



# Post-Infusion Follow-Up

## Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number: \_\_\_\_\_

CIBMTR Research ID: \_\_\_\_\_

Event date: \_\_\_\_\_  
                    YYYY                    MM                    DD

Visit:

- 100 day
- 6 months
- 1 year
- 2 years
- > 2 years, Specify: \_\_\_\_\_

Report all findings SINCE DATE OF LAST REPORT unless otherwise specified.

### Vital Status

Information should come from an actual examination by the Transplant Center provider or the local provider who is following the recipient post-infusion.

1. Date of actual contact with the recipient to determine medical status for this follow-up report:

\_\_\_\_-\_\_\_\_-\_\_\_\_  
YYYY MM DD

2. Specify the recipient's survival status at the date of last contact

- Alive – Answers to subsequent questions should reflect clinical status.  
 Dead – Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. Complete the Recipient Death Data Form 2900.

3. Did the recipient receive a subsequent infusion?

- Yes – Also complete Indication for CIBMTR Data Reporting Form 2814  
 No

### Granulopoiesis / Neutrophil Recovery

To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.

4. Was there evidence of initial hematopoietic recovery?

- Yes (*ANC  $\geq$  500/mm<sup>3</sup> achieved and sustained for 3 lab values*) – Go to question 5  
 No (*ANC  $\geq$  500/mm<sup>3</sup> was not achieved*) – Go to question 11  
 Not applicable (*ANC never dropped below 500/mm<sup>3</sup> at any time after the start of the preparative regimen*) – Go to question 11  
 Previously reported (*recipient's initial hematopoietic recovery was recorded on a previous report*) – Go to question 11

5. Date ANC  $\geq$  500/mm<sup>3</sup>: (*first of 3 lab values*) \_\_\_\_\_  
YYYY MM DD

6. Following the initial hematopoietic recovery, was there subsequent decline in ANC to  $<$  500/mm<sup>3</sup> for  $\geq$  3 days?

- Yes – Go to question 7  
 No – Go to question 11

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7. Date of decline in ANC to  $< 500/\text{mm}^3$  for  $\geq 3$  days: *(first of 3 days that the ANC declined)*

\_\_\_\_-\_\_\_\_-\_\_\_\_  
YYYY MM DD

8. Did recipient recover and maintain ANC  $\geq 500/\text{mm}^3$  following the decline?

- Yes – **Go to questions 9**
- No – **Go to question 11**

9. Date of ANC recovery

- Known – **Go to questions 10**
- Unknown – **Go to question 11**

10. Date of ANC recovery: \_\_\_\_\_  
YYYY MM DD

### Megakaryopoiesis / Platelet Recovery

**This section relates to initial platelet recovery. All dates should reflect no transfusions in the previous 7 days. To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.**

11. Was an initial platelet count  $\geq 20 \times 10^9/\text{L}$  achieved?

- Yes – **Go to question 12**
- No – **Go to question 15**
- Not applicable *(platelet count never dropped below  $20 \times 10^9/\text{L}$ )* – **Go to questions 13**
- Previously reported *( $\geq 20 \times 10^9/\text{L}$  was achieved and reported previously)* – **Go to question 13**

12. Date platelets  $\geq 20 \times 10^9/\text{L}$ : \_\_\_\_\_  Date estimated  
YYYY MM DD

13. Was an initial platelet count  $\geq 50 \times 10^9/\text{L}$  achieved?

- Yes – **Go to question 14**
- No – **Go to questions 15**
- Not applicable *(platelet count never dropped below  $50 \times 10^9/\text{L}$ )* – **Go to questions 15**
- Previously reported *( $\geq 50 \times 10^9/\text{L}$  was achieved and reported previously)* – **Go to question 15**

14. Date platelets  $\geq 50 \times 10^9/\text{L}$ : \_\_\_\_\_  Date estimated  
YYYY MM DD









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(cells/ $\mu$ L)

x  $10^6$ /L (x 1/ $\text{mm}^3$ ) (x 1/ $\mu$ L)

### Gene Therapy Persistence Testing

50. Were tests performed to detect persistence of the gene therapy product infusion?
- Yes – **Also complete Gene Therapy Persistence Form 2103**
  - No

### Chimerism Studies

**This section relates to chimerism studies from allogeneic infusions only. If this was an autologous infusion, continue with the Infection section.**

51. Were chimerism studies performed? (**Allogeneic infusions only**)
- Yes – **Also complete Chimerism Essential Data Form 2451 (for forms completed after July 25,2025)**
  - No

