Patient Initials [ ][ ][ ] PB-SAM Number [2][0] [ ][ ][ ]

\*AAAAAAA

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

	1. ELIGIBILITY CHECKLIST					
	1.1. Inclusion Criteria					
		YES	NO (ineligible)			
a)	Age between 2 months and 59 months					
b)	Admitted to hospital with an acute non-traumatic illness (Within this time, children requiring CPR or unable to take orally (NPO) will be re-evaluated daily)					
c)	Enrolled within 72 hours of admission*					
d)	<ul> <li>Severe malnutrition (weight for height &lt; -3z scores of the median WHO growth standards and/or MUAC <ul> <li>Age &gt; 6months &lt;115mm</li> <li>2- &lt;6 months &lt;110mm</li> </ul> </li> <li>or symmetrical oedema of at least the feet related to malnutrition, i.e. not related to a primary cardiac or renal disorder)</li> </ul>					
e)	Parent or guardian able and available to consent					
g)	Presence of two or more features of severity as specified in Table below**					
h)	Primary caregiver plans to stay in the study area during the duration of the study					
	1.2. Exclusion Criteria					
		YES (Ineligible)	NO			
c)	Known congenital cardiac disease					
d)	Known terminal illness e.g. cancer					
e)	Admission for surgery, or likely to require surgery within 6m					
f)	Admission for trauma?					
g)	Sibling enrolled in study					
h)	Previously enrolled in this trial or currently enrolled in this trial					
i)	Known stomach or duodenal ulcer					
j)	Known liver disorder or exocrine pancreatic disorder – e.g. biliary atresia, history of gallstones, cystic fibrosis or clinical jaundice					
k)	Known intolerance or allergy to any study medication					
I)	Direct Bilirubin levels Above 25 µmol/L (Kampala site only)					

# PB-SAM Enrolment CRF v1.5MMMMPatient Initials [ ][ ]PB-SAM Number [2][0] [ ][ ]

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

#### \*\*Severity characteristics, two or more within 48h of each other are required for enrolment\*\*\*

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

If eligible by 2 criteria, please continue to admission

\* screening is a continuous process during the first 72 hours from admission

	k)	Are the above severity characteristics present now at enrolment?	🗆 No
--	----	--	------

I) If No, have source documents been copied and filed? 
Yes No

If the severity characteristics are not present at enrolment (k), they must have been documented in clinical notes within 48h prior to enrolment for eligibility to be valid. Source document evidence should now be photocopied and filed (I) for audits and monitoring; DO NOT keep source documents with CRF

	2. ADMISSION TO F	IOSPITAL 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	: 🗆 🗆 unknown
		24h Clock
2.3.	Hospital IP Number	
	(Use Serial number for Kilifi site)	
2.4.	Date of consent	
2.5.	Time of consent	
		: 24h Clock
2.6.	Consented by Initials	

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S	Screening Number [ M] [   ] [   ] [   ] (Kampala only)				
2.7.	<b>DATE of enrolment</b> <i>i.e.</i> date consented and seen by research team	$\frac{1}{D} \frac{1}{M} \frac{1}{M} \frac{1}{Y} \frac{1}$			
2.8.	TIME of enrolment	: 24h Clock			
2.9.	Sex	Male     Female			
2.10.	DOB	$\frac{1}{D} \frac{1}{M} \frac{1}{M} \frac{1}{Y} \frac{1}$			
2.11.	Is the DOB:	□ True □ 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	<ul> <li>Fever / Hotness of body</li> <li>Difficulty breathing</li> </ul>	□ Vomiting □ Diarrhoea <14 days	□ Lethargy □ Convulsions			
	complaints at admission? (Select all that apply)	□ Cough<14 days □ Diarrhoea >14 days	Cough>14days				
		Altered consciousness	☐ Blood in stool ☐ Body swelling (oedema)	□ Poor feeding			
3.2.	Skin changes (if checked at 3.1)	□ Blisters □ Thickening of	ion □ Hypopigmentation □ skin s been present Days/_				
3.3.	Hair Changes (if checked at 3.1)	□ Reddened colour □ Ligh □ Thinner than usual	t colour 🗆 Straighter than u	isual			

