Form 4000 R5.0: Cellular Therapy Essential Data Pre-Infusion Form

Key Fields

Sequence Number: ____________________________
Date Received: ____________________________
CIBMTR Center Number: ____________________________
CIBMTR Research ID: ____________________________
Event date: ____________________________

Recipient Data

This form must be completed for all recipients of non-HCT cellular products. For recipients of hematopoietic cell transplants, complete a form 2400 - Pre-Transplant Essential Data.

This form reflects baseline recipient data for one course of cellular therapy.

1 Ethnicity

☒ Hispanic or Latino
☒ Not Hispanic or Latino
☒ Not applicable (not a resident of the USA)
☒ Unknown

2 Race (check all that apply)

☒ White
☒ Black or African American
☒ Asian
☒ American Indian or Alaska Native
☒ Native Hawaiian or Other Pacific Islander
☒ Not reported
☒ Unknown

3 Has the recipient signed an IRB / Ethics Committee-approved consent form for submitting research data to the CIBMTR?

☒ Yes (patient consented)
☒ No (patient declined)
☒ Not approached
☒ Not applicable

4 Date form was signed: ____________________________

5 Is the recipient participating in a cellular therapy clinical trial?

☒ yes ☒ no

Clinical Trials (1)

6 Study sponsor

☒ BMT CTN
☒ RCI BMT
☒ USIDNET
☒ COG
☒ Corporate / Industry
☒ EudraCT
☒ UMIN
☒ Investigator initiated
☒ Other

7 Specify corporate / industry sponsor name: ____________________________

8 Specify EudraCT number: ____________________________

9 Specify UMIN number: ____________________________

10 Specify other sponsor: ____________________________

11 Specify the ClinicalTrials.gov identification number: ____________________________
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Center: CRID:

<table>
<thead>
<tr>
<th>Questions: 14 - 28</th>
<th>Cellular Therapy and HCT History</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Is the recipient receiving cellular therapy outside the context of a clinical trial?</td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>No</td>
</tr>
<tr>
<td>13 Specify the reason for not being on a clinical trial (check all that apply)</td>
<td></td>
</tr>
<tr>
<td>- Institutional guidelines / standard treatment</td>
<td></td>
</tr>
<tr>
<td>- Hospital exemption</td>
<td></td>
</tr>
<tr>
<td>- Compassionate use</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Questions: 17 - 22</th>
<th>Prior Cellular Therapies (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Is this the first application of cellular therapy (non-HCT)?</td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>No (recipient has previously been treated using cellular therapy)</td>
</tr>
<tr>
<td>- Unknown</td>
<td></td>
</tr>
<tr>
<td>15 Were all prior cellular therapies (non-HCT) reported to the CIBMTR?</td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>No</td>
</tr>
<tr>
<td>- Unknown</td>
<td></td>
</tr>
<tr>
<td>16 Specify the number of prior cellular therapies:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Questions: 17 - 22</th>
<th>Prior Cellular Therapies (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 Date of the prior cellular therapy:</td>
<td></td>
</tr>
<tr>
<td>- Date estimated</td>
<td></td>
</tr>
<tr>
<td>18 Was the cellular therapy performed at a different institution?</td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Specify the institution that performed the prior cellular therapy:

<table>
<thead>
<tr>
<th>Questions: 17 - 22</th>
<th>Prior Cellular Therapies (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 Name:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
</tr>
<tr>
<td>State:</td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td></td>
</tr>
</tbody>
</table>

Specify the indication for the prior cellular therapy:

<table>
<thead>
<tr>
<th>Questions: 17 - 22</th>
<th>Prior Cellular Therapies (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 Specify the indication for the prior cellular therapy</td>
<td></td>
</tr>
<tr>
<td>- Promote stem cell engraftment (e.g. co-infusion with HCT)</td>
<td></td>
</tr>
<tr>
<td>- Suboptimal donor chimerism (post-HCT)</td>
<td></td>
</tr>
<tr>
<td>- Immune reconstitution (post-HCT)</td>
<td></td>
</tr>
<tr>
<td>- GVHD prophylaxis (with HCT)</td>
<td></td>
</tr>
<tr>
<td>- GVHD treatment (post-HCT)</td>
<td></td>
</tr>
<tr>
<td>- Prevent disease relapse (post-HCT)</td>
<td></td>
</tr>
<tr>
<td>- Relapsed, persistent or progressive disease (post-HCT)</td>
<td></td>
</tr>
<tr>
<td>- Infection treatment</td>
<td></td>
</tr>
<tr>
<td>- Infection prophylaxis</td>
<td></td>
</tr>
<tr>
<td>- B cell lymphoproliferative disorder (PTLD, EBV lymphoma)</td>
<td></td>
</tr>
<tr>
<td>- Autoimmune disease</td>
<td></td>
</tr>
<tr>
<td>- Cardiovascular disease</td>
<td></td>
</tr>
<tr>
<td>- Musculoskeletal disorder</td>
<td></td>
</tr>
<tr>
<td>- Neurologic disease</td>
<td></td>
</tr>
<tr>
<td>- Ocular disease</td>
<td></td>
</tr>
<tr>
<td>- Pulmonary disease</td>
<td></td>
</tr>
<tr>
<td>- Solid tumor</td>
<td></td>
</tr>
<tr>
<td>- Malignant hematologic disorder</td>
<td></td>
</tr>
<tr>
<td>- Non-malignant disorder</td>
<td></td>
</tr>
<tr>
<td>- Unknown</td>
<td></td>
</tr>
<tr>
<td>- Other indication</td>
<td></td>
</tr>
</tbody>
</table>