### Engraftment Syndrome

52. Did engraftment syndrome occur?
- Yes – **Go to question 53**
  - No – **Go to question 63**

53. Date of engraftment syndrome onset: \_\_\_\_\_

YYYY                      MM                      DD

54. Specify the symptoms of engraftment syndrome (*check all that apply*)
- Development of hepatic dysfunction (*with either bilirubin  $\geq$  2 mg/dL or transaminase levels  $\geq$  2 times normal*) – **Go to question 56**
  - Development of renal insufficiency (*serum creatinine  $\geq$  2 times baseline*) – **Go to question 56**
  - Diarrhea – **Go to question 56**
  - Erythrodermic rash (*involving > 25% of body surface area*) – **Go to question 56**
  - Fever ( *$\geq$  38.3° C or > 100.9° F with no identifiable infectious etiology*) – **Go to question 56**
  - Non-cardiogenic pulmonary edema (*manifested by diffuse pulmonary infiltrates and hypoxia*) – **Go to question 56**
  - Transient encephalopathy – **Go to question 56**
  - Weight gain ( *$\geq$  2.5% of baseline body weight*) – **Go to question 56**
  - Other symptom – **Go to question 55**

55. Specify other symptom: \_\_\_\_\_

56. Was a biopsy performed?

- Yes – **Go to question 57**
- No – **Go to question 60**

57. Specify sites *(check all that apply)*

- Lower gastrointestinal (GI) – **Go to question 59**
- Skin – **Go to question 59**
- Other site – **Go to question 58**

58. Specify other site: \_\_\_\_\_

59. Was documentation submitted to the CIBMTR? *(pathology report) (CIBMTR recommends attaching the pathology report)*

- Yes
- No

60. Specify therapy given for engraftment syndrome *(check all that apply)*

- Corticosteroids *(systemic)* – **Go to question 62**
- Tocilizumab (Actemra) – **Go to question 62**
- Other therapy – **Go to question 61**
- None – **Go to question 62**

61. Specify other therapy: \_\_\_\_\_

62. Did engraftment syndrome resolve?

- Yes
- No

### Acute Graft vs. Host Disease (GVHD)

**If an allogeneic donor was used for the recipient's infusion, report all acute graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue with the Infection section.**

63. Select specific therapy used after the start of the preparative regimen to prevent acute GVHD *(check all that apply) (Note: do not include growth factors reported in questions 15-23, or ex vivo T-cell depletion reported on the Product Insert. Do not include drugs given as part of the preparative regimen)*

- Abatacept (Orencia) – **Go to question 72**

- Alemtuzumab (Campath) – **Go to question 64**
- ALG, ALS, ATG, ATS – **Go to question 65**
- Blinded randomized trial – **Go to question 68**
- Corticosteroids (systemic) (*e.g. prednisone, dexamethasone*) – **Go to question 72**
- Cyclophosphamide (Cytoxan) – **Go to question 69**
- Cyclosporine (CSA, Neoral, Sandimmune) – **Go to question 72**
- Methotrexate (MTX) (Amethopterin) – **Go to question 72**
- Mycophenolate mofetil (MMF) (CellCept, Myfortic) – **Go to question 72**
- Sirolimus (Rapamycin, Rapamune) – **Go to question 72**
- Tacrolimus (Prograf) – **Go to question 72**
- Other in vivo monoclonal antibody – **Go to question 70**
- Other agent – **Go to question 71**
- None – **Go to question 72**

64. Alemtuzumab (Campath) total dose: \_\_\_\_\_ mg

65. ALG, ALS, ATG, ATS total dose: \_\_\_\_\_ mg

66. Specify ALG, ALS, ATG, ATS source

- ATGAM (horse) – **Go to question 68**
- ATG – Fresenius (rabbit) – **Go to question 68**
- Thymoglobulin (rabbit) – **Go to question 68**
- Other – **Go to question 67**

67. Specify other source: \_\_\_\_\_

68. Specify blinded randomized trial agent: \_\_\_\_\_

69. Cyclophosphamide (Cytoxan) total dose: \_\_\_\_\_ mg

70. Specify other in vivo monoclonal antibody: \_\_\_\_\_

71. Specify other agent: \_\_\_\_\_

72. Did acute GVHD develop?

- Yes – **Go to question 73**
- No – **Go to question 74**
- Unknown – **Go to question 74**



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- Negative
- Inconclusive / equivocal
- Not done

80. Other site

- Positive– **Go to question 81**
- Suggestive – **Go to question 81**
- Negative – **Go to question 81**
- Inconclusive / equivocal – **Go to question 81**
- Not done – **Go to question 82**

81. Specify other site: \_\_\_\_\_

82. Was documentation submitted to the CIBMTR? (*e.g. pathology report*) (*CIBMTR recommends attaching the pathology report*)

- Yes
- No

83. Overall grade of acute GVHD at diagnosis

- I - *Rash on ≤ 50% of skin, no liver or gut involvement*
- II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting*
- III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus*
- IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL, and/or grossly bloody stool*
- Not applicable (*acute GVHD present but cannot be graded*)

**List the stage for each organ at diagnosis of acute GVHD**

84. Skin

- Stage 0 – *No rash, or no rash attributable to acute GVHD*
- Stage 1 – *Maculopapular rash, < 25% of body surface*
- Stage 2 – *Maculopapular rash, 25–50% of body surface*
- Stage 3 – *Generalized erythroderma, > 50% of body surface*
- Stage 4 – *Generalized erythroderma with bullae formation and/or desquamation*

