

How long will your child be in this study? Your child will participate only once in this study and will not have to do anything after today. The research team will contact you if they find something in your child's blood or stool that should be treated. You may contact the leader of the research study (Principal or co-Principal Investigators) using the addresses and telephone numbers on page 4 of this consent form) at anytime, if you have any questions.

What will your child be asked to do in this study? If you agree for your child to take part in the study, the following will be done:

- Your child's medical records will be reviewed to determine whether he or she has Burkitt lymphoma.
 - If a diagnosis has not been confirmed by examining a piece of tissue from the swelling, a doctor at [**name of hospital**] will take a piece of Burkitt lymphoma to be examined to determine whether your child has or does not have Burkitt lymphoma.
 - A small piece of the tissue will be taken by the study for research.
 - The results from this examination will be returned to your doctor, who will give them to you. If Burkitt lymphoma is found, your child will be given the treatment for Burkitt lymphoma by the doctors at this hospital.
 - If your child has already been diagnosed by tissue examination at another hospital, no new tissue will be taken at this hospital to confirm Burkitt lymphoma as part of the research study. If you agree to participate in the EMBLEM study, we will ask for your permission to receive a piece of the tissue that was used to make the diagnosis at the hospital laboratory where the child was diagnosed so that our doctors can examine it and confirm the Burkitt lymphoma diagnosis. [SHOW PATHOLOGY RELEASE FORM TO THE PREVIOUSLY DIAGNOSED PARTICIPANT. THE FORM SHOULD BE COMPLETED ONLY FOR PARTICIPANTS WHO HAVE CONSENTED TO PARTICIPATE IN THE STUDY]
- You and your child will be asked questions (questionnaire interview) about previous illnesses, family, home life, and home environment by a research study nurse.
- Your child will be weighed and his or her height measured by a research study nurse.
- Your child will be asked to give a blood sample (1-2 teaspoonfuls), a saliva sample, and a stool sample to be tested as part of the research study. A research study nurse will take the blood from your child and, to avoid your child being pricked several times to get blood samples for tests required as part of treatment and for research, the nurse will take the blood samples at the same time when blood samples requested by your child's doctor.
- Your child's information (questionnaire) and samples will be labeled only with numbers, not your child's name.
- Your child's blood will be tested for anemia (low blood count), for the function of the kidneys and liver, for malaria (the parasite that causes fevers and chills), and for HIV (the virus that causes AIDS). HIV is detected frequently in adults with Burkitt lymphoma in America and Europe, but it has not been found to be very common in children with Burkitt lymphoma in Africa. Thus, the chances that your child has HIV are very small.
 - Your child's HIV test result will be given to you in person, if you want it. The other blood test results (not HIV) will be given to your child's doctor so that the treatment your child may need can be arranged quickly.

- Your child’s saliva will be tested for two very common viruses (EBV and HHV8). Most people who are infected with these viruses experience no symptoms, but researchers think that these viruses may increase the chance of developing Burkitt lymphoma. The tests for EBV and HHV8 will be done after about one year and because there is no treatment for them, the results will not be returned to you.
- Your child’s stool will be tested for parasites. Your child will be given treatment if parasites are detected in stool.
- Your child’s blood sample, along with blood from all children in the EMBLEM study, will be frozen and tested in the future for certain changes in some genes. Genes are inherited from parents and ancestors and may influence who gets or does not get a particular disease.
 - About 1-2 years from now, the researchers will test the blood for changes in approximately 20 genes that increase or decrease risk for malaria. By comparing the frequency of genes that influence the risk for malaria in children with and without Burkitt lymphoma, the researchers will be able to show indirectly whether malaria is related to Burkitt lymphoma. Because there are no treatments for differences in genes, the results from the gene tests will not be returned to you.
 - Farther in the future, perhaps in 5 years, EMBLEM researchers will test the frozen blood for changes in all the genes (approximately 30,000 genes) to find if there are differences in genes between children with and without Burkitt lymphoma. Someday it might be possible to identify a person by differences in the 30,000 genes. So to make sure your child cannot be identified, the results for the 30,000 genes will be available only in a way (by grouping or scrambling) that your child and other children in the study cannot be identified. The results for the 30,000 genes will not be returned to you because they will not change your child’s medical care.
- After the researchers complete the tests described above, the remaining specimens will be stored indefinitely by the NCI. These stored specimens may be used in future tests after obtaining permission from NCI. You or your child will not be contacted about these tests.
- You will receive an Information Sheet listing the procedures we have discussed today.

What are the benefits to your child being in EMBLEM? By participating in EMBLEM, your child will help doctors to learn about the causes of Burkitt lymphoma in children. This knowledge may lead to prevention or better treatments of other children with Burkitt lymphoma in the future. You and your child will benefit by learning about causes of common illnesses and by having improved blood tests for anemia (low blood count) and malaria, a test for stool parasites, and timely treatment of parasites that are detected. We do not expect to find that your child has HIV infection. If we do, you and your child will be referred for HIV counseling and treatment at clinics that provide these services at no cost. Finally, you, your child and other children in the house will receive treated mosquito bednets to use at night so that the risk of being bitten by mosquitoes at night and, therefore, of getting malaria is reduced.

