

PB-SAM Enrolment CRF v1.2



Patient Initials [ ][ ][ ][ ]

PB-SAM Number [1][0][ ][ ][ ]

Screening Number [ M ][ ][ ][ ][ ] (Kampala only)

1. ELIGIBILITY CHECKLIST			
1.1. Inclusion Criteria			
		YES	NO (ineligible)
a)	Age between 2 months and 59 months	<input type="checkbox"/>	<input type="checkbox"/>
b)	Admitted to hospital with an acute non-traumatic illness ( <i>Within this time, children requiring CPR or unable to take orally (NPO) will be re-evaluated daily</i> )	<input type="checkbox"/>	<input type="checkbox"/>
c)	Enrolled within 72 hours of admission	<input type="checkbox"/>	<input type="checkbox"/>
d)	Severe malnutrition ( <b>weight for height</b> < -3z scores of the median WHO growth standards and/or MUAC <ul style="list-style-type: none"> <li>• <b>Age &gt; 6months &lt;115mm</b></li> <li>• <b>2- &lt;6 months &lt;110mm</b></li> </ul> or <b>symmetrical oedema</b> of at least the feet related to malnutrition, i.e. not related to a primary cardiac or renal disorder)	<input type="checkbox"/>	<input type="checkbox"/>
e)	Parent or guardian able and available to consent	<input type="checkbox"/>	<input type="checkbox"/>
f)	Able to feed orally in usual state of health	<input type="checkbox"/>	<input type="checkbox"/>
g)	Presence of two or more features of severity as specified in Table below**	<input type="checkbox"/>	<input type="checkbox"/>
h)	Primary caregiver plans to stay in the study area during the duration of the study	<input type="checkbox"/>	<input type="checkbox"/>
1.2. Exclusion Criteria			
		YES (Ineligible)	NO
a)	Known congenital syndrome	<input type="checkbox"/>	<input type="checkbox"/>
b)	Cleft palate	<input type="checkbox"/>	<input type="checkbox"/>
c)	Known congenital cardiac disease	<input type="checkbox"/>	<input type="checkbox"/>
d)	Known terminal illness e.g. cancer	<input type="checkbox"/>	<input type="checkbox"/>
e)	Admission for surgery, or likely to require surgery within 6m	<input type="checkbox"/>	<input type="checkbox"/>
f)	Admission for trauma?	<input type="checkbox"/>	<input type="checkbox"/>
g)	Sibling enrolled in study	<input type="checkbox"/>	<input type="checkbox"/>
h)	Previously enrolled in this trial or currently enrolled in this trial	<input type="checkbox"/>	<input type="checkbox"/>
i)	Known stomach or duodenal ulcer	<input type="checkbox"/>	<input type="checkbox"/>
j)	Known liver disorder or exocrine pancreatic disorder – e.g. biliary atresia, history of gallstones, cystic fibrosis or clinical jaundice	<input type="checkbox"/>	<input type="checkbox"/>
k)	Known intolerance or allergy to any study medication	<input type="checkbox"/>	<input type="checkbox"/>
l)	<input type="checkbox"/> Direct Bilirubin levels Above <b>25umol/L</b> (Kampala site only)	<input type="checkbox"/>	<input type="checkbox"/>

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**\*\*Severity characteristics, two or more are required for enrolment**

a) <input type="checkbox"/> Respiratory distress	<input type="checkbox"/> subcostal indrawing or <input type="checkbox"/> nasal flaring or <input type="checkbox"/> head nodding <input type="checkbox"/> grunting
b) <input type="checkbox"/> Oxygenation	<input type="checkbox"/> central cyanosis or <input type="checkbox"/> SaO <sub>2</sub> <90% (adjusted for altitude)
c) <input type="checkbox"/> Circulation	<input type="checkbox"/> Limb temperature gradient or <input type="checkbox"/> cap refill >3 seconds
d) <input type="checkbox"/> AVPU	< "A"
e) <input type="checkbox"/> Pulse	> 180 per min [ _____ beats per minute]
f) <input type="checkbox"/> Hb	< 7g/dl [ _____ . ____g/dl]
g) <input type="checkbox"/> WBC	< 4 or > 17.5 x 10 <sup>9</sup> /l [ _____ . ____10 <sup>9</sup> /l]
h) <input type="checkbox"/> Blood glucose	< 3mmol/L [ _____ . ____mmol/L]
i) <input type="checkbox"/> Documented temperature at admission or screening	<input type="checkbox"/> <36 or <input type="checkbox"/> >38.5°C
j) <input type="checkbox"/> Very low MUAC	MUAC <11cm