85. Lower intestinal tract (*use mL/day for adult recipients and mL/kg/day for pediatric recipients*)

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- Stage 0 – *No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*
- Stage 1 – *Diarrhea 500 - 1000 mL/day (adult), or 10 – 19.9 mL/kg/day (pediatric)*
- Stage 2 – *Diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*
- Stage 3 – *Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*
- Stage 4 – *Severe abdominal pain, with or without ileus, and / or grossly bloody stool*

86. Upper intestinal tract

- Stage 0 – *No persistent nausea or vomiting*
- Stage 1 – *Persistent nausea or vomiting*

87. Liver

- Stage 0 – *No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)*
- Stage 1 – *Bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)*
- Stage 2 – *Bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)*
- Stage 3 – *Bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)*
- Stage 4 – *Bilirubin > 15.0 mg/dL (> 256 µmol/L)*

88. Other site(s) involved with acute GVHD

- Yes – **Go to question 89**
- No – **Go to question 90**

89. Specify other site(s): \_\_\_\_\_

### List the maximum severity of organ involvement

90. Maximum overall grade of acute GVHD

- I - *Rash on ≤ 50% of skin, no liver or gut involvement* – **Go to question 91**
- II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting* – **Go to question 91**
- III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus* – **Go to question 91**
- IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL, and / or grossly bloody stool* – **Go to question 91**
- Not applicable (*acute GVHD present but cannot be graded*) – **Go to question 92**

91. First date of maximum overall grade of acute GVHD: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

YYYY MM DD

**Specify organ involvement at time of maximum grade**

92. Skin

- Stage 0 – *No rash, or no rash attributable to acute GVHD*
- Stage 1 – *Maculopapular rash, < 25% of body surface*
- Stage 2 – *Maculopapular rash, 25–50% of body surface*
- Stage 3 – *Generalized erythroderma, > 50% of body surface*
- Stage 4 – *Generalized erythroderma with bullae formation and / or desquamation*

93. Lower intestinal tract (*use mL/day for adult recipients and mL/kg/day for pediatric recipients*)

- Stage 0 – *No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*
- Stage 1 – *Diarrhea 500 - 1000 mL/day (adult), or 10 – 19.9 mL/kg/day (pediatric)*
- Stage 2 – *Diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*
- Stage 3 – *Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*
- Stage 4 – *Severe abdominal pain, with or without ileus, and / or grossly bloody stool*

94. Upper intestinal tract

- Stage 0 – *No persistent nausea or vomiting*
- Stage 1 – *Persistent nausea or vomiting*

95. Liver

- Stage 0 – *No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)*
- Stage 1 – *Bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)*
- Stage 2 – *Bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)*
- Stage 3 – *Bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)*
- Stage 4 – *Bilirubin > 15.0 mg/dL (> 256 µmol/L)*

96. Other site(s) involved with acute GVHD

- Yes – **Go to question 97**
- No – **Go to question 98**

97. Specify other site(s): \_\_\_\_\_

**Specify treatment given for acute GVHD (include prophylactic agents continued after aGVHD diagnosis)**

98. Corticosteroids (*topical GI*) (*check all that apply*)

- Beclomethasone

- Budesonide
- None

**Copy and complete questions 99 – 111 to report each systemic treatment given.**

99. Select systemic treatment used to treat acute GVHD
- Alemtuzumab (Campath) – **Go to question 100**
  - ALG, ALS, ATG, ATS – **Go to question 100**
  - Alpha-1 antitrypsin (AAT) – **Go to question 100**
  - Anti CD25 (Zenapax, Daclizumab, AntiTAC) – **Go to question 100**
  - Blinded randomized trial – **Go to question 100**
  - Corticosteroids (systemic) (e.g. prednisone, dexamethasone) – **Go to question 100**
  - Cyclosporine (CSA, Neoral, Sandimmune) – **Go to question 100**
  - Etanercept (Enbrel) – **Go to question 100**
  - Extra-corporeal photopheresis (ECP) – **Go to question 100**
  - Infliximab (Remicade) – **Go to question 100**
  - In vivo immunotoxin – **Go to question 100**
  - Mycophenolate mofetil (MMF) (CellCept, Myfortic) – **Go to question 100**
  - Pentostatin (Nipent) – **Go to question 100**
  - PUVA (Psoralen and UVA) – **Go to question 100**
  - Ruxolitinib (Jakafi) – **Go to question 100**
  - Sirolimus (Rapamycin, Rapamune) – **Go to question 100**
  - Tacrolimus (Prograf) – **Go to question 100**
  - Tocilizumab (Actemra) – **Go to question 100**
  - Other in vivo monoclonal antibody – **Go to question 100**
  - Other JAK2 inhibitor – **Go to question 100**
  - Other agent – **Go to question 100**
  - None – **Go to question 112**
100. Specify if the treatment was continued from prophylaxis
- Yes – **Go to question 102**
  - No – **Go to question 101**
  - Previously reported – **Go to question 102**

