Form 4100 R2.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

Key Fields

Sequence Number: ______________________
Date Received: __ __ __ __ - __ __- __ __
CIBMTR Center Number: ______________________
CIBMTR Research ID: ______________________
Event date: __ __ __ __ - __ __- __ __
Visit □ 100 day □ 6 months □ 1 year □ 2 years □ > 2 years,
Specify: ______________________

Survival Questions: 1 - 6

1 Date of actual contact with the recipient to determine medical status for this follow-up report: __ __ __ __ - __ __- __ __
2 Specify the recipient's survival status at the date of last contact
   □ Alive - Answers to subsequent questions should reflect clinical status since the date of last report
   □ Dead - Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death
3 Primary cause of death ______________________
4 Specify: ______________________

Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org.
Retain the original form at the transplant center.
5 Contributing cause of death (check all that apply)
- Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed
- Acute GVHD
- Chronic GVHD
- Graft rejection or failure
- Cytokine release syndrome
- Infection, organism not identified
- Bacterial infection
- Fungal infection
- Viral infection
- Protozoal infection
- Other infection
- Idiopathic pneumonia syndrome (IPS)
- Pneumonitis due to Cytomegalovirus (CMV)
- Pneumonitis due to other virus
- Other pulmonary syndrome (excluding pulmonary hemorrhage)
- Diffuse alveolar damage (without hemorrhage)
- Acute respiratory distress syndrome (ARDS) (other than IPS)
- Liver failure (not VOD)
- Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS)
- Cardiac failure
- Pulmonary failure
- Central nervous system (CNS) failure
- Renal failure
- Gastrointestinal (GI) failure (not liver)
- Multiple organ failure
- Other organ failure
- New malignancy (post-HCT or post-cellular therapy)
- Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed)
- Pulmonary hemorrhage
- Diffuse alveolar hemorrhage (DAH)
- Intracranial hemorrhage
- Gastrointestinal hemorrhage
- Hemorrhagic cystitis
- Other hemorrhage
- Thromboembolic
- Disseminated intravascular coagulation (DIC)
- Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS))
- Other vascular
- Accidental death
- Suicide
- Other cause

6 Specify: __________________________________________________________________________________

Subsequent Cellular Infusions

Questions: 7 - 11
**Form 4100 R2.0: Cellular Therapy Essential Data Follow-Up Form**

**Center:**

**CRID:**

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All additional cellular therapy infusions given for the same indication per protocol require a separate infusion form and should be reported on the Form 4000 for this course of cellular therapy. If a cellular therapy was administered for treatment of a different indication, or in response to disease progression / no response, a new Form 4000 (Pre-CTED) must be completed.

7 Has the recipient received a new course of cellular therapy (unplanned) since the date of last report?
- Yes
- No

8 Specify the reason for which cellular therapy was given
- Failure to respond or in response to disease assessment
- New indication

9 Date of cellular therapy: __ __ __ __ - __ __- __ __

10 Did the recipient receive an HCT since the date of last report?
- Yes - Also complete Pre-TED Form 2400 for the subsequent HCT
- No

11 Date of HCT: __ __ __ __ - __ __- __ __

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### Best Response to Cellular Therapy

**Questions: 12 - 14**

12 What was the best response to the cellular therapy?
- Complete response
- Normalization of organ function
- Partial response
- Partial normalization of organ function
- No response
- Disease progression or worsening of organ function
- Not applicable (e.g. infection prophylaxis)
- Unknown

13 Was the date of best response previously reported?
- Yes
- No

14 Date response established: __ __ __ __ - __ __- __ __

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### Disease Relapse or Progression

**Questions: 15 - 16**

15 Was a disease relapse or progression detected since the date of last report?
- Yes
- No

16 Date documented: __ __ __ __ - __ __- __ __

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### New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

**Questions: 17 - 21**

Report new malignancies that are different than the disease / disorder for which cellular therapy was performed. Do not include relapse, progression or transformation of the same disease subtype.

17 Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? (include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)
- Yes
- No

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### New Malignancy (1)

**Questions: 18 - 21**

Report each new malignancy diagnosed since the date of last report. The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.

18 Specify the new malignancy

19 Specify other new malignancy:

20 Date of diagnosis: __ __ __ __ - __ __- __ __

21 Was the new malignancy donor / cell product derived?
- Yes
- No
- Not done

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### Persistence of Cells

**Questions: 22 - 43**

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Mail, fax or email this form to Minneapolis. Fax: 612-527-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.
This section pertains to the evaluation of persistence of a cellular product in the recipient.

