Form 2145 R3.0: Systemic Lupus Erythematosus Post-HSCT Data

Center: CRID:

Key Fields

Sequence Number: ____________________________
Date Received: __ __ __ __ - __ __- __ __
CIBMTR Center Number: ____________________________
CIBMTR Recipient ID: ____________________________

Today's Date: __ __ __ __
Date of HSCT for which this form is being completed: __ __ __ __

HSCT Type (check all that apply):
- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

Product Type (check all that apply):
- Marrow
- PBSC
- Cord blood
- Other product

Specify: ____________________________

Visit:
- 100 day
- 6 months
- 1 year
- 2 years
- > 2 years

Specify: ____________________________

Disease Assessment Post-HSCT
Questions: 1 - 1

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.

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

2 Did the recipient receive any treatment for SLE since the date of the last report?
   - yes
   - no
   - Unknown

3 Was androgen treatment given?
   - yes
   - no
   - Unknown

4 Reason for treatment: ____________________________

5 Specify: ____________________________

6 Date treatment started: __ __ __ __

7 Currently receiving?
   - yes
   - no
8 Was antimalarial drug treatment given?
   - Yes
   - No
   - Unknown
9 Reason for treatment: __________________________
10 Specify: __________________________
11 Date treatment started: __ __ __ __ - __ __
12 Currently receiving?
   - Yes
   - No
13 Was azathioprine (Azasan, Imuran) treatment given?
   - Yes
   - No
   - Unknown
14 Reason for treatment: __________________________
15 Specify: __________________________
16 Date treatment started: __ __ __ __ - __ __
17 Currently receiving?
   - Yes
   - No
18 Were corticosteroids given?
   - Yes
   - No
   - Unknown
19 Reason for treatment: __________________________
20 Specify: __________________________
21 Date treatment started: __ __ __ __ - __ __
22 Currently receiving?
   - Yes
   - No
23 Was cyclophosphamide (CTX, Cytoxan, Neosar) treatment given?
   - Yes
   - No
   - Unknown
24 Reason for treatment: __________________________
25 Specify: __________________________
26 Date treatment started: __ __ __ __ - __ __
27 Currently receiving?
   - Yes
   - No
28 Was cyclosporine (CsA, Neoral, Sandimmune) treatment given?
   - Yes
   - No
   - Unknown
29 Reason for treatment: __________________________
30 Specify: __________________________
31 Date treatment started: __ __ __ __ - __ __
32 Currently receiving?
   - Yes
   - No
33 Was intravenous immune globulin (IVIG) treatment given?
   - Yes
   - No
   - Unknown
Reason for treatment: ____________________________

Specify: ____________________________

Date treatment started: __ __ __ __ - __ __ - __ __

Currently receiving?

Yes  No

Was lymphocytopheresis treatment given?

Yes  No  Unknown

Reason for treatment: ____________________________

Specify: ____________________________

Date treatment started: __ __ __ __ - __ __ - __ __

Currently receiving?

Yes  No

Was methotrexate (MTX, Folex) treatment given?

Yes  No  Unknown

Reason for treatment: ____________________________

Specify: ____________________________

Date treatment started: __ __ __ __ - __ __ - __ __

Currently receiving?

Yes  No

Was mycophenolate mofetil (MMF, CellCept) treatment given

Yes  No  Unknown

Reason for treatment: ____________________________

Specify: ____________________________

Date treatment started: __ __ __ __ - __ __ - __ __

Currently receiving?

Yes  No

Was plasmapheresis treatment given?

Yes  No  Unknown

Reason for treatment: ____________________________

Specify: ____________________________

Date treatment started: __ __ __ __ - __ __ - __ __

Currently receiving?

Yes  No

Was rituximab (anti-CD20, Rituxan) treatment given?

Yes  No  Unknown

Reason for treatment: ____________________________

Specify: ____________________________
**Disease Status at the Time of Evaluation for This Reporting Period**

Specify if the following Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) criteria were present at the time of the most recent evaluation and were attributable to Lupus:

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>69</td>
<td>Arthritis — More than 2 joints with pain and signs of inflammation (i.e., tenderness, swelling, or effusion).</td>
<td></td>
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<tr>
<td>70</td>
<td>Alopecia - Ongoing abnormal, patchy, or diffuse loss of hair due to active lupus.</td>
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</tr>
<tr>
<td>71</td>
<td>Cerebrovascular accident (CVA) - New onset of cerebrovascular accident(s). Exclude arteriosclerosis or hypertensive causes.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>72</td>
<td>Cranial nerve disorder - New onset of sensory or motor neuropathy involving cranial nerves. Include vertigo due to lupus.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Example:**