101. Date treatment started: \_\_\_\_\_

YYYY                      MM                      DD



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- Yes – **Go to question 163**
- No – **Go to question 182**
- Unknown – **Go to question 182**

115. Onset of chronic GVHD was

- Progressive (*acute GVHD present within 2 weeks prior to onset of chronic GVHD*)
- Interrupted (*acute GVHD resolved, then chronic GVHD developed*)
- De novo (*acute GVHD never developed*)

116. Were signs of acute GVHD present at the time of chronic GVHD diagnosis (overlap syndrome)?

- Yes
- No

117. What scale was used to determine the recipient's functional status? (*at time of chronic GVHD diagnosis*)

- Karnofsky (*recipient age  $\geq$  16 years*) – **Go to question 118**
- Lansky (*recipient age  $\geq$  1 year and  $<$  16 years*) – **Go to question 119**

#### Performance score

118. Karnofsky scale (*recipient age  $\geq$  16 years*) – **Go to question 120**

- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity
- 80 Normal activity with effort
- 70 Cares for self; unable to carry on normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care
- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly

119. Lansky scale (*recipient age  $\geq$  1 year and  $<$  16 years*) - **Go to question 120**

- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play, tires more easily, otherwise active
- 70 Both greater restrictions of, and less time spent in, active play
- 60 Ambulatory up to 50% of time, limited active play with assistance / supervision

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- 50 Considerable assistance required for any active play; fully able to engage in quiet play
- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (e.g., TV)
- 10 Completely disabled, not even passive play

120. Platelets: (*at diagnosis of chronic GVHD*) \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L (x 1/mm<sup>3</sup>) (x 1/μL) (cells/μL)

121. Total serum bilirubin: (*at diagnosis of chronic GVHD*) \_\_\_\_\_ . \_\_\_\_\_  mg/dL  
 μmol/L

122. Was chronic GVHD evaluated by biopsy (histology)? (*at diagnosis*)

- Yes – **Go to question 123**
- No – **Go to question 130**

**Specify result(s)**

123. Skin

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

124. Lower gastrointestinal (GI)

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

125. Upper gastrointestinal (GI)

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal

- Not done

126. Liver

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

127. Lung

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

128. Other site

- Positive – **Go to question 129**
- Suggestive – **Go to question 129**
- Negative – **Go to question 129**
- Inconclusive / equivocal – **Go to question 129**
- Not done – **Go to question 130**

129. Specify other site: \_\_\_\_\_

130. Specify organs involved at diagnosis of chronic GHVD (*check all that apply*)

- Skin – **Go to question 131**
- Mouth – **Go to question 136**
- Eyes – **Go to question 140**
- Gastrointestinal (GI) Tract – **Go to question 144**
- Liver – **Go to question 148**
- Lungs – **Go to question 151**
- Joints and fascia – **Go to question 156**
- Genital tract – **Go to question 159**

**Skin**

131. NIH score percent BSA involved

- Score 0 – *No BSA involved, no sclerotic features*
- Score 1 – *1-18% BSA*
- Score 2 – *19-50% BSA, or superficial sclerotic features “not hidebound” (able to pinch)*
- Score 3 – *>50% BSA, deep sclerotic features, hidebound, impaired mobility, or ulceration*

132. Skin features score

- No sclerotic features
- Superficial sclerotic features “not hidebound” (able to pinch)
- Deep sclerotic features, hidebound (unable to pinch), impaired mobility, or ulceration

133. Specify skin GVHD features present at diagnosis of chronic GVHD (*check all that apply*)

- Maculopapular rash / erythema
- Lichen planus-like features
- Papulosquamous lesions or ichthyosis
- Keratosis pilaris-like GVHD
- None

**Specify if any skin abnormalities were present, but explained entirely by non-GVHD causes**

134. Abnormality present but explained entirely by non-GVHD documented cause

- Yes – **Go to question 135**
- No – **Go to question 136**

135. Specify cause: \_\_\_\_\_

**Mouth**

136. NIH mouth score

- Score 0 – *No symptoms*
- Score 1 – *Mild symptoms with disease signs but not limiting oral intake significantly*
- Score 2 – *Moderate symptoms with disease signs with partial limitation of oral intake*
- Score 3 – *Severe symptoms with disease signs on examination with major limitation of oral intake*

137. Lichen planus-like features

- Yes

- No

**Specify if any mouth abnormalities were present, but explained entirely by non-GVHD causes**

138. Abnormality present but explained entirely by non-GVHD documented cause

- Yes – **Go to question 139**
- No – **Go to question 140**

139. Specify cause: \_\_\_\_\_

**Eyes**

140. NIH eyes score

- Score 0 – *No symptoms*
- Score 1 – *Mild dry eye symptoms not affecting ADL (requirement of lubricant eye drops ≤ 3x per day)*
- Score 2 – *Moderate dry eye symptoms partially affecting ADL (requiring lubricant eye drops > 3x per day or punctal plugs), without new vision impairment due to keratoconjunctivitis sicca (KCS)*
- Score 3 – *Severe dry eye symptoms significantly affecting ADL (special eyewear to relieve pain) OR unable to work because of ocular symptoms OR loss of vision due to keratoconjunctivitis sicca (KCS)*

