

PB-SAM Enrolment CRF v1.5



Patient Initials [ ][ ][ ]

PB-SAM Number [4][0][ ][ ][ ]

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

| 1. ELIGIBILITY CHECKLIST |   |                          |                          |
|--------------------------|---|--------------------------|--------------------------|
| 1.1. Inclusion Criteria  |   |                          |                          |
|                          |   | YES                      | NO<br>(ineligible)       |
| a)                       | Age between 2 months and 59 months  | <input type="checkbox"/> | <input type="checkbox"/> |
| b)                       | Admitted to hospital with an acute non-traumatic illness ( <i>Within this time, children requiring CPR or unable to take orally (NPO) will be re-evaluated daily</i> )  | <input type="checkbox"/> | <input type="checkbox"/> |
| c)                       | Enrolled within 72 hours of admission*  | <input type="checkbox"/> | <input type="checkbox"/> |
| d)                       | Severe malnutrition ( <b>weight for height &lt; -3z</b> scores of the median WHO growth standards and/or MUAC <ul style="list-style-type: none"> <li>• Age &gt; 6months &lt;115mm</li> <li>• 2- &lt;6 months &lt;110mm</li> </ul> or <b>symmetrical oedema</b> of at least the feet related to malnutrition, i.e. not related to a primary cardiac or renal disorder) | <input type="checkbox"/> | <input type="checkbox"/> |
| e)                       | Parent or guardian able and available to consent  | <input type="checkbox"/> | <input type="checkbox"/> |
| g)                       | Presence of two or more features of severity as specified in Table below**  | <input type="checkbox"/> | <input type="checkbox"/> |
| h)                       | Primary caregiver plans to stay in the study area during the duration of the study  | <input type="checkbox"/> | <input type="checkbox"/> |
| 1.2. Exclusion Criteria  |   |                          |                          |
|                          |   | YES<br>(Ineligible)      | NO                       |
| c)                       | Known congenital cardiac disease  | <input type="checkbox"/> | <input type="checkbox"/> |
| d)                       | Known terminal illness e.g. cancer  | <input type="checkbox"/> | <input type="checkbox"/> |
| e)                       | Admission for surgery, or likely to require surgery within 6m   | <input type="checkbox"/> | <input type="checkbox"/> |
| f)                       | Admission for trauma?   | <input type="checkbox"/> | <input type="checkbox"/> |
| g)                       | Sibling enrolled in study   | <input type="checkbox"/> | <input type="checkbox"/> |
| h)                       | Previously enrolled in this trial or currently enrolled in this trial   | <input type="checkbox"/> | <input type="checkbox"/> |
| i)                       | Known stomach or duodenal ulcer   | <input type="checkbox"/> | <input type="checkbox"/> |
| j)                       | Known liver disorder or exocrine pancreatic disorder – e.g. biliary atresia, history of gallstones, cystic fibrosis or clinical jaundice  | <input type="checkbox"/> | <input type="checkbox"/> |
| k)                       | Known intolerance or allergy to any study medication  | <input type="checkbox"/> | <input type="checkbox"/> |
| l)                       | <input type="checkbox"/> Direct Bilirubin levels Above 25 $\mu\text{mol/L}$ (Kampala site only)   | <input type="checkbox"/> | <input type="checkbox"/> |

