Donor Health History

Report the presence or history of the following conditions:

1. Known allergy to G-CSF or to *E. coli*-derived recombinant protein products:
   - [ ] Yes
   - [ ] No
   If yes, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.

2. History of iritis and/or episcleritis:
   - [ ] Yes
   - [ ] No
   If yes, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.

3. Previous serious adverse reaction to anesthesia:
   - [ ] Yes
   - [ ] No

4. Pregnant female (positive $\beta$-hCG) or uninterruptible breastfeeding:
   - [ ] Yes
   - [ ] No
   If yes, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.

5. Receiving experimental therapy or investigational agents:
   - [ ] Yes
   - [ ] No
   If yes, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.

6. First-degree relative (i.e., parent, full sibling, or child) with a history of leukemia or lymphoma:
   - [ ] Yes
   - [ ] No
7. Hemorrhage requiring medical attention:

☐ Yes  Go to questions 8-12
☐ No  Go to question 14

Specify diagnosis:

8. Gastrointestinal (GI) / ulcers:

☐ Yes
☐ No

9. Genitourinary (GU) / hemorrhagic cystitis:

☐ Yes
☐ No

10. Central nervous system (CNS):

☐ Yes
☐ No

11. Significant surgical / post-partum bleeding or trauma:

☐ Yes
☐ No

12. Other significant hemorrhage:

☐ Yes  Go to question 13
☐ No  Go to question 14

13. If yes, specify significant hemorrhage:_____________________________________

14. Autoimmune disease:

☐ Yes  Go to questions 15-19  If yes, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.

☐ No  Go to question 21

Specify diagnosis:

15. Multiple sclerosis (MS):

☐ Yes
☐ No

16. Rheumatoid arthritis (RA):

☐ Yes
☐ No

17. Scleroderma:

☐ Yes
☐ No

18. Systemic lupus erythematosus (SLE):

☐ Yes
☐ No

19. Other autoimmune disease:

☐ Yes  Go to question 20
☐ No  Go to question 21
20. If yes, specify autoimmune disease: ____________________________________________

21. Cardiovascular conditions:
   □ Yes  Go to questions 22-24
   □ No   Go to question 32

   **Specify diagnosis:**

   22. Atrial arrhythmias (including atrial fibrillation):
       □ Yes
       □ No

   23. Ventricular arrhythmias:
       □ Yes
       □ No

   24. Other arrhythmias:
       □ Yes  Go to question 25
       □ No   Go to question 26-30

       25. If yes, specify arrhythmias: ____________________________________________

   26. Congestive heart failure:
       □ Yes
       □ No

   27. Coronary artery disease (no prior MI):
       □ Yes
       □ No

   28. Hypertension:
       □ Yes
       □ No

   29. History of myocardial infarction (MI):
       □ Yes
       □ No

   30. Other cardiovascular:
       □ Yes  Go to question 31
       □ No   Go to question 32

       31. If yes, specify cardiovascular condition: ____________________________________

   32. CNS / psychiatric:
       □ Yes  Go to questions 33-37
       □ No   Go to question 44

   **Specify diagnosis:**

   33. Anxiety:
       □ Yes
       □ No
34. Bipolar disorder:
   - Yes
   - No

35. Currently treated with lithium:
   - Yes  If yes, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.
   - No

36. Depression:
   - Yes
   - No

37. Other psychiatric:
   - Yes  Go to question 38
   - No  Go to question 39-42

   38. If yes, specify psychiatric condition: ___________________________________

39. Meningitis / encephalitis:
   - Yes
   - No

40. Seizure disorder:
   - Yes
   - No

41. Stroke / cerebrovascular accident (CVA):
   - Yes
   - No

42. Other CNS:
   - Yes  Go to question 43
   - No  Go to question 44

   43. If yes, specify CNS condition: ___________________________________________

44. Endocrine:
   - Yes  Go to questions 45-49
   - No  Go to question 51

   **Specify diagnosis:**

45. Diabetes mellitus:
   - Yes
   - No

46. Hyperthyroidism:
   - Yes
   - No

47. Hypothyroidism:
   - Yes
   - No
48. Osteoporosis:
   □ Yes
   □ No

49. Other endocrine:
   □ Yes  Go to question 50
   □ No   Go to question 51

   50. If yes, specify endocrine condition: ________________________________

51. Gastrointestinal:
   □ Yes  Go to questions 52-56
   □ No   Go to question 58

   Specify diagnosis:

   52. Crohn’s disease:
       □ Yes
       □ No

   53. Ulcerative colitis:
       □ Yes
       □ No

   54. Peptic ulcer disease (PUD):
       □ Yes
       □ No

   55. Gastroesophageal reflux disease (GERD):
       □ Yes
       □ No

   56. Other gastrointestinal:
       □ Yes  Go to question 57
       □ No   Go to question 58

   57. If yes, specify gastrointestinal condition: ________________________________

58. Genitourinary:
   □ Yes  Go to questions 59-61
   □ No   Go to question 63

   Specify diagnosis:

   59. Renal failure requiring dialysis:
       □ Yes
       □ No

   60. Renal insufficiency requiring medical treatment:
       □ Yes
       □ No

   61. Other genitourinary:
       □ Yes  Go to question 62
       □ No   Go to question 63
62. If yes, specify genitourinary condition:______________________________

63. Hematologic:
   □ Yes  Go to questions 64-66  If yes, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.
   □ No  Go to question 68

   Specify diagnosis:
   64. Deep vein thrombosis:
      □ Yes
      □ No
   65. Thromboembolism:
      □ Yes
      □ No
   66. Other hematologic:
      □ Yes  Go to question 67
      □ No  Go to question 68

   67. If yes, specify hematologic condition:______________________________

68. Liver disease:
   □ Yes  Go to questions 69-72
   □ No  Go to question 74

   Specify diagnosis:
   69. Chronic viral hepatitis:
      □ Yes
      □ No
   70. Cirrhosis:
      □ Yes
      □ No
   71. Drug toxicity:
      □ Yes
      □ No
   72. Other liver disease:
      □ Yes  Go to question 73
      □ No  Go to question 74

   73. If yes, specify liver disease:_____________________________________

74. Pulmonary:
   □ Yes  Go to questions 75-77
   □ No  Go to question 79
Specify diagnosis:

75. Asthma / reactive airway disease:
   □ Yes
   □ No

76. Chronic obstructive pulmonary disease (COPD):
   □ Yes
   □ No

77. Other pulmonary:
   □ Yes  Go to question 78
   □ No  Go to question 79

78. If yes, specify pulmonary condition: ____________________________________________

79. Other significant coexisting disease:
   □ Yes  Go to question 80
   □ No  Go to question 81

80. Specify significant coexisting disease: ____________________________________________

Conditions Present at Baseline Screening

Using the following Modified Toxicity Criteria, review each body symptom with the donor. For each symptom associated with a system, select the statement that most closely reflects the donor’s current condition. In the Modified Toxicity Criteria below, the term “activities of daily living” (ADL) refers to tasks performed by individuals in a typical day that allow independent living. Basic activities of daily living include feeding, dressing, hygiene, and physical mobility.

Flu-Like Symptoms

81. Fever in absence of infections:
   □ None (grade 0)
   □ 38.0 – 39.0° C / 100.0 – 102.2° F (grade 1)
   □ Greater than 39.0 – 40.0° C / 102.2 – 104.0° F (grade 2)
   □ Greater than 40.0° C / 104.0° F for less than 24 hours (grade 3)
   □ Greater than 40.0° C / 104.0° F for more than 24 hours (grade 4)

Constitutional Symptoms

82. Fatigue (lethargy, malaise, asthenia):
   □ None (grade 0)
   □ Mild fatigue over baseline (grade 1)
   □ Moderate or causing difficulty performing some ADL (grade 2)
   □ Severe fatigue interfering with ADL (grade 3)
   □ Disabling (grade 4)
83. Rashes on skin:

- None (grade 0)
- Macular or papular eruption or erythema that is asymptomatic (discrete areas of raised or flat, discolored and/or reddened skin patches, with no other symptoms) (grade 1)
- Macular or papular eruption or erythema with pruritus or other associated symptoms (same as above in conjunction with symptoms such as itching and pain) (grade 2)
- Severe, generalized erythroderma or macular, papular, or vesicular eruption (same as above with the possible addition of fluid-filled blisters; also, the condition is not widely spaced, but instead covers the majority of the body) (grade 3)
- Generalized exfoliative dermatitis or ulcerating dermatitis (skin inflammation leading to peeling and/or ulceration) (grade 4)

84. Injection site reaction (filgrastim, IV, or marrow collection):

- None (grade 0)
- Pain; itching; erythema (grade 1)
- Pain and swelling with inflammation or phlebitis (grade 2)
- Ulceration or necrosis that is severe; operative intervention indicated (grade 3)

85. Nausea:

- None (grade 0)
- Loss of appetite without alteration in eating habits (grade 1)
- Oral intake decreased without significant weight loss, dehydration or malnutrition (grade 2)
- Inadequate oral caloric or fluid intake (grade 3)
- Life-threatening consequences (grade 4)

86. Vomiting:

- None (grade 0)
- 1 episode in 24 hours (grade 1)
- 2–5 episodes in 24 hours (grade 2)
- 6 or more episodes in 24 hours (grade 3)
- Life-threatening consequences (grade 4)