- For Arthritis, if present, add 4 points to the total SLEDAI score (question 93).
73 Fever - > 38°C. Exclude infectious cause.
   yes Add 1 point to the total SLEDAI score (question 93)
   no
   Unknown

74 Hematuria - > 5 red blood cells/high power field. Exclude stone, infection, or other cause.
   yes Add 4 points to the total SLEDAI score (question 93)
   no
   Unknown

75 Increased DNA binding - >25% binding by Farr assay, or above normal range for testing laboratory.
   yes Add 2 points to the total SLEDAI score (question 93)
   no
   Unknown

76 Leukopenia - < 3,000 white blood cells/mm3 (x 10^9/L). Exclude drug causes.
   yes Add 1 point to the total SLEDAI score (question 93)
   no
   Unknown

77 Low complement - Decrease in CH50, C3, or C4 below the lower limit of normal for testing laboratory.
   yes Add 2 points to the total SLEDAI score (question 93)
   no
   Unknown

78 Lupus headache - Severe, persistent headache: may be migrainous, but must be nonresponsive to narcotic analgesia.
   yes Add 8 points to the total SLEDAI score (question 93)
   no
   Unknown

79 Mucosal ulcers — Ongoing oral or nasal ulcerations due to active lupus.
   yes Add 2 points to the total SLEDAI score (question 93)
   no
   Unknown
80 Myositis — Proximal muscle aching/weakness associated with elevated creatine phosphokinase/aldolase or electromyogram changes, or a biopsy showing myositis.

- yes Add 4 points to the total SLEDAI score (question 93)
- no
- Unknown

81 New rash - Ongoing inflammatory lupus rash.

- yes Add 2 points to the total SLEDAI score (question 93)
- no
- Unknown

82 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.

- yes Add 8 points to the total SLEDAI score (question 93)
- no
- Unknown

83 Pericarditis — Classic and severe pericardial pain, rub, effusion, or electrocardiogram confirmation.

- yes Add 2 points to the total SLEDAI score (question 93)
- no
- Unknown

84 Pleurisy - Classic and severe pleuritic chest pain, pleural rub, effusion, or new pleural thickening due to lupus.

- yes Add 2 points to the total SLEDAI score (question 93)
- no
- Unknown

85 Proteinuria - > 0.5 gm/24 hours. New onset or recent increase of > 0.5 gm/24 hours.

- yes Add 4 points to the total SLEDAI score (question 93)
- no
- Unknown

86 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.

- yes Add 8 points to the total SLEDAI score (question 93)
- no
- Unknown
<table>
<thead>
<tr>
<th>Question Number</th>
<th>Condition Description</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>87</td>
<td>Pyuria - &gt; 5 white blood cells/high power field. Exclude infection.</td>
<td></td>
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<tr>
<td></td>
<td>yes Add 4 points to the total SLEDAI score (question 93)</td>
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<tr>
<td></td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Unknown</td>
<td></td>
<td></td>
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<tr>
<td>88</td>
<td>Seizures — Recent onset (last 10 days). Exclude metabolic, infectious, or drug cause,</td>
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<tr>
<td></td>
<td>or seizure due to past irreversible CNS damage.</td>
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<tr>
<td></td>
<td>yes Add 8 points to the total SLEDAI score (question 93)</td>
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<tr>
<td></td>
<td>no</td>
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<tr>
<td></td>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>89</td>
<td>Thrombocytopenia - &lt; 100,000 platelets/mm$^3$(x 10$^{9}$/L).</td>
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<td></td>
<td>yes Add 1 point to the total SLEDAI score (question 93)</td>
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<tr>
<td></td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Unknown</td>
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<tr>
<td>90</td>
<td>Urinary casts - Heme-granular or red blood cell casts.</td>
<td></td>
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<tr>
<td></td>
<td>yes Add 4 points to the total SLEDAI score (question 93)</td>
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<tr>
<td></td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Unknown</td>
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<td></td>
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<tr>
<td>91</td>
<td>Vasculitis — Ulceration, gangrene, tender finger nodules, periungual infarction, splinter hemorrhages, or biopsy or angiogram proof of vasculitis.</td>
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<tr>
<td></td>
<td>yes Add 8 points to the total SLEDAI score (question 93)</td>
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<tr>
<td></td>
<td>no</td>
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<tr>
<td></td>
<td>Unknown</td>
<td></td>
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<tr>
<td>92</td>
<td>Visual disturbance - Retinal and eye changes of SLE. Include cytoid bodies, retinal hemorrhages, serous exudate or hemorrhages in the choroid, optic neuritis, scleritis, or episcleritis. Exclude hypertension, infection, or drug causes.</td>
<td></td>
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<tr>
<td></td>
<td>yes Add 8 points to the total SLEDAI score (question 93)</td>
<td></td>
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<tr>
<td></td>
<td>no</td>
<td></td>
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<tr>
<td></td>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>93</td>
<td>Total SLEDAI score:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>94</td>
<td>Was an MRI scan of the brain performed since the date of the last report?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>yes</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>no</td>
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<tr>
<td></td>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Date of most recent MRI brain scan:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.
### Laboratory Studies at the Time of Evaluation for This Reporting Period