What are the discomforts and possible risks to your child being in EMBLEM? You or your child may experience some discomfort with some questions you will be asked during the interview. You or your child are free not to answer any questions. Your child will experience discomfort from the needle prick when taking a blood sample. We will avoid an extra needle prick by trying to take blood for the research tests at the same time as the blood that your child’s doctor here at **[name of hospital]** has requested. You or your child may experience discomfort because of the plan to test your child’s blood for HIV, the virus that causes AIDS. We are following the advice (policy) of the **Uganda AIDS Commission**. So you and your child have the right to know the HIV test result, and we encourage you,

to find out. You also have the right to choose not to know your child's HIV result. If the results show that your child is HIV-positive, you and your child may experience emotional distress from learning those results. You and your child will be referred you to a hospital that specializes in treating children with HIV infection, where you and your child will receive additional counseling and treatment for HIV and its complications at no cost to you.

Your privacy: Your child's information that EMBLEM is collecting will be kept private and will be in locked files. Only people who are authorized to handle that information will see it. To make sure that you and your child cannot be identified when the research information is being compared, your child's name will be separated from the research information (questionnaire and samples). Only information (questionnaire) and samples labeled with numbers, not your child's name, will be sent to researchers. Any forms bearing your child's name will be left in the country at the hospital where the study is conducted, where they will be kept in locked files. The research results will be presented to other scientists using numbers that are not linked to you or your family's name and village. Your child's name will never be used to communicate information to other researchers.

Storage and future use of blood, saliva and tumor samples: Your child's samples (except the stool) will be frozen and stored indefinitely by the National Cancer Institute (NCI) in the United States. The samples will be labeled only with numbers that are not linked to your child's name. NCI will make sure that any research tests conducted in the future using your child's samples are consistent with the consent that you and your child will sign today. You and your child will not be contacted about these future research tests, and the results from those research tests will not be returned to you. You and your child will not receive any money or other benefit from any discoveries made from using the samples. You or your child can ask the local study staff to be removed from future comparisons using the procedures explained below.

The right to refuse or withdraw from the study: Your child's participation in EMBLEM is voluntary. Your child's treatment here at [name of hospital] will be the same whether your child participates or not. Your decision will not change your child's medical treatment. Refusal or withdrawal will not reduce any benefits to which you or your child are otherwise entitled. You or your child can refuse to participate now, or you can change your mind and withdraw from the study in the future without penalty. You or your child can withdraw from the study by informing the EMBLEM team leaders whose names are written on this consent form. When your request to withdraw is received, it will be sent to the PI at NCI, who will write to you to confirm that your information was deleted from the study files and your samples were removed and destroyed.

If you have other questions about EMBLEM, you can ask them at any time-now or in the future. You can ask **Dr. Tobias Kinyera**, the Project Leader for EMBLEM, **Dr. Martin D. Ogwang**, the head of the local research team at St. Mary's Hospital, Lacor, Gulu, **Dr. Patrick Kerchan**, the head of the local research team at Kuluva Hospital, Arua, or **Mr. Tom Lutalo** who is the chairman of the **Uganda Virus Research Institute Science and Ethics Committee**, the ethics committee that approved EMBLEM in Uganda. The contact information is provided below:

Contact Information: Name; Station, and Telephone number:

Dr. Tobias Kinyera, St. Mary's Hospital Lacor, Gulu Tel: +256 (772) 541976 (Mobile); **Dr. Martin D. Ogwang**, St. Mary's Hospital Lacor, Gulu - Tel: +256 (471) 432310 (Office) +256 (772) 593901 (Mobile); **Dr. Patrick Kerchan**, Kuluva Hospital, Arua; Tel: + 256 (476) 421198 (office) + 256 (772) 444135 (Mobile); **Mr. Tom Lutalo, Chairman, Uganda Virus Research Institute Science and Ethics Committee, Nakiwogo Road, P.O. Box 49, Entebbe, Tel: +256 (414) 321962 (Office) +256 (712) 732129 (Mobile).**

(1) Consent of Parent or Guardian for the Child to Participate in the Study

I have read or somebody has explained to me all of the above. I understand the following:

- What the EMBLEM study is about and how and why it is being done.
- If I decide to participate my child will undergo an interview and samples will be obtained, and that my child and I will not have to do anything after today; this is a one time participation.
- I have been told of the risks, discomforts, and possible benefits from the study.
- I have been told about the gene tests that will be done over the next 2-5 years.
- I have been explained that the storage of any remaining samples of blood, saliva, and Burkitt lymphoma tumor tissue that remain from these tests will be stored indefinitely by NCI and may be used in future tests.
- I understand that I will not be contacted about any future tests, but I can withdraw my information or samples if I wish. I am aware that my information will remain confidential
- I will receive a copy of this consent form and am aware that if I need more questions answered that the study contact phone numbers are located on the first page of this form.

