Form 2131 R3.0: Immune Deficiencies Post-HSCT Data

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Has this patient's data been previously reported to USIDNET?

yes no

USIDNET 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: _____

Laboratory Studies Post-HSCT

Questions: 1 - 43

1 Date of most recent hematologic testing: __ __ __ __ - __ __- __ __

2 WBC not tested

WBC: _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

3 Lymphocytes not tested

Lymphocytes: _____ %

4 Eosinophils not tested

Eosinophils: _____ %

5 Polymorphonuclear leukocytes (PMN) not tested

Polymorphonuclear leukocytes (PMN): _____ %

6 Hemoglobin not tested

Hemoglobin: _____ g/dL g/L mmol/L

transfused RBC < 30 days from date of most current testing

7 Platelets not tested

Platelets: _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

transfused platelets < 7 days from date of most current testing

Immunoglobulin Analysis

Specify the most recent quantitative immunoglobulins measured since the date of the last report.

For questions 8–13, also report immunoglobulins in the Form 2100 – 100 Days Post-HSCT Data beginning at question 55, or in the Form 2200 — Six Months to Two Years Post-HSCT Data beginning at question 26.

For questions 16–17, also report IVIG in the Form 2100 – 100 Days Post-HSCT Data beginning at question 61, or in the Form 2200 — Six Months to Two Years Post-HSCT Data beginning at question 32.

8 IgG not tested

IgG: _____ mg/dL g/dL g/L

9 Date tested: __ __ __ __ - __ __- __ __

10 IgM not tested

IgM: _____ mg/dL g/dL g/L

11 Date tested: __ __ __ __ - __ __- __ __

12 IgA not tested

IgA: _____ mg/dL g/dL g/L

13 Date tested: __ __ __ __ - __ __- __ __

14 IgE not tested

IgE: _____ IU/mL

15 Date tested: __ __ __ __ - __ __- __ __

16 Did the recipient receive supplemental intravenous immunoglobulins (IVIG) since the date of the last report?

yes no Unknown

17 Was therapy ongoing within one month of immunoglobulin testing?

yes no

Lymphocyte Analysis

Specify the most recent lymphocyte assessment measured since the date of the last report.

18 Were lymphocyte analyses performed?

yes no

19 Date of most recent testing performed: __ __ __ __ - __ __- __ __

20 Absolute lymphocyte count: _____ cells / ul (cells / mm^3)

21 CD3 not tested

CD3 (T cells) % of total lymphocytes _____ %

- or -

CD3 (T cells) value _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

22 CD4 (T helper cells) not tested

CD4 (T helper cells) % of total lymphocytes _____ %

- or -

CD4 (T helper cells) value _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

23 CD8 (cytotoxic T cells) not tested

CD8 (cytotoxic T cells) % of total lymphocytes _____ %

- or -

CD8 (cytotoxic T cells) value _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

24 CD20 (B lymphocyte cells) not tested

CD20 (B lymphocyte cells) % of total lymphocytes _____ %

- or -

CD20 (B lymphocyte cells) value _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

25 CD56 (natural killer (NK) cells) not tested

CD56 (natural killer (NK) cells) % of total lymphocytes _____ %

- or -

CD56 (natural killer (NK) cells) value _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

26 CD4+/CD45RA+ (memory T cells) not tested

CD4+/CD45RA+ (naive T cells) % of total lymphocytes _____ %

- or -

CD4+/CD45RA+ (naive T cells) value _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

27 CD4+/CD45RO+ (memory T cells) not tested

CD4+/CD45RO+ (memory T cells) % of total lymphocytes _____ %

- or -

CD4+/CD45RO+ (memory T cells) value _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Antibody Response

Specify the most recent antibody responses measured since the date of the last report.

28 Date antibody responses were assessed: __ __ __ __ - __ __- __ __

29 Bacteriophage phi X-174 or other neoantigen

Absent Low Normal Not Tested

30 Diptheria

Absent Low Normal Not Tested

31 Isohemagglutinin anti-A

Absent Low Normal Not Tested

32 Isohemagglutinin anti-B

Absent Low Normal Not Tested

33 Protein conjugated HIB or pneumococcal vaccine

Absent Low Normal Not Tested

34 Tetanus

Absent Low Normal Not Tested

35 Unconjugated pneumococcal polysaccharide: _____ / _____

Number of serotypes producing a protective level **/Total serotypes tested from vaccine**

36 Conjugated pneumococcal polysaccharide: _____ / _____

Number of serotypes producing a protective level **/Total serotypes tested from vaccine**

Lymphocyte Function

Specify the most recent lymphocyte function measured since the date of the last report.

