PB-SAM Enrolment CRF v1.5

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

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)	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	☐	☐
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	☐	☐
l)	☐ Direct Bilirubin levels Above 25 **µmol/L** (Kampala site only)	☐	☐

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

a)	☐ Respiratory distress	☐ subcostal indrawing or ☐ nasal flaring or ☐ head nodding ☐ **grunting**
b)	☐ Oxygenation	☐ central cyanosis or ☐ 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

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

k) Are the above severity characteristics present now at enrolment? ☐ Yes ☐ No

l) 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 (l) for audits and monitoring; DO NOT keep source documents with CRF

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**	__ __: __ __ ☐ 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**	___ ___ ___

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2.7.	**DATE of enrolment** *i.e. date consented and seen by research team*	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*
2.8.	**TIME of enrolment**	__ __: __ __ *24h Clock*
2.9.	**Sex**	☐ Male ☐ Female
2.10.	**DOB**	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*
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 complaints at admission?** *(Select all that apply)*	☐ Fever / Hotness of body ☐ Vomiting ☐ Lethargy ☐ Difficulty breathing ☐ Diarrhoea <14 days ☐ Convulsions ☐ Cough<14 days ☐ Cough>14days ☐ Diarrhoea >14 days ☐ Altered consciousness ☐ Blood in stool ☐ Poor feeding ☐ skin changes (*fill in 3.2*) ☐ Body swelling (oedema) ☐Hair changes (*fill in 3.3*) ☐ Other_____
3.2.	**Skin changes** *(if checked at 3.1)*	☐ Rash ☐ Hyperpigmentation ☐ Hypopigmentation ☐ Peeling ☐ Blisters ☐ Thickening of skin How long have skin changes 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 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)**	☐ 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** *(to be taken using SECA 416 infantometer provided for study)*	☐ Length ☐ 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

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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**	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.	**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)?**	☐ Y ☐ **N**
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 ☐ Isoniazid ☐ Rifampin ☐ Pyrazinamide (PZA) ☐ Ethambutol ☐ Other
	Long term antibiotic prophylaxis ☐ Co-trimoxazole ☐ Penicillin

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9. TREATMENT GIVEN BEFORE ARRIVAL AT STUDY HOSPITAL

9.1.	**Intravenous Antibiotics Given?** *(select any that apply)*	☐ **Not given** ☐ Benzylpenicillin ☐ Gentamicin ☐ Ceftriaxone ☐ Co-amoxiclav ☐ Flu/Cloxacillin ☐ Chloramphenicol ☐ Ampicillin ☐ Amikacin ☐ Meropenem ☐ Levofloxacin ☐ Vancomycin ☐ Metronidazole ☐ Co-trimoxazole ☐ Penicillin ☐ Other_____
9.2.	**Oral Antibiotics Given?** *(select any that apply)*	☐ **Not given** ☐ 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 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** *(select one)*	☐ **Clear** ☐ Needs active support ☐ Obstructed/Stridor
11.2.	**Breathing** *(select all that apply)*	☐ **Normal – no concerns**, *(move to circulation)* ☐ Central cyanosis ☐ Nasal flaring ☐ Reduced air-entry ☐ Wheeze ☐ Acidotic Breathing ☐ Grunting ☐ Lower chest wall indrawing ☐ Crackles ☐ Dull to percussion ☐ Head nodding

