width: 15px; text-align: center;">4</td> </tr> </table>							-	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	Insert barcode number or label: <table border="1" style="width: 100%; height: 40px; margin: 5px 0;"> <tr> <td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td> <td style="width: 10px; text-align: center;">-</td> <td style="width: 15px; text-align: center;">H</td> <td style="width: 15px; text-align: center;">1</td> <td style="width: 15px; text-align: center;">5</td> </tr> </table>							-	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:

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 (xx)

1. Date of SAE:

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 /

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 /

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DAY MONTH YEAR

2. Date of birth:

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 /

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 /

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DAY MONTH YEAR

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:

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(24 HR)

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:

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 /

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 /

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 /

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DAY MONTH YEAR TIME (24 HR)

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:

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 /

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 /

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 /

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DAY MONTH YEAR TIME (24 HR)

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 border="1" style="display: inline-table; width: 40px; height: 20px; vertical-align: middle;"><tr><td style="width: 10px;"></td><td style="width: 10px;"></td><td style="width: 10px;"></td><td style="width: 10px;"></td></tr></table>							

**CRF 16:
 CASE SERIOUS ADVERSE EVENT**

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PARTICIPANT ID

SAE event number for this child:

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 (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:

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

Code:

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9. SAE Severity:

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

SITE LOGO

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: _____

Form Completed By: _____

--	--	--	--

Staffcode

Local Safety Monitor: _____

--	--	--	--

Staffcode

Supervisor Signature: _____

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Staffcode

Verification Date:

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DAY MONTH YEAR

SITE LOGO

CRF 17: CASE MORTALITY

_____|_____|_____|_____|_____|_____|

PARTICIPANT ID

DATE OF DEATH: _____|_____|_____|_____|_____|_____|

DAY

MONTH

YEAR

1 - YES 0 - NO 8 - UNK

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"/> 05 - Meningitis |
| <input type="checkbox"/> 02 - Gastorenteritis | <input type="checkbox"/> 06 - Malnutrition |
| <input type="checkbox"/> 03 - Malaria | <input type="checkbox"/> 07 - HIV |
| <input type="checkbox"/> 04 - Dehydration/shock | <input type="checkbox"/> 09 - Sepsis (any cause) |
| <input type="checkbox"/> 99 - Other, specify: _____ | Code: _____ _____ _____ _____ |

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"/> Meningitis |
| <input type="checkbox"/> Gastorenteritis | <input type="checkbox"/> Malnutrition |
| <input type="checkbox"/> Malaria | <input type="checkbox"/> HIV |
| <input type="checkbox"/> Dehydration/shock | <input type="checkbox"/> Sepsis (any cause) |
| <input type="checkbox"/> Other, specify _____ | Code: _____ _____ _____ _____ |

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

MONTH

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: 40px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 10px;"></td></tr></table>			
<input type="checkbox"/>	02 - Home				
<input type="checkbox"/>	99 - Other, specify: _____	Code: <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 10px;"></td></tr></table>			

7. Is a death certificate available?

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

1-YES 0-NO 8-UNK

a. Immediate cause of death (check one):

8-UNK

<input type="checkbox"/> 01 - Pneumonia	<input type="checkbox"/> 05 - Meningitis			
<input type="checkbox"/> 02 - Gastroenteritis	<input type="checkbox"/> 06 - Malnutrition			
<input type="checkbox"/> 03 - Malaria	<input type="checkbox"/> 07 - HIV			
<input type="checkbox"/> 04 - Dehydration/shock	<input type="checkbox"/> 09 - Sepsis (any cause)			
<input type="checkbox"/> 99 - Other, specify: _____	Code: <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 10px;"></td></tr></table>			

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

8 - UNK 9 - NONE

<input type="checkbox"/> Pneumonia	<input type="checkbox"/> Meningitis			
<input type="checkbox"/> Gastroenteritis	<input type="checkbox"/> Malnutrition			
<input type="checkbox"/> Malaria	<input type="checkbox"/> HIV			
<input type="checkbox"/> Dehydration/shock	<input type="checkbox"/> Sepsis (any cause)			
<input type="checkbox"/> Other, specify: _____	Code: <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 10px;"></td></tr></table>			