I voluntarily consent for my child to participate as follows.

1. BE INTERVIEWED

Signature or Mark of Parent or Guardian

Date: ___ / ___ / ___
Day Month Year

2. FOR SAMPLES TO BE OBTAINED

Signature or Mark of Parent or Guardian

Date: ___ / ___ / ___
Day Month Year

3. FOR BLOOD AND SALIVA SAMPLES TO BE STORED INDEFINITELY FOR FUTURE TESTS

Signature or Mark of Parent or Guardian

Date: ___ / ___ / ___
Day Month Year

Name of adult giving consent for the child to participate

Relationship to Child: Birth Mother _____ Other Parent or Guardian _____

THE FOLLOWING SECTION MUST BE COMPLETED BY A WITNESS WHO OBSERVED THE WHOLE PROCESS FOR PARTICIPANTS WHO CANNOT READ AND WRITE:

I was present while the benefits, risks, procedures, and storage of blood, saliva, and tumor tissue samples were read to the parent or guardian. The parent or guardian was given the opportunity to ask questions about his or her child being in the study and has agreed to have his or her child take part in this research.

Date: ___ / ___ / ___
Day Month Year

Signature of Witness: _____

Date: ___ / ___ / ___
Day Month Year

Signature of Interviewer: _____

Screening Number: |__||__||__| |__||__||__||__| |__||__||__||__|

FORM CEF1 - EMBLEM CASE ELIGIBILITY SCREENER

COMPLETE THIS FORM FOR NEWLY DIAGNOSED BURKITT LYMPHOMA (BL) PATIENTS \leq 14 YEARS OF AGE.

1. TODAY'S DATE: |__||__|| / |__||__|| / |__||__||__||__||
DAY MONTH YEAR

2. PATIENT NAME: _____

Months 1

3. DATE OF BIRTH: |__||__|| / |__||__|| / |__||__||__||__|| OR AGE: |__||__|| Years 2
DAY MONTH YEAR

4. Has a diagnosis of BL been made clinically and/or confirmed histologically?

Yes 1

No 2 [PATIENT IS NOT ELIGIBLE, **SKIP TO QUESTION 10**]

5. Is patient \leq 14 years of age?

Yes 1

No 2 [PATIENT IS NOT ELIGIBLE, **SKIP TO QUESTION 10**]

6. Is resident address within the study catchment area? [REFER TO LIST OF ELIGIBLE DISTRICTS]

Yes 1

No 2 [PATIENT IS NOT ELIGIBLE, **SKIP TO QUESTION 10**]

7. Did patient live in study region for at least 4 months before developing symptoms of BL?

Yes 1

No 2 [PATIENT IS NOT ELIGIBLE, **SKIP TO QUESTION 10**]

8. Has patient ever received chemotherapy treatment for BL?

Yes 1 [PATIENT IS NOT ELIGIBLE, **SKIP TO QUESTION 10**]

No 2

9. Is patient stable enough to be approached for study enrollment?

Yes 1

No 2 [GO TO RE-CONTACT TABLE]

Hospital ID

(stick label here)

Initials/Date

Transcribed by: _____

Checked by: _____

Subject ID

(stick label here)

RE-CONTACT TABLE

For patients who are **not** stable enough for enrollment initially, note date of re-contact following consultation with the physician to determine favorable changes in the patient's condition.

9a. DAY 1 POST INITIAL CONTACT: |__||__| / |__||__| / |__||__||__||__|
DAY MONTH YEAR

Is patient stable enough to be approached for study enrollment?

- Yes 1 **Skip to Q10 - RE-CONTACT APPROPRIATE**
- No 2 CONSULT WITH PHYSICIAN AGAIN ON **DAY 2** POST INITIAL CONTACT TO DETERMINE IF PATIENT'S CONDITION HAS STABILIZED.

9b. DAY 2 POST INITIAL CONTACT: |__||__| / |__||__| / |__||__||__||__|
DAY MONTH YEAR

Is patient stable enough to be approached for study enrollment?

- Yes 1 **Skip to Q10 - RE-CONTACT APPROPRIATE**
- No 2 CONSULT WITH PHYSICIAN AGAIN ON **DAY 3** POST INITIAL CONTACT TO DETERMINE IF PATIENT'S CONDITION HAS STABILIZED.

9c. DAY 3 POST INITIAL CONTACT: |__||__| / |__||__| / |__||__||__||__|
DAY MONTH YEAR

Is patient stable enough to be approached for study enrollment?