*If eligible by 2 criteria, please continue to admission*

**2. ADMISSION TO HOSPITAL AND TRIAL ENROLMENT**

2.1.	DATE arrived at the hospital	____/____/_____ D D / M M / Y Y Y Y
2.2.	TIME arrived at the hospital	____:____ <input type="checkbox"/> unknown 24h Clock
2.3.	Hospital IP Number (Use Serial number for Kilifi site)	_____
2.4.	Date of consent	____/____/_____ D D / M M / Y Y Y Y
2.5.	Time of consent	____:____ 24h Clock
2.6.	Consented by Initials	_____
2.7.	DATE of enrolment <i>i.e. date consented and seen by research team</i>	____/____/_____ D D / M M / Y Y Y Y
2.8.	TIME of enrolment	____:____ 24h Clock

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2.9.	Sex	<input type="checkbox"/> Male	<input type="checkbox"/> Female
2.10.	DOB	____/____/_____ D D / M M / Y Y Y Y	
2.11.	Is the DOB:	<input type="checkbox"/> True	<input type="checkbox"/> Estimated*

\*if DOB is estimated, and the day is uncertain, write '15' for DD

3. PRESENTING AND CURRENT COMPLAINTS		
3.1.	What were the presenting complaints at admission? (Select all that apply)	<input type="checkbox"/> Fever / Hotness of body <input type="checkbox"/> Vomiting <input type="checkbox"/> Lethargy <input type="checkbox"/> Difficulty breathing <input type="checkbox"/> Diarrhoea <14 days <input type="checkbox"/> Convulsions <input type="checkbox"/> Cough<14 days <input type="checkbox"/> Cough>14days <input type="checkbox"/> Diarrhoea >14 days <input type="checkbox"/> Altered consciousness <input type="checkbox"/> Blood in stool <input type="checkbox"/> Poor feeding <input type="checkbox"/> skin changes (fill in 3.2) <input type="checkbox"/> Body swelling (oedema) <input type="checkbox"/> Hair changes (fill in 3.3) <input type="checkbox"/> Other _____
3.2.	Skin changes (if checked at 3.1)	<input type="checkbox"/> Rash <input type="checkbox"/> Hyperpigmentation <input type="checkbox"/> Hypopigmentation <input type="checkbox"/> Peeling <input type="checkbox"/> Blisters <input type="checkbox"/> Thickening of skin How long have skin changes been present ____ Days/____ Months
3.3.	Hair Changes (if checked at 3.1)	<input type="checkbox"/> Reddened colour <input type="checkbox"/> Light colour <input type="checkbox"/> Straighter than usual <input type="checkbox"/> Thinner than usual

4. TREATMENT FOR THIS ILLNESS	
4.1.	Have you visited a hospital for this illness? (Select any that apply)

No     Outpatient     Inpatient (Overnight stay)

5. BIRTH HISTORY				
5.1.	Birth details (Select any that apply)			
5.2.	Preterm (< 37weeks)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
5.3.	Born small (<2.5kg)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
5.4.	Twin/multiple births	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
5.5.	Born at term	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

6. ANTHROPOMETRY		
6.1.	Weight (to be taken using SECA scales for CHAIN study)	____.____ kg
6.2.	Length/Height (to be taken using SECA 416 infantometer provided for study)	<input type="checkbox"/> Length <input type="checkbox"/> Height Measurer 1: ____ . ____ cm    Measurer 2: ____ . ____ cm
6.3.	MUAC (To be taken using MUAC tape for CHAIN study)	Measurer 1: ____ . ____ cm    Measurer 2: ____ . ____ cm
6.4.	Head circumference (To be taken using CHAIN measuring tape)	Measurer 1: ____ . ____ cm    Measurer 2: ____ . ____ cm
6.5.	Staff Initials	Measurer 1: _____    Measurer 2: _____

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NB: If the child is unwell the Length and Head Circumference can be taken at a later time.