CRF 17: CASE MORTALITY

PARTICIPANT ID

DATE OF DEATH:

DAY

MONTH

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

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

- Pneumonia
- Gastorenteritis
- Malaria
- Dehydration/shock
- Meningitis
- Malnutrition
- HIV
- 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

- Pneumonia
- Gastorenteritis
- Malaria
- Dehydration/shock
- Meningitis
- Malnutrition
- HIV
- Sepsis (any cause)

Other, specify: _____ Code:

Other, specify: _____ Code:

Other, specify: _____ Code:

SITE LOGO

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

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:

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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:

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Comments:

Interviewer's Name: _____

STAFF CODE:

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Supervisor Signature: _____

STAFF CODE:

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Day

Month

Year

SITE LOGO

CRF 18: STUDY TERMINATION

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PARTICIPANT ID

Date of termination

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DAY

MONTH

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"><tr><td></td><td></td><td></td></tr></table>			
<input type="checkbox"/>	8 - UNK			

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 Month Year

CRF 19: LAB: SPECIMEN RECEPTION

DATE
SPECIMEN
RECEIVED

DAY	

MONTH		

YEAR			

1. Specimen ID (barcode label):

Scan or Affix Barcode Label											
										-	

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 case tube #1	<input type="checkbox"/>	3A - NP STGG Swab	<input type="checkbox"/>	6C - Third Gastric Aspirate
<input type="checkbox"/>	1D - EDTA case tube #2	<input type="checkbox"/>	3B - NP VTM and OP Swab	<input type="checkbox"/>	7A - Urine
<input type="checkbox"/>	1E - EDTA control tube #1	<input type="checkbox"/>	3B - NP VTM Swab ONLY	<input type="checkbox"/>	7B - 30 Day Follow up Urine
<input type="checkbox"/>	1F - EDTA control 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:

TIME (24 hour clock)			

4. Specimen volume:

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

CRF 19: LAB: SPECIMEN RECEPTION

DATE SPECIMEN RECEIVED

DAY	MONTH	YEAR
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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:

Day *Month* *Year*

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

DATE
SPECIMEN
RECEIVED

DAY	

MONTH		

YEAR			

1. Specimen ID (barcode label):

Scan or Affix Barcode Label										

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 Aspirate – 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:

µl				

Volume should be recorded for the pleural aspirates only.

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

DATE SPECIMEN RECEIVED

DAY	MONTH	YEAR
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5. Status: 1 - Accepted for processing
 2 - Rejected – specify reason below (check all that apply):

Contact study personnel immediately if any apply



- | | |
|--------------------------|--|
| <input type="checkbox"/> | a. Specimen unlabeled |
| <input type="checkbox"/> | b. Specimen ID does not match ID on requisition form |
| <input type="checkbox"/> | c. Specimen container is leaking |
| <input type="checkbox"/> | 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:

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Supervisor Verification Date:

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Day Month Year

CRF 190TH: OTHER LAB: RECEPTION

DATE
SPECIMEN
RECEIVED

DAY

MONTH

YEAR

Scan or Affix Barcode Label

1. Specimen ID (barcode label):

 -

2. Other Specimen Type:

Other, specify: _____

Code:

3. Time received in laboratory:

TIME (24 hour clock)

4. Specimen volume:

µl

 N/A

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

Comments: _____

7. Person Receiving Specimen Staff Code:

Supervisor Staff Code:

Supervisor Verification Date:

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%; height: 20px; margin-top: 5px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>					<table border="1" style="width: 100%; border: 1px solid gray; margin-top: 5px;"> <tr> <td style="text-align: center; padding: 5px;">Scan/Affix Barcode Label</td> </tr> <tr> <td style="text-align: center;"> <table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table> </td> </tr> </table> <div style="margin-top: 5px; text-align: right;"> 9 - N/A <input type="checkbox"/> </div>	Scan/Affix Barcode Label	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>									<input type="checkbox"/> 1 - C <input type="checkbox"/> 2 - U <input type="checkbox"/> 3 - NC
Scan/Affix Barcode Label																
<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>																
b. Organism 2 <table border="1" style="width: 100%; height: 20px; margin-top: 5px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>					<table border="1" style="width: 100%; border: 1px solid gray; margin-top: 5px;"> <tr> <td style="text-align: center; padding: 5px;">Scan/Affix Barcode Label</td> </tr> <tr> <td style="text-align: center;"> <table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table> </td> </tr> </table> <div style="margin-top: 5px; text-align: right;"> 9 - N/A <input type="checkbox"/> </div>	Scan/Affix Barcode Label	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>									<input type="checkbox"/> 1 - C <input type="checkbox"/> 2 - U <input type="checkbox"/> 3 - NC
Scan/Affix Barcode Label																
<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>																
c. Organism 3 <table border="1" style="width: 100%; height: 20px; margin-top: 5px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>					<table border="1" style="width: 100%; border: 1px solid gray; margin-top: 5px;"> <tr> <td style="text-align: center; padding: 5px;">Scan/Affix Barcode Label</td> </tr> <tr> <td style="text-align: center;"> <table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table> </td> </tr> </table> <div style="margin-top: 5px; text-align: right;"> 9 - N/A <input type="checkbox"/> </div>	Scan/Affix Barcode Label	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>									<input type="checkbox"/> 1 - C <input type="checkbox"/> 2 - U <input type="checkbox"/> 3 - NC
Scan/Affix Barcode Label																
<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> <td style="width: 25px;"></td> </tr> </table>																

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)	<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"/>
b. AMP (Ampicillin)	<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"/>
c. CAZ (Ceftazidime)	<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"/>
d. CH (Chloramphenicol)	<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"/>
e. CIP (Ciprofloxacin)	<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"/>
f. CN (Gentamicin)	<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"/>
g. CRO (Ceftriaxone)	<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"/>
h. CTX (Cefotaxime)	<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"/>
i. DA (Clindamycin)	<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"/>
j. ERY (Erythromycin)	<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"/>
k. FOX (Cefoxitin)	<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"/>
l. IPM (Imipenem)	<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"/>
m. OX (Oxacillin)	<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"/>
n. P (Penicillin)	<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"/>
o. SXT (Cotrimoxazole)	<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"/>
p. TET (Tetracycline)	<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"/>
q. VA (Vancomycin)	<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"/>
r. Other: _____ Code: <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"/>	<input type="text"/> <input type="text"/>	<input type="text"/>
s. Other: _____ Code: <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"/>	<input type="text"/> <input type="text"/>	<input type="text"/>
t. Other: _____ Code: <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"/>	<input type="text"/> <input type="text"/>	<input type="text"/>
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 < >

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 µg/mL

b. Ceftriaxone or Cefotaxime (choose one) < >

--	--

 .

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 µg/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 < >

--	--

 .

--	--	--

 µg/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.

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SITE LOGO



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:

--	--	--	--

Supervisor Staff Code:

--	--	--	--

Supervisor Verification Date:

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Day Month Year

CRF 21: LAB RESULT: PNEUMOCOCCAL PCR

DATE FORM INITIATED:
DAY MONTH YEAR

NOT DONE:
Stop here and end form

Scan or Affix Barcode Label:

 -

1. Nucleic acid extract aliquot ID (barcode label):

2. Date of nucleic acid extraction:

DAY MONTH YEAR

3. Volume of blood extracted:

μL

4. Technician who performed extraction :

STAFF CODE

5. Date of PCR run:

DAY MONTH YEAR

6. Technician who performed PCR run :

STAFF CODE

Comments: _____

Supervisor Staff Code:

Supervisor Verification Date:
Day Month Year

CRF 23: LAB RESULT: CORE BLOOD TESTS

HIV ANTIBODY TEST

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

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

NOT DONE:
Skip to next section

(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

NOT DONE:
Skip to Q15

12. Date of test:

DAY MONTH YEAR

13. CD4 test result:

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

b. CD4 percent: . % 9 - Not done

14. Technician's Staff Code:

CRF 23: LAB RESULT: CORE BLOOD TESTS

SICKLE CELL TEST [THALASSEMIA TESTING for Thailand]