- Yes 1 **Continue to Q10 - RE-CONTACT APPROPRIATE**
- No 2 [PATIENT IS STILL NOT STABLE AND IS THUS NOT ELIGIBLE]

10. PATIENT ELIGIBLE FOR STUDY:

- Yes 1
- No 2 **[SKIP TO QUESTION 12]**

11. CONSENT OBTAINED:

- Yes 1
- No 2 [PATIENT IS NOT ELIGIBLE]

12. SCREENER'S ID: |__|__|__|__|__|__|__|__|__|__|

Hospital ID
(stick label here)

Transcribed by: _____
Checked by: _____
Initials/Date

Subject ID
(stick label here)

Patient Name: _____

Patient Age: |__|_|_| . |__|_|

Years

Months

Patient Sex: Male Female

FORM HIFH1 - COMPLETE BLOOD COUNT (CBC)/ ERYTHROCYTE SEDIMENTATION RATE (ESR) RESULTS

Date of Test: |__|_|_| / |__|_|_| / |__|_|_|_|_|_| or Not Done _____
Day Month Year

CHECK "N/A" FOR ANY RESULT THAT IS NOT AVAILABLE

	Complete Blood Count	N/A	Results	Units
a)	White Blood Cell (WBCs)	<input type="checkbox"/> 1	_ _ . _	(10 ⁹)/L
b)	Red Blood Cells (RBCs)	<input type="checkbox"/> 1	_ _ . _ _	(10 ¹²)/L
c)	Hemoglobin (Hgb)	<input type="checkbox"/> 1	_ _ . _	g/dL
d)	Hematocrit (Hct)	<input type="checkbox"/> 1	_ _ . _	%
e)	Mean Corp. Volume (MCV)	<input type="checkbox"/> 1	_ _	fL
f)	Mean Corp. Hemoglobin (MCH)	<input type="checkbox"/> 1	_ _ . _	pg
g)	Mean Corp. Hemoglobin Concentration (MCHC)	<input type="checkbox"/> 1	_ _ . _	g/dL
h)	Relative Distribution Width (RDW)	<input type="checkbox"/> 1	_ _ . _	%
i)	Platelets (PLT)	<input type="checkbox"/> 1	_ _	(10 ⁹)/L
j)	Mean Platelet Volume (MPV)	<input type="checkbox"/> 1	_ _ . _	fL
k)	Neutrophils (Polymorphs)	<input type="checkbox"/> 1	_ _ . _	%
l)	Lymphocytes (Lymphs)	<input type="checkbox"/> 1	_ _ . _	%
m)	Monocytes (Monos)	<input type="checkbox"/> 1	_ _ . _	%
n)	Eosinophils (Eos)	<input type="checkbox"/> 1	_ _ . _	%
o)	Basophils (Basos)	<input type="checkbox"/> 1	_ _ . _	%

Date of ESR: |__|_|_| / |__|_|_| / |__|_|_|_|_|_| **or** Not Done 1
Day Month Year

Start Time: |__|_|:|__|_| (24 hr clock time) start time unknown 1

Stop Time: |__|_|:|__|_| (24 hr clock time) stop time unknown 1

Height of Plasma Column (in Millimeters): |__|_|_| mm

Hospital ID
(stick label here)

Initials/Date

Transcribed by: _____
 Checked by: _____

Subject ID
(stick label here)

Patient Name: _____

Patient Age: |__| |__| . |__|

Years

Months

Patient Sex: Male Female

FORM HIFM2 - THICK MALARIA PARASITE SMEAR RESULTS

Date of Test: |__||__| / |__||__| / |__||__||__||__| or Not Done _____
Day Month Year

Complete the following items using the lab results from the thick malaria smear.

- a) Malaria Microscopy Result:
- Scanty 1
 - + Positive 2
 - ++ Positive 3
 - +++ Positive 4
 - Negative 5
 - Not Done 6

b) Parasite Count (Enter actual number) |__||__||__||__| or Not Done 1
Count/100 HPF

c) Photos Taken of Slide?

Yes 1

No 2

Hospital ID

(stick label here)

Initials/Date

Transcribed by: _____

Checked by: _____

Subject ID

(stick label here)

Patient Name: _____

Years
 Months

Patient Sex: Male Female

FORM HIFM3 - MALARIA RAPID TEST RESULTS

Date of Test: |__||__| / |__||__| / |__||__||__||__| or Not Done 1 _____
Day Month Year

a) Malaria Antigen Test Result (check all that apply):

- P. falciparum* 1
- P. malarie* 1
- P. ovale* 1
- P. vivax* 1
- Other species 1
- All negative 1

b) Photos Taken of Strip?