	4. TR	ATMENT FO	OR THIS ILLNESS	
4.1.	Have you visited a hospital for this	🗆 No	Outpatient	Inpatient (Overnight stay)
	illness? (Select any that apply)			

			5. BIRT	'H HIS	STORY
5.1.	Birth details				
	(Select any that apply)				
5.2.	Preterm (< 37weeks)	□ Yes	🗆 No		Unknown
5.3.	Born small (<2.5kg)	□ Yes	🗆 No		Unknown
5.4.	Twin/multiple births	□ Yes	🗆 No		Unknown
5.5.	Born at term	□ Yes	🗆 No		Unknown

	6. ANTHROPOMETRY					
6.1.	Weight					
	(to be taken using SECA scales for CHAIN study)	kg				
6.2.	Length/Height	Length     Length     Height				
	(to be taken using SECA 416 infantometer provided for study)	Measurer 1: cm Measurer 2: cm				
6.3.	MUAC					
	(To be taken using MUAC tape for CHAIN study)	Measurer 1: cm Measurer 2: cm				

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6.4.	Head circumference				
	(To be taken using CHAIN measuring tape)			Measurer 1:	_ cm Measurer 2: cm
6.5.	Staff Initials			Maagurar 1.	Maagurar 2
				Measurer 1:	Measurer 2:

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> (Includes other hospitals / health centres. Select 1)	<b><math>\square</math> No</b> $\square$ < 1 week ago $\square$ 1 week-1month ago $\square$ >1month ago
7.2.	Any medication last 7 days before admission. (Select all that apply)	<ul> <li>□ No medication</li> <li>□ Antibiotic</li> <li>□ Antimalarial</li> <li>□ Traditional</li> <li>□ Deworming</li> <li>□ Vitamin</li> <li>□ Yes, but unknown</li> <li>□ Other (Specify)</li> </ul>
7.3.	Has the child previously had oedema (body swelling)?	
7.4.	Urine production in last 24hrs? (Select 1)	□ Normal or greater □ Less than normal □ Not passing urine □ Unknown

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

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	Screening Number [ M] [ ] [ ] [ ] (Kampala only)				
	9. TREATMENT GIVEN BEFORE ARRIVAL AT STUDY HOSPITAL				
9.1.	Intravenous Antibiotics Given?	□ Not given			
	(select any that apply)	Benzylpenicillin	Gentamicin	Ceftriaxone	
		🗖 Co-amoxiclav	☐ Flu/Cloxacillin	Chloramphenicol	
		🗖 Ampicillin	🗖 Amikacin	☐ Meropenem	
		Levofloxacin	Vancomycin	Metronidazole	
		Co-trimoxazole	Penicillin		
		Other			
9.2.	Oral Antibiotics Given?	□ Not given			
	(select any that apply)	🗖 Amoxicillin	Erythromycin	Azithromycin	
		Co-trimoxazole	Metronidazole	Ciprofloxacin	
		Cefalexin / cefaclor	Co-amoxiclav	Nalidixic acid	
		□Penicillin	□ Flucloxacillin	Levofloxacin	
				🗖 Other	

	10. ENROLMENT VITAL SIGNS				
10.1.	Axillary temperature	°C			
10.2.	Respiratory rate				
	(Count for 1 minute)	/minute			
10.3.	Heart rate				
	(Count for 1 minute)	/minute			
10.4.	SaO2				
	(To be taken from finger or toe using pulse oximeter)	%			
		Leave blank if unrecordable			
10.5.	Where was SaO2 Measured?	Measured on Oxygen	Measured in Room Air		
		Unrecordable			

