First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

CASE REPORT FORM

Study site	☐ KILIFI ☐ MOMBASA ☐ NAIROBI ☐ MBALE
Participant Initials	_____ _____ _____
Inpatient/Serial Number	___ ___ ___ ___ ___ ___
Study Number	**F 1 2 7 5**
PK Participant	☐ Y ☐ N
Sticker 1	*Put sticker here*
Sticker 2	*Put sticker here*

Contacts	**Name**	**Telephone**	**Email**
Trial Coordinator	Mr. Isaiah Njagi	+254723652868	injagi@kemri-wellcome.org
Clinical Lead	Dr Caroline Ogwang	+254720221228	cogwang@kemri-wellcome.org
Data Manager	Ms Sheila Murunga	+254714545640	smurunga@kemri-wellcome.org
Lab Coordinator	Mr Joseph Waichungo	+254724144264	jwaichungo@kemri-wellcome.org
Trial pharmacist	Dr Jimmy Shangala	+254709983343	jshangala@kemri-wellcome.org
Principal Investigator	Prof James Berkley	+254720867011	jberkley@kemri-wellcome.org
Kilifi site	Mr Shalton Mwaringa	+254733866636	smwaringa@kemri-wellcome.org
Mombasa site	Ms Laura Mwalekwa	+254723425664	lmwalekwa@kemri-wellcome.org
Nairobi site	Ms Molline Timbwa	+254710257675	mtimbwa@kemri-wellcome.org
Mbale site	Dr Peter Olupot-Olupot	+256772457217	polupotolupot@yahoo.com
Local Safety Monitor	Dr Mainga Hamaluba	+254709983946	mhamaluba@kemri-wellcome.org
Clinical Trials Facility	KEMRI/Wellcome Trust Research Programme, P.O Box 230-80108, Kilifi, Kenya. Tel: +254 730 163 000		

Instructions for Handling and Completing the Case Report Form

- Please use only black ball point pen to complete CRFs
- Only authorized individuals should write on these CRFs
- Please fill in the header on each page
- Data correction: Cross out the mistake (the mistake has to remain readable), write the correction alongside together with your initials and date of correction. In Case of a not self-explanatory mistake please add the reason for correction. Do not use typewriter correction fluid (Tipp-Ex).

~~01~~	11	2	0	0	8

03 RCH 03/11/2008

- Into open boxes / numeric fields please enter

numbers | 4 | 9 |

Or ticks ☑

- Always enter digits **right aligned** and fill **open spaces** to the left with **zeroes**

0	7	5

- Please mark data which could **not** be recorded as follows: **Cross out** boxes and write **"NOT DONE"** on the side
- Date: Day. Month. Year:

2	0	1	1	2	0	0	8
D	D	M	M	Y	Y	Y	Y

- Please enter initials in the following order: First letter of the first name, First two letters of the surname

M	A	M
First	MI	Last

- Please do not omit to date and sign the pages where required.

Study course, data collection and sample collection

	SCREENING & ELIGIBILTY	ENROLMENT	DAILY INPATIENT REVIEW	DISCHARGE	DAY 14	DAY 45	DAY 90	READMISSION TO HOSPITAL
Standard case management	X	X	X	X				X
Routine clinical investigations *(haematology, biochemistry, blood culture, HIV and malaria)*		X						X
Give study information	X	X	X	X	X	X	X	X
Informed consent	X							
Anthropometry	X	X	X	X	X	X	X	X
Health and demographic data collection		X	X	X	X	X	X	X
Rectal swabs for antimicrobial resistance and pathogen detection		X		X		X	X	X
Whole stool for faecal inflammatory markers				X		X		
Plasma and whole blood sample for pathogen detection and biomarkers of infection		X		X				X
Pharmacokinetics sampling in a subset of participants	Enrolment & 2 further samples within 24 hours of starting antibiotics							

Child Initials | | | | FLACSAM — First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition | F | 1 | 2 | 7 | 5 |