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

|  |  |
|--|--|
| a) <input type="checkbox"/> Respiratory distress                             | <input type="checkbox"/> subcostal indrawing or <input type="checkbox"/> nasal flaring or <input type="checkbox"/> head nodding<br><input type="checkbox"/> grunting |
| b) <input type="checkbox"/> Oxygenation                                      | <input type="checkbox"/> central cyanosis or <input type="checkbox"/> SaO <sub>2</sub> <90% (adjusted for altitude)  |
| c) <input type="checkbox"/> Circulation                                      | <input type="checkbox"/> Limb temperature gradient or <input type="checkbox"/> cap refill >3 seconds   |
| d) <input type="checkbox"/> AVPU   | < "A"  |
| e) <input type="checkbox"/> Pulse  | > 180 per min [ _____beats per minute]   |
| f) <input type="checkbox"/> Hb   | < 7g/dl [ _____g/dl]   |
| g) <input type="checkbox"/> WBC  | < 4 or > 17.5 x 10 <sup>9</sup> /l [ _____10 <sup>9</sup> /l]  |
| h) <input type="checkbox"/> Blood glucose                                    | < 3mmol/L [ _____mmol/L]   |
| i) <input type="checkbox"/> Documented temperature at admission or screening | <input type="checkbox"/> <36 or <input type="checkbox"/> >38.5°C   |
| j) <input type="checkbox"/> 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                              | ____/____/_____<br>D D / M M / Y Y Y Y                  |
| 2.2. | TIME arrived at the hospital                              | ____:____ <input type="checkbox"/> unknown<br>24h Clock |
| 2.3. | Hospital IP Number<br>(Use Serial number for Kilifi site) | _____   |
| 2.4. | Date of consent   | ____/____/_____<br>D D / M M / Y Y Y Y                  |
| 2.5. | Time of consent   | ____:____<br>24h Clock                                  |
| 2.6. | Consented by Initials                                     | ____  |

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|       |  |   |
|-------|--|---|
| 2.7.  | <b>DATE of enrolment</b><br><i>i.e. date consented and seen by research team</i> | ___/___/_____<br>D D / M M / Y Y Y Y                              |
| 2.8.  | <b>TIME of enrolment</b>   | __:__:_____<br>24h Clock  |
| 2.9.  | <b>Sex</b>   | <input type="checkbox"/> Male <input type="checkbox"/> Female     |
| 2.10. | <b>DOB</b>   | ___/___/_____<br>D D / M M / Y Y Y Y                              |
| 2.11. | <b>Is the DOB:</b>   | <input type="checkbox"/> True <input type="checkbox"/> Estimated* |

\*if DOB is estimated, and the day is uncertain, write '15' for DD

| 3. PRESENTING AND CURRENT COMPLAINTS |  |   |
|--------------------------------------|--|---|
| 3.1.                                 | <b>What were the presenting complaints at admission?</b><br><i>(Select all that apply)</i> | <input type="checkbox"/> Fever / Hotness of body <input type="checkbox"/> Vomiting <input type="checkbox"/> Lethargy<br><input type="checkbox"/> Difficulty breathing <input type="checkbox"/> Diarrhoea <14 days <input type="checkbox"/> Convulsions<br><input type="checkbox"/> Cough<14 days <input type="checkbox"/> Cough>14days<br><input type="checkbox"/> Diarrhoea >14 days<br><input type="checkbox"/> Altered consciousness <input type="checkbox"/> Blood in stool <input type="checkbox"/> Poor feeding<br><input type="checkbox"/> skin changes <i>(fill in 3.2)</i> <input type="checkbox"/> Body swelling (oedema)<br><input type="checkbox"/> Hair changes <i>(fill in 3.3)</i><br><input type="checkbox"/> Other _____ |
| 3.2.                                 | <b>Skin changes</b> <i>(if checked at 3.1)</i>   | <input type="checkbox"/> Rash <input type="checkbox"/> Hyperpigmentation <input type="checkbox"/> Hypopigmentation <input type="checkbox"/> Peeling<br><input type="checkbox"/> Blisters <input type="checkbox"/> Thickening of skin<br>How long have skin changes been present ___ Days/___ Months   |
| 3.3.                                 | <b>Hair Changes</b> <i>(if checked at 3.1)</i>   | <input type="checkbox"/> Reddened colour <input type="checkbox"/> Light colour <input type="checkbox"/> Straighter than usual<br><input type="checkbox"/> Thinner than usual  |

| 4. TREATMENT FOR THIS ILLNESS |   |
|-------------------------------|---|
| 4.1.                          | <b>Have you visited a hospital for this illness?</b> <i>(Select any that apply)</i> |

