Disease Assessment at Diagnosis

1. What was the date of diagnosis of Systemic Lupus Erythematosus (SLE)?
   - Month
   - Day
   - Year

Specify if the following American College of Rheumatology (ACR) criteria for SLE were present at diagnosis:

2. Serositis – a) pleuritis – convincing history of pleuritic pain or rub heard by a physician, or evidence of pleural effusion ~OR~ b) pericarditis – documented by ECG, rub, or evidence of pericardial effusion
   - Yes
   - No
   - Unknown

3. Oral ulcers — oral or nasopharyngeal ulceration, usually painless, observed by a physician
   - Yes
   - No
   - Unknown

4. Arthritis — non-erosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling, or effusion
   - Yes
   - No
   - Unknown

5. Photosensitivity — skin rash as a result of unusual reaction to sunlight, by patient history or physician observation
   - Yes
   - No
   - Unknown

6. Hematologic disorder — a) hemolytic anemia – with reticulocytosis ~OR~ b) thrombocytopenia – < 100,000/mm³ platelets in the absence of offending drugs ~OR~ c) leukopenia – < 4000/mm³ total on two or more occasions ~OR~ d) lymphopenia < 1500/mm³ on two or more occasions
   - Yes
   - No
   - Unknown

7. Renal disorder — a) persistent proteinuria > 0.5 grams per day or > 3+ on urine dipstick if quantitation not performed ~OR~ b) cellular casts – may be red cell, hemoglobin, granular, tubular, or mixed
   - Yes
   - No
   - Unknown

8. Antinuclear antibody — an abnormal titer of antinuclear antibody by immunofluorescence or an equivalent assay at any point in time and in the absence of drugs known to be associated with “drug-induced lupus” syndrome
   - Yes
   - No
   - Unknown
9. Immunologic disorder — a) anti-DNA: antibody to native DNA in abnormal titer – OR – b) anti-Sm: presence of antibody to Sm nuclear antigen – OR – c) positive antiphospholipid antibody – OR – d) false positive serologic test for syphilis known to be positive for at least 6 months and confirmed by Treponema pallidum immobilization or fluorescent treponemal antibody absorption test

10. Neurologic disorder — a) seizures – in the absence of offending drugs or known metabolic derangements – OR – b) psychosis – in the absence of offending drugs or known metabolic derangements, e.g., uremia, ketoacidosis, or electrolyte imbalance

11. Malar rash — fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds

12. Discoid rash — erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions

13. Were any of the recipient’s family members also affected with SLE?
   1  yes  2  no  3  unknown

Specify the recipient’s familial relationships to blood relatives affected with SLE:

14. 1  yes  2  no  Monozygotic twin

15. 1  yes  2  no  Dizygotic twin

16. 1  yes  2  no  Other first-degree relative (parent, sibling, child)

17. Was lupus nephritis present prior to mobilization for stem cell collection (or high-dose therapy if mobilization was not done)?
   1  yes  2  no  3  unknown

18. Was a renal biopsy performed?
   1  yes  Continue with table below
   2  no  Continue with question 22
   3  unknown

19. Date of most recent renal biopsy prior to mobilization for stem cell collection (or high-dose therapy if mobilization was not done):
   1  known
   2  not known

Month Day Year

20. Specify the degree of lupus nephritis (LN) according to the International Society of Nephrology / Renal Pathology Society (ISN / RPS) classification:

   1  Class I — minimal mesangial LN
   2  Class II — mesangial proliferative LN
   3  Class III — focal LN
   4  Class IV — diffuse LN
   5  Class V — membranous LN
   6  Class VI — advanced sclerosis LN

21. Is a copy of the renal biopsy pathology report attached?
   1  yes
   2  no
Pre-HSCT Treatment for Systemic Lupus Erythematosus

22. Did the recipient receive any disease-modifying treatments between the time of diagnosis and prior to mobilization for stem cell collection (or high-dose therapy if mobilization was not done)?