Eligibility Checklist		
Age between 2 months and 13 years inclusive	☐ Y	☐ N – ineligible
Being admitted to hospital with Severe Acute Malnutrition	☐ Y	☐ N- ineligible
Meets WHO criteria for IV antibiotics	☐ Y	☐ N- ineligible
Lives in locally and willing to come for follow up	☐ Y	☐ N- ineligible
No known allergy or contraindication to study drugs	☐ Y	☐ N- ineligible
No documented indication for other classes of antibiotics instead	☐ Y	☐ N- ineligible
This child has not previously been enrolled in the FLACSAM trial	☐ Y	☐ N- ineligible
Consent given	☐ Y	☐ N- ineligible

I confirm this child is eligible for the FLACSAM trial	*Initials* ___ ___ ___	*Signed*

Admission, Consent & Enrolment			
Sex	☐ Male ☐ Female	**Date of Birth**	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*
		Is the DOB	☐ True ☐ Estimated*
		**if DOB is estimated, and the day or month is uncertain, write '15' for DD and '07' for MM*	
DATE of ADMISSION	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*	**TIME of ADMISSION**	__ __: __ __ *24h Clock*
DATE of CONSENT	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*	**DATE of ENROLMENT**	__ __/ __ __/ __ __ __ __ *D D / M M / Y Y Y Y*
TIME of CONSENT *(By parent/guardian)*	__ __: __ __ *24h Clock*	**TIME of ENROLMENT**	__ __: __ __ *24h Clock*
CONSENTED by *initials*	___ ___ ___	**ENROLLED by** *initials*	___ ___ ___

Anthropometry at Admission			
Weight	___ ___ . ___ ___kg	**Oedema**	☐ None ☐ + ☐ ++ ☐ +++
MUAC	___ ___ . ___ cm	**Length/Height**	☐ Length ☐ Height ___ ___ ___ . ___ cm
Measured by (initials)	___ ___ ___	☐ Length measurement not possible due to physical reasons	

Child Initials | | | |

FLACSAM
First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

F	1	2	7	5

Initial Observations			
Respiratory rate *Count for 1 minute*	____ ____ ____/minute	**SaO2** *To be taken from finger or toe using pulse oximeter*	____ ____ ____ % *Write **XXX** if not recordable*
Heart rate *Count for 1 minute*	____ ____ ____/minute		☐ Measured in Oxygen ☐ Measured in Room Air ☐ Not recordable
Axillary temperature	____ ____. ____ °C		

Presenting Complaints for the Current Illness					
How long has this illness episode lasted?	☐ <3 days	☐ 3-6 days	☐ 7-13 days	☐ 14-27 days	☐ ≥ 28 days

What are the MAIN symptoms? (Select all that apply)

☐ Fever / Hotness of body	☐ Vomiting	☐ Lethargy
☐ Difficulty breathing	☐ Diarrhoea <14 days	☐ Convulsions
☐ Cough<14 days	☐ Diarrhoea >14 days	☐ Altered consciousness
☐ Cough>14days	☐ Blood in stool	☐ Not feeding (or failed appetite test)
☐ Poor feeding/ Weight loss	☐ Developmental delay	☐ Body swelling/bilateral limb swelling/bilateral oedema
☐ Rash/skin lesion	☐ Other *(only one complaint, if not covered by above options)* _____	

What was the main reason for bringing the child to this hospital <u>today</u>? *Reasons given, select one*

☐Inpatient referral by health care worker	☐ Caregiver concern of child's condition
☐Outpatient referral by health care worker	☐ Primary caregiver returned home (e.g. if working away)
☐ Received money for transport to hospital (e.g. from family, neighbour, paid work)	
☐Other _____	

Have you sought treatment for this illness prior to coming to hospital? *Select all that apply*

☐ Shop	☐ Traditional/Homoeopathy/Herbalist
☐ Government hospital	☐ Pharmacy
☐ Government dispensary	☐ Private Medical Facility
☐ Other_____	☐ No treatment sought

<u>Are there any documented</u> antibiotics given within the last 24 hours prior to this admission?	☐ Yes	☐ No

Child recently admitted to hospital?	☐ No	☐ < 1 week ago	☐ <1 month ago
	☐ 1 to 6 months ago	☐ >6 months ago	

Child Initials | | | | FLACSAM First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition | F | 1 | 2 | 7 | 5 |