No  Outpatient  Inpatient (Overnight stay)

| 5. BIRTH HISTORY |  |                              |  |
|------------------|--|------------------------------|--|
| 5.1.             | <b>Birth details</b><br><i>(Select any that apply)</i> |                              |  |
| 5.2.             | <b>Preterm (&lt; 37weeks)</b>                          | <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| 5.3.             | <b>Born small (&lt;2.5kg)</b>                          | <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| 5.4.             | <b>Twin/multiple births</b>                            | <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| 5.5.             | <b>Born at term</b>                                    | <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> Unknown |

| 6. ANTHROPOMETRY |   |  |
|------------------|---|--|
| 6.1.             | <b>Weight</b><br><i>(to be taken using SECA scales for CHAIN study)</i>                     | ____.____ kg   |
| 6.2.             | <b>Length/Height</b><br><i>(to be taken using SECA 416 infantometer provided for study)</i> | <input type="checkbox"/> Length <input type="checkbox"/> Height<br>Measurer 1: ____ cm Measurer 2: ____ cm |
| 6.3.             | <b>MUAC</b><br><i>(To be taken using MUAC tape for CHAIN study)</i>                         | Measurer 1: ____ cm Measurer 2: ____ cm  |

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|             |  |   |
|-------------|--|---|
| <b>6.4.</b> | <b>Head circumference</b><br><i>(To be taken using CHAIN measuring tape)</i> | Measurer 1: ____ . ____ cm Measurer 2: ____ . ____ cm |
| <b>6.5.</b> | <b>Staff Initials</b>  | 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 |   |  |
|--------------------|---|--|
| <b>7.1.</b>        | <b>Previously admitted to hospital.</b><br><i>(Includes other hospitals / health centres. Select 1)</i> | <input type="checkbox"/> No <input type="checkbox"/> < 1 week ago <input type="checkbox"/> 1 week-1month ago <input type="checkbox"/> >1month ago  |
| <b>7.2.</b>        | <b>Any medication last 7 days before admission.</b><br><i>(Select all that apply)</i>                   | <input type="checkbox"/> No medication <input type="checkbox"/> Antibiotic <input type="checkbox"/> Antimalarial <input type="checkbox"/> Traditional<br><input type="checkbox"/> Deworming <input type="checkbox"/> Vitamin <input type="checkbox"/> Yes, but unknown<br><input type="checkbox"/> Other (Specify) _____ |
| <b>7.3.</b>        | <b>Has the child previously had oedema (body swelling)?</b>   | <input type="checkbox"/> Y <input type="checkbox"/> N  |
| <b>7.4.</b>        | <b>Urine production in last 24hrs?</b><br><i>(Select 1)</i>   | <input type="checkbox"/> Normal or greater <input type="checkbox"/> Less than normal <input type="checkbox"/> Not passing urine<br><input type="checkbox"/> Unknown  |

| 8. LONG TERM MEDICATION  |  |
|--|--|
| <b>8.1 Was child on any long term medication before hospitalization?</b><br><i>(select any that apply)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No<br><br><b>If Yes, select any that apply.</b><br><b>ARV's</b><br><input type="checkbox"/> Zidovudine/azidothymidine (ZDV/AZT) <input type="checkbox"/> Lamivudine (3TC) <input type="checkbox"/> Abacavir (ABC)<br><input type="checkbox"/> Nevirapine (NVP) <input type="checkbox"/> Efavirenz (EFV) <input type="checkbox"/> Lopinavir/Ritonavir (Kaletra, LPV/r) <input type="checkbox"/> Other<br><b>Neuro</b><br><input type="checkbox"/> Phenobarbital <input type="checkbox"/> Valproic acid <input type="checkbox"/> Levetiracetam <input type="checkbox"/> Lamotrigine <input type="checkbox"/> Other<br><b>Sickle cell</b><br><input type="checkbox"/> Hydroxyurea <input type="checkbox"/> Other<br><b>Anti-TBs</b><br><input type="checkbox"/> Isoniazid <input type="checkbox"/> Rifampin <input type="checkbox"/> Pyrazinamide (PZA) <input type="checkbox"/> Ethambutol <input type="checkbox"/> Other<br><br>Long term antibiotic prophylaxis<br><input type="checkbox"/> Co-trimoxazole <input type="checkbox"/> Penicillin |