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11.3.	**Circulation:** **a) Cap Refill** (select one) **b) Peripheral temperature** (select one) **c) Pulse Volume** (select one)**:**	☐ **<2s** ☐ 2-3s ☐ >3s ☐ **Warm peripheries** ☐ Cold peripheries ☐ **Normal** ☐Weak
11.4.	**Disability:** **a) Conscious level** *(select one)* **b) Fontanelle** *(select one)* **c) Tone** *(select one)* **d) Posture** *(select one)* **e) Activity** *(select one)*	☐ **Alert** ☐ Voice ☐ Pain ☐ Unresponsive ☐ **Normal** ☐ Bulging ☐ Sunken ☐ Not present ☐ **Normal** ☐ Hypertonic ☐ Hypotonic ☐ **Normal** ☐ Decorticate ☐Decerebrate ☐ **Normal** ☐ Irritable/Agitated ☐ Lethargic
11.5.	**Dehydration:** **a) Sunken eyes?** *(Select one)* **b) Skin pinch** *(Select one)*	☐ Y ☐ **N** ☐ **Immediate** ☐ <2 seconds ☐ >2 seconds
11.6.	**Oedema** *(select any that apply)*	☐ None ☐ both feet/ankles ☐ lower legs ☐ hands or lower arms ☐ face
11.7.	**Drinking/Breastfeeding** *(Select one)*	☐ **Normal** ☐ Poorly ☐ Not drinking ☐ Eager / 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)*	☐ Y ☐ **N**
11.11.	**ENT/Oral/Eyes** *(select any that apply)*	☐ **Mouth Normal** ☐ Oral ulceration ☐ Oral candidiasis ☐ Stomatitis ☐ **Ears Normal** ☐ Pus from ear ☐ Tender swelling behind ear (mastoiditis) ☐ Lymphadenopathy ☐ **Eyes Normal** ☐ Conjunctivitis ☐ Eye discharge ☐ Visual impairment
11.12.	**Skin** **a) Type of skin lesion** *(select any that apply)*	☐ **Normal** ☐ Hyperpigmentation ☐ Depigmentation ☐ Broken skin ☐ Dermatitis ☐ 'Flaky paint' ☐ Cellulitis ☐ Impetigo ☐ Pustules ☐ Vesicles ☐ Desquamation ☐ Macular or papular
	b) Site of skin lesions. *(select any that apply)*	☐ **Not applicable (No rash)** ☐ Palms / soles ☐ Trunk ☐ Face / scalp ☐ Legs ☐ Buttocks ☐ Arms ☐ Perineum

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12. SUSPECTED CHRONIC CONDITIONS			
Select confirmed, 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 <u>actively attending</u> outpatient nutrition program?** *(Select one)*	☐ Supplementary (*corn soy blend, RUSF, khichuri, halwa)* ☐ Therapeutic *(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 breastfeeding)** ☐ 0-3m ☐ 4-6m ☐ 7-12m ☐ >12m ☐ Unknown

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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

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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 ☐ Gentamicin ☐ Ceftriaxone ☐ Co-amoxiclav ☐ Flu/Cloxacillin ☐ Chloramphenicol ☐ Ampicillin ☐ Amikacin ☐ Meropenem ☐ Levofloxacin ☐ Vancomycin ☐ Metronidazole ☐ Other_____
15.4.	**Oral Antibiotics Given?** *(select any that apply)*	☐ **Not given** ☐ Amoxicillin ☐ Erythromycin ☐ Azithromycin ☐ Co-trimoxazole ☐ Metronidazole ☐ Ciprofloxacin ☐ Cefalexin / cefaclor ☐ Co-amoxiclav ☐ Nalidixic acid ☐Penicillin ☐ Flucloxacillin ☐ Levofloxacin ☐ Other _____

16. SUSPECTED INITIAL DIAGNOSES:		
Clinical diagnosis should be based on examination and investigation findings. Tick the <u>three most likely</u> diagnoses.		
16.1.	**Common Infections** *(select any that apply)*	☐ pneumonia ☐ Severe pneumonia ☐ Gastroenteritis ☐ Sepsis ☐ Malaria ☐ Soft tissue infection ☐ UTI ☐ URTI ☐ Osteomyelitis ☐ Febrile illness unspecified ☐ Enteric fever ☐ Not applicable
16.2.	**Other suspected diagnosis** *(select any that apply)*	☐ Anaemia ☐ Adverse Drug Reaction ☐ 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

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		☐ Renal impairment ☐ Sickle Cell Disease ☐ Suspected Toxicity ☐ Thalassaemia ☐ Varicella ☐ Other, specify: _____

17. ADMISSION INVESTIGATIONS 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**	__ __ / __ __ / __ __ __ __ *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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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**	__ __/__ __/__ __ __ __ *D D / M M / Y Y Y Y*
	c) **Time**	__ __:__ __ *24 h clock*
19.2	a) **CRF Reviewed by (Initials)**	__ __ __
	b) **Date**	__ __/__ __/__ __ __ __ *D D / M M / Y Y Y Y*
	c) **Time**	__ __:__ __ *24 h clock*