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SPLIT			
$sitecode	User:	System Date:	Mode: Development
Site Name:			

Symptomatic EBV/LPD Followup (ELF)

Version: 5.0; 12-20-07

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

Disease diagnosis date: **09/01/2006**
Date of last assessment:

1. Date of EBV disease/LPD followup evaluation or resolution: *(ELFDATE)* _____ *(mm/dd/yyyy)*
2. EBV disease *(ELFSEBV)*

New - 1
Continuing - 2
Resolved - 3

OR

LPD not associated with EBV disease *(ELFSLPDN)*

New - 1
Continuing - 2
Resolved - 3

OR

LPD associated with EBV disease *(ELFSLPDW)*

New - 1
Continuing - 2
Resolved - 3

If any of the above are New, complete this form, and enroll the participant into a new EBV/LPD segment

3. Signs or symptoms suggestive of persistent EBV disease/LPD? *(ELFSYMPT)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes, code each of the following:

a. Fever: *(ELFFEVER)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

b. Stridor: *(ELFSTRID)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

c. Lymphadenopathy: *(ELFLYMPH)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes to lymphadenopathy, code the following:

1. Laryngeal, pharyngeal, or tonsils: *(ELFLPHAR)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
2. Peripheral (auxilla, groin, neck): *(ELFLPERI)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
3. Intra-abdominal: *(ELFLABDM)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
4. Intrathoracic: *(ELFLTHOR)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

d. GI (diarrhea, abdominal/intestinal mass, GI bleeding, etc.): *(ELFGI)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

e. Hepatic (hepatomegaly, jaundice, abnormal LFTs, etc.): *(ELFHEPAT)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

f. Increasing spleen size: *(ELFINCSP)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

g. Lung: *(ELFLUNG)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

h. CNS: *(ELFCNS)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

i. Other: *(ELFOTHSY)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If *Other*, please specify: *(ELFSYMOT)* _____

4. Followup EBV disease evaluation results: *(ELFFER)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes, indicate:

a. Circulating EBV DNA by PCR: *(ELFCEDBP)* ☐ Negative/Undetectable-0 ☐ Positive-1 ☐ Not evaluated-2

If Positive, please enter the viral load, units, and source. If Negative, please enter the lower limit of detection of the PCR assay for the viral load and units, if known.

Viral load: *(ELFVLGT)*

< > *(ELFVIRAL)* *(xxxxx)*

Units: *(ELFVUNIT)*

copies / 500 ng DNA - 1
genomes / 10^5 lymphocytes - 2
copies DNA / ul - 3
cells / 10^6 PBMC - 4
copies / mcg PBMC DNA - 5
*Additional Options Listed Below

If *Other*, specify: *(ELFVUNTO)*

Source: *(ELFVSRCE)*

Whole blood - 1
Plasma - 2
Serum - 3

b. New (since last report) EBV demonstrated in tissue (in-situ stain): *(ELFPOSHS)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes, code each of the following:

Tissue Biopsied	0- Positive	1- Negative	2- Not Biopsied
Lymph node or tonsils:	*(ELFTLYMP)* ☐	☐	☐
Liver:	*(ELFTLIVR)* ☐	☐	☐
GI tract:	*(ELFTGITR)* ☐	☐	☐
Lung:	*(ELFTLUNG)* ☐	☐	☐
Other:	*(ELFTOTH)* ☐	☐	☐

If *Other*, please specify: *(ELFTISOT)*

5. New (since last report) biopsy with positive histology for LPD: *(ELFBLPD)* ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes for a new biopsy, indicate tissue biopsed:

Tissue Biopsied	0- Positive	1- Negative	2- Not Biopsied
Lymph node or tonsils:	*(ELFTBLYM)* ☐	☐	☐
Liver:	*(ELFTBLIV)* ☐	☐	☐
GI tract:	*(ELFTBGIT)* ☐	☐	☐
Lung:	*(ELFTBLUN)* ☐	☐	☐
Other:	*(ELFTBOTH)* ☐	☐	☐

If *Other*, please specify: *(ELFBIOPO)*

If biopsy performed, answer the following:

a. Type B-cell: *(ELFBCELL)* ☐ No - 0 ☐ Yes - 1

If Yes, code the following:

1. Monomorphic: *(ELFMONOM)* ☐ No - 0 ☐ Yes - 1
2. Polymorphic: *(ELFPOLYM)* ☐ No - 0 ☐ Yes - 1
3. Unknown: *(ELFUNK)* ☐ No - 0 ☐ Yes - 1

b. Type T-cell: *(ELFTCELL)* ☐ No - 0 ☐ Yes - 1

6. Immunosuppression:

	Currently Using	Maintenance or Reduced	CsA Formulation

Steroids:	*(ELFSTED)* No - 0 Yes - 1	*(ELFSTEMR)* Maintenance - 1 Reduced - 2	
Tacrolimus:	*(ELFTACD)* No - 0 Yes - 1	*(ELFTACMR)* Maintenance - 1 Reduced - 2	
CsA:	*(ELFCSAD)* No - 0 Yes - 1	*(ELFCSAMR)* Maintenance - 1 Reduced - 2	*(ELFCSAFR)* Sandimmune - 0 Neoral - 1 Generic under formulation - 2
Mycophenolate Mofetil:	*(ELFMYCD)* No - 0 Yes - 1	*(ELFMYCMR)* Maintenance - 1 Reduced - 2	
Azathioprine:	*(ELFAZAD)* No - 0 Yes - 1	*(ELFAZAMR)* Maintenance - 1 Reduced - 2	
Sirolimus:	*(ELFRAPD)* No - 0 Yes - 1	*(ELFRAPMR)* Maintenance - 1 Reduced - 2	
Other:	*(ELFOTHD)* No - 0 Yes - 1	*(ELFOTHMR)* Maintenance - 1 Reduced - 2	

If *Other*, please specify: *(ELFIMOTH)*

7. Other treatment of EBV disease/LPD:

	# Days Treated Since Last Assessment	Currently Using
Ganciclovir:	*(ELFNDGAN)* *(xxx)*	*(ELFGANCI)* No - 0 Yes - 1
Acyclovir:	*(ELFNDACY)* *(xxx)*	*(ELFACYCL)* No - 0 Yes - 1
CMV hyperimmuno globulin:	*(ELFNDCMV)* *(xxx)*	*(ELFCMVHI)* No - 0 Yes - 1
Immunoglobulin:	*(ELFNDGLB)* *(xxx)*	*(ELFIMMUN)* No - 0 Yes - 1
Interferon:	*(ELFNDINT)* *(xxx)*	*(ELFINTER)* No - 0 Yes - 1
Low dose Cytoxan:	*(ELFLDCYD)* *(xxx)*	*(ELFLDCYT)* No - 0 Yes - 1
Systemic chemotherapy:	*(ELFNDSCH)* *(xxx)*	*(ELFCHEMO)* No - 0 Yes - 1
Anti CD20 mAb (Rituximab):	*(ELFDCD20)* *(xxx)*	*(ELFACD20)* No - 0 Yes - 1
Surgical excision of discrete lesions:		*(ELFSURGX)* No - 0 Yes - 1
Other:	*(ELFNDTRO)* *(xxx)*	*(ELFTROTH)* No - 0 Yes - 1

If Other, specify: *(ELFTROT1)*

8. If immunosuppression was stopped or reduced, did the participant develop rejection? *(ELFREJEC)* No - 0 Yes - 1 Not applicable - 9

9. Comments: *(ELFCOMM)*

Additional Selection Options for ELF

Units:
copies / ml - 6
Other - 9