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**9. TREATMENT GIVEN BEFORE ARRIVAL AT STUDY HOSPITAL**

|   |   |   |  |                                       |
|---|---|---|--|---------------------------------------|
| <b>9.1. Intravenous Antibiotics Given?</b><br>(select any that apply) | <input type="checkbox"/> <b>Not given</b>     | <input type="checkbox"/> Benzylpenicillin | <input type="checkbox"/> Gentamicin      | <input type="checkbox"/> Ceftriaxone  |
|   | <input type="checkbox"/> Co-amoxiclav         | <input type="checkbox"/> Flu/Cloxacillin  | <input type="checkbox"/> Chloramphenicol |                                       |
|   | <input type="checkbox"/> Ampicillin           | <input type="checkbox"/> Amikacin         | <input type="checkbox"/> Meropenem       |                                       |
|   | <input type="checkbox"/> Levofloxacin         | <input type="checkbox"/> Vancomycin       | <input type="checkbox"/> Metronidazole   |                                       |
|   | <input type="checkbox"/> Co-trimoxazole       | <input type="checkbox"/> Penicillin       |  |                                       |
|   | <input type="checkbox"/> Other _____          |   |  |                                       |
| <b>9.2. Oral Antibiotics Given?</b><br>(select any that apply)        | <input type="checkbox"/> <b>Not given</b>     | <input type="checkbox"/> Amoxicillin      | <input type="checkbox"/> Erythromycin    | <input type="checkbox"/> Azithromycin |
|   | <input type="checkbox"/> Co-trimoxazole       | <input type="checkbox"/> Metronidazole    | <input type="checkbox"/> Ciprofloxacin   |                                       |
|   | <input type="checkbox"/> Cefalexin / cefaclor | <input type="checkbox"/> Co-amoxiclav     | <input type="checkbox"/> Nalidixic acid  |                                       |
|   | <input type="checkbox"/> Penicillin           | <input type="checkbox"/> Flucloxacillin   | <input type="checkbox"/> Levofloxacin    |                                       |
|   |   |   | <input type="checkbox"/> Other _____     |                                       |

**10. ENROLMENT VITAL SIGNS**

|  |  |
|--|--|
| <b>10.1. Axillary temperature</b>  | _____ . _____ °C   |
| <b>10.2. Respiratory rate</b><br>(Count for 1 minute)                      | _____ /minute  |
| <b>10.3. Heart rate</b><br>(Count for 1 minute)                            | _____ /minute  |
| <b>10.4. SaO2</b><br>(To be taken from finger or toe using pulse oximeter) | _____ %<br>Leave blank if unrecordable   |
| <b>10.5. Where was SaO2 Measured?</b>                                      | <input type="checkbox"/> Measured on Oxygen <input type="checkbox"/> Measured in Room Air<br><br><input type="checkbox"/> Unrecordable |

**11. EXAMINATION**

|  |   |
|--|---|
| <i>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</i> |   |
| <b>11.1. Airway</b><br>(select one)  | <input type="checkbox"/> <b>Clear</b> <input type="checkbox"/> Needs active support<br><input type="checkbox"/> Obstructed/Stridor  |
| <b>11.2. Breathing</b><br>(select all that apply)  | <input type="checkbox"/> <b>Normal – no concerns, (move to circulation)</b><br><input type="checkbox"/> Central cyanosis <input type="checkbox"/> Nasal flaring <input type="checkbox"/> Reduced air-entry<br><input type="checkbox"/> Wheeze <input type="checkbox"/> Acidotic Breathing <input type="checkbox"/> Grunting<br><input type="checkbox"/> Lower chest wall indrawing <input type="checkbox"/> Crackles <input type="checkbox"/> Dull to percussion<br><input type="checkbox"/> Head nodding |