15. Date of test:
DAY MONTH YEAR

16. Specimen ID (barcode label): -
Scan or Affix Barcode Label: Same as Above

17. Technician's Staff Code:

18. a. Solubility testing results
 1 - Positive 2 - Negative 9 - N/A

b. Test result / HB type: (check one) 09 - 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, specify: _____ Other code:

c. Hemoglobin Fractions
A . % 9 - N/A F . % 9 - N/A
A₂ . % 9 - N/A Cs . % 9 - N/A
E . % 9 - N/A H . % 9 - N/A

MALARIA TESTING

NOT DONE:
Skip to next section

19. Date of test:
DAY MONTH YEAR

20. Specimen ID (barcode label): -
Scan or Affix Barcode Label:

21. Technician's Staff Code:

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:

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

**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:

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

29. CD4 test result:

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

b. CD4 percent: . % 9 - Not done

SITE LOGO



**CRF 23:
LAB RESULT: CORE BLOOD TESTS**

30. Technician's Staff Code:

Comments: _____

Supervisor Staff Code:
Day Month Year

SITE LOGO

CRF 24: LAB RESULT: NP CULTURE



DATE FORM INITIATED:
DAY MONTH YEAR

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"/>
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1. Specimen ID:

2. Date / time put up for culture:

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

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="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <table border="1" style="margin: auto;"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td>-</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </table>	<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"/>	<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="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <table border="1" style="margin: auto;"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td>-</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </table>	<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"/>	<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="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <table border="1" style="margin: auto;"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td>-</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </table>	<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"/>	<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="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not done		Scan or affix barcode label: <table border="1" style="margin: auto;"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td>-</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </table>	<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"/>	<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 flocced swab/OP swab 02 - Induced sputum 03 - Lung aspirate
- 04 - NP flocced 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 MONTH YEAR

Quality Assessment and Gram Stain

1. a. Date:

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 /

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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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3. Specimen type:

1 - Induced sputum 2 - ETT aspirate

4. Technician's Staff Code:

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NOT DONE:
Stop here and end form

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

1 - <10	<input type="checkbox"/>
2 - 10-25	<input type="checkbox"/>
3 - >25	<input type="checkbox"/>

6. Mucus seen? *(check one)*

1 - Yes	<input type="checkbox"/>
0 - No	<input type="checkbox"/>

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

1 - <10	<input type="checkbox"/>
2 - 10-25	<input type="checkbox"/>
3 - >25	<input type="checkbox"/>

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"/>

SITE LOGO

**CRF 26:
LAB RESULT: INDUCED SPUTUM MICRO-CULTURE**

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PARTICIPANT ID

DATE FORM INITIATED:

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DAY

MONTH

YEAR

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

Antibiotic Code:	Organism 1		Organism 2		Organism 3		Organism 4	
	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)	<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. AMP (Ampicillin)	<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. CAZ (Ceftazidime)	<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. CH (Chloramphenicol)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. CIP (Ciprofloxacin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. CN (Gentamicin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g. CRO (Ceftriaxone)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. CTX (Cefotaxime)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
i. DA (Clindamycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
j. ERY (Erythromycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
k. FOX (Cefoxitin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
l. IPM (Imipenem)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
m. OX (Oxacillin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
n. P (Penicillin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
o. SXT (Cotrimoxazole)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
p. TET (Tetracycline)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
q. VA (Vancomycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
r. Other: _____ Code: <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"/>
s. Other: _____ Code: <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"/>
t. Other: _____ Code: <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"/>
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	<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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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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 .

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 µg/mL

b. Ceftriaxone or Cefotaxime (choose one) < >

--	--

 .