Examination	
Airway: *(select one)*	☐ Clear ☐ Needs active support ☐ Obstructed/Stridor
Breathing: *(select all that apply)*	☐ Normal – no concerns, (move on to circulation ☐ Central cyanosis ☐ Nasal flaring ☐ Reduced air-entry ☐ Wheeze ☐ Acidotic Breathing ☐ Grunting ☐ Lower chest wall in drawing ☐ Crackles ☐ Head nodding ☐ Dull to percussion
Circulation: Cap Refill *(select one)*	☐ <2 secs ☐ 2-3 secs ☐ >3 secs
Temperature Gradient *(select one)*	☐ Warm peripheries ☐ Shoulder ☐ Elbow ☐ Hand
Disability: Conscious level *(select one)*	☐ Alert ☐ Voice ☐ Pain ☐ Unresponsive
Fontanelle *(select one)*	☐ Present & Normal ☐ Bulging ☐ Sunken ☐ Not present
Tone *(select one)*	☐ Normal ☐ Hypertonic ☐ Hypotonic
Posture *(select one)*	☐ Normal ☐ Decorticate ☐ Decerebrate
Activity *(select one)*	☐ Normal ☐ Irritable/Agitated ☐ Lethargic
Dehydration: Sunken eyes (select one)	☐ N ☐ Y
Skin pinch *(select one)*	☐ Immediate ☐ up to 2 seconds ☐ >2 seconds
Drinking/ Breastfeeding *(select one)*	☐ Normal ☐ Poorly ☐ Not drinking ☐ Eager / Thirsty
Abdomen *(select any that apply)*	☐ Normal – no concerns ☐ Distension ☐ Hepatomegaly ☐ Tenderness ☐ Splenomegaly ☐ Other abdominal mass
Jaundice *(select one)*	☐ Not jaundiced ☐ + ☐ ++ ☐ +++

ENT/Oral/Eyes *(select any that apply)*	Mouth	Ear	Eye
	☐ Mouth Normal	☐ Ears Normal	☐ Eyes Normal
	☐ Oral ulceration	☐ Pus from ear	☐ Conjunctivitis
	☐ Oral candidiasis	☐ Tender swelling behind ear (mastoiditis)	☐ Eye discharge
	☐ Stomatitis	☐ Lymphadenopathy	☐ Signs of Vit. A deficiency/visual impairment

Skin *(select any that apply)*	☐ Normal	☐ Hyperpigmentation	☐ Depigmentation
	☐ Pustules	☐ Dermatitis	☐ 'Flaky paint'
	☐ Cellulitis	☐ Impetigo	☐ Broken skin
	☐ Vesicles	☐ Desquamation	☐ Macular or papular

Site of skin lesions *(select any that apply)*	☐ No Rash	☐ Trunk	☐ Face / scalp / head / neck		☐ Legs
	☐ Palms/soles	☐ Buttocks	☐ Arms		☐ Perineum
Signs of Rickets *(select one)*	☐ None	☐ Rachitic rosary	☐ Swollen knees	☐ Bow legs	☐ Wrist widening
	☐ Frontal bossing				

HIV Status at Presentation
(Follow the arrow)

HIV Status *(tick one)*

☐ **Known HIV infected**
PCR +ve or >18 months old & antibody +ve

Fill this box →

Current ART *(tick one)*
☐ NVP/AZT prophylaxis
☐ Full ART
☐ None
☐ Unknown

Co-trimoxazole prophylaxis *(tick one)*
☐ Y
☐ N
☐ Unknown

☐ **Known HIV exposed**

☐ Antibody +ve under 18 months old, not confirmed by PCR

☐ PCR negative

☐ Known to be HIV exposed but child untested

Fill both boxes ↕

☐ **Not known HIV infected or exposed**

Fill this box →

RDT *(tick one)*
☐ Reactive
☐ Indeterminate
☐ Non-reactive
☐ Declined

If reactive and below 18 months/indeterminate, PCR sent:
Y ☐
N, missed ☐

All Participants: Is anyone else in the household taking co-trimoxazole prophylaxis?	☐ Y	☐ N	☐ Unknown