	11. EXAMINATION				
	Examination should be performed by CHAIN study c	linician trained in clinical e	xamination of children, and ab	le to formulate a	
	diagnosis based on clinical history and findings. Ref	er to Clinical Examination S	SOP		
11.1.	Airway	□ Clear □ Needs active support			
	(select one)	□ Obstructed/Stridor			
11.2.	Breathing	□ Normal – no concerns, (move to circulation)			
	(select all that apply)	Central cyanosis	□ Nasal flaring	□ Reduced air- entry	
		□ Wheeze	□ Acidotic Breathing	□ Grunting	
		Lower chest wall	□ Crackles	🗆 Dull to	
		indrawing		percussion	
		□ Head nodding			

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S	creening Nu	umber [ M] [ ]		(Kampala only)	
11.3.	Circulation: a) Cap Refill (select one)		□ <2s □ 2-		
	. ,	al temperature	🛛 Warm peripheri	ies 🗆 Cold pe	eripheries
	c) Pulse Volu (select one):	-	Normal	□Weak	
11.4.	Disability:				
	a) Conscious	<b>level</b> (select one)	□ Alert	□ Voice □	□ Pain □ Unresponsive
	b) Fontanelle	e (select one)	Normal	□ Bulging	□ Sunken
	c) Tone (sele	ect one)	Normal	□ Hypertonic	Hypotonic
	d) Posture (s	elect one)	Normal	Decorticate	Decerebrate
	e) Activity (s	elect one)	Normal	□ Irritable/Agitated	d Lethargic
11.5.	Dehydration: a) Sunken e	<b>yes?</b> (Select one)	<b>П Ү <b>П №</b></b>		
	b) Skin pinc	<b>h</b> (Select one)	Immediate	□ <2 seco	ands $\Box$ >2 seconds
11.6.	<b>Oedema</b> (select any that apply	<i>y</i> )	□ None □ bo	oth feet/ankles	□ lower legs
	(	,	□ hands or lower a	arms 🛛 face	
11.7.	Drinking/Breast (Select one)	feeding	D Normal	D Poorly	□ Not □ Eager / drinking Thirsty
11.8.	Abdomen (select any that apply	)	Normal – no concerns	□ Distension	□ Hepatomegaly
			□ Tenderness	□ Splenomegaly	□ Other abdominal mass
11.9.	Signs of Rickets (select any that apply	/)	□ None	U Wrist widening	g 🛛 Rachitic rosary
	(	,	□ Swollen knees	□ Bow legs	□ Frontal bossing
11.10.	Jaundice (Select one)		<b>П</b> Ү <b>П</b> М		
11.11.	ENT/Oral/Eyes (select any that appl	ly)	<ul><li>☐ Mouth Normal</li><li>☐ Stomatitis</li></ul>	□ Oral ulceration	n 🛛 Oral candidiasis
			<b>Ears Normal</b> ear (mastoiditis)	□ Pus from ear □ Lymphadenop	☐ Tender swelling behind athy
			<b>Eyes Normal</b>	□ Conjunctivitis nt	Eye discharge
11.12.	Skin		Normal	□ Hyperpigment	ation Depigmentation
		kin lesion	🗆 Broken skin	Dermatitis	□ 'Flaky paint'
	(select any	ιπαι αρριγ)	Cellulitis	🗆 Impetigo	Pustules
			□ Vesicles	Desquamation	
	•	in lesions.	□ Not applicable ( □ Face / scalp	No rash) 🗆 Palms /	′ soles 🛛 Trunk
	, , , , , , , , , , , , , , , , , , , ,			ittocks 🛛 Arms	D Perineum

## PB-SAM Enrolment CRF v1.5Patient Initials [ ][ ]PB-SAM Number [2][0] [ ][ ]

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	12. SUSPECTED CHRONIC CONDITIONS			
Select co	onfirmed, suspected or none for all conditions:	Confirmed/Suspected (diagnosed previously/ recorded/ clinician's impression)	None	
12.1.	Cerebral palsy/neurological problem/epilepsy (Select one)			
12.2.	Sickle Cell disease (select one)			
12.3.	Thalassaemia (Select one)			
12.4.	Visual problem / Blindness (select one)			