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|        |  |   |
|--------|--|---|
| 11.3.  | <b>Circulation:</b>  | <input type="checkbox"/> <2s <input type="checkbox"/> 2-3s <input type="checkbox"/> >3s   |
|        | a) <b>Cap Refill</b><br>(select one)                       | <input type="checkbox"/> Warm peripheries <input type="checkbox"/> Cold peripheries   |
|        | b) <b>Peripheral temperature</b><br>(select one)           | <input type="checkbox"/> Normal <input type="checkbox"/> Weak   |
| 11.4.  | c) <b>Pulse Volume</b><br>(select one):                    |   |
|        | <b>Disability:</b>   |   |
|        | a) <b>Conscious level</b> (select one)                     | <input type="checkbox"/> Alert <input type="checkbox"/> Voice <input type="checkbox"/> Pain <input type="checkbox"/> Unresponsive   |
|        | b) <b>Fontanelle</b> (select one)                          | <input type="checkbox"/> Normal <input type="checkbox"/> Bulging <input type="checkbox"/> Sunken <input type="checkbox"/> Not present   |
|        | c) <b>Tone</b> (select one)                                | <input type="checkbox"/> Normal <input type="checkbox"/> Hypertonic <input type="checkbox"/> Hypotonic  |
|        | d) <b>Posture</b> (select one)                             | <input type="checkbox"/> Normal <input type="checkbox"/> Decorticate <input type="checkbox"/> Decerebrate   |
| 11.5.  | e) <b>Activity</b> (select one)                            | <input type="checkbox"/> Normal <input type="checkbox"/> Irritable/Agitated <input type="checkbox"/> Lethargic  |
|        | <b>Dehydration:</b>  |   |
| 11.6.  | a) <b>Sunken eyes?</b> (Select one)                        | <input type="checkbox"/> Y <input type="checkbox"/> N   |
|        | b) <b>Skin pinch</b> (Select one)                          | <input type="checkbox"/> Immediate <input type="checkbox"/> <2 seconds <input type="checkbox"/> >2 seconds  |
| 11.6.  | <b>Oedema</b><br>(select any that apply)                   | <input type="checkbox"/> None <input type="checkbox"/> both feet/ankles <input type="checkbox"/> lower legs<br><input type="checkbox"/> hands or lower arms <input type="checkbox"/> face   |
| 11.7.  | <b>Drinking/Breastfeeding</b><br>(Select one)              | <input type="checkbox"/> Normal <input type="checkbox"/> Poorly <input type="checkbox"/> Not drinking <input type="checkbox"/> Eager / Thirsty  |
| 11.8.  | <b>Abdomen</b><br>(select any that apply)                  | <input type="checkbox"/> Normal – no concerns <input type="checkbox"/> Distension <input type="checkbox"/> Hepatomegaly<br><input type="checkbox"/> Tenderness <input type="checkbox"/> Splenomegaly <input type="checkbox"/> Other abdominal mass  |
| 11.9.  | <b>Signs of Rickets</b><br>(select any that apply)         | <input type="checkbox"/> None <input type="checkbox"/> Wrist widening <input type="checkbox"/> Rachitic rosary<br><input type="checkbox"/> Swollen knees <input type="checkbox"/> Bow legs <input type="checkbox"/> Frontal bossing   |
| 11.10. | <b>Jaundice</b><br>(Select one)                            | <input type="checkbox"/> Y <input type="checkbox"/> N   |
| 11.11. | <b>ENT/Oral/Eyes</b><br>(select any that apply)            | <input type="checkbox"/> Mouth Normal <input type="checkbox"/> Oral ulceration <input type="checkbox"/> Oral candidiasis<br><input type="checkbox"/> Stomatitis<br><input type="checkbox"/> Ears Normal <input type="checkbox"/> Pus from ear <input type="checkbox"/> Tender swelling behind ear (mastoiditis) <input type="checkbox"/> Lymphadenopathy<br><input type="checkbox"/> Eyes Normal <input type="checkbox"/> Conjunctivitis <input type="checkbox"/> Eye discharge<br><input type="checkbox"/> Visual impairment |
| 11.12. | <b>Skin</b>  | <input type="checkbox"/> Normal <input type="checkbox"/> Hyperpigmentation <input type="checkbox"/> Depigmentation  |
|        | a) <b>Type of skin lesion</b><br>(select any that apply)   | <input type="checkbox"/> Broken skin <input type="checkbox"/> Dermatitis <input type="checkbox"/> 'Flaky paint'<br><input type="checkbox"/> Cellulitis <input type="checkbox"/> Impetigo <input type="checkbox"/> Pustules<br><input type="checkbox"/> Vesicles <input type="checkbox"/> Desquamation <input type="checkbox"/> Macular or papular   |
|        | b) <b>Site of skin lesions.</b><br>(select any that apply) | <input type="checkbox"/> Not applicable (No rash) <input type="checkbox"/> Palms / soles <input type="checkbox"/> Trunk<br><input type="checkbox"/> Face / scalp<br><input type="checkbox"/> Legs <input type="checkbox"/> Buttocks <input type="checkbox"/> Arms <input type="checkbox"/> Perineum   |