- Yes 1
- No 2

Hospital ID

(stick label here)

Initials/Date

Transcribed by: _____

Checked by: _____

Subject ID

(stick label here)

Top Copy: Affix Hospital ID label and Return to Study Office
Bottom Copy: Retain by Lab

Patient Name: _____

Years

Patient Sex: Male Female

Months

FORM HIFM4 - STOOL MICROSCOPY RESULTS

Date of Test: |__||__| / |__||__| / |__||__||__||__| or Not Done |__||__||__||__|
 Day Month Year

Photos Taken of Slide? Yes 1 No 2

Cells/Parasites in Stool	Microscopy Result (Check Column)					
	Scanty 1	If Scanty, count/LPF	+Positive 2	++Positive 3	+++Positive 4	Negative 5
a) Cellular Abnormalities (record text results)						
i.						
ii.						
iii.						
b) Ova						
i. Hookworm						
ii. Schistosoma						
iii. Strongyloides						
iv. Other (Specify):						
c) Cysts						
i. Hookworm						
ii. Schistosoma						
iii. Strongyloides						
iv. Other (Specify):						
d) Larvae						
i. Hookworm						
ii. Schistosoma						
iii. Strongyloides						
iv. Other (Specify):						
e) Trophozoites						
i. Amoeba						
ii. Balantidium coli						
iii. Giardia						
iv. Other (Specify):						

Comments on macroscopic appearance:

Hospital ID
(stick label here)

Transcribed by: _____
 Checked by: _____

Subject ID
(stick label here)

Patient Name: _____

Years

Patient Sex: Male Female

Months

FORM HIFM5 - LUMBAR PUNCTURE RESULTS

Date of Test: |__||__| / |__||__| / |__||__||__||__| or Not Done 1 _____
Day Month Year

a) Appearance (Check all that apply): Clear 1
Blood stained 1
Turbid 1
Other, 1
specify _____

b) Tumor Cells present in CSF: Yes 1
No 2
Unknown 3

c) Count of Tumor Cells in CSF: |__||__||__||__| / ul or Not Done 1

d) Total White Blood Cell Count in CSF: |__||__||__||__| / ul or Not Done 1

e) Red Blood Cell Count in CSF: |__||__||__||__| / ul or Not Done 1

f) Pandy Test Results: Positive 1
Negative 2
Not Done 3

Hospital ID
(stick label here)

Transcribed by: _____
Checked by: _____
Initials/Date

Subject ID
(stick label here)

Patient Name: _____

Patient Age: |__| |__| . |__|

Years

Months

Patient Sex: Male Female

FORM HIFP2 - BL HISTOLOGY RESULTS

Date of Test: |__| |__| / |__| |__| / |__| |__| |__| |__| or Not Done _____
Day Month Year

BL Status: Burkitt's Lymphoma Diagnosed 1

Burkitt's Lymphoma Not Diagnosed 2

Hospital ID
(stick label here)

Initials/Date
Transcribed by: _____
Checked by: _____

Subject ID
(stick label here)

Patient Name: _____

Patient Age: |__| |__| . |__|

Years

Months

Patient Sex: Male Female

FORM HIFR1 - CHEST X-RAY RESULTS

Date of Test: |__||__| / |__||__| / |__||__||__||__| or Not Done _____
Day Month Year

Please comment on the size and infiltration of the lungs.

Thoracic Organ (check all that apply)		
a) Lungs	i. Right lung:	ii. Left lung:
	Normal <input type="checkbox"/> 1	Normal <input type="checkbox"/> 1
	Infiltrated <input type="checkbox"/> 2	Infiltrated <input type="checkbox"/> 2
	Fluid present <input type="checkbox"/> 3	Fluid present <input type="checkbox"/> 3
Comments:		
b) Pericardial Sac	Normal <input type="checkbox"/> 1	
	Infiltrated <input type="checkbox"/> 2	
	Fluid present <input type="checkbox"/> 3	
Comments:		
c) Mediastinal Space	Normal <input type="checkbox"/> 1	
	Infiltrated <input type="checkbox"/> 2	
	Fluid present <input type="checkbox"/> 3	
Comments:		

Hospital ID
(stick label here)

Initials/Date

Transcribed by: _____
Checked by: _____

Subject ID
(stick label here)

Patient Name: _____

Patient Age: |__| |__| . |__|

Years

Months

Patient Sex: Male Female

FORM HIFR2 - ULTRASOUND RESULTS

Date of Test: |__| |__| / |__| |__| / |__| |__| |__| |__| or Not Done _____
 Day Month Year

Please comment on the size and infiltration of major abdominal organs.