7. PREVIOUS HEALTH	
7.1. <b>Previously admitted to hospital.</b> <i>(Includes other hospitals / health centres. Select 1)</i>	<input type="checkbox"/> No <input type="checkbox"/> < 1 week ago <input type="checkbox"/> 1 week-1month ago <input type="checkbox"/> >1month ago
7.2. <b>Any medication last 7 days before admission.</b> <i>(Select all that apply)</i>	<input type="checkbox"/> No medication <input type="checkbox"/> Antibiotic <input type="checkbox"/> Antimalarial <input type="checkbox"/> Traditional <input type="checkbox"/> Deworming <input type="checkbox"/> Vitamin <input type="checkbox"/> Yes, but unknown <input type="checkbox"/> Other (Specify) _____
7.3. <b>Has the child previously had oedema (body swelling)?</b>	<input type="checkbox"/> Y <input type="checkbox"/> N
7.4. <b>Urine production in last 24hrs?</b> <i>(Select 1)</i>	<input type="checkbox"/> Normal or greater <input type="checkbox"/> Less than normal <input type="checkbox"/> Not passing urine <input type="checkbox"/> Unknown

8. LONG TERM MEDICATION	
8.1 <b>Was child on any long term medication before hospitalization?</b> <i>(select any that apply)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <b>If Yes, select any that apply.</b> <b>ARV's</b> <input type="checkbox"/> Zidovudine/azidothymidine (ZDV/AZT) <input type="checkbox"/> Lamivudine (3TC) <input type="checkbox"/> Abacavir (ABC) <input type="checkbox"/> Nevirapine (NVP) <input type="checkbox"/> Efavirenz (EFV) <input type="checkbox"/> Lopinavir/Ritonavir (Kaletra, LPV/r) <input type="checkbox"/> Other
	<b>Neuro</b> <input type="checkbox"/> Phenobarbital <input type="checkbox"/> Valproic acid <input type="checkbox"/> Levetiracetam <input type="checkbox"/> Lamotrigine <input type="checkbox"/> Other
	<b>Sickle cell</b> <input type="checkbox"/> Hydroxyurea <input type="checkbox"/> Other
	<b>Anti-TBs</b> <input type="checkbox"/> Isoniazid <input type="checkbox"/> Rifampin <input type="checkbox"/> Pyrazinamide (PZA) <input type="checkbox"/> Ethambutol <input type="checkbox"/> Other
	Long term antibiotic prophylaxis <input type="checkbox"/> Co-trimoxazole <input type="checkbox"/> Penicillin



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**9. TREATMENT GIVEN BEFORE ARRIVAL AT STUDY HOSPITAL**

<b>9.1. Intravenous Antibiotics Given?</b> <i>(select any that apply)</i>	<input type="checkbox"/> <b>Not given</b>
	<input type="checkbox"/> Benzylpenicillin <input type="checkbox"/> Gentamicin <input type="checkbox"/> Ceftriaxone <input type="checkbox"/> Co-amoxiclav <input type="checkbox"/> Flu/Cloxacillin <input type="checkbox"/> Chloramphenicol <input type="checkbox"/> Ampicillin <input type="checkbox"/> Amikacin <input type="checkbox"/> Meropenem <input type="checkbox"/> Levofloxacin <input type="checkbox"/> Vancomycin <input type="checkbox"/> Metronidazole <input type="checkbox"/> Co-trimoxazole <input type="checkbox"/> Penicillin
	<input type="checkbox"/> Other _____
	<b>9.2. Oral Antibiotics Given?</b> <i>(select any that apply)</i>
	<input type="checkbox"/> <b>Not given</b> <input type="checkbox"/> Amoxicillin <input type="checkbox"/> Erythromycin <input type="checkbox"/> Azithromycin <input type="checkbox"/> Co-trimoxazole <input type="checkbox"/> Metronidazole <input type="checkbox"/> Ciprofloxacin <input type="checkbox"/> Cefalexin / cefaclor <input type="checkbox"/> Co-amoxiclav <input type="checkbox"/> Nalidixic acid <input type="checkbox"/> Penicillin <input type="checkbox"/> Flucloxacillin <input type="checkbox"/> Levofloxacin <input type="checkbox"/> Other _____