87. Loss of appetite (anorexia):

- None (grade 0)
- Loss of appetite without alteration in eating habits (grade 1)
- Altered intake without significant weight loss or malnutrition (grade 2)
- Significant weight loss or malnutrition (grade 3)
- Life-threatening (grade 4)

88. Inability to sleep (insomnia):

- Normal (grade 0)
- Occasional difficulty sleeping, not interfering with function (grade 1)
- Difficulty sleeping, interfering with function but not interfering with ADL (grade 2)
- Frequent difficulty sleeping, interfering with ADL (grade 3)
- Disabling (grade 4)
89. Dizziness, vertigo, or lightheadedness
   □ None (grade 0)
   □ With head movements only; not interfering with function (grade 1)
   □ Interfering with function, but not interfering with ADL (grade 2)
   □ Interfering with ADL (grade 3)
   □ Disabling (grade 4)

90. Fainting (syncope):
   □ None (grade 0)
   □ Present (grade 3)
   □ Life-threatening consequences (grade 4)

Sites of Pain
For each of the sites listed below, indicate the severity of pain present using the following scale:
0 = none (grade 0)
1 = mild pain not interfering with function (grade 1)
2 = moderate pain interfering with function but not ADL (grade 2)
3 = severe pain severely interfering with ADL (grade 3)
4 = disabling (grade 4)

91. Back:
   □ None (grade 0)
   □ Mild (grade 1)
   □ Moderate (grade 2)
   □ Severe (grade 3)
   □ Disabling (grade 4)

92. Bones (including sternum and ribs):
   □ None (grade 0)
   □ Mild (grade 1)
   □ Moderate (grade 2)
   □ Severe (grade 3)
   □ Disabling (grade 4)

93. Headache:
   □ None (grade 0)
   □ Mild (grade 1)
   □ Moderate (grade 2)
   □ Severe (grade 3)
   □ Disabling (grade 4)

94. Hip:
   □ None (grade 0)
   □ Mild (grade 1)
   □ Moderate (grade 2)
   □ Severe (grade 3)
   □ Disabling (grade 4)

95. IV site:
   □ None (grade 0)
   □ Mild (grade 1)
   □ Moderate (grade 2)
   □ Severe (grade 3)
   □ Disabling (grade 4)
96. Joints (excluding hip):
   - None (grade 0)
   - Mild (grade 1)
   - Moderate (grade 2)
   - Severe (grade 3)
   - Disabling (grade 4)

97. Limbs (arms, legs, hands, feet):
   - None (grade 0)
   - Mild (grade 1)
   - Moderate (grade 2)
   - Severe (grade 3)
   - Disabling (grade 4)

98. Muscles:
   - None (grade 0)
   - Mild (grade 1)
   - Moderate (grade 2)
   - Severe (grade 3)
   - Disabling (grade 4)

99. Neck:
   - None (grade 0)
   - Mild (grade 1)
   - Moderate (grade 2)
   - Severe (grade 3)
   - Disabling (grade 4)

100. Throat:
    - None (grade 0)
    - Mild (grade 1)
    - Moderate (grade 2)
    - Severe (grade 3)
    - Disabling (grade 4)

101. Other pain site:
    - None (grade 0)  Go to question 103
    - Mild (grade 1)  Go to question 102
    - Moderate (grade 2)  Go to question 102
    - Severe (grade 3)  Go to question 102
    - Disabling (grade 4)  Go to question 102

102. Specify other pain site: ___________________________

Donor Assessment

103. Donor height without shoes:
    ___ ___ ___  □ in
         □ cm

104. Donor weight without shoes:
    ___ ___ ___  □ lbs
         □ kg
105. Pulse: 
    ___ ___ ___ beats per minute

106. Blood pressure:
    ___ ___ ___ mmHg (systolic)
    ___ ___ ___ mmHg (diastolic)

107. Temperature:
    ___ ___ ___ ° F
    ___ ___ ___ ° C

**Laboratory Studies**

108. Was a serum pregnancy test performed?

    ☐ Yes  Go to questions 109-110
    ☐ Not applicable: male donor, or female donor not of child bearing potential  Go to question 111

109. Date of pregnancy test:
    ___ ___ ___ ___ - ___ ___ - ___ ___ YYYY                             MM                      DD

110. Specify pregnancy test result:
    ☐ Positive  If positive, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.
    ☐ Negative

111. Was a sickle cell hemoglobin test performed?

    ☐ Yes  Go to questions 112-113
    ☐ No   Go to question 115
    ☐ Testing not required (donor center exempt)  Go to question 115

112. Specify test result:
    ☐ Positive  If positive, the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.
    ☐ Negative

113. Specify test method used:

    ☐ Hemoglobin electrophoresis  Go to question 115
    ☐ Hemoglobin S solubility  Go to question 115
    ☐ High performance liquid chromatography (HPLC) fractionation  Go to question 115
    ☐ Isoelectric focusing  Go to question 115
    ☐ Other test method  Go to question 114

114. Specify other sickle cell hemoglobin test method used: ______________________________
Hematology

CBC

115. Date of sample collection:

YYYY MM DD

116. WBC:

___ ___ x 10⁹/L

117. Hemoglobin:

___ ___ g/dL

118. Hematocrit:

___ ___ %

119. Platelets:

___ ___ x 10⁹/L

If platelet count is less than 150 x10⁹/L the donor is not suitable to donate PBSC. Contact NMDP Case Management immediately.

