

# ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Initials:

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Today's Date:

		2	0		
Month	Day	Year			

Infusion Date:

		2	0		
Month	Day	Year			

CIBMTR Center Number:

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## Systemic Lupus Erythematosus Post-HSCT Data

Registry Use Only

Sequence Number:

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Date Received:

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CIBMTR Center Number:

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CIBMTR Recipient ID:

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Today's Date:

		2	0		
Month	Day	Year			

Date of HSCT for which this form is being completed:

Month	Day	Year			

HSCT type:  autologous  allogeneic, unrelated  allogeneic, related  syngeneic (identical twin)

Product type:  marrow  PBSC  cord blood  other product, specify: \_\_\_\_\_

Visit:  100 day  6 month  1 year  2 years  > 2 years, specify: \_\_\_\_\_

**To be completed in conjunction with a Form 2100 – 100 Days Post-HSCT Data, Form 2200 – Six Months to Two Years Post-HSCT Data, or Form 2300 – Yearly Follow-Up for Greater Than Two Years Post-HSCT Data. Information reported here should reflect the date of last contact as reported in the post-HSCT data collection form, or immediately prior to death.**

### Disease Assessment Post-HSCT

1. Specify the date the recipient was evaluated for this report:

		2	0		
Month	Day	Year			

### Post-HSCT Treatment for Systemic Lupus Erythematosus

2. Did the recipient receive any treatment for SLE since the date of the last report?

- 1  yes → **Continue with table below**
- 2  no → **Continue with question 59**
- 3  unknown

Therapy Given?	Reason for Therapy Code <small>see page 2</small>	Date Therapy Started	Currently Receiving?
		<small>Month Day Year</small>	
3. Androgens			
1 <input type="checkbox"/> yes →	4. <input type="checkbox"/>	5. If Code 4 — Other reason, specify: _____	6. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2 0 <input type="checkbox"/> <input type="checkbox"/>
2 <input type="checkbox"/> no			7. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
3 <input type="checkbox"/> unknown			
8. Antimalarial drugs			
1 <input type="checkbox"/> yes →	9. <input type="checkbox"/>	10. If Code 4 — Other reason, specify: _____	11. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2 0 <input type="checkbox"/> <input type="checkbox"/>
2 <input type="checkbox"/> no			12. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
3 <input type="checkbox"/> unknown			
13. Azathioprine (Azasan, Imuran)			
1 <input type="checkbox"/> yes →	14. <input type="checkbox"/>	15. If Code 4 — Other reason, specify: _____	16. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2 0 <input type="checkbox"/> <input type="checkbox"/>
2 <input type="checkbox"/> no			17. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
3 <input type="checkbox"/> unknown			
18. Corticosteroids <input type="checkbox"/>			
1 <input type="checkbox"/> yes →	19. <input type="checkbox"/>	20. If Code 4 — Other reason, specify: _____	21. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2 0 <input type="checkbox"/> <input type="checkbox"/>
2 <input type="checkbox"/> no			22. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
3 <input type="checkbox"/> unknown			

**Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.**

**Fax this form to your designated campus (Milwaukee 414-456-6165 or Minneapolis 612-627-5895).**

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		2	0		
Month	Day	Year			

		2	0		
Month	Day	Year			

CIBMTR Center Number:

CIBMTR Recipient ID:

Therapy Given?	Reason for Therapy Code <small>see below</small>	Date Therapy Started	Currently Receiving?
		<small>Month Day Year</small>	
23. Cyclophosphamide (CTX, Cytoxan, Neosar) 1 <input type="checkbox"/> yes → 24. <input type="checkbox"/> 25. If Code 4 — Other reason, specify: 26. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/> <input type="text"/>			27. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
28. Cyclosporine (CsA, Neoral, Sandimmune) 1 <input type="checkbox"/> yes → 29. <input type="checkbox"/> 30. If Code 4 — Other reason, specify: 31. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/> <input type="text"/>			32. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
33. Intravenous immune globulin (IVIg) 1 <input type="checkbox"/> yes → 34. <input type="checkbox"/> 35. If Code 4 — Other reason, specify: 36. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/> <input type="text"/>			37. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
38. Lymphocytapheresis 1 <input type="checkbox"/> yes → 39. <input type="checkbox"/> 40. If Code 4 — Other reason, specify: 41. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/> <input type="text"/>			42. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
43. Mycophenolate mofetil (MMF, CellCept) 1 <input type="checkbox"/> yes → 44. <input type="checkbox"/> 45. If Code 4 — Other reason, specify: 46. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/> <input type="text"/>			47. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
48. Plasmapheresis 1 <input type="checkbox"/> yes → 49. <input type="checkbox"/> 50. If Code 4 — Other reason, specify: 51. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/> <input type="text"/>			52. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
53. Other treatment 1 <input type="checkbox"/> yes → 54. <input type="checkbox"/> 55. If Code 4 — Other reason, specify: 56. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/> <input type="text"/>			57. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
58. Specify other treatment: _____			