**10. ENROLMENT VITAL SIGNS**

<b>10.1. Axillary temperature</b>	_____ °C
<b>10.2. Respiratory rate</b> <i>(Count for 1 minute)</i>	_____/minute
<b>10.3. Heart rate</b> <i>(Count for 1 minute)</i>	_____/minute
<b>10.4. SaO2</b> <i>(To be taken from finger or toe using pulse oximeter)</i>	_____ % <i>Leave blank if unrecordable</i>
<b>10.5. Where was SaO2 Measured?</b>	<input type="checkbox"/> Measured on Oxygen <input type="checkbox"/> Measured in Room Air  <input type="checkbox"/> Unrecordable

**11. EXAMINATION**

<i>Examination should be performed by CHAIN study clinician trained in clinical examination of children, and able to formulate a diagnosis based on clinical history and findings. Refer to Clinical Examination SOP</i>	
<b>11.1. Airway</b> <i>(select one)</i>	<input type="checkbox"/> <b>Clear</b> <input type="checkbox"/> Needs active support <input type="checkbox"/> Obstructed/Stridor
<b>11.2. Breathing</b> <i>(select all that apply)</i>	<input type="checkbox"/> <b>Normal – no concerns, (move to circulation)</b> <input type="checkbox"/> Central cyanosis <input type="checkbox"/> Nasal flaring <input type="checkbox"/> Reduced air-entry <input type="checkbox"/> Wheeze <input type="checkbox"/> Acidotic Breathing <input type="checkbox"/> Grunting

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		<input type="checkbox"/> Lower chest wall indrawing <input type="checkbox"/> Head nodding	<input type="checkbox"/> Crackles	<input type="checkbox"/> Dull to percussion		
11.3.	<b>Circulation:</b> a) <b>Cap Refill</b> (select one) b) <b>Peripheral temperature</b> (select one) c) <b>Pulse Volume</b> (select one):	<input type="checkbox"/> <2s <input type="checkbox"/> 2-3s <input type="checkbox"/> >3s	<input type="checkbox"/> Warm peripheries	<input type="checkbox"/> Cold peripheries		
		<input type="checkbox"/> Normal <input type="checkbox"/> Weak				
11.4.	<b>Disability:</b> a) <b>Conscious level</b> (select one) b) <b>Fontanelle</b> (select one) c) <b>Tone</b> (select one) d) <b>Posture</b> (select one) e) <b>Activity</b> (select one)	<input type="checkbox"/> Alert	<input type="checkbox"/> Voice	<input type="checkbox"/> Pain	<input type="checkbox"/> Unresponsive	
		<input type="checkbox"/> Normal	<input type="checkbox"/> Bulging	<input type="checkbox"/> Sunken	<input type="checkbox"/> Not present	
		<input type="checkbox"/> Normal	<input type="checkbox"/> Hypertonic	<input type="checkbox"/> Hypotonic		
		<input type="checkbox"/> Normal	<input type="checkbox"/> Decorticate	<input type="checkbox"/> Decerebrate		
		<input type="checkbox"/> Normal	<input type="checkbox"/> Irritable/Agitated	<input type="checkbox"/> Lethargic		
11.5.	<b>Dehydration:</b> a) <b>Sunken eyes?</b> (Select one) b) <b>Skin pinch</b> (Select one)	<input type="checkbox"/> Y <input type="checkbox"/> N				
		<input type="checkbox"/> Immediate	<input type="checkbox"/> <2 seconds	<input type="checkbox"/> >2 seconds		
11.6.	<b>Oedema</b> (select any that apply)	<input type="checkbox"/> None	<input type="checkbox"/> both feet/ankles	<input type="checkbox"/> lower legs		
		<input type="checkbox"/> hands or lower arms	<input type="checkbox"/> face			
11.7.	<b>Drinking/Breastfeeding</b> (Select one)	<input type="checkbox"/> Normal	<input type="checkbox"/> Poorly	<input type="checkbox"/> Not drinking	<input type="checkbox"/> Eager / Thirsty	
11.8.	<b>Abdomen</b> (select any that apply)	<input type="checkbox"/> Normal – no concerns	<input type="checkbox"/> Distension	<input type="checkbox"/> Hepatomegaly		
		<input type="checkbox"/> Tenderness	<input type="checkbox"/> Splenomegaly	<input type="checkbox"/> Other abdominal mass		
11.9.	<b>Signs of Rickets</b> (select any that apply)	<input type="checkbox"/> None	<input type="checkbox"/> Wrist widening	<input type="checkbox"/> Rachitic rosary		
		<input type="checkbox"/> Swollen knees	<input type="checkbox"/> Bow legs	<input type="checkbox"/> Frontal bossing		
11.10.	<b>Jaundice</b> (Select one)	<input type="checkbox"/> Y <input type="checkbox"/> N				
11.11.	<b>ENT/Oral/Eyes</b> (select any that apply)	<input type="checkbox"/> Mouth Normal	<input type="checkbox"/> Oral ulceration	<input type="checkbox"/> Oral candidiasis		
		<input type="checkbox"/> Stomatitis				
		<input type="checkbox"/> Ears Normal	<input type="checkbox"/> Pus from ear <input type="checkbox"/> Lymphadenopathy	<input type="checkbox"/> Tender swelling behind ear (mastoiditis)		
		<input type="checkbox"/> Eyes Normal	<input type="checkbox"/> Conjunctivitis	<input type="checkbox"/> Eye discharge		
		<input type="checkbox"/> Visual impairment				