37 Date lymphocyte function was assessed: __ __ __ __ - __ __- __ __

38 Anti-CD3

Absent

Low (10-30% of control)

Normal

Not tested

39 Candida antigen

Absent

Low (10-30% of control)

Normal

Not tested

40 Concavalin A (ConA)

Absent

Low (10-30% of control)

Normal

Not tested

41 Phytohemagglutinin (PHA)

Absent

Low (10-30% of control)

Normal

Not tested

42 Pokeweed mitogen (PWM)

- Absent
- Low (10-30% of control)
- Normal
- Not tested

43 Tetanus antigen

- Absent
- Low (10-30% of control)
- Normal
- Not tested

Clinical Features Assessed Post-HSCT

Questions: 44 - 94

Infections Identified Post-HSCT

Specify the presence of all clinically significant infections identified since the date of the last report. If any given infection was identified, use the Codes for Commonly Reported Organisms to report the organism present. Only report an organism once, even if it was identified at the same site in subsequent infections.

Also report infections in the Form 2100 – 100 Days Post-HSCT Data beginning at question 379, or in the Form 2200 — Six Months to Two Years Post-HSCT Data beginning at question 319.

44 Site of infection: hepatitis

yes no

Hepatitis-Organism (1)

Questions: 45 - 46

45 Organism: _____

46 Specify other organism: _____

47 If hepatitis was present, was it a prominent feature of ID? yes no

48 Meningitis / encephalitis

yes no

Meningitis/Encephalitis-Organism (1)

Questions: 49 - 50

49 Organism: _____

50 Specify other organism: _____

51 If meningitis / encephalitis was present, was it a prominent feature of ID?

yes no

52 Site of infection: pneumonia

yes no

Pneumonia-Organism (1)

Questions: 53 - 54

53 Organism: _____

54 Specify other organism: _____

55 If pneumonia was present, was it a prominent feature of ID?

yes no

56 Site of infection: severe or protracted diarrhea

yes no

Severe/protracted diarrhea-Organism (1)	Questions: 57 - 58

57 Organism: _____

58 Specify other organism: _____

59 If diarrhea was present, was it a prominent feature of ID?

yes no

60 Site of infection: systemic infection

yes no

Systemic infection-Organism (1)	Questions: 61 - 62

61 Organism: _____

62 Specify other organism: _____

63 If systemic infection was present, was it a prominent feature of ID?

yes no

64 Site of infection: other infection

yes no

Other infection-Organism (1)	Questions: 65 - 66

65 Organism: _____

66 Specify other organism: _____

67 Specify other infection site: _____

68 If other infection was present, was it a prominent feature of ID?

yes no

Clinical Status Post-HSCT

69 Did the recipient experience any of the following clinical features (since the date of the last report)?

yes no

Specify clinical features:

70 Autoimmune hemolytic anemia

yes no

71 Is autoimmune hemolytic anemia prominent?

yes no

72 Is failure to thrive (weight<5th percentile) present?

yes no

73 Is failure to thrive (weight<5th percentile) prominent?

yes no

74 Is acute graft versus host disease present?

yes no

75 Is acute graft versus host disease prominent?

yes no

76 Is chronic graft versus host disease present?

yes no

77 Is chronic graft versus host disease prominent?

yes no

78 Is growth hormone deficiency present?

yes no

79 Is growth hormone deficiency prominent?

yes no

80 Is growth retardation (height<5th percentile) present?

yes no

81 Is growth retardation (height<5th percentile) prominent?

yes no

82 Is lymphoproliferative disease present?

yes no

83 Is lymphoproliferative disease prominent?

yes no

84 Is thrombotic thrombocytopenic purpura present?

yes no

85 Is thrombotic thrombocytopenic purpura prominent?

yes no

86 Is Veno-occlusive disease (VOD) present?

yes no

87 Is Veno-occlusive disease (VOD) prominent?

yes no

88 Are warts present?

yes no

89 Are warts prominent?

yes no

90 Are other clinical features present?

yes no

91 Are other clinical features prominent?

yes no

92 Specify other clinical features: _____

93 Did the recipient receive parenteral nutrition (since the date of the last report)?

yes no

94 Did the recipient receive mechanical ventilation (since the date of the last report)?

yes no

Post-HSCT Treatment for Immune Deficiency

Questions: 95 - 166

95 Was treatment given (since the date of the report)?

yes no

Also report immunosuppressive medications given to prevent or treat GVHD in the corresponding questions on the Form 2000-Recipient Baseline Data, Form 2100-100 Days Post-HSCT Data, Form 2200-Six Month to Two Years Post-HSCT Data, or Form 2300-Yearly Follow-Up for Greater Than Two Years Post-HSCT Data.