### Reason for Therapy Codes

1 planned per protocol   2 continued from prior to HSCT   3 relapse / progression of SLE   4 other reason   5 reason unknown

### Disease Status at the Time of Evaluation for This Reporting Period

Specify if the following Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) criterion were present since the date of the last report:

	Score	Criterion
59. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	<b>4</b>	Arthritis — More than 2 joints with pain and signs of inflammation (i.e., tenderness, swelling, or effusion).
60. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	<b>2</b>	Alopecia — Ongoing abnormal, patchy, or diffuse loss of hair due to active lupus.
61. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	<b>8</b>	Cerebrovascular accident (CVA) — New onset of cerebrovascular accident(s). Exclude arteriosclerosis or hypertensive causes.
62. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	<b>8</b>	Cranial nerve disorder — New onset of sensory or motor neuropathy involving cranial nerves. Include vertigo due to lupus.
63. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	<b>1</b>	Fever — > 38°C. Exclude infectious cause.

CIBMTR Form 2145 (SLE) v1.0 (2-7) July 2007  
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**Fax this form to your designated campus (Milwaukee 414-456-6165 or Minneapolis 612-627-5895).**

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Initials:

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Today's Date:

		2	0		
Month	Day	Year			

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		2	0		
Month	Day	Year			

CIBMTR Center Number:

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CIBMTR Center Number: 

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	Score	Criterion
64. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	4	Hematuria — > 5 red blood cells/high power field. Exclude stone, infection, or other cause.
65. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	2	Increased DNA binding — > 25% binding by Farr assay, or above normal range for testing laboratory.
66. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	1	Leukopenia — < 3,000 white blood cells/mm <sup>3</sup> (x 10 <sup>9</sup> /L). Exclude drug causes.
67. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	2	Low complement — Decrease in CH50, C3, or C4 below the lower limit of normal for testing laboratory.
68. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	8	Lupus headache — Severe, persistent headache: may be migrainous, but must be nonresponsive to narcotic analgesia.
69. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	2	Mucosal ulcers — Ongoing oral or nasal ulcerations due to active lupus.
70. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	4	Myositis — Proximal muscle aching/weakness associated with elevated creatine phosphokinase/aldolase or electromyogram changes, or a biopsy showing myositis.
71. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	2	New rash — Ongoing inflammatory lupus rash.
72. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	8	Organic brain syndrome — 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.
73. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	2	Pericarditis — Classic and severe pericardial pain, rub, effusion, or electrocardiogram confirmation.
74. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	2	Pleurisy — Classic and severe pleuritic chest pain, pleural rub, effusion, or new pleural thickening due to lupus.
75. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	4	Proteinuria — > 0.5 gm/24 hours. New onset or recent increase of > 0.5 gm/24 hours.
76. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	8	Psychosis — Altered ability to function in normal activity due to severe disturbance in the perception of reality. Include hallucinations, incoherence, marked loose associations, impoverished thought content, marked illogical thinking, bizarre, disorganized or catatonic behavior. Exclude uremia and drug causes.
77. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	4	Pyuria — > 5 white blood cells/high power field. Exclude infection.
78. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	8	Seizures — Recent onset (last 10 days). Exclude metabolic, infectious, or drug cause, or seizure due to past irreversible CNS damage.
79. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	1	Thrombocytopenia — < 100,000 platelets/mm <sup>3</sup> (x 10 <sup>9</sup> /L).
80. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	4	Urinary casts — Heme-granular or red blood cell casts.
81. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	8	Vasculitis — Ulceration, gangrene, tender finger nodules, periungual infarction, splinter hemorrhages, or biopsy or angiogram proof of vasculitis.
82. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	8	Visual disturbance — Retinal and eye changes of SLE. Include cytooid bodies, retinal hemorrhages, serous exudate or hemorrhages in the choroid, optic neuritis, scleritis, or episcleritis. Exclude hypertension, infection, or drug causes.
83. Total SLEDAI score:		

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Month Day

20  
Year

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20  
Year

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84. Was an MRI scan of the brain performed since the date of the last report?