141. Keratoconjunctivitis sicca (KCS) confirmed by ophthalmologist?

- Yes
- No
- Not done

**Specify if any eye abnormalities were present, but explained entirely by non-GVHD causes**

142. Abnormality present but explained entirely by non-GVHD documented cause

- Yes – **Go to question 143**
- No – **Go to question 144**

143. Specify cause: \_\_\_\_\_

**Gastrointestinal (GI) Tract**

144. NIH gastrointestinal (GI) tract score

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- Score 0 – *No symptoms*
- Score 1 – *Symptoms without significant weight loss (< 5%)*
- Score 2 – *Symptoms associated with mild to moderate weight loss (5-15%) OR moderate diarrhea without significant interference with daily living*
- Score 3 – *Symptoms associated with significant weight loss (> 15%), requires nutritional supplementation for most calorie needs OR esophageal dilation OR severe diarrhea with significant interference with daily living*

**Specify if any GI abnormalities were present, but explained entirely by non-GVHD causes**

145. Abnormality present but explained entirely by non-GVHD documented cause

- Yes – **Go to question 146**
- No – **Go to question 147**

146. Specify cause: \_\_\_\_\_

147. Specify Gastrointestinal (GI) tract GVHD features present at diagnosis of chronic GVHD (*check all that apply*)

- Esophageal web / proximal stricture or ring
- Dysphagia
- Anorexia
- Nausea
- Vomiting
- Diarrhea
- Weight loss  $\geq 5\%$
- Failure to thrive
- None

**Liver**

148. NIH liver score

- Score 0 – *Normal total bilirubin and ALT or AP <3 x ULN*
- Score 1 – *Normal total bilirubin with ALT  $\geq 3$  to 5 x ULN or AP  $\geq 3$  x ULN*
- Score 2 – *Elevated total bilirubin but  $\leq 3$  mg/dL or ALT >5 ULN*
- Score 3 – *Elevated total bilirubin > 3 mg/dL*

**Specify if any liver abnormalities were present, but explained entirely by non-GVHD causes**

149. Abnormality present but explained entirely by non-GVHD documented cause

- Yes – **Go to question 150**
- No – **Go to question 151**

150. Specify cause: \_\_\_\_\_

### Lungs

151. NIH lung score
- Score 0 – *No symptoms*
  - Score 1 – *Mild symptoms (shortness of breath after climbing one flight of steps)*
  - Score 2 – *Moderate symptoms (shortness of breath after walking on flat ground)*
  - Score 3 – *Severe symptoms (shortness of breath at rest; requiring oxygen)*
152. Were pulmonary function tests performed?
- Yes – **Go to question 153**
  - No – **Go to question 154**
153. Specify FEV1 percent: \_\_\_\_\_ %

### Specify if any lung abnormalities were present, but explained entirely by non-GVHD causes

154. Abnormality present but explained entirely by non-GVHD documented cause
- Yes – **Go to question 155**
  - No – **Go to question 156**
155. Specify cause: \_\_\_\_\_

### Joints and fascia

156. NIH joints and fascia score
- Score 0 – *No symptoms*
  - Score 1 – *Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL*
  - Score 2 – *Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis, moderate decrease ROM AND mild to moderate limitation of ADL*
  - Score 3 – *Contractures WITH significant decrease ROM AND significant limitation of ADL (e.g. unable to tie shoes, button shirts, dress self, etc.)*

**Specify if any joint or fascia abnormalities were present, but explained entirely by non-GVHD causes**

157. Abnormality present but explained entirely by non-GVHD documented cause
- Yes – **Go to question 158**
  - No – **Go to question 159**

158. Specify cause: \_\_\_\_\_

**Genital tract**

159. NIH genital tract score
- Score 0 – *No signs*
  - Score 1 – *Mild signs and females with or without discomfort on exam*
  - Score 2 – *Moderate signs and may have symptoms with discomfort on exam*
  - Score 3 – *Severe signs with or without symptoms*
160. Currently sexually active?
- Yes
  - No
  - Unknown

**Specify if any genital tract abnormalities were present, but explained entirely by non-GVHD causes**

161. Abnormality present but explained entirely by non-GVHD documented cause
- Yes – **Go to question 162**
  - No – **Go to question 163**

162. Specify cause: \_\_\_\_\_

**Maximum grade of chronic GVHD**

163. Maximum grade of chronic GVHD (*according to best clinical judgment*)
- Mild – **Go to question 164**
  - Moderate – **Go to question 164**
  - Severe – **Go to question 164**
  - Unknown – **Go to question 165**