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11.12.	<b>Skin</b>	<input type="checkbox"/> Normal	<input type="checkbox"/> Hyperpigmentation	<input type="checkbox"/> Depigmentation
	<b>a) Type of skin lesion</b> (select any that apply)	<input type="checkbox"/> Broken skin <input type="checkbox"/> Cellulitis <input type="checkbox"/> Vesicles	<input type="checkbox"/> Dermatitis <input type="checkbox"/> Impetigo <input type="checkbox"/> Desquamation	<input type="checkbox"/> 'Flaky paint' <input type="checkbox"/> Pustules <input type="checkbox"/> Macular or papular
	<b>b) Site of skin lesions.</b> (select any that apply)	<input type="checkbox"/> Not applicable (No rash) <input type="checkbox"/> Face / scalp <input type="checkbox"/> Legs	<input type="checkbox"/> Palms / soles <input type="checkbox"/> Buttocks <input type="checkbox"/> Arms	<input type="checkbox"/> Trunk <input type="checkbox"/> Perineum

## 12. SUSPECTED CHRONIC CONDITIONS

Select confirmed, suspected or none for all conditions:		Confirmed/Suspected (diagnosed previously/ recorded/ clinician's impression)	None
12.1.	<b>Cerebral palsy/neurological problem/epilepsy</b> (Select one)	<input type="checkbox"/>	<input type="checkbox"/>
12.2.	<b>Sickle Cell disease</b> (select one)	<input type="checkbox"/>	<input type="checkbox"/>
12.3.	<b>Thalassaemia</b> (Select one)	<input type="checkbox"/>	<input type="checkbox"/>
12.4.	<b>Visual problem / Blindness</b> (select one)	<input type="checkbox"/>	<input type="checkbox"/>

## 13. FEEDING PRIOR TO ADMISSION

13.1.	<b>Prior to this admission child <u>actively attending</u> outpatient nutrition program?</b> (Select one)	<input type="checkbox"/> Supplementary (corn soy blend, RUSF, khichuri, halwa) <input type="checkbox"/> Therapeutic (RUTF, Plumpy-nut) <input type="checkbox"/> None			
13.2.	<b>Has the child eaten solid food in last 24 hrs</b> (Select one)	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
13.3.	<b>Has child taken liquids or breastfed in last 24 hrs</b> (Select one)	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
13.4.	<b>Is the child currently breastfeeding?</b> (Select one)	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
13.5.	<b>Does the child usually have other feeds other than breastmilk?</b> (Select one)	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
13.6.	<b>If NOT breastfeeding at all, age stopped in months?</b> (select one)	<input type="checkbox"/> N/A (still breastfeeding) <input type="checkbox"/> 0-3m <input type="checkbox"/> 4-6m <input type="checkbox"/> 7-12m <input type="checkbox"/> >12m <input type="checkbox"/> Unknown			



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#### 14. IMMEDIATE CLINICAL INVESTIGATIONS AND HIV STATUS AT ENROLMENT