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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. influenzae* 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

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

Comments: _____

Supervisor Staff Code:

Supervisor Verification Date: / /
Day Month Year

CRF 28: LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM INITIATED:

DAY MONTH YEAR

Specimen number:

NOT DONE:
Stop here and end form

1. Date/time put up for culture:

DAY MONTH YEAR TIME (24 hour clock)

Scan or affix barcode label:

-

2. Specimen ID (barcode label):

3. Specimen type (*check one*):

- 1 - Pleural fluid
- 2 - Lung aspirate

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

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:

DAY MONTH 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 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<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+	Insert barcode number or 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"/> - <input type="text"/> <input type="text"/>	<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
c. Organism 2 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Insert barcode number or 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"/> - <input type="text"/> <input type="text"/>	<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
d. Organism 3 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Insert barcode number or 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"/> - <input type="text"/> <input type="text"/>	<input type="checkbox"/> 1: C <input type="checkbox"/> 2: U <input type="checkbox"/> 3: NC
e. Organism 4 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Insert barcode number or 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"/> - <input type="text"/> <input type="text"/>	<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:

DAY MONTH YEAR

10. Antibiotic Susceptibility Testing:

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

	Organism 1		Organism 2		Organism 3		Organism 4	
	<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 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)	<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. AMP (Ampicillin)	<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. CAZ (Ceftazidime)	<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. CH (Chloramphenicol)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. CIP (Ciprofloxacin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. CN (Gentamicin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g. CRO (Ceftriaxone)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. CTX (Cefotaxime)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
i. DA (Clindamycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
j. ERY (Erythromycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
k. FOX (Cefoxitin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
l. IPM (Imipenem)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
m. OX (Oxacillin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
n. P (Penicillin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

CRF 28: LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM INITIATED:

DAY
MONTH
YEAR

	Organism 1	Organism 2	Organism 3	Organism 4
	<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"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
o. SXT (Cotrimoxazole)	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>
p. TET (Tetracycline)	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>
q. VA (Vancomycin)	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>
r. Other: _____ Code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>
s. Other: _____ Code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>
t. Other: _____ Code: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <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: < > . µg/mL

b. Ceftriaxone or Cefotaxime (choose one) < > . µg/mL

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

**CRF 28:
LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE**

DATE FORM INITIATED:

DAY MONTH 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	<input type="text"/> <input type="text"/> . <input type="text"/> g/dL
b. Glucose	<input type="text"/> <input type="text"/> . <input type="text"/> mmol/L
c. Not Done	<input type="checkbox"/>

14. Technician's Staff Code:

BinaxNOW Pneumococcal Antigen Testing – Pleural Fluid Only

15. Technician's Staff Code:

16. Test result: 1 – Positive 2 – Negative 3 – Indeterminate 9 - Not done

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

MIC Etest® performed? 1 - Yes 0 – No 9 – N/A

CRF 28: LAB RESULT: PLEURAL FLUID - LUNG ASPIRATE

DATE FORM INITIATED:

--	--

--	--	--

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DAY MONTH YEAR

a. Vancomycin Etest® results < > . µg/mL

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

18. Was *S. pneumoniae* isolated?

1 – YES 0 – NO

If Yes, what serotypes were identified:

a.

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

b.

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

c.

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

d.

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

19. Was *H. influenzae* isolated?

1-YES 0-NO

If Yes, what serotype was identified:

a.

--	--	--	--

Comments: _____

Supervisor Staff Code:

--	--	--	--

Supervisor Verification Date:

--	--

--	--	--

--	--	--	--

Day *Month* *Year*

SITE LOGO

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"><tr><td></td><td></td><td></td><td></td></tr></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 9 - N/A

Comments:

Form Completed by: _____ Staff Code:

--	--	--	--

Supervisor Signature: _____ Staff Code:

--	--	--	--

Supervisor Verification Date:

--	--

 Day

--	--	--

 Month

--	--	--	--

 Year

SITE LOGO

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: 9 - N/A
Day Month Year

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:

SITE LOGO

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

SITE LOGO

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

SITE LOGO



CRF 31Ai: EPI CONTROL PRE-SCREENING

SITE ID

Reporting period:

Month

Year

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 31Aii: DSS CONTROL PRE-SCREENING

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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

--	--

SITE LOGO

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

SITE LOGO



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 (x100 oil objective)