Suspected Chronic Conditions

Select confirmed, suspected or none for all conditions:	None	Suspected *(clinician's impression)*	Confirmed *(diagnosed previously/ recorded)*
Cerebral palsy/neurological problem/ epilepsy	☐	☐	☐
Sickle Cell Disease family *history, crisis*	☐	☐	☐
Cardiac disease	☐	☐	☐
Visual problem / Blindness *Not fixing and following*	☐	☐	☐
Losing weight or not gaining weight	☐	☐	☐
Other congenital abnormality (incl. cleft palate, downs)	☐	☐	☐

TB Screening

Known TB (on treatment)	**Child has cough >14 days**	**Household contact has TB, or cough >14 days**	**Child has suspected extra-pulmonary TB**
☐ Y ☐ N	☐ Y ☐ N	☐ Y ☐ N	☐ Y ☐ N

INITIAL TREATMENT	
Admitted to: *(select one)*	☐ Admission to ward ☐ Admission to HDU ☐ Admission to ICU
Date and time IV antibiotics given	__ __ / __ __ / __ __ __ __ *DD/MM/YYYY* ___ ___:___ ___ *24h clock* ☐Not given
Initial Intravenous Antibiotics *(Select any that apply)*	☐ Penicillin ☐ Gentamicin ☐ Ceftriaxone ☐ Co-amoxiclav/Augmentin ☐ Flu/Cloxacillin ☐ Chloramphenicol ☐ Ampicillin ☐ Amikacin ☐ Ceftazidime ☐ Cefotaxime ☐ Vancomycin ☐ Metronidazole ☐ Other_____
Date and Time Oral Antibiotics given	__ __ / __ __ / __ __ __ __ *DD/MM/YYYY* ___ ___:___ ___ *24h clock* ☐Not given
Initial Oral Antibiotics *(Select any that apply)*	☐ Metronidazole/Placebo ☐ Amoxicillin ☐ Azithromycin ☐ Co-trimoxazole ☐ Erythromycin ☐ Ciprofloxacin ☐ Cefalexin / Cefaclor ☐ Co-amoxiclav/Augmentin ☐ Nalidixic acid ☐ Penicillin ☐ Flucloxacillin ☐ Other: _____
Initial treatment <u>given</u> *(Select any that apply)* **(the first 6 hours following enrolment)**	☐ IV Fluid Bolus ☐ IV Maintenance Fluids ☐ Oxygen ☐ Warmth (heater, blanket) ☐ IV Glucose ☐ Oral Glucose ☐ Commercial F75 ☐ Blood transfusion ☐ Commercial F100 ☐ Phenobarbitone ☐ Locally prepared F75 ☐ Diazepam ☐ Local prepared F100 ☐ Paracetamol ☐ Expressed breast milk ☐ Ibuprofen ☐ Dilute F100/dilute milk or formula ☐ Antimalarial ☐ Other milk/ formula/ feed ☐ ReSoMal ☐ RUTF ☐ ORS ☐ Nasogastric tube ○ None of these treatments were given ☐ Other_____

Suspected Initial Diagnoses

Tick up to THREE most likely diagnoses.

Respiratory

- ☐ LRTI/pneumonia
- ☐ Bronchiolitis
- ☐ URTI
- ☐ Pulmonary TB
- ☐ Otitis media
- ☐ Asthma
- ☐ Aspiration e.g. of feed

General

- ☐ Anaemia
- ☐ Sickle Cell Disease
- ☐ Renal impairment
- ☐ Nephrotic syndrome
- ☐ Nephritis
- ☐ Liver dysfunction
- ☐ Ileus
- ☐ Cardiac disease

Infection

- ☐ Gastroenteritis
- ☐ Sepsis
- ☐ Confirmed Malaria
- ☐ Extra pulmonary TB
- ☐ Soft tissue infection
- ☐ UTI
- ☐ HIV related illness
- ☐ Measles
- ☐ Varicella
- ☐ Osteomyelitis
- ☐ Confirmed enteric fever
- ☐ Febrile illness unspecified
- ☐ Typhoid/paratyphoid with perforation