21 Specify other indication: ____________________________
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Center: CRID:

22 What was the cell source for the prior cellular therapy? (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

HCT History

23 Has the recipient ever had a prior HCT?
- Yes
- No
- Unknown

24 Were all prior HCTs reported to the CIBMTR?
- Yes
- No
- Unknown

Prior HCTs (1)

25 Date of the prior HCT: __ __ __ __ - __ __- __ __

26 Was the HCT performed at a different institution?
- Yes
- No

Specify the institution that performed the prior HCT:

27 Name: ____________________________

City: ____________________________

State: ____________________________

Country: ____________________________

28 Specify the HSC source(s) for the prior HCT (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Product Identification

29 Specify the total number of products: (per protocol) (as part of this course of cellular therapy) ____________________________

30 Is the product genetically modified?
- Yes
- No

Donor Information (1)

31 Specify the cell source
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

32 Specify the related donor type
- Syngeneic (monozygotic twin)
- HLA-identical sibling (may include non-monozygotic twin)
- HLA-matched other relative
- HLA-mismatched relative

33 Was this donor used for any prior cellular therapies or HCT? (for this recipient)
- Yes
- No
- Unknown
Form 4000 R5.0: Cellular Therapy Essential Data Pre-Infusion Form

34 What is the tissue source of the cellular product? (check all that apply)

- Bone marrow
- Cord blood unit
- Peripheral blood
- Adipose tissue
- Amniotic fluid
- Cardiac tissue
- Hepatic tissue
- Neuronal tissue
- Ophthalmic tissue
- Pancreatic tissue
- Placenta
- Tumor
- Umbilical cord
- Other tissue source
- Unknown

35 Specify other tissue source:

36 What is the cell type? (Check all that apply)

- Lymphocytes (unselected)
- CD4+ lymphocytes
- CD8+ lymphocytes
- Cytotoxic T lymphocytes (CTLs)
- Natural killer cells (NK cells)
- Dendritic cells / tumor cell hybridomas (tumor vaccines)
- Mesenchymal stromal stem cells (MSCs)
- Unspecified mononuclear cells
- Endothelial progenitor cells
- Human umbilical cord perivascular (HUCPV) cells
- Cardiac progenitor cells
- Islet cells
- Oligodendrocytes
- Other cell type

37 Specify other cell type:

38 Where was the cellular therapy product manufactured / processed?

- Pharmaceutical / biotech company
- Cell processing laboratory off site
- Cell processing laboratory at the same center as the product is being infused
- Other site

39 Specify other site:

40 Specify pharmaceutical / biotech company

- Atara Biotherapeutics
- Bellicum Pharmaceuticals
- Bluebird Bio
- Celgene
- Juno Therapeutics
- Kite Pharma
- Mesoblast
- Novartis
- Other pharmaceutical company
Form 4000 R5.0: Cellular Therapy Essential Data Pre-Infusion Form

Specify the institution / company where the cellular product was manufactured:

41 Name: ____________________________
City: ____________________________
State: ____________________________
Country: ____________________________

42 Name of product
- Tisagenlecleucel (Kymriah®)
- Axicabtagene Cileoleucel (Yescarta®)
- Other product

43 Specify other product: ____________________________

Planned HCT

44 Is a subsequent HCT part of the overall treatment protocol?
- Yes  No

45 Specify the HCT type
- Autologous  Allogeneic

46 Specify the circumstances in which the subsequent HCT will be performed
- Regardless of response to cellular therapy
- Only if the patient responds to cellular therapy
- Only if the patient fails to respond or has an incomplete response

Indication for Cellular Therapy Questions: 47 - 60

47 Is the cellular therapy being given for prevention?
- Yes  No

48 Reason for prevention
- GVHD prophylaxis (with HCT)
- Prevent disease relapse (post-HCT)
- Infection prophylaxis

49 Indication for cellular therapy
- Suboptimal donor chimerism (Post-HCT)
- Immune reconstitution (Post-HCT)
- GVHD treatment (Post-HCT)
- Malignant hematologic disorder - Also complete CIBMTR Form 2402
- Non-malignant disorder - Also complete CIBMTR Form 2402
- Solid tumor - Also complete CIBMTR Form 2402
- Cardiovascular disease
- Musculoskeletal disease
- Neurologic disease
- Ocular disease
- Pulmonary disease
- Infection treatment
- Other indication