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

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## Screening Number [M] [] [] [] (Kampala only) 14. IMMEDIATE CLINICAL INVESTIGATIONS AND HIV STATUS AT ENROLMENT

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

# PB-SAM Enrolment CRF v1.5Patient Initials [ ][ ]PB-SAM Number [2][0] [ ][ ]

	Screening Number	[M][][]]	[ ] (Kampala only)	
	15. TRE	ATMENT IN STUDY HOS	PITAL BEFORE ENROLM	ENT
15.1.	Admitted to: (select one)	Admission to ward	Admission to HDU	Admission to ICU
15.2.	Date and time First antibiotics given	// (dd/mm/yyyy)	:::::::	□Not given
15.3.	Intravenous Antibiotics Given? (select any that apply)	<ul> <li>Not given</li> <li>Benzylpenicillin</li> <li>Co-amoxiclav</li> </ul>	☐ Gentamicin ☐ Flu/Cloxacillin	□ Ceftriaxone □ Chloramphenicol
		Ampicillin     Levofloxacin     Other	<ul><li>Amikacin</li><li>Vancomycin</li></ul>	<ul><li>Meropenem</li><li>Metronidazole</li></ul>
15.4.	<b>Oral Antibiotics Given?</b> (select any that apply)	<ul> <li>Not given</li> <li>Amoxicillin</li> <li>Co-trimoxazole</li> <li>Cefalexin / cefaclor</li> <li>Penicillin</li> </ul>	<ul> <li>Erythromycin</li> <li>Metronidazole</li> <li>Co-amoxiclav</li> <li>Flucloxacillin</li> </ul>	<ul> <li>Azithromycin</li> <li>Ciprofloxacin</li> <li>Nalidixic acid</li> <li>Levofloxacin</li> <li>Other</li> </ul>

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			ED INITIAL DIAG		
Clinical a	liagnosis should be based on e	xamination and investigation j	findings. Tick the <u>thre</u>	<u>e most likely</u> diagnoses.	
16.1.	Common Infections	🗆 pneumonia	Severe pneur	nonia	
10.1.	(select any that apply)	□ Gastroenteritis	□ Sepsis		
		□ Soft tissue infection			
			Osteomyelitis		
		☐ Febrile illness unspeci		Enteric fever	
		□ Not applicable			
16.2.	Other suspected	□ Anaemia			
	diagnosis	Adverse Drug Reaction	า		
	(select any that apply)	□ Asthma			
	(	□ Bronchiolitis			
		□ Cerebral palsy			
		Developmental delay			
		Epilepsy			
		Extra pulmonary TB			
		□ Failed appetite test or	nly		
		Febrile convulsions			
		Hydrocephalus			
		□ Ileus			
		Liver disease			
		□ Measles			
		Nephrotic syndrome			
		Otitis media			
		□ Other encephalopathy	/		
		Probable meningitis			
		Pulmonary TB			

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S	creening Number [ M] [   ] [	][	]	[	]	(Kampala only)
	Renal impairment					
	□ Sickle Cell Disease	<b>!</b>				
	□ Suspected Toxicity	,				
	🗖 Thalassaemia					
	Varicella					
	□ Other, specify:					

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

	18. SAMPLES TAKEN BY		
18.1.	Blood Samples taken by (initials)		
18.2.	Rectal Swabs taken by (initials)		
18.3.	Stool taken by (initials)		

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

	19. CRF COMPLETION		
19.1.	a)	CRF Completed by (Initials) – to be signed when complete. Do not sign if any fields are empty	
	b)	Date	$\frac{1}{D} \frac{1}{D} \frac{1}{M} \frac{1}{M} \frac{1}{Y} \frac{1}$
	c)	Time	: 24 h clock
19.2	a)	CRF Reviewed by (Initials)	
	b)	Date	$\frac{1}{D} \frac{1}{D} \frac{1}{M} \frac{1}{M} \frac{1}{Y} \frac{1}$
	c)	Time	: 24 h clock