<b>14.1.</b>	<b>Malaria RDT?</b> <i>(select one)</i>	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Not done
<b>14.2.</b>	<b>HIV status known?</b>	<input type="checkbox"/> <b>Child not previously tested, not known to be exposed</b>  <input type="checkbox"/> known PCR positive <input type="checkbox"/> antibody positive, unknown PCR status <input type="checkbox"/> known exposed, known PCR negative <i>(children under 18m with PCR result SEEN BY RESEARCH TEAM. If not seen select below and perform HIV RDT)</i> <input type="checkbox"/> child untested, but known to be HIV exposed
<b>14.3.</b>	<b>a) If not known positive, HIV RDT results now?</b> <i>(select one)</i>	<input type="checkbox"/> Reactive / positive <input type="checkbox"/> Non-Reactive / Negative <input type="checkbox"/> Indeterminate <input type="checkbox"/> Declined testing  <input type="checkbox"/> Testing not offered by study team <i>(e.g. culturally not sensitive)</i>
	<b>b) If RDT results now is positive, was PCR sample sent?</b> <i>(select one)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No missed <input type="checkbox"/> No referred
<b>14.4.</b>	<b>Biological mother present at enrolment?</b> <i>(select one)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>14.5.</b>	<b>HIV test offered to caregiver?</b> <i>(Offer if only biological mother)</i>	<input type="checkbox"/> Reactive <input type="checkbox"/> Non-reactive <input type="checkbox"/> Declined  <input type="checkbox"/> mother is known positive <input type="checkbox"/> Missed <input type="checkbox"/> child in care home  <input type="checkbox"/> Not offered by study team <i>(e.g. culturally not sensitive)</i>  <input type="checkbox"/> Mother not available





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**15. TREATMENT IN STUDY HOSPITAL BEFORE ENROLMENT**

<b>15.1.</b>	<b>Admitted to:</b> <i>(select one)</i>	<input type="checkbox"/> Admission to ward	<input type="checkbox"/> Admission to HDU	<input type="checkbox"/> Admission to ICU
<b>15.2.</b>	<b>Date and time First antibiotics given</b>	___/___/____ : ____ <i>(dd/mm/yyyy) 24h clock</i>		<input type="checkbox"/> Not given
<b>15.3.</b>	<b>Intravenous Antibiotics Given?</b> <i>(select any that apply)</i>	<input type="checkbox"/> <b>Not given</b> <input type="checkbox"/> Benzylpenicillin <input type="checkbox"/> Gentamicin <input type="checkbox"/> Ceftriaxone <input type="checkbox"/> Co-amoxiclav <input type="checkbox"/> Flu/Cloxacillin <input type="checkbox"/> Chloramphenicol <input type="checkbox"/> Ampicillin <input type="checkbox"/> Amikacin <input type="checkbox"/> Meropenem <input type="checkbox"/> Levofloxacin <input type="checkbox"/> Vancomycin <input type="checkbox"/> Metronidazole <input type="checkbox"/> Other _____		
<b>15.4.</b>	<b>Oral Antibiotics Given?</b> <i>(select any that apply)</i>	<input type="checkbox"/> <b>Not given</b> <input type="checkbox"/> Amoxicillin <input type="checkbox"/> Erythromycin <input type="checkbox"/> Azithromycin <input type="checkbox"/> Co-trimoxazole <input type="checkbox"/> Metronidazole <input type="checkbox"/> Ciprofloxacin <input type="checkbox"/> Cefalexin / cefaclor <input type="checkbox"/> Co-amoxiclav <input type="checkbox"/> Nalidixic acid <input type="checkbox"/> Penicillin <input type="checkbox"/> Flucloxacillin <input type="checkbox"/> Levofloxacin <input type="checkbox"/> Other _____		

**16. SUSPECTED INITIAL DIAGNOSES:**

*Clinical diagnosis should be based on examination and investigation findings. Tick the three most likely diagnoses.*