10 yes 20 no

Treatment Stopped

<table>
<thead>
<tr>
<th>Treatment Given?</th>
<th>Treatment Stopped?</th>
<th>Stopped Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>yes</td>
<td>26. If code 3, specify other reason: ____________________________</td>
</tr>
<tr>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>unknown</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

23. Androgens

10 yes 20 no 30 unknown

24. Continuing with question 77

25. If code 3, specify other reason: ____________________________

26. If code 3, specify other reason: ____________________________

27. Antimalarial drugs

10 yes 20 no 30 unknown

28. Continuing with question 77

29. If code 3, specify other reason: ____________________________

30. If code 3, specify other reason: ____________________________

31. Azathioprine (Azasan, Imuran)

10 yes 20 no 30 unknown

32. Continuing with question 77

33. If code 3, specify other reason: ____________________________

34. If code 3, specify other reason: ____________________________

35. Corticosteroids (C)

10 yes 20 no 30 unknown

36. Continuing with question 77

37. If code 3, specify other reason: ____________________________

38. If code 3, specify other reason: ____________________________

39. Was prednisone or other corticosteroid dosing changed between diagnosis and just prior to mobilization for stem cell collection?

10 dose unchanged 20 dose increased 30 dose decreased 40 unknown

40. Cyclophosphamide (CTX, Cytoxan, Neosar)

10 yes 20 no 30 unknown

41. Continuing with question 77

42. If code 3, specify other reason: ____________________________

43. If code 3, specify other reason: ____________________________

44. Cyclosporine (CsA, Neoral, Sandimmune)

10 yes 20 no 30 unknown

45. Continuing with question 77

46. If code 3, specify other reason: ____________________________

47. If code 3, specify other reason: ____________________________

48. Intravenous immune globulin (IVIG)

10 yes 20 no 30 unknown

49. Continuing with question 77

50. If code 3, specify other reason: ____________________________

51. If code 3, specify other reason: ____________________________

52. Lymphocytopheresis

10 yes 20 no 30 unknown

53. Continuing with question 77

54. If code 3, specify other reason: ____________________________

55. If code 3, specify other reason: ____________________________
### Treatment Stopped

<table>
<thead>
<tr>
<th>Code</th>
<th>Treatment Given?</th>
<th>Treatment Stopped?</th>
<th>Stopped Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>56.</td>
<td>Methotrexate (MTX, Folex)</td>
<td>yes</td>
<td>57. yes</td>
</tr>
<tr>
<td>60.</td>
<td>Mycophenolate mofetil (MMF, CellCept)</td>
<td>yes</td>
<td>61. yes</td>
</tr>
<tr>
<td>64.</td>
<td>Plasmapheresis</td>
<td>yes</td>
<td>65. yes</td>
</tr>
<tr>
<td>68.</td>
<td>Rituximab (anti-CD20, Rituxan)</td>
<td>yes</td>
<td>69. yes</td>
</tr>
<tr>
<td>72.</td>
<td>Other treatment</td>
<td>yes</td>
<td>73. yes</td>
</tr>
</tbody>
</table>

#### Codes for Treatment Stopped

- 1. Failure
- 2. Toxicity
- 3. Other reason
- 4. Reason unknown

If code 3, specify other reason: ____________________________

### Laboratory Studies Prior to Mobilization Therapy for Stem Cell Collection

#### WBC

- Yes
- No

Specify units: 1) $\times 10^9/L$ (x $10^9/mm^3$)

#### Hemoglobin

- Yes
- No

Specify units: 1) g/dL

#### Platelets

- Yes
- No

Specify units: 1) $\times 10^9/L$ (x $10^9/mm^3$)

#### Serum creatinine

- Yes
- No

Specify units: 1) mg/dL

---

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>84. Creatinine clearance:</td>
<td>Known/Not known</td>
</tr>
<tr>
<td>85. Urine protein (24-hour):</td>
<td>Known/Not known</td>
</tr>
<tr>
<td>86. Urine protein / creatinine ratio:</td>
<td>Known/Not known</td>
</tr>
<tr>
<td>87. Were urine RBC / RBC casts detected?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>88. Erythrocyte sedimentation rate:</td>
<td>Known/Not known</td>
</tr>
<tr>
<td>89. Complement level of CH50:</td>
<td>Decreased/Normal/Unknown</td>
</tr>
<tr>
<td>90. Complement level of C3:</td>
<td>Decreased/Normal/Unknown</td>
</tr>
<tr>
<td>91. Complement level of C4:</td>
<td>Decreased/Normal/Unknown</td>
</tr>
<tr>
<td>92. Antibody for anti-ANA:</td>
<td>Positive/Negative/Unknown</td>
</tr>
<tr>
<td>93. Antibody level of anti-dsDNA:</td>
<td>Increased/Normal/Unknown</td>
</tr>
<tr>
<td>94. Antibody level of anti-Sm:</td>
<td>Increased/Normal/Unknown</td>
</tr>
<tr>
<td>95. Antibody level of anti-SS-A (anti-Ro):</td>
<td>Increased/Normal/Unknown</td>
</tr>
<tr>
<td>96. Antibody level of anti-SS-B (anti-La):</td>
<td>Increased/Normal/Unknown</td>
</tr>
</tbody>
</table>
97. Anti-cardiolipin IgG level:
   1. increased
   2. normal
   3. unknown