Abdominal Organ (check all that apply)			
a) Kidney	i. Right kidney: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	ii. Left kidney: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	
Comments:			
b) Liver	i. Right lobe: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	ii. Middle lobe: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	iii. Left lobe: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3
Comments:			
c) Ovaries <input type="checkbox"/> Not Applicable	i. Right ovary: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	ii. Left ovary: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	
Comments:			
d) Testes <input type="checkbox"/> Not Applicable	i. Right testis: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	ii. Left testis: Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3	
Comments:			
e) Spleen	Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3		
Comments:			
f) Retroperitoneal space (Mesenteric Lymph Nodes)	Normal <input type="checkbox"/> 1 Enlarged <input type="checkbox"/> 2 Infiltrated <input type="checkbox"/> 3		
Comments:			

Hospital ID
(stick label here)

Initials/Date

Transcribed by: _____
 Checked by: _____

Subject ID
(stick label here)

Patient Name: _____

Patient Age: |__| |__| . |__|

Years

Months

Patient Sex: Male Female

FORM HIPE1 – HEIGHT AND WEIGHT MEASUREMENTS

Date: |__||__| / |__||__| / |__||__||__||__| or Not Done _____
Day Month Year

Interviewer ID: |__| |__| |__|

1) Height |__| |__| |__| Centimeters (cm)

- Method of height measurement:
- 1 Subject standing
 - 2 Subject lying down
 - 3 Height not measured

2) Weight |__| |__| |__|. |__| Kilograms (kg)

- Method of weight measurement:
- 1 Subject standing on scale
 - 2 Subject held on scale
 - 3 Weight not measured

Hospital ID
(stick label here)

Transcribed by: _____
Checked by: _____
Initials/Date

Subject ID
(stick label here)

Patient Name: _____

Patient Age: |__| |__| . |__|

Years
 Months

Patient Sex: Male Female

FORM HIPE2 – TUMOR ANATOMIC SITE

To be completed by Paediatrician

Date: |__| |__| / |__| |__| / |__| |__| |__| |__| or Not Done _____
Day Month Year

Paediatrician ID: |__| |__| |__|

Please indicate initial site(s) where the child’s Burkitt’s Lymphoma tumor was located.
Check body location and if “yes”, indicate side (or sides), if applicable.

	BODY LOCATION	Yes 1	No 2	SIDE		
				Left 1	Middle 1	Right 1
a)	Eye/Orbit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
b)	Maxilla	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
c)	Mandible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
d)	Salivary glands	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> (Sublingual)	<input type="checkbox"/> (Submandibular)	<input type="checkbox"/> (Parotid)
e)	Pharynx	<input type="checkbox"/>	<input type="checkbox"/>			
f)	Kidney	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
g)	Liver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h)	Ovary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
i)	Testis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
j)	Spleen	<input type="checkbox"/>	<input type="checkbox"/>			
k)	Muscle, Arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
l)	Muscle, Leg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
m)	Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Hospital ID
(stick label here)

Initials/Date
Transcribed by: _____
Checked by: _____

Subject ID
(stick label here)

Patient Name: _____ Patient Age: |__| |__| . |__|

Years
 Months

Patient Sex: Male Female

FORM PROC1 - LAB REQUISITION

Sample Type:

- 2 ml Purple top EDTA tube [P]
- 3 ml Purple top EDTA tube [P]
- 2.5 ml Tiger top SST tube [TT]
- Blood Slide
- Stool Sample
- CSF Sample
- Other, (specify) _____ vol _____ ml

Ordered By: |__| |__| |__| Date: |__| |__| |__| - |__| |__| |__| - |__| |__| |__| |__|
DAY MONTH YEAR

Collected By: |__| |__| |__| Date: |__| |__| |__| - |__| |__| |__| - |__| |__| |__| |__| Time: |__| |__| : |__| |__|
DAY MONTH YEAR (24 hr clock)

Received in Lab By: |__| |__| |__| Date: |__| |__| |__| - |__| |__| |__| - |__| |__| |__| |__| Time: |__| |__| : |__| |__|
DAY MONTH YEAR (24 hr clock)

Lab Accession Number Assigned: _____

LAB Requests [tubes in order of preference]

- HIV-1 Screen [P,TT]
- Complete Blood Count (CBC) + ESR [P]
- Complete Blood Count (CBC) + ESR [P] – Portable CBC
- Reticulocyte Count [P]
- Manual Differential [P]
- Sedimentation Rate [P]
- Malaria Thick Smear [P]
- Malaria Thin Smear [P]
- Malaria Antigen Test [P]
- Stool Microscopy
- Liver Function [TT]
- Renal Function Test [TT]
- CSF Microscopy and Chemistry
- CSF Cytology

If any test was not done, indicate which test and reason not done:

Hospital ID (stick label here)
--

Initials/Date

Transcribed by: _____

Checked by: _____

Subject ID (stick label here)

Top Copy: Affix Subject ID label and retain for tracking purposes
Middle Copy: Return to Study Office
Bottom Copy: Retain by Lab

Patient Name: _____ Patient Age: |__| |__| . |__|

Years
 Months

Patient Sex: Male Female

FORM PROC2 - PROCEDURE REQUISITION

Procedure Type:

- Abdominal Ultrasound
- Chest X-ray
- Tumor Biopsy
- Bone Marrow Aspirate
- Lumbar Puncture
- Other

