PB-SAM Enrolment CRF v1

PB-SAM Number [1][0] [0][0][3] [ ][ ][ ]

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)	Admitted 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	☐	☐

****Severity characteristics, two or more 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

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.	**DATE of enrolment** *i.e. date consented and seen by research team*	__ __/__ __/__ __ __ __ *D D / M M / Y Y Y Y*
2.4.	**TIME of enrolment**	__ __: __ __ *24h Clock*
2.5.	**Sex**	☐ Male ☐ Female
2.6.	**DOB**	__ __/__ __/__ __ __ __ *D D / M M / Y Y Y Y*
2.7.	**Is the DOB:**	☐ True ☐ Estimated*
2.8.	**Date of consent**	__ __/__ __/__ __ __ __ *D D / M M / Y Y Y Y*
2.9.	**Time of consent**	__ __: __ __ *24h Clock*
2.10.	**Consented by Initials**	___ ___ ___

**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)*	☐ Premature ☐ Born at term	☐ Born small <2.5kg ☐ Unknown	☐Twin/multiple birth

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
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)*	**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

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
		☐ 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 _____
9.3.	**Initial treatment <u>given</u>** *(Select any that apply. For IV fluid bolus, and IV fluids specify type and volume in ml, and duration)*	☐ IV Fluid Bolus	☐ IV Maintenance Fluids
		☐ Oxygen	☐ Warmth (heater, warmed fluids)
		☐ IV Glucose ☐ Oral glucose	☐ Commercial F75
		☐ Blood transfusion	☐ Commercial F100
		☐ Phenobarbitone	☐ Locally prepared F75/ milk suji
		☐ Diazepam	☐ Local prepared F100 / milk suji 100
		☐ Paracetamol	☐ Expressed breast milk
		☐ Ibuprofen	☐ Dilute F100
		☐ Antimalarial	☐ Other milk/ formula/ feed
		☐ ReSoMal	☐ Other
		☐ ORS	_____

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
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

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 usually 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

14. IMMEDIATE CLINICAL INVESTIGATIONS AND HIV STATUS AT ENROLMENT		
14.1.	**Malaria RDT?** *(select one)*	☐ Positive ☐ Negative ☐ Not done
14.2.	**HIV status known?**	☐ **No, child not previously tested, not known to be exposed** ☐ Yes, known PCR positive ☐ Yes, antibody positive, unknown PCR status ☐ Yes, known exposed, known PCR negative (*children under 18m with PCR result SEEN BY RESEARCH TEAM. If not seen select below and perform HIV RDT* ☐ No, 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)*	☐ Yes, Reactive ☐ Yes, Non-reactive ☐ Yes, but Declined ☐ No, mother is known positive ☐ Missed ☐ N/A child in care home ☐ Not offered by study team *(e.g. culturally not sensitive)* ☐ Not applicable *(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 ☐ 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 _____
15.5.	**Initial treatment <u>given</u>** *(Select any that apply. For IV fluid bolus, and IV fluids specify type and volume in ml, and duration)*	☐ IV Fluid Bolus ☐ IV Maintenance Fluids ☐ Oxygen ☐ Warmth (heater, warmed fluids) ☐ IV Glucose ☐ Oral Glucose ☐ Commercial F75 ☐ Blood transfusion ☐ Commercial F100 ☐ Phenobarbitone ☐ Locally prepared F75/ milk suji ☐ Diazepam ☐ Local prepared F100 / milk suji 100 ☐ Paracetamol ☐ Expressed breast milk ☐ Ibuprofen ☐ Dilute F100 ☐ Antimalarial ☐ Other milk/ formula/ feed ☐ ReSoMal ☐ Other _____ ☐ ORS

16. SUSPECTED INITIAL DIAGNOSES:

Clinical diagnosis should be based on examination and investigation findings. Tick the <u>three most likely</u> diagnoses.

16.1.	**General** *(select any that apply)*	☐ Anaemia ☐ Sickle Cell Disease ☐ Thalassaemia ☐ Renal impairment ☐ Nephrotic syndrome ☐ Nephritis ☐ Ileus ☐ Liver dysfunction ☐ Not applicable
16.2.	**Respiratory** *(select any that apply)*	☐ LRTI/pneumonia ☐ Bronchiolitis ☐ URTI ☐ Pulmonary TB ☐ Otitis media ☐ Asthma ☐ Not applicable
16.3.	**Infection** *(select any that apply)*	☐ Gastroenteritis ☐ Sepsis ☐ Malaria ☐ Extra pulmonary TB ☐ Soft tissue infection ☐ UTI ☐ HIV related illness ☐ Measles ☐ Varicella ☐ Osteomyelitis ☐ Febrile illness unspecified ☐ Enteric fever

		☐ Not applicable
16.4.	**CNS** *(select any that apply)*	☐ Febrile convulsions ☐ Epilepsy ☐ Probable meningitis ☐ Other encephalopathy ☐ Hydrocephalus ☐ Developmental delay ☐ Cerebral palsy ☐ Not applicable
16.5.	**Other suspected diagnosis** *(select any that apply)*	☐ Other ☐ Unknown ☐ Failed appetite test only ☐ Suspected Toxicity ☐ Not applicable

17. ADMISSION INVESTIGATIONS AND SAMPLE COLLECTION		
17.1.	**CBC with differential taken?** *(As part of routine clinical care; select one)*	☐ Yes ☐ No
17.2.	**Clinical chemistry taken (iSTAT)** *(Kilifi and Dhaka; select one)*	☐ Yes ☐ No
17.3.	**EDTA blood taken** *(Select one)*	☐ Yes ☐ No
17.4.	**Blood culture taken** *(if available at site as oart of routine care; select one))*	☐ Y BEFORE ABX ☐ Y AFTER ABX ☐ No
17.5.	**Unable to take all blood samples, why?** *(Select one)*	☐ **Not applicable (all bloods taken)** ☐ Difficult venepuncture ☐ Child uncooperative ☐ Parent refused ☐ Other
17.6.	**Rectal swab taken** *(Select one)*	☐ Y BEFORE ABX ☐ Y AFTER ABX ☐ No
17.7.	**Time Rectal swabs taken**	___ ___: ___ ___ Hrs *24 h clock*
17.8.	**Stool sample taken?** *(Must be Taken within first 48h of enrolment; select one)***)**	☐ Yes ☐ No
17.9.	**Date stool sample taken**	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*

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**	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*
	c) **Time**	___ ___:___ ___ *24 h clock*