1. Recipient's gender:
   1. male
   2. female

2. Recipient's date of birth:

3. Did the recipient provide written consent for data submission for the purpose of research studies?
   1. yes
   2. no

4. Is the recipient participating in a cellular therapy clinical trial?
   1. yes
   2. no

5. Specify the clinical trial phase:
   1. phase I
   2. phase II
   3. phase III

6. Specify clinical trial design:
   1. yes
   2. no
   - Blinded
   - Randomized
   - Placebo controlled

7. Specify the clinical trial site(s):
   1. single institution
   2. multi-center

This form must be completed for all recipients of cellular products for regenerative medicine indications. For recipients of hematopoietic stem cell transplants, complete a form 2400 – Pre-Transplant Essential Data.

This form captures all cellular infusions given to the same recipient within a period of 10 weeks. If additional infusions are administered beyond 10 weeks from the date of the first infusion, complete and submit another form 4000 – CTRM.

A series of collections should be considered a single product when they are all from the same donor and use the same collection method and technique (and mobilization, if applicable), even if the collections are performed on different days.

If the recipient's treatment required a preparative regimen prior to the infusion of a bone marrow-derived cellular product, refer to the forms instruction manual for guidance in completing this form.

Questions followed by the symbol "&" indicate additional information necessary to complete the question is referenced in the forms instruction manual; "A" indicates an appendix.

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
Indication for Cellular Therapy

10. Is this the first application of cellular therapy for this indication?
   1. yes
   2. no, recipient has been previously treated using cellular therapy

11. Specify indication for current treatment:
   1. continuing treatment
   2. failure of prior cellular therapy infusion(s)
   3. other indication ____________

12. Specify other indication for treatment:

13. Specify number of previous infusions:
   1. 1
   2. 2–5
   3. > 5

14. What was the status of the primary disease at the time of treatment with cellular therapy?
   1. acute disease
   2. acute exacerbation of chronic disease
   3. chronic disease

15. What was the specific disease indication for performing treatment with cellular therapy?
   1. autoimmune diseases (600)
   2. cardio and peripheral vascular disease, not otherwise specified (700)

16. Specify autoimmune disease:
   1. Crohn’s disease (649)
   2. ulcerative colitis (650)
   3. other bowel disorder (651)
   4. diabetes mellitus type I (660)
   5. rheumatoid arthritis (603)
   6. systemic lupus erythematosus (605)
   7. systemic sclerosis (607)
   8. other autoimmune disease (629)

17. Specify other bowel disorder:

18. Specify other autoimmune disease:

19. Specify cardiovascular disease:
   1. AMI, acute myocardial infarction (701)
   2. chronic coronary artery disease (ischemic, cardiomyopathy) (702)
   3. heart failure (non-ischemic etiology) (703)
   4. other cardiovascular disease (709)
   5. limb ischemia (710)
   6. thromboangiitis obliterans (711)
   7. other peripheral vascular disease (719)

20. Specify other cardiovascular disease:

21. Specify other peripheral vascular disease:

Baseline cardiovascular function parameters

Report results of function tests performed prior to any treatment with cellular therapy

22. Specify date baseline parameters were established: [Month Day Year]

23. Specify ejection fraction: [ ] %

24. Left ventricular end-diastolic volume: [ ] mL

25. Left ventricular end-systolic volume: [ ] mL
3. Specify musculoskeletal disease:

- avascular necrosis of femoral head (721)
- osteoarthritis (722)
- osteogenesis imperfecta (723)
- traumatic joint injury (724)
- other musculoskeletal disease (729)

35. Specify other musculoskeletal disease:

36. Specify neurologic disease:

- acute cerebral vascular ischemia (731)
- ALS, amyotrophic lateral sclerosis (732)
- Parkinson disease (733)
- spinal cord injury (734)
- cerebral palsy (753)
- congenital hydrocephalus (754)
- multiple sclerosis (602)
- myasthenia gravis (601)
- other neurologic disease (749)

37. Specify other neurologic disease:
Cellular Therapy Product

40. What is the intended distribution of the cellular product?
   1. single patient use (directed cellular product)
   2. multiple patient use (cell lines)

41. What is the tissue source of the cellular product?
   - Hematopoietic sources
     1. bone marrow
     2. cord blood unit
     3. peripheral blood
   - Non-hematopoietic sources
     4. adipose progenitor cells
     5. adipose tissue
     6. amniotic fluid
     7. cardiac progenitor cells
     8. cardiac tissue
     9. CD34+ enriched cells
     10. embryonic stem cells
     11. hepatic tissue
     12. induced pluripotent stem cells (iPS)
     13. neuronal tissue
     14. ophthalmic tissue
     15. pancreatic tissue
     16. placenta
     17. T-lymphocyte
     18. umbilical cord
     19. other tissue source