Prophylactic drugs paused for < 1 week should not be considered as "Prophylactic Drug Stopped."

96 Were antifungal drug(s) given as prophylaxis?

yes no

97 Were prophylactic antifungal drug(s) stopped?

yes no

98 date estimated Date unknown

Date prophylactic antifungal drug(s) stopped: __ __ __ __ - __ __- __ __

99 Were antiviral drug(s) given as prophylaxis?

yes no

100 Were prophylactic antiviral drug(s) stopped?

yes no

101 date estimated Date unknown

Date prophylactic antiviral drug(s) stopped: __ __ __ __ - __ __- __ __

102 Was co-trimoxazole (Bactim, Septra) given as prophylaxis?

yes no

103 Were co-trimoxazole (Bactrim, Septra) stopped?

yes no

104 date estimated Date unknown

Date co-trimoxazole (Bactrim, Septra) stopped: __ __ __ __ - __ __- __ __

Therapy paused for < 1 week shoudl not be considered "Therapy Stopped."

105 Was antithymocyte globulin (ATG, ATGAM, Thymoglobulin) given as therapy?

yes no

106 Was antithymocyte globulin (ATG, ATGAM, Thymoglobulin) stopped?

yes no

107 date estimated Date unknown

Date antithymocyte globulin (ATG, ATGAM, Thymoglobulin) stopped: __ __ __ __ - __ __- __ __

108 Were systemic corticosteroids given as therapy?

yes no

109 Were therapeutic systemic corticosteroids stopped?

yes no

110 date estimated Date unknown

Date therapeutic systemic corticosteroids stopped: __ __ __ __ - __ __- __ __

111 Were topical corticosteroids given as therapy?

yes no

112 Were therapeutic topical corticosteroids stopped?

yes no

113 date estimated Date unknown

Date therapeutic topical corticosteroids stopped: __ __ __ __ - __ __- __ __

114 Was cyclophosphamide (CTX, Cytoxan, Neosar) given as therapy?

yes no

115 Was therapeutic cyclophosphamide (CTX, Cytoxan, Neosar) stopped?

yes no

116 date estimated Date unknown

Date therapeutic cyclophosphamide (CTX, Cytoxan, Neosar) stopped: __ __ __ __ - __ __- __ __

117 Was cyclosporine (CsA, Neoral, Sandimmune) given as therapy?

yes no

118 Was therapeutic cyclosporine (CsA, Neoral, Sandimmune) stopped?

yes no

119 date estimated Date unknown

Date therapeutic cyclosporine (CsA, Neoral, Sandimmune) stopped? __ __ __ __ - __ __- __ __

120 Was in vivo monoclonal antibody given as therapy?

yes no

Specify monoclonal antibody:

121 Was alemtuzumab (Campath) given as therapy?

yes no

122 Was therapeutic alemtuzumab (Campath) stopped?

yes no

123 date estimated Date unknown

Date therapeutic alemtuzumab (Campath) stopped: __ __ __ __ - __ __- __ __

124 Was daclizumab (anti-CD25, Zenapax) given as therapy?

yes no

125 Was therapeutic daclizumab (anti-CD25, Zenapax) stopped?

yes no

126 date estimated Date unknown

Date therapeutic daclizumab (anti-CD25, Zenapax) stopped: __ __ __ __ - __ __- __ __

127 Was etanercept (Enbrel) given as therapy?

yes no

128 Was therapeutic etanercept (Enbrel) stopped?

yes no

129 date estimated Date unknown

Date therapeutic etanercept (Enbrel) stopped: __ __ __ __ - __ __- __ __

130 Was infliximab (anti-TNF-α, Remicade) given as therapy?

yes no

131 Was therapeutic infliximab (anti-TNF-α, Remicade) stopped?

yes no

132 date estimated Date unknown

Date therapeutic infliximab (anti-TNF-α, Remicade) stopped: __ __ __ __ - __ __- __ __

133 Was muromonab (anti-CD3, OKT3) given as therapy?

yes no

134 Was therapeutic muromonab (anti-CD3, OKT3) stopped?

yes no

135 date estimated Date unknown

Date therapeutic muromonab (anti-CD3, OKT3) stopped: __ __ __ __ - __ __- __ __

136 Was rituximab (anti-CD20, Rituxan, Mab Thera) given as therapy?

yes no

137 Was therapeutic rituximab (anti-CD20, Rituxan, Mab Thera) stopped?

yes no

138 date estimated Date unknown

Date therapeutic rituximab (anti-CD20, Rituxan, Mab Thera) stopped: __ __ __ __ - __ __- __ __