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### 12. SUSPECTED CHRONIC CONDITIONS

| Select confirmed, suspected or none for all conditions: |   | Confirmed/Suspected<br>(diagnosed previously/<br>recorded/ clinician's<br>impression) | None                     |
|---|---|---|--------------------------|
| 12.1.   | Cerebral palsy/neurological problem/epilepsy (Select one) | <input type="checkbox"/>  | <input type="checkbox"/> |
| 12.2.   | Sickle Cell disease<br>(select one)                       | <input type="checkbox"/>  | <input type="checkbox"/> |
| 12.3.   | Thalassaemia (Select one)                                 | <input type="checkbox"/>  | <input type="checkbox"/> |
| 12.4.   | Visual problem / Blindness<br>(select one)                | <input type="checkbox"/>  | <input type="checkbox"/> |

### 13. FEEDING PRIOR TO ADMISSION

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



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





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

**15. TREATMENT IN STUDY HOSPITAL BEFORE ENROLMENT**

|              |  |  |   |   |
|--------------|--|--|---|---|
| <b>15.1.</b> | <b>Admitted to:</b><br>(select one)                              | <input type="checkbox"/> Admission to ward   | <input type="checkbox"/> Admission to HDU | <input type="checkbox"/> Admission to ICU |
| <b>15.2.</b> | <b>Date and time First antibiotics given</b>                     | ___/___/____<br>(dd/mm/yyyy)   |   | ___:___<br>24h clock                      |
| <b>15.3.</b> | <b>Intravenous Antibiotics Given?</b><br>(select any that apply) | <input type="checkbox"/> <b>Not given</b><br><input type="checkbox"/> Benzylpenicillin <input type="checkbox"/> Gentamicin <input type="checkbox"/> Ceftriaxone<br><input type="checkbox"/> Co-amoxiclav <input type="checkbox"/> Flu/Cloxacillin <input type="checkbox"/> Chloramphenicol<br><input type="checkbox"/> Ampicillin <input type="checkbox"/> Amikacin <input type="checkbox"/> Meropenem<br><input type="checkbox"/> Levofloxacin <input type="checkbox"/> Vancomycin <input type="checkbox"/> Metronidazole<br><input type="checkbox"/> Other _____                 |   |   |
| <b>15.4.</b> | <b>Oral Antibiotics Given?</b><br>(select any that apply)        | <input type="checkbox"/> <b>Not given</b><br><input type="checkbox"/> Amoxicillin <input type="checkbox"/> Erythromycin <input type="checkbox"/> Azithromycin<br><input type="checkbox"/> Co-trimoxazole <input type="checkbox"/> Metronidazole <input type="checkbox"/> Ciprofloxacin<br><input type="checkbox"/> Cefalexin / cefaclor <input type="checkbox"/> Co-amoxiclav <input type="checkbox"/> Nalidixic acid<br><input type="checkbox"/> Penicillin <input type="checkbox"/> Flucloxacillin <input type="checkbox"/> Levofloxacin<br><input type="checkbox"/> Other _____ |   |   |