- 1  yes  
2  no  
3  unknown

85. Date of most recent MRI brain scan:

  
Month Day

20  
Year

86. Specify results of most recent MRI brain scan:

- 1  normal  
2  abnormal  
3  unknown

## Laboratory Studies at the Time of Evaluation for This Reporting Period

87. Creatinine clearance:

- 1  known  
2  not known

  
• 

Specify units:

- 1  mL/min  
2  mL/sec

88. Cerebral spinal fluid (CSF) protein:

- 1  known  
2  not known

  
• 

- 1  mg/dL  
2  g/L

89. Cerebral spinal fluid (CSF) IgG:

- 1  known  
2  not known

- 1  mg/dL  
2  g/L

90. Cerebral spinal fluid (CSF) cell count:

- 1  known  
2  not known

91. Urine protein (24-hour):

- 1  known  
2  not known

  
• 

- 1  mg / 24 hours  
2  g / day

92. Were urine RBC / RBC casts detected?

- 1  yes  
2  no  
3  unknown

93. Erythrocyte sedimentation rate:

- 1  known  
2  not known

  
mm / hour

94. Complement activity level of CH50:

- 1  decreased  
2  normal  
3  unknown

95. Complement activity level of C3:

- 1  decreased  
2  normal  
3  unknown

96. Complement activity level of C4:

- 1  decreased  
2  normal  
3  unknown

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 /  /   
Month Day Year

Infusion Date:

 /  /   
Month Day Year

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97. Antibody activity for anti-ANA:

- 1  positive
- 2  negative
- 3  unknown

98. Antibody activity level of anti-dsDNA:

- 1  increased
- 2  normal
- 3  unknown

99. Antibody activity level of anti-Sm:

- 1  increased
- 2  normal
- 3  unknown

100. Antibody activity level of anti-SS-A (anti-Ro):

- 1  increased
- 2  normal
- 3  unknown

101. Antibody activity level of anti-SS-B (anti-La):

- 1  increased
- 2  normal
- 3  unknown

102. Anti-cardiolipid IgG level:

- 1  increased
- 2  normal
- 3  unknown

103. Anti-cardiolipid IgM level:

- 1  increased
- 2  normal
- 3  unknown

104. Lupus-anticoagulant level:

- 1  increased
- 2  normal
- 3  unknown

Specify the results of the following pulmonary function tests performed since the date of the last report:

105. Date pulmonary function tests were performed:  /  /   
Month Day Year

106. Vital capacity (VC):

- 1  known →  .  % (predicted value)
- 2  not known

107. Was the actual VC value in the normal range (≥ 80% of predicted value)?

- 1  yes
- 2  no

108. D<sub>L</sub>CO:

- 1  known →  .  % (predicted value)
- 2  not known

109. Was the actual D<sub>L</sub>CO value in the normal range (≥ 80% of predicted value)?

- 1  yes
- 2  no

110. D<sub>L</sub>CO corrected for hemoglobin:

- 1  known →  .  % (predicted value)
- 2  not known

111. Was the D<sub>L</sub>CO value (corrected for hemoglobin) in the normal range (≥ 80% of predicted value)?

- 1  yes
- 2  no



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131. Did the recipient complete a Health Assessment Questionnaire (HAQ) since the date of the last report?

- 1  yes  
2  no  
3  unknown

132. Recipient's score:

				.	
--	--	--	--	---	--

133. Worst possible function score:

				.	
--	--	--	--	---	--

134. Best possible function score:

				.	
--	--	--	--	---	--

135. Signed: \_\_\_\_\_

*Person completing form*

Please print name: \_\_\_\_\_

Phone number: (\_\_\_\_\_) \_\_\_\_\_

Fax number: (\_\_\_\_\_) \_\_\_\_\_

E-mail address: \_\_\_\_\_