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

Number of leucocytes per representative LPF (x10 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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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*	1 - Solid Media <input type="checkbox"/> 2 - Broth <input type="checkbox"/> 3 - Both <input type="checkbox"/> 9 - Not seen <input type="checkbox"/>			
b. Organism 1 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<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+	Insert barcode number or 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"/>	<input type="checkbox"/> 1: C - Confirmed <input type="checkbox"/> 2: U - Updated <input type="checkbox"/> 3: NC - Not Confirmed
c. Organism 2 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<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+	Insert barcode number or 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"/>	<input type="checkbox"/> 1: C - Confirmed <input type="checkbox"/> 2: U - Updated <input type="checkbox"/> 3: NC - Not Confirmed
d. Organism 3 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<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+	Insert barcode number or 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"/>	<input type="checkbox"/> 1: C - Confirmed <input type="checkbox"/> 2: U - Updated <input type="checkbox"/> 3: NC - Not Confirmed
e. Organism 4 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<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+	Insert barcode number or 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"/>	<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.

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

	Organism 1		Organism 2		Organism 3		Organism 4	
	<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 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)	<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. AMP (Ampicillin)	<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. CAZ (Ceftazidimine)	<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. CH (Chloramphenicol)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. CIP (Ciprofloxacin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. CN (Gentamicin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g. CRO (Ceftriaxone)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. CTX (Cefotaxime)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
i. DA (Clindamycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
j. ERY (Erythromycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
k. FOX (Cefoxitin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
l. IPM (Imipenem)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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

1: S = Susceptible

2: I = Intermediate

3: R = Resistant

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	Organism 1		Organism 2		Organism 3		Organism 4	
	<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 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)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
n. P (Penicillin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
o. SXT (Cotrimoxazole)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
p. TET (Tetracycline)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
q. VA (Vancomycin)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
r. Other: _____ Code: <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"/>
s. Other: _____ Code: <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"/>
t. Other: _____ Code: <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"/>
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	

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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:

> . $\mu\text{g/mL}$
 <

b. Ceftriaxone or Cefotaxime (choose one)

< . $\mu\text{g/mL}$
 >

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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12. Was *S. pneumoniae* isolated?

1 – Yes 0 – No

If Yes, what serotypes were identified:

a.

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

b.

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

c.

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

d.

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

13. Was *H. influenzae* isolated?

1-Yes 0-No

If Yes, what serotype was identified:

a.

--	--	--	--

Technician Reporting Final Results:

--	--	--	--

Initial QC By:

--	--	--	--

Supervisor Staff Code:

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Supervisor Verification Date:

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MONTH

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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: <table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td> </td><td> </td><td> </td><td> </td><td>H</td><td>11</td><td colspan="4"> </td> </tr> </table>															H	11					1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
				H	11																		
b. H12? 1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>	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><td> </td> </tr> <tr> <td> </td><td> </td><td> </td><td> </td><td>H</td><td>12</td><td colspan="4"> </td> </tr> </table>															H	12					1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
				H	12																		
c. H13? 1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>	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><td> </td> </tr> <tr> <td> </td><td> </td><td> </td><td> </td><td>H</td><td>13</td><td colspan="4"> </td> </tr> </table>															H	13					1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
				H	13																		
d. H14? 1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>	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><td> </td> </tr> <tr> <td> </td><td> </td><td> </td><td> </td><td>H</td><td>14</td><td colspan="4"> </td> </tr> </table>															H	14					1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
				H	14																		
e. H15? 1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>	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><td> </td> </tr> <tr> <td> </td><td> </td><td> </td><td> </td><td>H</td><td>15</td><td colspan="4"> </td> </tr> </table>															H	15					1 - Good quality <input type="checkbox"/> 2 - Poor/small/disrupted <input type="checkbox"/>	1 - Yes <input type="checkbox"/> 0 - No <input type="checkbox"/>
				H	15																		

MICROSCOPY (GENERAL QUESTIONS FOR CASE)

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

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

<p align="center">9 - NOT DONE: Stop here and end form</p> <p align="center"><input type="checkbox"/></p>
--

3. Special Stains performed on biopsies

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

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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"/>

SITE LOGO



CRF 33:
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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: [][][][]

8. Date: [][] [][][] [][][][]
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Comments: _____

Technician's Staff Code: [][][][]

Supervisor Staff Code: [][][][]

Supervisor Verification Date: [][] [][][] [][][][]
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