139 Was any other monoclonal antibody given as therapy?

yes no

140 Was therapeutic other monoclonal antibody stopped?

yes no

141 date estimated Date unknown

Date therapeutic other monoclonal antibody stopped: __ __ __ __ - __ __- __ __

142 Specify other monoclonal antibody: _____

143 Was lenalidomide (Revlimid) given as therapy?

yes no

144 Was therapeutic lenalidomide (Revlimid) stopped?

yes no

145 date estimated Date unknown

Date therapeutic lenalidomide (Revlimid) stopped: __ __ __ __ - __ __- __ __

146 Was mycophenolate mofetil (MMF, Cellcept) given as therapy?

yes no

147 Was therapeutic mycophenolate mofetil (MMF, Cellcept) stopped?

yes no

148 ☐ date estimated ☐ Date unknown

Date therapeutic mycophenolate mofetil (MMF, Cellcept) stopped: __ __ __ __ - __ __- __ __

149 Was photopheresis / extracorporeal phototherapy (ECP)given as therapy?

☐ yes ☐ no

150 Was therapeutic photopheresis / extracorporeal phototherapy (ECP) stopped?

☐ yes ☐ no

151 ☐ date estimated ☐ Date unknown

Date therapeutic photopheresis / extracorporeal phototherapy (ECP) stopped: __ __ __ __ - __ __- __ __

152 Was sirolimus (Rapamune) given as therapy?

☐ yes ☐ no

153 Was therapeutic sirolimus (Rapamune) stopped?

☐ yes ☐ no

154 ☐ date estimated ☐ Date unknown

Date therapeutic sirolimus (Rapamune) stopped: __ __ __ __ - __ __- __ __

155 Was tacrolimus (FK506, Prograf) given as therapy?

☐ yes ☐ no

156 Was therapeutic tacrolimus (FK506, Prograf) stopped?

☐ yes ☐ no

157 ☐ date estimated ☐ Date unknown

Date therapeutic tacrolimus (FK506, Prograf) stopped: __ __ __ __ - __ __- __ __

158 Was thalidomide (Thalomid) given as therapy?

☐ yes ☐ no

159 Was therapeutic thalidomide (Thalomid)stopped?

☐ yes ☐ no

160 ☐ date estimated ☐ Date unknown

Date therapeutic thalidomide (Thalomid)stopped: __ __ __ __ - __ __- __ __

161 Was any other immunosuppressive drug given as therapy?

☐ yes ☐ no

162 Was the other therapeutic immunosuppressive drug stopped?

☐ yes ☐ no

163 ☐ date estimated ☐ Date unknown

Date other therapeutic immunosuppressive drug stopped: __ __ __ __ - __ __- __ __

164 Specify other immunosuppressive drug: _____

165 Did the recipient receive any other significant treatment(s) for ID (since the date of the last report)?

☐ yes ☐ no

166 Specify other treatment(s): _____

Form 2131 R3.0: Immune Deficiencies Post-HSCT Data

Center: CRID:

Status of Hematologic Engraftment

Questions: 167 - 172

This section refers to quantitative analyses utilizing discriminating DNA markers. Peripheral blood cells must undergo seperation or sorting into T, B, or lymphoid vs. myeloid populations to perform this determination. If RFLP analyses indicate only donor type hemotopoiesis, mark T-cell, B-cell, and myeloid as "predominantly or completely donor."

Also, report chimerism in the Form 2100-100 Days Post-HSCT Data beginning at question 77 or Form 2200-Six Months to Two Years Post-HSCT Data beginning at question 48.

167 What is the current status of T-cell engraftment?

- predominantly or completely donor (>= 80% donor chimerism)
- Mixed chimerism
- only host T-cells detected (< 5% donor)
- Unknown

168 Most recent date T-cell engraftment was assessed: __ __ __ __ - __ __- __ __ Date of most recent T-cell engraftment assessment unknown

169 What is the current status of B-cell engraftment?

- predominantly or completely donor (>= 80% donor chimerism)
- Mixed chimerism
- only host B-cells detected (< 5% donor)
- Unknown

170 Most recent date B-cell engraftment was assessed: __ __ __ __ - __ __- __ __ Date of most recent B-cell engraftment assessment unknown?

171 What is the current status of myeloid engraftment?

- predominantly or completely donor (>= 80% donor chimerism)
- Mixed chimerism
- only host myeloid cells detected (< 5% donor)
- Unknown

172 Most recent date myeloid engraftment was assessed: __ __ __ __ - __ __- __ __ Date of most recent myeloid engraftment assessment unknown

First Name: _____ Last Name: _____

Phone number: _____ Fax number: _____

E-mail address: _____