42. Specify the status of the peripheral blood used as the tissue source:
   1. mobilized
   2. non-mobilized

43. Specify the iPS tissue source:
   1. derived from skin tissue
   2. derived from other tissue
   3. other iPS tissue source

44. Specify other iPS tissue source:

45. Specify other tissue source:

46. What is the cell type of the cellular product?
   1. dendritic cells
   2. endothelial progenitor cells
   3. human umbilical cord perivascular (HUCPV) cells
   4. islet cells
   5. mesenchymal stromal cells
   6. microglia
   7. natural killer cells
   8. unselected mononuclear cells
   9. other cell type

47. Specify other cell type:
Product Processing / Manipulation

48. Was the cellular product manipulated prior to infusion?

1. yes
2. no
3. unknown

Specify all methods used to manipulate the cellular product:

49. 1. yes 2. no Cell expansion
50. Specify cell expansion:

51. 1. yes 2. no Cell selection
52. Specify cell selection:

53. 1. yes 2. no Growth factor(s)
54. Specify growth factor(s):

55. 1. yes 2. no Induced cell differentiation

56. 1. yes 2. no Non-viral transfection
57. Specify non-viral transfection:

58. 1. yes 2. no Viral transfection
59. Specify viral transfection:

59. 1. yes 2. no Other manipulation
61. Specify other manipulation:

Cellular Therapy Product Infusion

62. What was the route of product infusion?

If there was more than one route of infusion, copy and complete questions 62-70 for each route of infusion.

1. intra arterial
2. intramuscular
3. intraperitoneal
4. intrathecal
5. intravenous
6. locally in the tissue
7. other route of infusion

63. Specify artery:
1. coronary
2. femoral
3. other artery

64. Specify other artery:

65. Specify local site:
1. bone
2. heart
3. liver
4. other site

66. Specify other organ / tissue site:

67. Specify other cell type:

68. Specify the total number of cellular infusions administered within 10 weeks from the date of the first infusion:
Exponent: Specify units:

1. kg
2. m²

69. Specify the median number of cells infused per administration:
Exponent: Specify units:

1. kg
2. m²

70. Specify the total number of cells infused within 10 weeks from the date of the first infusion:

71. Was any other procedure performed in conjunction with the cellular therapy?

1. yes
2. no
3. unknown

72. Specify procedure:
1. coronary artery bypass surgery
2. coronary stent placement
3. decompression of spinal cord injury
4. matrix implant
5. other procedure

73. Specify other procedure:
### CIBMTR Recipient ID:

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### CIBMTR Center Number:

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#### 74. Were there any adverse events or incidents associated with the cellular infusion(s)?

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<tbody>
<tr>
<td>Yes</td>
<td>No</td>
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#### 75. Specify severity:

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<tr>
<td>Mild — transient reaction requiring no treatment, or treatment with oral medication</td>
<td>Moderate — symptomatic reaction requiring parenteral medication</td>
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#### Response to Cellular Therapy

76. Specify the date the clinical response to cellular therapy was established:

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77. What was the best clinical / biologic response to the cellular therapy?

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<tbody>
<tr>
<td>Complete response</td>
<td>Normalization of organ function</td>
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78. Was there laboratory, radiologic, or other evidence of response?

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<tbody>
<tr>
<td>Yes</td>
<td>No</td>
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79. Specify organ function parameter:

80. Specify response:

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<tr>
<td>Improved</td>
<td>Normalized</td>
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#### 81. What is the recipient's survival status at the time of this report?

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<thead>
<tr>
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<tbody>
<tr>
<td>Alive</td>
<td>Dead</td>
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82. Specify the date of the most recent follow-up:

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83. Specify the date of death:

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84. Specify the main cause of death:

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<tr>
<td>Disease relapse or progression, or persistent disease</td>
<td>Related to cell therapy</td>
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85. Specify other cause of death:

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<tbody>
<tr>
<td>Other cause of death</td>
<td>Unknown</td>
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</tbody>
</table>

86. Signed: ____________________________

请您打印姓名：______________________________

请提供电话：(____________) ____________________

请提供传真：(____________) ____________________

E-mail address: ________________________________

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).