<table>
<thead>
<tr>
<th>Question</th>
<th>Known</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>96</td>
<td>Specify results of most recent MRI brain scan:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>abnormal, related to SLE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>abnormal, unrelated to SLE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>97</td>
<td>Creatinine clearance:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td>98</td>
<td>mL/min</td>
<td>mL/sec</td>
</tr>
<tr>
<td>99</td>
<td>Cerebral spinal fluid (CSF) protein:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td>100</td>
<td>mg/dL</td>
<td>g/L</td>
</tr>
<tr>
<td>101</td>
<td>Cerebral spinal fluid (CSF) IgG:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td>102</td>
<td>mg/dL</td>
<td>g/L</td>
</tr>
<tr>
<td>103</td>
<td>Cerebral spinal fluid (CSF) cell count:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td>104</td>
<td></td>
<td></td>
</tr>
<tr>
<td>105</td>
<td>Urine protein (24-hour):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td>106</td>
<td>mg/24 hours</td>
<td>g/day</td>
</tr>
<tr>
<td>107</td>
<td>Urine protein / creatinine ratio:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td>108</td>
<td></td>
<td></td>
</tr>
<tr>
<td>109</td>
<td>Were urine RBC / RBC casts detected?</td>
<td>yes</td>
</tr>
<tr>
<td>110</td>
<td>Erythrocyte sedimentation rate:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td>111</td>
<td>mm / hour</td>
<td></td>
</tr>
<tr>
<td>112</td>
<td>Complement level of CH50:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decreased</td>
<td>Normal</td>
</tr>
</tbody>
</table>
113  Complement level of C3:
- Decreased
- Normal
- Unknown

114  Complement level of C4:
- Decreased
- Normal
- Unknown

115  Antibody for anti-ANA:
- Positive
- Negative
- Unknown

116  Antibody level of anti-dsDNA:
- Increased
- Normal
- Unknown

117  Antibody level of anti-Sm:
- Increased
- Normal
- Unknown

118  Antibody level of anti-SS-A (anti-Ro):
- Increased
- Normal
- Unknown

119  Antibody level of anti-SS-B (anti-La):
- Increased
- Normal
- Unknown

120  Anti-cardiolipin IgG level:
- Increased
- Normal
- Unknown

121  Anti-cardiolipin IgM level:
- Increased
- Normal
- Unknown

122  Lupus-anticoagulant level:
- Increased
- Normal
- Unknown

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

123  Date pulmonary function tests were performed: ___ ___ ___ - ___ ___ ___

124  Vital capacity (VC):
- Known
- Not known

125  % (predicted value)

126  Was the actual VC value in the normal range (≥ 80% of predicted value)?
- yes
- no

127  DLCO:
- Known
- Not known

128  % (predicted value)

129  Was the actual DLCO value in the normal range (≥ 80% of predicted value)?
- yes
- no

130  DLCO corrected for hemoglobin:
- Known
- Not known
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>131 % (predicted value)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>132 Was the D(^15)CO value (corrected for hemoglobin) in the normal range (≥ 80% of predicted value)?</td>
<td>yes</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>133 Was oxygen desaturation present on exercise testing?</td>
<td>yes</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>134 Was an echocardiogram performed since the date of the last report?</td>
<td>yes</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>135 Was pericardial effusion present?</td>
<td>yes</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>136 Specify the size of the area of accumulated excess fluid:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>small</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>moderate</td>
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<td></td>
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<tr>
<td>large</td>
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<tr>
<td>137 Left ventricular ejection fraction:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Known</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Not known</td>
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<td></td>
<td></td>
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<tr>
<td>138 %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>139 Was pulmonary artery hypertension present?</td>
<td>yes</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>140 Specify the estimated systolic pulmonary artery pressure: mm Hg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>141 Was a multiple gate acquisition scan (MUGA test / nuclear ventriculography) performed since the date of the last report?</td>
<td>yes</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>142 Specify the left ventricular ejection fraction: %</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

First Name: _____________________ Last Name: _____________________

Phone number: _____________________ Fax number: _____________________

E-mail address: _____________________