Ordered By: |__| |__| |__| Date: |__| |__| |__| - |__| |__| |__| - |__| |__| |__| |__| Time: |__| |__| : |__| |__| (24 hr clock)
DAY MONTH YEAR

Order Received By: |__| |__| |__| Date: |__| |__| |__| - |__| |__| |__| - |__| |__| |__| |__| Time: |__| |__| : |__| |__| (24 hr clock)
DAY MONTH YEAR

Test Performed By: _____ Date: |__| |__| |__| - |__| |__| |__| - |__| |__| |__| |__|
DAY MONTH YEAR

Test unable to be performed

Explanation:

Hospital ID
(stick label here)

Initials/Date
Transcribed by: _____
Checked by: _____

Subject ID
(stick label here)

Top Copy: Affix Subject ID label and retain for tracking purposes
Middle Copy: Return to Study Office
Bottom Copy: Retain by Lab

Patient Name: _____

Patient Age: |__| |__| . |__|

Years
 Months

Patient Sex: Male Female

FORM RIF1 - RESEARCH BLOOD

A. COLLECTION OF 10 ml PURPLE TOP EDTA TUBE (To be completed at time of collection)

1. Was blood specimen collected?: 1 Yes Problem: 1 Poor venous access
2 No 2 Refused
3 Other, specify: _____ |__| |__|

2. Date of collection: |__| |__| / |__| |__| / |__| |__| |__| 3. Time of collection: |__| |__| : |__| |__| (24 hour clock time) 4. Collected by: |__| |__| |__|

B. PROCESSING OF 10 ml PURPLE TOP EDTA TUBE (To be completed by staff in the lab)

5. Date received at lab: |__| |__| / |__| |__| / |__| |__| |__| 6. Time received: |__| |__| : |__| |__| (24 hour clock time)

7. Received by: |__| |__| |__| 8. Estimated volume in tube: |__| |__| . |__| ml

Problem codes

- 1 = No problem
- 2 = Tube spilled
- 3 = Tube broken
- 4 = Other

9. Problems with condition of specimen? (use code): _____ |__| |__| If other, specify: _____ |__| |__|

10. Date specimen processed: |__| |__| / |__| |__| / |__| |__| |__| 11. Processed by: |__| |__| |__|

12. The following were produced for storage:

a. Plasma: 1 Yes 2 No, provide details in 13
Number of .5 ml Aliquots: |__| Sequence Number **0001**: Est. Volume: |__| . |__| ml
Sequence Number **0002**: Est. Volume: |__| . |__| ml
Number of 1+ ml Aliquots: |__| Sequence Number **0003**: Est. Volume: |__| . |__| ml
Sequence Number **0004**: Est. Volume: |__| . |__| ml

b. Buffy Coat: 1 Yes 2 No, provide details in 13
Number of Aliquots: |__| Sequence Number **0005**: Est. Volume: |__| . |__| ml
Sequence Number **0006**: Est. Volume: |__| . |__| ml

c. RBCs: 1 Yes 2 No, provide details in 13
Number of Aliquots: |__| Sequence Number **0007**: Est. Volume: |__| . |__| ml
Sequence Number **0008**: Est. Volume: |__| . |__| ml

13. Problems processing specimen? 1 Yes 2 No If Yes, describe:

14. Date specimen frozen: |__| |__| / |__| |__| / |__| |__| |__| 15. Time frozen: |__| |__| : |__| |__| (24 hour clock time)

Hospital ID
(stick label here)

BSI ID
(stick label here)

Subject ID
(stick label here)

Top Copy: Affix Subject ID label and retain for tracking purposes
Middle Copy: Return to Study Office
Bottom Copy: Retain by Lab

Patient Name: _____

Patient Age: |__| |__| . |__|

Years
 Months

Patient Sex: Male Female

FORM RIF2 - RESEARCH SALIVA

A. COLLECTION OF SALIVA (To be completed at time of collection)		
1. Was saliva specimen collected?: 1 <input type="checkbox"/> Yes Problem: 1 <input type="checkbox"/> Unable to produce saliva 2 <input type="checkbox"/> No 2 <input type="checkbox"/> Refused 3 <input type="checkbox"/> Other, specify: _____ __ __		
2. Date of collection: __ __ / __ __ / __ __ __ Day Month Year	3. Time of collection: __ __ : __ __ (24 hour clock time)	4. Collected by: __ __ __
B. PROCESSING OF SALIVA FOR RESEARCH (To be completed by staff in the lab)		
5. Date received at lab: __ __ / __ __ / __ __ __ Day Month Year	6. Time received: __ __ : __ __ (24 hr clock time)	
7. Received by: __ __ __	8. Estimated volume in tube: __ __ . __ ml	
<u>Problem codes</u> 1 = No problem 2 = Tube spilled 3 = Tube broken 4 = Other		
9. Problems with condition of specimen? (use code): __ If other, specify: _____ __ __		
10. Date specimen processed: __ __ / __ __ / __ __ __ Day Month Year	11. Processed by: __ __ __	
12. Were aliquots produced for storage?: 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No, provide details in 13 Number of Vials: __ Sequence Number 0009 : Estimated Volume __ . __ ml Sequence Number 0010 : Estimated Volume __ . __ ml Sequence Number 0011 : Estimated Volume __ . __ ml Sequence Number 0012 : Estimated Volume __ . __ ml		
13. Problems processing specimen? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No If Yes, describe: _____ _____		
14. Date specimen frozen: __ __ / __ __ / __ __ __ Day Month Year	15. Time frozen: __ __ : __ __ (24 hour clock time)	

