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

AAAAAAAA

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 | | | | | |
| I) | □ Direct Bilirubin levels Above 25 µmol/L (Kampala site only) | | | | | |

PB-SAM Enrolment CRF v1.5MMMMPatient Initials [][]PB-SAM Number [3][0] [][]

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

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 | \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

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

| k) Are the above severity characteristics present now | at enrolment? 🛛 Yes | 🗆 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 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 | : | | |
| | | 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 | | | |
| | | | | |

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

| S | Screening Number [M] [] [] [] (Kampala only) | | | | |
|-------|---|--|--|--|--|
| 2.7. | DATE of enrolment <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 | Fever / Hotness of body Difficulty breathing | □ 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 | | | |

PB-SAM Enrolment CRF v1.5 MMMM Patient Initials [][] PB-SAM Number [3][0] [][]

| S | creening Number [M] [] [] [] |] (Kampala only) |
|------|--|-------------------------------|
| 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) | \square No \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) | □ 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 | | | |
| | Sickle cell | | |
| | Anti-TBs | | |
| | 🗌 Isoniazid 🗌 Rifampin 🔲 Pyrazinamide (PZA) 🗌 Ethambutol 🗌 Other | | |
| | Long term antibiotic prophylaxis | | |

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

| | Screening Number [M] [] [] [] (Kampala only) | | | | | | |
|------|---|---|---|--|--|--|--|
| | 9. TREATMENT GIVEN BEFORE ARRIVAL AT STUDY HOSPITAL | | | | | | |
| 9.1. | Intravenous Antibiotics Given? (select any that apply) | Not given Benzylpenicillin Co-amoxiclav Ampicillin Levofloxacin Co-trimoxazole | □ Gentamicin □ Flu/Cloxacillin □ Amikacin □ Vancomycin □ Penicillin | Ceftriaxone Chloramphenicol Meropenem Metronidazole | | | |
| 9.2. | Oral Antibiotics Given? | Other D Not given | | | | | |
| 5.2. | (select any that apply) | ☐ Amoxicillin ☐ Co-trimoxazole ☐ Cefalexin / cefaclor ☐Penicillin | Erythromycin Metronidazole Co-amoxiclav Flucloxacillin | Azithromycin Ciprofloxacin Nalidixic acid 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 | clinician trained in clinical e | xamination of children, and ab | le 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 | □ 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 | | | | |

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

| 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 | level (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 | yes? (Select one) | П Ү П № | | |
| | b) Skin pinc | h (Select one) | Immediate | □ <2 seco | ands \Box >2 seconds |
| 11.6. | Oedema (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) | | П Ү П М | | |
| 11.11. | ENT/Oral/Eyes (select any that appl | ly) | ☐ Mouth Normal☐ Stomatitis | □ Oral ulceration | n 🛛 Oral candidiasis |
| | | | Ears Normal ear (mastoiditis) | □ Pus from ear □ Lymphadenop | ☐ Tender swelling behind athy |
| | | | Eyes Normal | □ 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 |
| | (select any that apply) | | | ittocks 🛛 Arms | D Perineum |

PB-SAM Enrolment CRF v1.5 PB-SAM Enrolment CRF v1.5 Patient Initials [][] PB-SAM Number [3][0] [][]

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

| | 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 | □ Suppleme | ntary (corn soy blend, RUSF, khichuri, halwa) | | |
| | outpatient nutrition program? (Select one) | □ Therapeut | ic (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? | □ N/A (still breastfeeding) | | | |
| | (select one) | □ 0-3m □ Unknown | □ 4-6m □ 7-12m □ >12m | | |

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

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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? | 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 |

PB-SAM Enrolment CRF v1.5Patient Initials [][]PB-SAM Number [3][0] [][]

| 0 | Screening Number | [M][][][] | [] (Kampala only) | | | | |
|-------|--|--|---|--|--|--|--|
| | 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) | ::::::: | □Not given | | | |
| 15.3. | Intravenous Antibiotics Given? (select any that apply) | Not given Benzylpenicillin Co-amoxiclav | □ Gentamicin □ Flu/Cloxacillin | □ Ceftriaxone □ Chloramphenicol | | | |
| | | Ampicillin Levofloxacin Other | Amikacin Vancomycin | MeropenemMetronidazole | | | |
| 15.4. | Oral Antibiotics Given? (select any that apply) | Not given Amoxicillin Co-trimoxazole Cefalexin / cefaclor Penicillin | Erythromycin Metronidazole Co-amoxiclav Flucloxacillin | Azithromycin Ciprofloxacin Nalidixic acid Levofloxacin Other | | | |

| | | | | 10050 | | |
|------------|--------------------------------|--------------------------------|--------------------------------|-------------------------------|--|--|
| | | | D INITIAL DIAG | | | |
| Clinical d | liagnosis should be based on e | xamination and investigation f | indings. Tick the <u>three</u> | <u>most likely</u> diagnoses. | | |
| 16.4 | | | | | | |
| 16.1. | Common Infections | D pneumonia | Severe pneum | | | |
| | (select any that apply) | Gastroenteritis | □ Sepsis | 🗆 Malaria | | |
| | | Soft tissue infection | | | | |
| | | | Osteomyelitis | | | |
| | | Febrile illness unspecif | fied | 🗆 Enteric fever | | |
| | | Not applicable | | | | |
| 16.2. | Other suspected | 🗆 Anaemia | | | | |
| | diagnosis | □ Adverse Drug Reaction | n | | | |
| | (select any that apply) | □ Asthma | | | | |
| | (| □ Bronchiolitis | | | | |
| | | Cerebral palsy | | | | |
| | | Developmental delay | | | | |
| | | □ Epilepsy | | | | |
| | | Extra pulmonary TB | | | | |
| | | □ Failed appetite test on | lv | | | |
| | | □ Febrile convulsions | | | | |
| | | □ Hydrocephalus | | | | |
| | | \square Ileus | | | | |
| | | Liver disease | | | | |
| | | Measles | | | | |
| | | □ Nephrotic syndrome | | | | |
| | | □ Otitis media | | | | |
| | | Other encephalopathy | , | | | |
| | | □ Probable meningitis | | | | |
| | | □ Pulmonary TB | | | | |

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

| S | Screening Number | M][][|][|] | [|] (Kampala only) |
|---|------------------|-----------------|----|---|---|------------------|
| | □ R | nal impairmen | t | | | |
| | | kle Cell Diseas | e | | | |
| | 🗆 Su | spected Toxicit | у | | | |
| | | alassaemia | | | | |
| | □ V | ricella | | | | |
| | | ner, 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 | / / 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) | | | | |

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

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TAA:

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 | |
| | c) | Time | : 24 h clock |