ATALAAAA PB-SAM Enrolment CRF v1.2

Patient Initials [][][] PB-SAM Number [3][0] [][][]

	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)	 Severe malnutrition (weight for height < -3z scores of the median WHO growth standards and/or MUAC Age > 6months <115mm 2- <6 months <110mm or symmetrical oedema of at least the feet related to malnutrition, i.e. not related to a primary cardiac or renal disorder) 				
e)	Parent or guardian able and available to consent				
f)	Able to feed orally in usual state of health				
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		
a)	Known congenital syndrome				
b)	Cleft palate				
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)				

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

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

a)	Respiratory distress	□ subcostal indrawing or □ nasal flaring or □ head nodding □ grunting
b)	□ Oxygenation	\Box central cyanosis or \Box SaO ₂ <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 ⁹ /l [10 ⁹ /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

	2. ADMISSION TO HO	OSPITAL 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	$\frac{1}{D} \frac{1}{M} \frac{1}{M} \frac{1}{Y} \frac{1}$
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

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

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. PRESENTIN	IG AND CURRENT COM	PLAINTS	
3.1.	What were the presenting	□ Fever / Hotness of body	Vomiting	□ Lethargy
	complaints at admission?	Difficulty breathing	🗆 Diarrhoea <14 days	Convulsions
	(Select all that apply)	Cough<14 days	Cough>14days	
		🗆 Diarrhoea >14 days		
		Altered consciousness	Blood in stool	□ Poor feeding
		□ skin changes (<i>fill in 3.2</i>)	□ Body swelling (oedema)	
		□Hair changes (<i>fill in 3.3</i>)		
		Other		
3.2.	Skin changes (if checked at 3.1)	□ Rash □ Hyperpigmentation □ Hypopigmentation □ Peeling		
	_	□ Blisters □ Thickening of skin		
		How long have skin change	s been present Days/_	Months
3.3.	Hair Changes (if checked at 3.1)	Reddened colour Light colour Straighter than usual		
		Thinner than usual		

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

	5. BIRTH HISTORY				
5.1.	Birth details				
	(Select any that apply)				
5.2.	Preterm (< 37weeks)	□ Yes	🗆 No	🛛 Un	nknown
5.3.	Born small (<2.5kg)	□ Yes	🗆 No	🛛 Un	nknown
5.4.	Twin/multiple births	□ Yes	🗆 No	🛛 Un	nknown
5.5.	Born at term	□ Yes	🗆 No	🗆 Un	nknown

	6. ANTHROPOMETRY					
6.1.	Weight					
	(to be taken using SECA scales for CHAIN study)	·	kg			
6.2.	Length/Height	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			
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:			

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

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

		7. PREVIOUS HEALTH
7.1.	Previously admitted to hospital. (Includes other hospitals / health centres. Select 1)	□ No □ < 1 week ago □ 1 week-1month ago □ >1month ago
7.2.	Any medication last 7 days before admission. (Select all that apply)	 □ No medication □ Antibiotic □ Antimalarial □ Traditional □ Deworming □ Vitamin □ Yes, but unknown □ Other (Specify)
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 Hydroxyurea Other	
	Anti-TBs	
	Long term antibiotic prophylaxis	

	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	Denicillin	
		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. ENROLMEN	NT VITAL SIGNS
10.1.	Axillary temperature	°C
10.2.	Respiratory rate (Count for 1 minute)	/minute
10.3.	Heart rate (Count for 1 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 clinician trained in clinical examination of children, and able to formulate a				
	diagnosis based on clinical history and findings. Refer to Clinical Examination SOP				
11.1.	Airway	🗆 Clear	Needs active support		
	(select one)	□ Obstructed/Stridor			
11.2.	Breathing Dormal – no concerns, (move to circulation)				
	(select all that apply)	Central cyanosis	□ Nasal flaring	□ Reduced air- entry	
		□ Wheeze	□ Acidotic Breathing	Grunting	

		□ Lower chest wall indrawing □ Head nodding	Crackles	Dull to percussion
11.3.	Circulation:	□ <2s □ 2-3	3s □ >3s	
	 a) Cap Refill (select one) b) Peripheral temperature (select one) 	U Warm peripheri	es 🛛 Cold periph	neries
	c) Pulse Volume (select one):	Normal	□Weak	
11.4.	Disability:			
	a) Conscious level (select one)	🗆 Alert	□ Voice □ Pa	ain 🗆 Unresponsive
	b) Fontanelle (select one)	🗆 Normal	□ □ S Bulging	unken present
	c) Tone (select one)	🗆 Normal	□ Hypertonic	🗆 Hypotonic
	d) Posture (select one)	Normal	Decorticate	Decerebrate
	e) Activity (select one)	🗆 Normal	Irritable/Agitated	□ Lethargic
11.5.	Dehydration: a) Sunken eyes? (Select one)	П Ү П №		
	b) Skin pinch (Select one)	Immediate	\Box <2 seconds	\Box >2 seconds
11.6.	Oedema (select any that apply)	□ None □ bo	th feet/ankles	□ lower legs
		□ hands or lower a	rms 🛛 face	
11.7.	Drinking/Breastfeeding (Select one)	🗆 Normal	L I Poorly	Not 🛛 Eager / inking 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	□ Wrist widening	Rachitic rosary
		Swollen knees	□ Bow legs	□ Frontal bossing
11.10.	Jaundice (Select one)	П Ү П N		
11.11.	ENT/Oral/Eyes (select any that apply)	☐ Mouth Normal □ Stomatitis	□ Oral ulceration	Oral candidiasis
		Ears Normal ear (mastoiditis)	□ Pus from ear □ Lymphadenopath	□ Tender swelling behind y
		Eyes Normal Visual impairmen	-	□ Eye discharge