98. Anti-cardiolipin IgM level:
   1. increased
   2. normal
   3. unknown

99. Lupus-anticoagulant level:
   1. increased
   2. normal
   3. unknown

Specify the results of the following pulmonary function tests performed prior to mobilization therapy for stem cell collection:

100. Date pulmonary function tests were performed: [ ] [ ] [ ] (Month Day Year)

101. Vital capacity (VC):
   1. known % (predicted value)
   2. not known

102. Was the actual VC value in the normal range (≥ 80% of predicted value)?
   1. yes
   2. no

103. DLCO:
   1. known % (predicted value)
   2. not known

104. Was the actual DLCO value in the normal range (≥ 80% of predicted value)?
   1. yes
   2. no

105. DLCO corrected for hemoglobin:
   1. known % (predicted value)
   2. not known

106. Was the DLCO value (corrected for hemoglobin) in the normal range (≥ 80% of predicted value)?
   1. yes
   2. no

107. Was oxygen desaturation present on exercise testing?
   1. yes
   2. no
   3. unknown

108. Was an echocardiogram performed prior to mobilization therapy for stem cell collection?
   1. yes
   2. no
   3. unknown

109. Was pericardial effusion present?
   1. yes
   2. no
   3. unknown

110. Specify the size of the area of accumulated excess fluid:
   1. small
   2. moderate
   3. large

111. Left ventricular ejection fraction:
   1. known %
   2. not known

112. Was pulmonary artery hypertension present?
   1. yes
   2. no
   3. unknown

113. Specify the estimated systolic pulmonary artery pressure:
   [ ] [ ] mm Hg

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
114. Was a multiple gate acquisition scan (MUGA test / nuclear ventriculography) performed prior to mobilization therapy for stem cell collection?
1. yes
2. no
3. unknown

115. Specify the left ventricular ejection fraction: ___________ %

Most Recent Disease Assessment Prior to the Start of the Preparative Regimen

Information for this section should come from the most recent evaluation performed ≤ 2 weeks prior to the preparative regimen. If the recipient was not evaluated prior to the preparative regimen, check here □ and continue with the signature lines at question 172.

116. Date of evaluation prior to the preparative regimen: ___________ Month ___________ Day ___________ Year

Specify if the following Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) criteria were present prior to the start of the preparative regimen and were attributable to Lupus:

<table>
<thead>
<tr>
<th>Score</th>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Arthritis</td>
<td>More than 2 joints with pain and signs of inflammation (i.e., tenderness, swelling, or effusion).</td>
</tr>
<tr>
<td>2</td>
<td>Alopecia</td>
<td>Ongoing abnormal, patchy, or diffuse loss of hair due to active lupus.</td>
</tr>
<tr>
<td>8</td>
<td>Cerebrovascular accident (CVA)</td>
<td>New onset of cerebrovascular accident(s). Exclude arteriosclerosis or hypertensive causes.</td>
</tr>
<tr>
<td>8</td>
<td>Cranial nerve disorder</td>
<td>New onset of sensory or motor neuropathy involving cranial nerves. Include vertigo due to lupus.</td>
</tr>
<tr>
<td>1</td>
<td>Fever</td>
<td>&gt; 38°C. Exclude infectious cause.</td>
</tr>
<tr>
<td>4</td>
<td>Hematuria</td>
<td>&gt; 5 red blood cells/high power field. Exclude stone, infection, or other cause.</td>
</tr>
<tr>
<td>2</td>
<td>Increased DNA binding</td>
<td>&gt; 25% binding by Farr assay, or above normal range for testing laboratory.</td>
</tr>
<tr>
<td>1</td>
<td>Leukopenia</td>
<td>&lt; 3,000 white blood cells/mm³ (x 10⁹/L). Exclude drug causes.</td>
</tr>
<tr>
<td>2</td>
<td>Low complement</td>
<td>Decrease in CH50, C3, or C4 below the lower limit of normal for testing laboratory.</td>
</tr>
<tr>
<td>8</td>
<td>Lupus headache</td>
<td>Severe, persistent headache: may be migrainous, but must be nonresponsive to narcotic analgesia.</td>
</tr>
<tr>
<td>2</td>
<td>Mucosal ulcers</td>
<td>Ongoing oral or nasal ulcerations due to active lupus.</td>
</tr>
<tr>
<td>4</td>
<td>Myositis</td>
<td>Proximal muscle aching/weakness associated with elevated creatine phosphokinase/aldolase or electromyogram changes, or a biopsy showing myositis.</td>
</tr>
<tr>
<td>2</td>
<td>New rash</td>
<td>Ongoing inflammatory lupus rash.</td>
</tr>
<tr>
<td>8</td>
<td>Organic brain syndrome</td>
<td>Altered mental function with impaired orientation, memory, or other intellectual function, with rapid onset and fluctuating clinical features. Include clouding of consciousness with reduced capacity to focus and inability to sustain attention to environment, plus at least 2 of the following: perceptual disturbance, incoherent speech, insomnia or daytime drowsiness or increased or decreased psychomotor activity. Exclude metabolic, infectious, or drug causes.</td>
</tr>
</tbody>
</table>
### Score Criterion