22 Were tests performed to detect persistence of the cellular product since the date of last report?
   ☐ Yes ☐ No

23 Was persistence evaluated by molecular assay? (e.g. PCR)
   ☐ Yes ☐ No

24 Date sample collected: __ __ __ __ - __ __- __ __

25 Specify the cell source
   ☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

26 Specify other cell source:

27 Were the infused cells detected?
   ☐ Yes ☐ No

28 Was persistence evaluated by flow cytometry testing? (immunophenotyping)
   ☐ Yes ☐ No

29 Date sample collected: __ __ __ __ - __ __- __ __

30 Specify the cell source
   ☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

31 Specify other cell source:

32 Were the infused cells detected?
   ☐ Yes ☐ No

33 Was persistence evaluated by immunohistochemistry?
   ☐ Yes ☐ No

34 Date sample collected: __ __ __ __ - __ __- __ __

35 Specify the cell source
   ☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

36 Specify other cell source:

37 Were the infused cells detected?
   ☐ Yes ☐ No

38 Was persistence evaluated by other method?
   ☐ Yes ☐ No

39 Specify other method: ____________________________________________

40 Date sample collected: __ __ __ __ - __ __- __ __

41 Specify the cell source
   ☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

42 Specify other cell source:

43 Were the infused cells detected?
   ☐ Yes ☐ No

This section is for allogeneic infusions only.

44 Did acute GVHD develop since the date of last report?
   ☐ Yes ☐ No ☐ Unknown

45 Date of acute GVHD diagnosis: __ __ __ __ __ __

46 Did acute GVHD persist since the date of last report?
   ☐ Yes ☐ No ☐ Unknown

47 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
   ☐ 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
   ☐ Not applicable (acute GVHD present but grade is not applicable)
List the stage for each organ at diagnosis of acute GVHD:

### 48 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

### 49 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

### 50 Upper intestinal tract
- Stage 0 - No persistent nausea or vomiting
- Stage 1 - Persistent nausea or vomiting

### 51 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)

### 52 Other site(s) involved with acute GVHD
- Yes
- No

### 53 Specify other site(s):

Specify the maximum overall grade of acute GVHD since the date of last report:

### 54 Maximum overall grade of acute GVHD
- 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
- 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
- Not applicable (acute GVHD present but grade is not applicable)

### 55 Date maximum overall grade of acute GVHD: __ _______ _______ _______ _______

### 56 Did chronic GVHD develop since the date of last report?
- Yes
- No
- Unknown

### 57 Date of chronic GVHD diagnosis: __ _______ _______ _______ _______ Date estimated

### 58 Did chronic GVHD persist since the date of last report?
- Yes
- No
- Unknown

Specify the maximum grade of chronic GVHD since the date of last report:

### 59 Maximum grade of chronic GVHD (according to best clinical judgment)
- Mild
- Moderate
- Severe
- Unknown
60 Specify if chronic GVHD was limited or extensive
  - Limited - Localized skin involvement and/or liver dysfunction
  - Extensive - One or more of the following:
    - generalized skin involvement; or,
    - liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
    - involvement of eye: Schirmer’s test with < 5 mm wetting; or
    - involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
    - involvement of any other target organ

61 Date of maximum grade of chronic GVHD: __ __ __ __ - __ __- __ __

62 Is the recipient still taking systemic steroids? (Do not report steroids for adrenal insufficiency, ≤ 10 mg/day for adults, < 0.1 mg/kg/day for children)
  - Yes
  - No
  - Not Applicable
  - Unknown

63 Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?
  - Yes
  - No
  - Not Applicable
  - Unknown

64 Did the recipient develop Cytokine Release Syndrome (CRS) since the date of last report?
  - Yes
  - No

65 Date of diagnosis: __ __ __ __ - __ __- __ __

66 Was therapy given? (for CRS)
  - Yes
  - No

Specify therapy given for CRS:
67 Specify therapy given for CRS (check all that apply)
  - Corticosteroids
  - Siltuximab
  - Tocilizumab
  - Other therapy

68 Specify other therapy:

69 Did cytokine release syndrome resolve?
  - Yes
  - No

70 Date resolved: __ __ __ __ - __ __- __ __

71 Neurotoxicity
  - Yes
  - No
  - Unknown

72 Date of onset: __ __ __ __ - __ __- __ __

Specify symptoms of neurotoxicity:
73 Specify symptoms of neurotoxicity (check all that apply)
  - Altered mental status
  - Aphasia
  - Hemiparesis or other focal motor deficit
  - Seizure(s)
  - Tremors
  - Visual hallucinations
  - Other symptom

74 Specify other symptom:

75 Did neurotoxicity resolve?
  - Yes
  - No

76 Date resolved: __ __ __ __ - __ __- __ __

77 Hemorrhagic stroke
  - Yes
  - No
  - Unknown

78 Date of onset: __ __ __ __ - __ __- __ __
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Center: CRID:

79 Other toxicity
   - Yes
   - No
   - Unknown

80 Date of onset: ______ - ______ - ______

81 Specify other toxicity:

Specify if the recipient has developed any of the following since the date of last report:

82 Fevers (≥ 100.4° F or ≥ 38° C)
   - Yes
   - No
   - Unknown

83 Date of onset: ______ - ______ - ______

84 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

85 Rigors
   - Yes
   - No
   - Unknown

86 Date of onset: ______ - ______ - ______

87 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

88 Malaise / fatigue
   - Yes
   - No
   - Unknown

89 Date of onset: ______ - ______ - ______

90 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

91 Anorexia
   - Yes
   - No
   - Unknown

92 Date of onset: ______ - ______ - ______

93 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

94 Myalgias / arthralgias
   - Yes
   - No
   - Unknown

95 Date of onset: ______ - ______ - ______

96 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

97 Nausea / vomiting
   - Yes
   - No
   - Unknown

98 Date of onset: ______ - ______ - ______

99 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

100 Other constitutional symptom
   - Yes
   - No
   - Unknown

101 Date of onset: ______ - ______ - ______

102 Specify other constitutional symptom:

103 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

104 Hypoxia requiring minimal supplemental oxygen (FiO2 ≤ 40%)
   - Yes
   - No
   - Unknown

105 Date of onset: ______ - ______ - ______

106 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   - Yes
   - No

107 Hypoxia requiring more than minimal supplemental oxygen (FiO2 > 40%)
   - Yes
   - No
   - Unknown

108 Date of onset: ______ - ______ - ______

109 Was mechanical ventilator support required?
   - Yes
   - No
   - Unknown

110 Date started: ______ - ______ - ______

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111 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   ☐ Yes ☐ No

112 Hypotension requiring therapy
   ☐ Yes ☐ No ☐ Unknown

113 Date of onset: __ __ __ __ - __ __- __ __

114 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
   ☐ Yes ☐ No

Specify therapy given for hypotension:

115 Intravenous fluids
   ☐ Yes ☐ No ☐ Unknown

116 Vasopressor(s)
   ☐ Yes ☐ No ☐ Unknown

117 Specify the number of vasopressors used for therapy
   1 ☐ ≥2 ☐ Unknown

118 Other therapy
   ☐ yes ☐ no ☐ Unknown

119 Specify other therapy:

120 Was hypotension controlled with therapy?
   ☐ Yes ☐ No ☐ Unknown

121 Has the recipient developed any grade 4 organ toxicity?
   ☐ Yes ☐ No ☐ Unknown

122 Liver
   ☐ Yes ☐ No ☐ Unknown

123 Date of onset: __ __ __ __ - __ __- __ __

124 Lungs
   ☐ Yes ☐ No ☐ Unknown

125 Date of onset: __ __ __ __ - __ __- __ __

126 Heart
   ☐ Yes ☐ No ☐ Unknown

127 Date of onset: __ __ __ __ - __ __- __ __

128 Kidneys
   ☐ Yes ☐ No ☐ Unknown

129 Date of onset: __ __ __ __ - __ __- __ __

130 Gastrointestinal (GI)
   ☐ Yes ☐ No ☐ Unknown

131 Date of onset: __ __ __ __ - __ __- __ __

132 Musculoskeletal
   ☐ Yes ☐ No ☐ Unknown

133 Date of onset: __ __ __ __ - __ __- __ __

134 Neurologic
   ☐ Yes ☐ No ☐ Unknown

135 Date of onset: __ __ __ __ - __ __- __ __

136 Other organ
   ☐ Yes ☐ No ☐ Unknown

137 Date of onset: __ __ __ __ - __ __- __ __

138 Specify other organ:

Specify the maximum lab results since the date of last report:

139 Interleukin-6
   ☐ Known ☐ Unknown

140 __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ _______
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Center: CRID:

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### Functional Status

**Questions: 154 - 157**

154 Was the recipient pregnant at any time in this reporting period? (Female only)
- [ ] Yes  
- [ ] No  
- [ ] Unknown

155 Was the recipient's female partner pregnant at any time in this reporting period? (Male only)
- [ ] Yes  
- [ ] No  
- [ ] Unknown

156 Was the recipient or recipient's partner still pregnant at the date of last contact?
- [ ] Yes  
- [ ] No  
- [ ] Unknown

157 Specify the outcome of pregnancy
- [ ] Live birth  
- [ ] Intrauterine fetal death  
- [ ] Spontaneous abortion  
- [ ] Elected abortion  
- [ ] Unknown

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First Name: ____________________________

Last Name: ____________________________

E-mail address: ________________________

Date: ____________ - ____________

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