Hospital ID
(stick label here)

BSI ID
(stick label here)

Subject ID
(stick label here)

Top Copy: Affix Subject ID label and retain for tracking purposes
Middle Copy: Return to Study Office
Bottom Copy: Retain by Lab

Hospital ID
(stick label here)

Subject ID
(stick label here)

FORM SLF1 - EMBLEM Lab-Link Form

BSI ID for blood and saliva specimens
(stick label here)

BSI ID for tissue specimens
(stick label here)

Specimen	Collected	Not Collected	Date Collected	Comment
Research blood (EDTA)	<input type="checkbox"/>	<input type="checkbox"/>		
Hospital blood (2 ml EDTA)	<input type="checkbox"/>	<input type="checkbox"/>		
Hospital blood (3 ml EDTA)	<input type="checkbox"/>	<input type="checkbox"/>		
Hospital blood (2.5 ml SST)	<input type="checkbox"/>	<input type="checkbox"/>		
Research saliva	<input type="checkbox"/>	<input type="checkbox"/>		
Stool specimen	<input type="checkbox"/>	<input type="checkbox"/>		
Tissue specimen	<input type="checkbox"/>	<input type="checkbox"/>		

FORM SLF2 - EMBLEM RESEARCH BLOOD AND SALIVA SPECIMEN TRACKING LOG

Seq	Material type	Additive	Draw date	Process date	Vol/Quan (x.x)	Units	Box	Box #	Box type	Row #	Col #	Comment
0001	Plasma	EDTA				ml	Plasma		A			
0002	Plasma	EDTA				ml	Plasma		B			
0003	Plasma	EDTA				ml	Plasma		A			
0004	Plasma	EDTA				ml	Plasma		B			
0005	Buffy coat	EDTA				ml	Buffy coat		A			
0006	Buffy coat	EDTA				ml	Buffy coat		B			
0007	RBC	EDTA				ml	RBC		A			
0008	RBC	EDTA				ml	RBC		B			
0009	Saliva	STM				ml	Saliva		A			
0010	Saliva	STM				ml	Saliva		B			
0011	Saliva	STM				ml	Saliva		A			
0012	Saliva	STM				ml	Saliva		B			

Hospital ID
(stick label here)

BSI ID for blood and saliva specimens
(stick label here)

Subject ID
(stick label here)

Affix Hospital and BSI ID labels to each page.

Top Copy: Return to Study Office where Subject ID label will be added
 Bottom Copy: Retain by Lab

Initials/Date
 Form completed by: _____
 Form checked by: _____

Patient Name: _____

- Years
- Months

Patient Sex: Male Female

FORM SLF3 - EMBLEM TRACKING FORM FOR CASE SUBJECTS

• Date Consent Signed (DDMMYYYY): / / , check appropriate tiers of consent:

Questionnaire 1 Specimens 1 Storage 1

• Date of Clinical BL Diagnosis (DDMMYYYY): / /

• Was a BL related biopsy performed at this hospital during this admission?

Yes 1 No 2

➔ Where was biopsy performed? _____

Was consent obtained to request specimen?

Yes 1 Date of Specimen Consent (DDMMYYYY): / /

No 2 COMMENTS: _____

• Does subject want to know the results of HIV testing? Yes 1 No 2

Check the appropriate box to indicate final status for each of the following activities:

Activity	Completed 1	Not Done 2	Reason Not Done-Use the following codes to report reason that an activity was not done:
			1= test/procedure not ordered 4=subject refused at consent 2=unable to obtain specimen 5= subject refused after consent 3=equipment out of order 6=other, specify _____
Interview questionnaire	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Height and Weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Tumor Anatomic Site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Histology specimen and report obtained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Saliva specimen collection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Blood for research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
HIV testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
CBC w/differential and ESR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Liver function tests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Renal function tests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Malaria thin smear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Malaria thick smear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Rapid Malaria Test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Stool microscopy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Chest x-ray	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Abdominal ultrasound	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Bone marrow aspirate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Lumbar puncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

Hospital ID
(stick label here)

Transcribed by: _____ *Initials/Date*
Checked by: _____

Subject ID
(stick label here)