**Copy and complete questions 169 – 181 to report each systemic treatment given.**

169. Select systemic treatment used to treat chronic GVHD
- Anti-IL2 – **Go to question 170**
  - Anti-IL6 – **Go to question 170**
  - Aldesleukin (interleukin-2, IL-2) – **Go to question 170**
  - Alemtuzumab (Campath) – **Go to question 170**
  - ALG, ALS, ATG, ATS – **Go to question 170**
  - Anti CD25 (Zenapax, Daclizumab, Anti-TAC) – **Go to question 170**
  - Azathioprine – **Go to question 170**
  - Azithromycin – **Go to question 170**
  - Belumosudil (Rezurock) – **Go to question 170**
  - Blinded randomized trial – **Go to question 170**
  - Bortezomib (Velcade) – **Go to question 170**
  - Corticosteroids (systemic) (e.g. prednisone, dexamethasone) – **Go to question 170**
  - Cyclosporine (CSA, Neoral, Sandimmune) – **Go to question 170**
  - Etanercept (Enbrel) – **Go to question 170**
  - Extra-corporeal photopheresis (ECP) – **Go to question 170**
  - Hydroxychloroquine (Plaquenil) – **Go to question 170**
  - Ibrutinib – **Go to question 170**
  - Imatinib mesylate (Gleevec) – **Go to question 170**
  - Infliximab (Remicade) – **Go to question 170**
  - Mesenchymal stem cells (MSCs) – **Go to question 170**
  - Methotrexate (MTX) (Amethopterin) – **Go to question 170**
  - Montelukast – **Go to question 170**
  - Mycophenolate mofetil (MMF) (CellCept, Myfortic) – **Go to question 170**
  - Pentostatin (Nipent) – **Go to question 170**
  - PUVA (Psoralen and UVA) – **Go to question 170**
  - Rituximab (Rituxan, MabThera) – **Go to question 170**
  - Ruxolitinib (Jakafi) – **Go to question 170**
  - Sirolimus (Rapamycin, Rapamune) – **Go to question 170**
  - Tacrolimus (Prograf) – **Go to question 170**
  - UVB – **Go to question 170**
  - Other interleukin inhibitor – **Go to question 170**
  - Other JAK 2 inhibitor – **Go to question 170**









## Infection

205. Did the recipient develop a clinically significant infection?

- Yes – **Go to question 206**
- No – **Go to question 214**

**Report each infection organism, site, and date of diagnosis.**

**Copy and complete questions 206 – 213 to report more than one infection.**

206. Organism

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> Achromobacter xylosoxidans                                  | <input type="checkbox"/> Neisseria meningitidis   | <input type="checkbox"/> Astrovirus   |
| <input type="checkbox"/> Acinetobacter (all species)                                 | <input type="checkbox"/> Nocardia (all species)   | <input type="checkbox"/> BK Virus   |
| <input type="checkbox"/> Actinomyces (all species)                                   | <input type="checkbox"/> Pasteurella multocida  | <input type="checkbox"/> Chikungunya Virus  |
| <input type="checkbox"/> Bacillus cereus   | <input type="checkbox"/> Proteus (all species)  | <input type="checkbox"/> Coronavirus (excluding COVID-19 (SARS-CoV-2))  |
| <input type="checkbox"/> Bacteroides fragilis  | <input type="checkbox"/> Pseudomonas aeruginosa   | <input type="checkbox"/> COVID-19 (SARS-CoV-2)  |
| <input type="checkbox"/> Bordetella pertussis (whooping cough)                       | <input type="checkbox"/> Pseudomonas non-aeruginosa   | <input type="checkbox"/> Cytomegalovirus (CMV)  |
| <input type="checkbox"/> Burkholderia cepacia  | <input type="checkbox"/> Rhodococcus (all species)  | <input type="checkbox"/> Dengue Virus   |
| <input type="checkbox"/> Campylobacter (all species)                                 | <input type="checkbox"/> Rickettsia (all species)   | <input type="checkbox"/> Enterovirus D68 (EV-D68)   |
| <input type="checkbox"/> Capnocytophaga (all species)                                | <input type="checkbox"/> Rothia (all species)   | <input type="checkbox"/> Enterovirus except polioviruses and D68 (including echoviruses and coxsackieviruses) |
| <input type="checkbox"/> Chlamydia pneumoniae  | <input type="checkbox"/> Salmonella (all species)   | <input type="checkbox"/>  |
| <input type="checkbox"/> Citrobacter (all species including freundii)                | <input type="checkbox"/> Serratia marcescens  | <input type="checkbox"/> Epstein-Barr Virus (EBV)   |
| <input type="checkbox"/> Clostridioides difficile (previously Clostridium difficile) | <input type="checkbox"/> Shigella (all species)   | <input type="checkbox"/> Hepatitis A Virus  |
| <input type="checkbox"/> Clostridium (all species except difficile)                  | <input type="checkbox"/> Staphylococcus aureus (Methicillin Resistant)  | <input type="checkbox"/> Hepatitis B Virus  |
| <input type="checkbox"/> Corynebacterium jeikeium                                    | <input type="checkbox"/> Staphylococcus aureus (Methicillin Sensitive)  | <input type="checkbox"/> Hepatitis C Virus  |
| <input type="checkbox"/> Cutibacterium acnes (previously, Propionibacterium acnes)   | <input type="checkbox"/> Staphylococcus epidermidis   | <input type="checkbox"/> Hepatitis E Virus  |
| <input type="checkbox"/> Enterobacter (all species)                                  | <input type="checkbox"/> Staphylococcus coagulase negative (excluding Staphylococcus epidermidis)                         | <input type="checkbox"/> Herpes Simplex Virus (HSV)   |
| <input type="checkbox"/> Enterococcus, vancomycin resistant (VRE)                    | <input type="checkbox"/> Stenotrophomonas maltophilia   | <input type="checkbox"/> Human herpesvirus 6 (HHV-6)  |
| <input type="checkbox"/> Enterococcus (all species)                                  | <input type="checkbox"/> Stomatococcus mucilaginosus  | <input type="checkbox"/> Human Immunodeficiency Virus 1 or 2  |
| <input type="checkbox"/> Escherichia (also E. coli)                                  | <input type="checkbox"/> Streptococci, viridans group (all species including mitis, anginosus, mutans, salivarius, bovis) | <input type="checkbox"/> Human metapneumovirus  |
| <input type="checkbox"/> Fusobacterium (all species)                                 | <input type="checkbox"/> Streptococcus pneumoniae   | <input type="checkbox"/> Human Papillomavirus (HPV)   |
|  |   | <input type="checkbox"/> Human Parainfluenza Virus (all species)  |

