Cellular Therapy for Regenerative Medicine

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

7. Specify 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.
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 (680)
   5 ☐ rheumatoid arthritis (603)
   6 ☐ systemic lupus erythematos (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 ☐ thromboangitis 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
26. Specify the method used to measure ejection fraction:
   1. echocardiogram (ECHO, cardiac ultrasound, ECG, EKG)
   2. fast scan cardiac computed axial tomography (CT) imaging
   3. Gated SPECT (single photon emission computed tomography)
   4. magnetic resonance imaging (MRI)
   5. multiple-gated acquisition (MUGA) scan
   6. ventriculography

27. Specify the total number of previous infarcts:  
   ☐ unknown / not applicable

28. If decreased cardiac function is present, specify the recipient's Classification of Functional Capacity and Objective Assessment — American Heart Association (previously known as New York Heart Association (NYHA) Functional Classification):
   1. class I
   2. class II
   3. class III
   4. class IV
   5. unknown / not applicable

29. If a history of angina is present, specify the recipient's Canadian Cardiovascular Society Angina Grading Scale:
   1. class I
   2. class II
   3. class III
   4. class IV
   5. unknown / not applicable

30. Specify the recipient's ankle brachial pressure index (ABPI / API):  

31. Were any other measures of cardiac performance assessed prior to any treatment with cellular therapy?
   1. yes
   2. no

32. Specify other cardiac performance measure:

33. Specify results:

34. Specify musculoskeletal disease:
   1. avascular necrosis of femoral head (721)
   2. osteoarthritis (722)
   3. osteogenesis imperfecta (723)
   4. traumatic joint injury (724)
   5. other musculoskeletal disease (729)

35. Specify other musculoskeletal disease:

36. Specify neurologic disease:
   1. acute cerebral vascular ischemia (731)
   2. ALS, amiotrophic lateral sclerosis (732)
   3. Parkinson disease (733)
   4. spinal cord injury (734)
   5. cerebral palsy (753)
   6. congenital hydrocephalus (754)
   7. multiple sclerosis (602)
   8. myasthenia gravis (601)
   9. 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:

60. 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:

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

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

1 [ ] yes
2 [ ] no
3 [ ] unknown

75. Specify severity:
1 [ ] mild — transient reaction requiring no treatment, or treatment with oral medication
2 [ ] moderate — symptomatic reaction requiring parenteral medication
3 [ ] severe — life-threatening or anaphylaxis

Response to Cellular Therapy

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

Month Day Year

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

1 [ ] complete response
2 [ ] normalization of organ function
3 [ ] partial response or partial normalization of organ function
4 [ ] any response, followed by disease progression or worsening of organ function
5 [ ] no response
6 [ ] disease progression or worsening of organ function
7 [ ] unknown

78. Was there laboratory, radiologic, or other evidence of response?

1 [ ] yes
2 [ ] no
3 [ ] unknown

79. Specify organ function parameter:

80. Specify response:
1 [ ] improved
2 [ ] normalized
3 [ ] unchanged
4 [ ] worse

81. What is the recipient’s survival status at the time of this report?

1 [ ] alive
2 [ ] dead

82. Specify the date of the most recent follow-up:

Month Day Year

83. Specify the date of death:

Month Day Year

84. Specify the main cause of death:
1 [ ] disease relapse or progression, or persistent disease
2 [ ] related to cell therapy
3 [ ] other cause of death
4 [ ] unknown

85. Specify other cause of death:

86. Signed: ________________________________

Person completing form

Please print name: ________________________________

Phone: (__________)

Fax: (__________)

E-mail address: ________________________________