**16. SUSPECTED INITIAL DIAGNOSES:**Clinical diagnosis should be based on examination and investigation findings. Tick the three most likely diagnoses.

|              |   |  |
|--------------|---|--|
| <b>16.1.</b> | <b>Common Infections</b><br>(select any that apply)         | <input type="checkbox"/> pneumonia <input type="checkbox"/> Severe pneumonia<br><input type="checkbox"/> Gastroenteritis <input type="checkbox"/> Sepsis <input type="checkbox"/> Malaria<br><input type="checkbox"/> Soft tissue infection <input type="checkbox"/> UTI<br><input type="checkbox"/> URTI <input type="checkbox"/> Osteomyelitis<br><input type="checkbox"/> Febrile illness unspecified <input type="checkbox"/> Enteric fever<br><input type="checkbox"/> Not applicable   |
| <b>16.2.</b> | <b>Other suspected diagnosis</b><br>(select any that apply) | <input type="checkbox"/> Anaemia<br><input type="checkbox"/> Adverse Drug Reaction<br><input type="checkbox"/> Asthma<br><input type="checkbox"/> Bronchiolitis<br><input type="checkbox"/> Cerebral palsy<br><input type="checkbox"/> Developmental delay<br><input type="checkbox"/> Epilepsy<br><input type="checkbox"/> Extra pulmonary TB<br><input type="checkbox"/> Failed appetite test only<br><input type="checkbox"/> Febrile convulsions<br><input type="checkbox"/> Hydrocephalus<br><input type="checkbox"/> Ileus<br><input type="checkbox"/> Liver disease<br><input type="checkbox"/> Measles<br><input type="checkbox"/> Nephrotic syndrome<br><input type="checkbox"/> Otitis media<br><input type="checkbox"/> Other encephalopathy<br><input type="checkbox"/> Probable meningitis<br><input type="checkbox"/> Pulmonary TB |

PB-SAM Enrolment CRF v1.5



Patient Initials [ ][ ][ ][ ]

PB-SAM Number [4][0][ ][ ][ ]

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

|  |  |   |
|--|--|---|
|  |  | <input type="checkbox"/> Renal impairment<br><input type="checkbox"/> Sickle Cell Disease<br><input type="checkbox"/> Suspected Toxicity<br><input type="checkbox"/> Thalassaemia<br><input type="checkbox"/> Varicella<br><input type="checkbox"/> Other, specify: _____ |
|--|--|---|

**17. ADMISSION INVESTIGATIONS AND SAMPLE COLLECTION**

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

**18. SAMPLES TAKEN BY**

|              |  |       |
|--------------|--|-------|
| <b>18.1.</b> | <b>Blood Samples taken by (initials)</b> | _____ |
| <b>18.2.</b> | <b>Rectal Swabs taken by (initials)</b>  | _____ |
| <b>18.3.</b> | <b>Stool taken by (initials)</b>         | _____ |

PB-SAM Enrolment CRF v1.5



Patient Initials [ ][ ][ ][ ]

PB-SAM Number [4][0][ ][ ][ ]

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

**19. CRF COMPLETION**

|       |   |   |
|-------|---|---|
| 19.1. | a) <b>CRF Completed by (Initials) – to be signed when complete.</b><br><i>Do not sign if any fields are empty</i> | _____   |
|       | b) <b>Date</b>  | ____/____/_____<br><i>D D / M M / Y Y Y Y</i> |
|       | c) <b>Time</b>  | ____:_____<br><i>24 h clock</i>               |
| 19.2  | a) <b>CRF Reviewed by (Initials)</b>  | _____   |
|       | b) <b>Date</b>  | ____/____/_____<br><i>D D / M M / Y Y Y Y</i> |
|       | c) <b>Time</b>  | ____:_____<br><i>24 h clock</i>               |