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- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Haemophilus influenzae   | <input type="checkbox"/> Streptococcus, Group A (Streptococcus pyogenes)   | <input type="checkbox"/> Human T-lymphotropic Virus 1 or 2   |
| <input type="checkbox"/> Haemophilus non-influenzae                                     | <input type="checkbox"/> Streptococcus, Group B (Streptococcus agalactiae)   | <input type="checkbox"/> Influenza A Virus   |
| <input type="checkbox"/> Klebsiella (all species)                                       | <input type="checkbox"/> Treponema (syphilis)  | <input type="checkbox"/> Influenza B Virus   |
| <input type="checkbox"/> Lactobacillus (all species, including bulgaricus, acidophilus) | <input type="checkbox"/> Vibrio (all species)  | <input type="checkbox"/> Influenza, NOS  |
| <input type="checkbox"/> Legionella pneumophila   | <input type="checkbox"/> Yersinia enterocolitica   | <input type="checkbox"/> JC Virus (Progressive Multifocal Leukoencephalopathy (PML))                   |
| <input type="checkbox"/> Legionella non-pneumophila                                     | <input type="checkbox"/> Suspected bacterial infection   | <input type="checkbox"/> Measles Virus (Rubeola)   |
| <input type="checkbox"/> Leptospira (all species)                                       | <input type="checkbox"/> Aspergillus flavus  | <input type="checkbox"/> Mumps Virus   |
| <input type="checkbox"/> Leptotrichia buccalis  | <input type="checkbox"/> Aspergillus fumigatus   | <input type="checkbox"/> Norovirus   |
| <input type="checkbox"/> Leuconostoc (all species)                                      | <input type="checkbox"/> Aspergillus niger   | <input type="checkbox"/> Parvovirus B19  |
| <input type="checkbox"/> Listeria monocytogenes   | <input type="checkbox"/> Aspergillus terreus   | <input type="checkbox"/> Polioviruses  |
| <input type="checkbox"/> Micrococcus, NOS   | <input type="checkbox"/> Aspergillus ustus   | <input type="checkbox"/> Respiratory Syncytial Virus (RSV)   |
| <input type="checkbox"/> Moraxella catarrhalis  | <input type="checkbox"/> Aspergillus, NOS  | <input type="checkbox"/> Rhinovirus (all species except Rhinovirus / enterovirus (not differentiated)) |
| <input type="checkbox"/> Mycobacterium abscessus  | <input type="checkbox"/> Blastomyces (all species, including dermatitidis)   | <input type="checkbox"/> Rhinovirus / enterovirus (not differentiated)                                 |
| <input type="checkbox"/> Mycobacterium avium - intracellulare (MAC, MAI)                | <input type="checkbox"/> Candida albicans  | <input type="checkbox"/> Rotavirus (all species)   |
| <input type="checkbox"/> Mycobacterium chelonae   | <input type="checkbox"/> Candida auris   | <input type="checkbox"/> Rubella Virus   |
| <input type="checkbox"/> Mycobacterium fortuitum  | <input type="checkbox"/> Candida parapsilosis  | <input type="checkbox"/> Sapovirus   |
| <input type="checkbox"/> Mycobacterium haemophilum                                      | <input type="checkbox"/> Candida non-albicans (excluding C. parapsilosis and C. auris)   | <input type="checkbox"/> Varicella Virus   |
| <input type="checkbox"/> Mycobacterium kansasii   | <input type="checkbox"/> Coccidioides (all species)  | <input type="checkbox"/> West Nile Virus (WNV)   |
| <input type="checkbox"/> Mycobacterium marinum  | <input type="checkbox"/> Cryptococcus gattii   | <input type="checkbox"/> Suspected viral infection   |
| <input type="checkbox"/> Mycobacterium mucogenicum                                      | <input type="checkbox"/> Cryptococcus neoformans   | <input type="checkbox"/> Cryptosporidium (all species)   |
| <input type="checkbox"/> Mycobacterium tuberculosis (tuberculosis, Koch bacillus)       | <input type="checkbox"/> Fusarium (all species)  | <input type="checkbox"/> Giardia (lamblia)   |
| <input type="checkbox"/> Mycoplasma (all species)                                       | <input type="checkbox"/> Histoplasma (all species, including capsulatum)   | <input type="checkbox"/> Helminths (all species)   |
| <input type="checkbox"/> Neisseria gonorrhoeae  | <input type="checkbox"/> Lomentospora prolificans  | <input type="checkbox"/> Strongyloides stercoralis   |
|   | <input type="checkbox"/> Mucorales (all species including Rhizopus, Mucor, Rhizomucor, Absidia, Lichtheimia, Cunninghamella species) | <input type="checkbox"/> Toxoplasma gondii   |
|   | <input type="checkbox"/> Pneumocystis (PCP / PJP)  | <input type="checkbox"/> Trypanosoma cruzi (Chaga's Disease)   |
|   | <input type="checkbox"/> Scedosporium (all species)  | <input type="checkbox"/> Other organism – <b>Go to question 207</b>                                    |
|   | <input type="checkbox"/> Suspected fungal infection  |  |
|   | <input type="checkbox"/> Adenovirus  |  |