CNS

- ☐ Febrile convulsions
- ☐ Epilepsy
- ☐ LP confirmed meningitis
- ☐ Clinically suspected meningitis
- ☐ Other encephalopathy
- ☐ Hydrocephalus
- ☐ Developmental delay unspecified
- ☐ Cerebral palsy
- ☐ Congenital syndrome

Other diagnosis:

- ☐ Failed appetite test only/malnutrition only
- ☐ Suspected drug toxicity
  (if due to study drug, complete toxicity CRF)
- ☐ Other known diagnosis
  _____
- ☐ Unknown diagnosis

CLINICIANS IMPRESSION OF RISK

What does the clinical team think the risk of mortality is during this admission? Select one

☐ Almost certainly not	☐ Very unlikely	☐ Quite unlikely	☐ Unsure	☐ Quite likely	☐ Very likely	☐ Almost certainly

Study Samples

Date blood samples taken	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*	**Date blood culture taken:**	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*
EDTA 0.5ml *(whole blood)*	☐ Y ☐Low Volume ☐ N	**Blood culture***	☐ Y BEFORE ABX ☐ Y AFTER ABX ☐ N
EDTA 1ml *(plasma)*	☐ Y ☐Low Volume ☐ N		
Sodium Heparin 1ml *(plasma)*	☐ Y ☐Low Volume ☐ N		
PK baseline sample 1ml *use PK bedside tool*	☐ Y ☐Low Volume ☐ N		
Unable to take blood samples, why?	☐ N/A ☐ Child uncooperative ☐ Difficult venepuncture ☐ Parent refused ☐ Other		
Malaria RDT	☐ Positive ☐ Negative ☐ Missed		
Rapid glucose test done	☐ Y ☐ N __ __ . __ mmol/L		
Rectal swabs taken *(should be two)*	☐ Y BEFORE ABX ☐ Y AFTER ABX ☐ N	**Tick which were taken:**	☐ For culture (transport media) ☐ For storage (dry)
Blood Samples taken by *initials*	__ __ __		
Rectal Swabs taken by *initials*	__ __ __		
Clinical Section of Enrolment CRF Completed by (Initials) *to be signed when complete.*	__ __ __	*Date* __ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*	

*For blood culture samples, 'before/after ABX' refers to antibiotics given at this hospital.

Further social and feeding history should be taken once all admission procedures have been completed

Initials of person interviewing caregiver and completing this section	☐ Doctor ☐ Clinical officer ☐ Nurse ___ ___ ___ ☐ Field worker ☐ Other

Primary Caregiver Information This is the person who has responsibility for day to day care of the child, but is not a substitute carer such as childminder or grandparent who cares for child whilst, for example, mother is at work.			
Who is the Primary Caregiver? *(Select one)*	☐ Biological Parent ☐ Grandparent ☐ Sibling ☐ Aunt/Uncle/Cousin ☐ Stepmother/Stepfather ☐Care home/Orphanage ☐ Other_____		
Is the child's biological father alive?	☐ Y ☐ N ☐ Unknown	**Is the child's biological mother alive?**	☐ Y ☐ N ☐ Unknown

Coming to Hospital	
How did you travel to the hospital? *(tick all that apply)*	
☐ Car/Taxi(K)/Special Hire(Ug) ☐ Bus/Matatu(K)/Taxi(Ug) ☐Motorbike ☐ Tuk-tuk ☐ Bicycle ☐ Train ☐ Walking ☐ Ambulance ☐ Other_____	
How long did it take you to travel to hospital?	☐ <1h ☐ 1-<2h ☐ 2-4h ☐ >4h ☐ > 1 day
How much did it cost you and the child to travel to hospital today (in local currency)?	___ ___ ___ ___ ☐KSh ☐UGX ☐Don't' know

Birth History		
Source of information	☐ Maternal/caregiver recall ☐ Book/medical records	
Birth details *(Select any that apply)*	☐ Premature ☐ Born underweight (<2.5kg) ☐Twin/multiple birth ☐ Born at term ☐Unknown	
Delivery location *(Select one)*	☐ Born in hospital ☐ Community facility/clinic with midwife/nurse midwife/doctor ☐ Home with midwife/nurse ☐ Home without birth attendant ☐ Other ☐ Home with traditional birth attendant (untrained) ☐ Unknown	
Mother's age NOW	___ ___years ☐ unknown/unavailable	
Participant birth order	___ ___ of ___ ___ total live births (*e.g. if youngest of 3 children 3 of 3, if oldest of 3 children 1 of 3)*	