WBC Differential

120. Segmented neutrophils:

___ ___ %

121. Band neutrophils:

___ ___ %

122. Lymphocytes:

___ ___ %

123. Monocytes:

___ ___ %

124. Eosinophils:

___ ___ %

125. Basophils:

___ ___ %

126. Metamyelocytes:

___ ___ %

127. Myelocytes:

___ ___ %

128. Promyelocytes:

___ ___ %

129. Blasts:

___ ___ %

130. Other (e.g., LUC, unclassified cells):

___ ___ %
Assessment of Venous Access
A qualified staff person should determine if the donor has adequate venous access to allow for the apheresis procedure.

131. Were the donor's veins examined for adequate access for the apheresis procedure?

☐ Yes  Go to question 132
☐ No   Go to question 133

132. Specify the condition of the donor's veins:

☐ Good
☐ Fair
☐ Poor

Donor Consent to Donate
Specify the consent form(s) signed by the donor:

133. PBSC

☐ Yes  Go to questions 134-135
☐ No   Go to question 136

134. Date the donor signed the PBSC consent form:

YYYY MM DD

135. NMDP Apheresis Center number:


136. Bone marrow

☐ Yes  Go to questions 137-138
☐ No   Go to question 139

137. Date the donor signed the marrow consent form:

YYYY MM DD

138. NMDP Collection Center number:


139. Did the donor sign the research database consent form?

☐ Yes  Go to question 140
☐ No   Go to question 141

140. Date the donor signed the research database consent form:

YYYY MM DD
141. Did the donor sign the long-term donor follow-up consent form?
   □ Yes  Go to question 142
   □ No  Go to question 143
   □ Not applicable: Donor previously consented or declined to participate in long-term donor follow-up  Go to question 143

142. Date the donor signed the long-term donor follow-up consent form:
   ___ ___ ___ ___ - ___ ___ - ___ ___
   YYYY                             MM                      DD

Donor Suitability to Donate Stem Cells

143. After reviewing the results of the donor medical evaluation, it is determined that the donor is: (check only one)
   □ Suitable to donate both PBSCs and marrow  Go to question 150
   □ Suitable to donate PBSCs only and after evaluation unsuitable to donate marrow  Go to question 150
   □ Suitable to donate marrow only and after evaluation unsuitable to donate PBSCs  Go to question 150
   □ Workup was canceled by the Transplant Center before donor suitability was determined (Medical Director signatures are not required on this form)  Go to question 150
   □ Unsuitable to donate PBSCs and marrow  Go to questions 144-148
   (A minimum of one Medical Director Signature is required on this form)

   Specify the reason(s) the donor is unsuitable:

144. Abnormal lab results
   □ Yes
   □ No

145. Anesthesia risk
   □ Yes
   □ No

146. Surgical risk (other than anesthesia)
   □ Yes
   □ No

147. Exclusion criteria were met
   □ Yes
   □ No

148. Other reason
   □ Yes  Go to question 149
   □ No  Go to question 150

149. Specify reason: ____________________________________________________
150. Additional comments on donor suitability:

The statements and information contained in this data collection form are complete and correct to the best of my knowledge:

151. Signed: __________________________________________________________________________________

Person submitting form

Please print name: ____________________________________________________________________________

First and Last Name

Date: _______________________________________________________________________________________

Preferred method of contact: _________________________________________________________________

Phone number or e-mail address

To be completed by Medical Director

The statements and information contained in this data collection form are complete and correct to the best of my knowledge:

Apheresis Center Medical Director’s signature is required for all PBSC collections

152. Signature of Medical Director or appropriate designee:_______________________________________

Please print name: __________________________________________________________________________

First and Last Name

Date: ______________________________________________________________________________________

Collection Center Medical Director’s signature is required for all bone marrow donations

153. Signature of Medical Director or appropriate designee:________________________________________

Please print name: __________________________________________________________________________

First and Last Name

Date: ______________________________________________________________________________________

Donor Center Medical Director’s signature is required for all collections of any product type

154. Signature of Investigator (Donor Center Medical Director)/Physician Sub-Investigator:_________

Please print name: __________________________________________________________________________

First and Last Name

Date: ______________________________________________________________________________________