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- 80 Normal activity with effort
- 70 Cares for self; unable to carry on normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care
- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly

236. Lansky scale (*recipient age ≥ 1 year and < 16 years*)

- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play, tires more easily, otherwise active
- 70 Both greater restrictions of, and less time spent in, active play
- 60 Ambulatory up to 50% of time, limited active play with assistance / supervision
- 50 Considerable assistance required for any active play; fully able to engage in quiet play
- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (e.g., TV)
- 10 Completely disabled, not even passive play

237. ECOG score

- 0 – Fully active, able to carry on all pre-disease performance without restriction
- 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
- 2 – Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 – Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
- 4 – Completely disabled; cannot carry on any selfcare; totally confined to bed or chair

238. Did the recipient become pregnant? (*Female only*)

- Yes – **Also complete Pregnancy Form 3501**
- No
- Unknown
- Previously reported (*Form 3501 already submitted for this event*)

239. Did the recipient's female partner become pregnant? (*Male only*)

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- Yes – **Also complete Pregnancy Form 3501**
- No
- Unknown
- Previously reported (*Form 3501 already submitted for this event*)

240. Has the recipient smoked tobacco cigarettes?

- Yes – **Go to question 241**
- No – **Go to question 243**
- Unknown – **Go to question 243**

241. Average number of packs per day (*20 cigarettes per pack*)

- Known – **Go to question 242**
- Unknown – **Go to question 243**

242. Average number of packs per day: \_\_\_\_ • \_\_\_\_

243. Specify the category which best describes the recipient's current occupation

- Professional, technical, or related occupation (*e.g., teacher / professor, nurse / physician, lawyer, engineer*) – **Go to question 245**
- Manager, administrator, or proprietor (*e.g., sales manager, real estate agent, postmaster*) – **Go to question 245**
- Clerical or related occupation (*e.g., secretary, clerk, mail carrier*) – **Go to question 245**
- Sales occupation (*e.g., sales associate, demonstrator, agent, broker*) – **Go to question 245**
- Service occupation (*e.g., police officer, cook, hairdresser*) – **Go to question 245**
- Skilled craft or related occupation (*e.g., carpenter, repair technician, telephone line worker*) – **Go to question 245**
- Equipment / vehicle operator or related occupation (*e.g., driver, railroad brakeman, sewer worker*) – **Go to question 245**
- Laborer (*e.g., helper, longshoreman, warehouse worker*) – **Go to question 245**
- Farmer (*e.g., owner, manager, operator, tenant*) – **Go to question 245**
- Member of the military – **Go to question 245**
- Homemaker – **Go to question 245**
- Under school age – **Go to question 245**
- Not employed – **Go to question 245**
- Unknown – **Go to question 245**
- Other – **Go to question 244**

244. Specify other occupation: \_\_\_\_\_

245. What is the recipient's current or most recent work status?

- Full time – **Go to end of form**
- Part time, by choice and not due to illness – **Go to question 247**
- Part time, due to illness – **Go to question 247**
- Unemployed, by choice and not due to illness – **Go to question 247**
- Unemployed, due to illness – **Go to question 247**
- Unemployed, student – **Go to question 247**
- Retired – **Go to question 246**
- Under school age – **Go to question 247**
- Unknown – **Go to question 247**

246. Specify retirement status

- With a source of income
- Without a source of income

247. Did the recipient claim any medical disability?

- Yes
- No