<table>
<thead>
<tr>
<th>Score</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>131.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>132.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>133.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>134.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>135.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>136.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>137.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>138.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>139.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>140.</td>
<td>yes 2 no 3 unknown</td>
</tr>
<tr>
<td>141.</td>
<td>Total SLEDAI score:</td>
</tr>
</tbody>
</table>

### Laboratory Studies Prior to the Start of the Preparative Regimen

<table>
<thead>
<tr>
<th>Test</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>145. Creatinine clearance</td>
<td>mL/min</td>
</tr>
<tr>
<td>146. Cerebral spinal fluid (CSF) protein</td>
<td>mg/dL</td>
</tr>
<tr>
<td>147. Cerebral spinal fluid (CSF) IgG</td>
<td>mg/dL</td>
</tr>
</tbody>
</table>

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
148. Cerebral spinal fluid (CSF) cell count:
   1. known
   2. not known

149. Urine protein (24-hour):
   1. known
   2. not known

150. Urine protein / creatinine ratio:
   1. known
   2. not known

151. Were urine RBC / RBC casts detected?
   1. yes
   2. no
   3. unknown

152. Erythrocyte sedimentation rate:
   1. known
   2. not known

153. Complement level of CH50:
   1. decreased
   2. normal
   3. unknown

154. Complement level of C3:
   1. decreased
   2. normal
   3. unknown

155. Complement level of C4:
   1. decreased
   2. normal
   3. unknown

156. Antibody for anti-ANA:
   1. positive
   2. negative
   3. unknown

157. Antibody level of anti-dsDNA:
   1. increased
   2. normal
   3. unknown

158. Antibody level of anti-Sm:
   1. increased
   2. normal
   3. unknown

159. Antibody level of anti-SS-A (anti-Ro):
   1. increased
   2. normal
   3. unknown

- Specify units:
  1. mg / 24 hours
  2. g / day

---

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
160. Antibody level of anti-SS-B (anti-La):
   1. increased
   2. normal
   3. unknown

161. Anti-cardiolipin IgG level:
   1. increased
   2. normal
   3. unknown

162. Anti-cardiolipin IgM level:
   1. increased
   2. normal
   3. unknown

163. Lupus-anticoagulant level:
   1. increased
   2. normal
   3. unknown

Specify the results of the following pulmonary function tests performed prior to the start of the preparative regimen:

164. Date pulmonary function tests were performed: 

165. Vital capacity (VC):
   1. known % (predicted value)
   2. not known % (predicted value) 

166. Was the actual VC value in the normal range (≥ 80% of predicted value)?
   1. yes
   2. no

167. \(D_LCO\):
   1. known % (predicted value)
   2. not known % (predicted value)

168. Was the actual \(D_LCO\) value in the normal range (≥ 80% of predicted value)?
   1. yes
   2. no

169. \(D_LCO\) corrected for hemoglobin:
   1. known % (predicted value)
   2. not known % (predicted value)

170. Was the \(D_LCO\) value (corrected for hemoglobin) in the normal range (≥ 80% of predicted value)?
   1. yes
   2. no

171. Was oxygen desaturation present on exercise testing?
   1. yes
   2. no
   3. unknown

172. Signed: ___________________________________________________________

   Person completing form

Please print name: _______________________________________________________

Phone: (________________________) ____________________________

Fax: (________________________) _________________________________________

E-mail address: _________________________________________________________