Feeding			
Currently in outpatient nutrition program? (*Select one*)	☐ None	☐ Supplementary *(corn soy blend, RUSF)*	☐ Therapeutic *(RUTF, Plumpy-nut)*
Has the child eaten these nutrition products in the last 3 days?	☐ None	☐ Supplementary	☐ Therapeutic
Currently Breastfeeding?	☐ Y ☐ N	**Is the child receiving feeds other than breast milk *(exclude medicine)*?**	☐ Y ☐ N

Assessment of HOUSEHOLD WASH (please answer all questions including children in care homes)		
What is the MAIN source of drinking water for members of your household? *tick the MAIN one*		
☐Piped water to dwelling	☐Cart with small tank	☐Bought from vendor
☐Piped water to yard/plot	☐Tanker truck	☐Rainwater
☐Piped water at neighbour	☐Bottled water	☐Stream/river/lake/pond/dam
☐Public tap/ Standpipe	☐Protected spring	☐Unknown
☐Protected well/borehole	☐Unprotected spring	
☐Unprotected well	☐Other_____	
What is the MAIN source of water used by household for other purposes such as cooking and handwashing? *tick the MAIN one*		
☐Piped water to dwelling	☐Cart with small tank	☐Bought from vendor
☐Piped water to yard / plot	☐Tanker truck	☐Rainwater
☐ Piped water at neighbour	☐Bottled water	☐Stream/river/lake/pond/dam
☐Public tap/standpipe	☐Protected spring	☐Unknown
☐Protected well/borehole	☐Unprotected spring	
☐Unprotected well	☐Other_____	
How long does it take to get DRINKING water and come back? (State 0 if water supplied within home or compound)	__ __ __minutes	☐ Don't know
In the past 2 weeks was the water from this source not available for at least one full day?	☐ Y ☐ N	☐ Unknown
Do you usually do anything to the water to make it safer to drink? *Select all that apply*		
☐ None	☐ Bleach/ chlorine / waterguard	☐ Strain through a cloth
☐ Let it stand and settle	☐ Use water filter (ceramic/sand/composite	☐ Solar disinfection
☐ Boiling	☐ Other _____	

Does your household have mains supplied electricity?	☐ Y ☐ N ☐ Unknown
What kind of toilet facility does your household usually use?	☐ Flush ☐ Pit latrine ☐ No facility / bush/ field/bucket
Do you share this toilet facility with other households?	☐ Y ☐ N ☐ Unknown
Where is this toilet facility located?	☐ In own dwelling ☐ In own yard / plot ☐ Elsewhere

Which animal does this household own? *(tick all that apply)*

☐ Cows/bulls ☐ Sheep ☐ Chickens or Ducks
☐ Horses/Donkeys/Mules ☐ Goats ☐ Other _____ ☐ None

Primary caregiver earns an income now? *Ask the person accompanying the child and select one*

☐Employed full time by someone else ☐Employed part time by someone else
☐Works for self ☐No work income
☐Works casually/irregularly for someone ☐Don't know
☐N/A care home

How many days worked a week? *Select one*

☐ <3 ☐ 3-5 ☐ >5 ☐ N/A, does not work for income

If the primary caregiver earns, main source of income? *Select one*

☐ Farmer ☐ Business/trader ☐ Labourer ☐ Domestic work
☐ Other private sector employment ☐ Public sector employment ☐ Retired with pension income
☐ Begging ☐ Other_____ ☐ N/A (not earning)

If the primary caregiver works (earning or non-earning), main place of work? *Select one*

☐ In/around home (where child lives) ☐ Away for <4 hours per day
☐Away >4 hours but comes home daily ☐Away > 8h a day but returns home daily
☐Away >1 day, comes home weekly ☐ Away comes home, less than weekly
☐Primary caregiver lives and works away ☐ Don't know ☐ N/A (not working at all)

Level of education completed the care giver? *Select one*

☐None ☐ Primary not completed ☐ Primary completed ☐Secondary completed
☐Graduate/Tertiary ☐N/A (Care home/Orphanage) ☐ Unknown