<b>16.1.</b>	<b>Common Infections</b> <i>(select any that apply)</i>	<input type="checkbox"/> pneumonia <input type="checkbox"/> Severe pneumonia <input type="checkbox"/> Gastroenteritis <input type="checkbox"/> Sepsis <input type="checkbox"/> Malaria <input type="checkbox"/> Soft tissue infection <input type="checkbox"/> UTI <input type="checkbox"/> URTI <input type="checkbox"/> Osteomyelitis <input type="checkbox"/> Febrile illness unspecified <input type="checkbox"/> Enteric fever <input type="checkbox"/> Not applicable
<b>16.2.</b>	<b>Other suspected diagnosis</b> <i>(select any that apply)</i>	<input type="checkbox"/> Anaemia <input type="checkbox"/> Adverse Drug Reaction <input type="checkbox"/> Asthma <input type="checkbox"/> Bronchiolitis <input type="checkbox"/> Cerebral palsy <input type="checkbox"/> Developmental delay <input type="checkbox"/> Epilepsy <input type="checkbox"/> Extra pulmonary TB <input type="checkbox"/> Failed appetite test only <input type="checkbox"/> Febrile convulsions <input type="checkbox"/> Hydrocephalus <input type="checkbox"/> Ileus <input type="checkbox"/> Liver disease <input type="checkbox"/> Measles <input type="checkbox"/> Nephrotic syndrome <input type="checkbox"/> Otitis media <input type="checkbox"/> Other encephalopathy <input type="checkbox"/> Probable meningitis

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		<input type="checkbox"/> Pulmonary TB <input type="checkbox"/> Renal impairment <input type="checkbox"/> Sickle Cell Disease <input type="checkbox"/> Suspected Toxicity <input type="checkbox"/> Thalassemia <input type="checkbox"/> Varicella <input type="checkbox"/> Other, specify: _____
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17. ADMISSION INVESTIGATIONS AND SAMPLE COLLECTION		
<b>17.1.</b>	<b>CBC taken?</b> <i>(Kilifi, Dhaka, Blantyre; As part of routine clinical care; select one)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>17.2.</b>	<b>Clinical chemistry taken (iSTAT)</b> <i>(Kilifi and Dhaka; select one)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA (Kampala, Blantyre)
<b>17.3.</b>	<b>Blood culture taken</b> <i>(if available at site as part of routine care; select one))</i>	<input type="checkbox"/> Y BEFORE ABX <input type="checkbox"/> Y AFTER ABX <input type="checkbox"/> No
<b>17.4.</b>	<b>EDTA 3ml blood taken (for storage)</b> <i>(Select one)</i>	<input type="checkbox"/> Yes  <input type="checkbox"/> No, Difficult venepuncture <input type="checkbox"/> No, Child uncooperative  <input type="checkbox"/> No, Parent refused <input type="checkbox"/> No, Other
<b>17.5.</b>	<b>Rectal swab taken</b> <i>(Select one)</i>	<input type="checkbox"/> Y BEFORE ABX <input type="checkbox"/> Y AFTER ABX <input type="checkbox"/> No
<b>17.6.</b>	<b>Date and Time Rectal swabs taken</b>	____/____/_____ <i>D D / M M / Y Y Y Y</i>  ____:____ Hrs <i>24 h clock</i>
<b>17.7.</b>	<b>Stool sample taken?</b> <i>(Must be Taken within first 48h of enrolment; select one)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>17.8.</b>	<b>Date and Time stool sample taken</b>	____/____/_____ <i>D D / M M / Y Y Y Y</i>  ____:____ Hrs <i>24 h clock</i>

18. SAMPLES TAKEN BY		
<b>18.1.</b>	<b>Blood Samples taken by (initials)</b>	_____
<b>18.2.</b>	<b>Rectal Swabs taken by (initials)</b>	_____
<b>18.3.</b>	<b>Stool taken by (initials)</b>	_____

PB-SAM Enrolment CRF v1.2



Patient Initials [ ][ ][ ]

PB-SAM Number [1][0][ ][ ][ ]

Screening Number [ M ][ ][ ][ ] [ ] (Kampala only)

**19. CRF COMPLETION**

<b>19.1.</b>	a) <b>CRF Completed by (Initials) – to be signed when complete.</b> <i>Do not sign if any fields are empty</i>	_____
	b) <b>Date</b>	____/____/_____ <i>D D / M M / Y Y Y Y</i>
	c) <b>Time</b>	____:____ <i>24 h clock</i>
<b>19.2</b>	a) <b>CRF Reviewed by (Initials)</b>	_____
	b) <b>Date</b>	____/____/_____ <i>D D / M M / Y Y Y Y</i>
	c) <b>Time</b>	____:____ <i>24 h clock</i>