

|              |       |              |                   |
|--------------|-------|--------------|-------------------|
| <b>SPLIT</b> |       |              |                   |
| \$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? (ELFSYMP)  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 (axilla, 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)

Units: (ELFVUNIT)

If Other, specify: (ELFVUNTO)

Source: (ELFVSRCE)

<  (ELFVIRAL)  (xxxxx)  
 >

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

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) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Liver:                 | (ELFTLIVR) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| GI tract:              | (ELFTGITR) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Lung:                  | (ELFTLUNG) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other:                 | (ELFTOTH) <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> |

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) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Liver:                 | (ELFTBLIV) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| GI tract:              | (ELFTBGIT) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Lung:                  | (ELFTBLUN) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other:                 | (ELFTBOTH) <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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:              | <input type="checkbox"/> No - 0<br><input type="checkbox"/> Yes - 1<br>(ELFSTED)  | <input type="checkbox"/> Maintenance - 1<br><input type="checkbox"/> Reduced - 2<br>(ELFSTEMR) |                                                                                                                                                        |
| Tacrolimus:            | <input type="checkbox"/> No - 0<br><input type="checkbox"/> Yes - 1<br>(ELFTACD)  | <input type="checkbox"/> Maintenance - 1<br><input type="checkbox"/> Reduced - 2<br>(ELFTACMR) |                                                                                                                                                        |
| CsA:                   | <input type="checkbox"/> No - 0<br><input type="checkbox"/> Yes - 1<br>(ELFCSAD)  | <input type="checkbox"/> Maintenance - 1<br><input type="checkbox"/> Reduced - 2<br>(ELFCSAMR) | <input type="checkbox"/> Sandimmune - 0<br><input type="checkbox"/> Neoral - 1<br><input type="checkbox"/> Generic under formulation - 2<br>(ELFCSAFR) |
| Mycophenolate Mofetil: | <input type="checkbox"/> No - 0<br><input type="checkbox"/> Yes - 1<br>(ELFMYCD)  | <input type="checkbox"/> Maintenance - 1<br><input type="checkbox"/> Reduced - 2<br>(ELFMYCMR) |                                                                                                                                                        |
| Azathioprine:          | <input type="checkbox"/> No - 0<br><input type="checkbox"/> Yes - 1<br>(ELFAZAD)  | <input type="checkbox"/> Maintenance - 1<br><input type="checkbox"/> Reduced - 2<br>(ELFAZAMR) |                                                                                                                                                        |
| Sirolimus:             | <input type="checkbox"/> No - 0<br><input type="checkbox"/> Yes - 1<br>(ELFRAPD)  | <input type="checkbox"/> Maintenance - 1<br><input type="checkbox"/> Reduced - 2<br>(ELFRAPMR) |                                                                                                                                                        |
| Other:                 | <input type="checkbox"/> No - 0<br><input type="checkbox"/> Yes - 1<br>(ELFOTH D) | <input type="checkbox"/> Maintenance - 1<br><input type="checkbox"/> Reduced - 2<br>(ELFOTHMR) |                                                                                                                                                        |

If Other, please specify: (ELFIMOTH)

7. Other treatment of EBV disease/LPD:

|                                        | # Days Treated Since Last Assessment | Currently Using                                                             |
|----------------------------------------|--------------------------------------|-----------------------------------------------------------------------------|
| Ganciclovir:                           | (ELFNDGAN) _____ (xxx)               | (ELFGANCI) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Acyclovir:                             | (ELFNDACY) _____ (xxx)               | (ELFACYCL) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| CMV hyperimmuno globulin:              | (ELFNDCMV) _____ (xxx)               | (ELFCMVHI) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Immunoglobulin:                        | (ELFNDGLB) _____ (xxx)               | (ELFIMMUN) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Interferon:                            | (ELFNDINT) _____ (xxx)               | (ELFINTER) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Low dose Cytoxin:                      | (ELFLDCYD) _____ (xxx)               | (ELFLDCYT) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Systemic chemotherapy:                 | (ELFNDSCH) _____ (xxx)               | (ELFCHEMO) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Anti CD20 mAb (Rituximab):             | (ELFD CD20) _____ (xxx)              | (ELFACD20) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Surgical excision of discrete lesions: |                                      | (ELFSURGX) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 |
| Other:                                 | (ELFN DTRO) _____ (xxx)              | (ELFTROTH) <input type="checkbox"/> No - 0 <input type="checkbox"/> 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