Substitute Care: Who usually looks after child when primary caregiver is working? *(Select all that apply)*

☐ Caregiver looks after child full time ☐ Biological Mother* ☐ Biological Father
☐ Sibling <18 years old ☐ Sibling ≥18 years old ☐ Grandparent
☐ Aunt/Uncle/Cousin ☐ Childcare facility outside home ☐ Child minder/ day care at home
☐ Care home/Orphanage ☐ No substitute care – child left alone ☐ Other substitute care, or unclear

** Do not tick this if the mother is the main caregiver*

Household Food Security			
During the past 7 DAYS, has ANY member of the household missed a meal due to food shortage?	☐ Y	☐ N	☐ Unknown
During the past 4 WEEKS:			
Did you worry that your household would not have enough food?	☐ Y	☐ N	☐ Unknown
Were any of your household unable to eat the kinds of food preferred because of a lack of resources?	☐ Y	☐ N	☐ Unknown
Have any of your household had to eat a limited variety of food due to lack of resources?	☐ Y	☐ N	☐ Unknown
Have any of your household eaten some foods that you didn't want to eat because of lack of resources?	☐ Y	☐ N	☐ Unknown
Have any of your household eaten fewer meals in a day because there was not enough food?	☐ Y	☐ N	☐ Unknown
Did household members go to sleep at night hungry because there was not enough food?	☐ Y	☐ N	☐ Unknown
Did you or your household members go a whole day and night without eating anything because there was not enough food?	☐ Y	☐ N	☐ Unknown

Social & Feeding section of Enrolment CRF Completed by *initials*	__ __ __	Date __ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*

Routine Laboratory Investigations								
Lab test done	**FBC**	☐ Y ☐ N	**Chemistry**	☐ Y ☐ N	**Blood Gases**	☐ Y ☐ N	**Lab glucose**	☐ Y ☐ N
Date		__ __/__ __/__ __ __ __ D D / M M / Y Y Y Y		__ __/__ __/__ __ __ __ D D / M M / Y Y Y Y		__ __/__ __/__ __ __ __ D D / M M / Y Y Y Y		__ __/__ __/__ __ __ __ D D / M M / Y Y Y Y

FBC								
Hb	**RBC**	**WBC**	**Neutrophils**	**Lymphocytes**	**Monocytes**	**Eosinophils**	**Basophils**	**Platelets**
__ __. __	__ . __	__ __ . __	__ __. __	__ __. __	__ . __	__ . __	__ . __	__ __ __.__
g/dL	$X10^6$/µL	$X10^3$/µL	$X10^3$/µL	$X10^3$/µL	$X10^3$/µL	$X10^3$/µL	$X10^3$/µL	$X10^3$/µL

**Differentials must be actual values not percentages* ** leave blank if missing results*

CLINICAL CHEMISTRY					
Na	**K**	**Ca**	**Glucose**	**Mg**	**Urea**
__ __ __	__ __ .__	__ .__ __	__ __ . __	__ . __ __	__ __ . __
mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L

Creatinine	**Albumin**	**Total Bilirubin**	**ALT**	**ALP**	**I.Phos**
__ __ __ __	__ __ . __	__ __ __	__ __ __ __	__ __ __ __	__ . __ __
µmol/L	g/L	µmol/L	IU/L	IU/L	IU/L

** leave blank if missing results*

BLOOD GAS					
pH	**PO_2**	**PCO_2**	**Bicarb**	**Lactate**	**Base Excess**
__ . __ __ __	__ __. __	__ __. __	__ __ . __	__ __ . __	__ __ . __
	kpa	Kpa	mmol/L	mmol/L	mmol/L

** leave blank if missing results*

**Units may vary from site to site, so please provide units as per your machine. Provide actual machine values*

MICROBIOLOGY	
Blood Culture done	☐ Y ☐ N *Enter results in microbiology CRF if a pathogen isolated*

Routine Investigations Results Section Completed by *initials*	__ __ __	Date __ __/__ __/__ __ __ __ D D/ M M / Y Y Y Y

END OF ADMISSION & ENROLMENT CRF