11.12.	Skin		🗖 Normal	Hyperpigmentati	on Depigmentation
	a)	Type of skin lesion (select any that apply)	□ Broken skin □ Cellulitis □ Vesicles	 Dermatitis Impetigo Desquamation 	☐ 'Flaky paint' ☐ Pustules ☐ Macular or papular
	b)	Site of skin lesions. (select any that apply)	□ Not applicable (I □ Face / scalp	ttocks □ Arms	

	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 PRIC	OR TO ADM	ISSION
13.1.	Prior to this admission child actively attending	□ Suppleme	ntary (corn soy blend, RUSF, khichuri, halwa)
	outpatient nutrition program? (Select one)	□ Therapeu	tic (RUTF, Plumpy-nut)
		□ 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 breastmilk? (Select one)	□ Yes	□ No
13.6.	If NOT breastfeeding at all, age stopped in months? (select one)	□ N/A (still □ 0-3m □ Unknown	breastfeeding) □ 4-6m □ 7-12m □ >12m

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	14. IMMEDIATE CLINICAL INVESTIGATIONS AND HIV STATUS AT ENROLMENT			
14.1.	Malaria RDT? (select one)	Positive Negative Not done		
14.2.	HIV status known?	Child not previously tested, not known to be exposed		
		 known PCR positive antibody positive, unknown PCR status known exposed, known PCR negative (children under 18m with PCR result SEEN BY RESEARCH TEAM. If not seen select below and perform HIV RDT child untested, but known to be HIV exposed 		
14.3.	a) If not known positive, HIV RDT results now? (select one)	Reactive / positive Non-Reactive / Negative Indeterminate Declined testing Testing not offered by study team (e.g. culturally not sensitive)		
	b) If RDT results now is positive, was PCR sample sent? (select one)	☐ Yes ☐ No missed ☐ No referred		
14.4.	Biological mother present at enrolment? (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		

	15. TREATMENT IN STUDY HOSPITAL BEFORE ENROLMENT				
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)	:: 24h clock	□Not given	
15.3.	Intravenous Antibiotics Given? (select any that apply)	 Not given Benzylpenicillin Co-amoxiclav Ampicillin Levofloxacin Other 	 Gentamicin Flu/Cloxacillin Amikacin Vancomycin 	 Ceftriaxone Chloramphenicol Meropenem Metronidazole 	
15.4.	Oral Antibiotics Given? (select any that apply)	 Other Not given Amoxicillin Co-trimoxazole Cefalexin / cefaclor Penicillin 	 Erythromycin Metronidazole Co-amoxiclav Flucloxacillin 	 Azithromycin Ciprofloxacin Nalidixic acid Levofloxacin Other 	

	16. SUSPECTED INITIAL DIAGNOSES:					
Clinical d	Clinical diagnosis should be based on examination and investigation findings. Tick the <u>three most likely</u> diagnoses.					
16.1.	Common Infections	pneumonia Severe pneumonia				
10.1.	(select any that apply)	Gastroenteritis	□ Sepsis	🗆 Malaria		
		□ Soft tissue infection				
		🗆 URTI	Osteomyelitis			
		Febrile illness unspecif	ied	Enteric fever		
		Not applicable				
16.2.	Other suspected	🗆 Anaemia				
	diagnosis	Adverse Drug Reaction				
	(select any that apply)	🗆 Asthma				
		Bronchiolitis				
		Cerebral palsy				
		Developmental delay				
		Epilepsy				
		Extra pulmonary TB				
		Failed appetite test only				
		Febrile convulsions				
		□ Hydrocephalus				
		🗆 Ileus				
		□ Liver disease				
		Measles				
		Nephrotic syndrome				
		Otitis media				
		Other encephalopathy				
		Probable meningitis				

Pulmonary TB
🛛 Renal impairment
□ Sickle Cell Disease
□ Suspected Toxicity
🗆 Thalassaemia
🗆 Varicella
Other, specify:

	17. ADMISSION INVESTIGATI	ONS AND SAMPLE COLLECTION
17.1.	CBC taken? (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.	Blood culture taken (if available at site as part of routine care; select one))	□ 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.	Stool sample taken? (Must be Taken within first 48h of enrolment; select one)	Yes No
17.8.	Date and Time stool sample taken	$ \begin{array}{c} - & - \\ D & D \\ \end{array} \begin{array}{c} / \\ M \\ M \\ \end{array} \begin{array}{c} / \\ Y \\ Y \\ Y \\ \end{array} \begin{array}{c} - \\ Y \\ Y \\ \end{array} \begin{array}{c} - \\ - \\ 24 \\ h \\ clock \end{array} \end{array} $

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

	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			
			//		
			\overline{D} \overline{D} \overline{M} \overline{M} \overline{Y} \overline{Y} \overline{Y} \overline{Y} \overline{Y}		
	c)	Time			
	1		·:		
			24 h clock		
19.2	a)	CRF Reviewed by (Initials)			
	b)	Date			
			/ /		
			\overline{D} \overline{D} \overline{M} \overline{M} \overline{Y} \overline{Y} \overline{Y} \overline{Y} \overline{Y}		
	c)	Time			
			:		
			24 h clock		