50 Date of diagnosis: __ __ __ __ - __ __- __ __
### Cardiovascular disease

51 Specify cardiovascular disease:
- AMI, acute myocardial infarction (701)
- Chronic coronary artery disease (ischemic, cardiomyopathy) (702)
- Heart failure (non-ischemic etiology) (703)
- Other cardiovascular disease (709)
- Limb ischemia (710)
- Thromboangiitis obliterans (711)
- Other peripheral vascular disease (719)

52 Specify other cardiovascular disease:

53 Specify other peripheral vascular disease:

### Musculoskeletal

54 Specify musculoskeletal disorder:
- Avascular necrosis of femoral head (721)
- Osteoarthritis (722)
- Osteogenesis imperfecta (723)
- Traumatic joint injury (724)
- Other musculoskeletal disorder (729)

55 Specify other musculoskeletal disorder:

### Neurologic Disease

56 Specify neurologic disease:
- Acute cerebral vascular ischemia (731)
- ALS, amiotrophic lateral sclerosis (732)
- Parkinson disease (733)
- Spinal cord injury (734)
- Cerebral palsy (753)
- Congenital hydrocephalus (754)
- Myasthenia gravis (601)
- Duchenne muscular dystrophy (735)
- Other neurologic disease (749)

57 Specify other neurologic disease:

### Ocular

58 Specify ocular disease:

### Pulmonary

59 Specify pulmonary disease:

### Other

60 Specify other indication:

### Infection

Questions: 61 - 67

Specify organism code(s):

61

62

63

64

65

66

67 Specify other organism:
### Disease Assessment at Last Evaluation Prior to Cellular Therapy

Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to cellular therapy.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>68</td>
<td>Was the disease assessed prior to the cellular therapy?</td>
</tr>
<tr>
<td>69</td>
<td>Was the disease status assessed by molecular testing? (e.g. PCR)</td>
</tr>
<tr>
<td>70</td>
<td>Date sample collected:</td>
</tr>
<tr>
<td>71</td>
<td>Was disease detected?</td>
</tr>
<tr>
<td>72</td>
<td>Was the status considered a disease relapse or progression?</td>
</tr>
<tr>
<td>73</td>
<td>Was the disease status assessed via flow cytometry? (immunophenotyping)</td>
</tr>
<tr>
<td>74</td>
<td>Date sample collected:</td>
</tr>
<tr>
<td>75</td>
<td>Was disease detected?</td>
</tr>
<tr>
<td>76</td>
<td>Was the status considered a disease relapse or progression?</td>
</tr>
<tr>
<td>77</td>
<td>Was the disease status assessed by cytogenetic testing? (karyotyping or FISH)</td>
</tr>
<tr>
<td>78</td>
<td>Was the disease status assessed via karyotyping?</td>
</tr>
<tr>
<td>79</td>
<td>Date sample collected:</td>
</tr>
<tr>
<td>80</td>
<td>Was disease detected?</td>
</tr>
<tr>
<td>81</td>
<td>Was the status considered a disease relapse or progression?</td>
</tr>
<tr>
<td>82</td>
<td>Was the disease status assessed via FISH?</td>
</tr>
<tr>
<td>83</td>
<td>Date sample collected:</td>
</tr>
<tr>
<td>84</td>
<td>Was disease detected?</td>
</tr>
<tr>
<td>85</td>
<td>Was the status considered a disease relapse or progression?</td>
</tr>
<tr>
<td>86</td>
<td>Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)</td>
</tr>
<tr>
<td>87</td>
<td>Date assessed:</td>
</tr>
<tr>
<td>88</td>
<td>Was disease detected?</td>
</tr>
<tr>
<td>89</td>
<td>Was the disease status assessed by clinical / hematologic assessment?</td>
</tr>
<tr>
<td>90</td>
<td>Date assessed:</td>
</tr>
<tr>
<td>91</td>
<td>Was disease detected?</td>
</tr>
<tr>
<td>92</td>
<td>What was the recipient's disease status immediately prior to the cellular therapy?</td>
</tr>
<tr>
<td>93</td>
<td>Date assessed:</td>
</tr>
</tbody>
</table>
**Question 94**: Was systemic therapy given immediately prior to cellular therapy as part of the cellular therapy protocol?
- [ ] Yes
- [ ] No

**Question 95**: Date started: __ __ __ __ - __ __- __ __

**Question 96**: Specify the reason for which the systemic therapy was given per protocol
- [ ] Lympho-depleting therapy
- [ ] Reduction of tumor burden
- [ ] Other reason

**Question 97**: Specify other reason: ________________________

**Question 98**: ALG, ALS, ATG, ATS
- [ ] Yes
- [ ] No

**Question 99**: Total dose: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ mg

**Question 100**: Date started: __ __ __ __ - __ __- __ __

**Question 101**: Specify source
- [ ] ATGAM (horse)
- [ ] ATG - Fresenius (rabbit)
- [ ] Thymoglobulin (rabbit)
- [ ] Other

**Question 102**: Specify other source: ________________________

**Question 103**: Anthracycline
- [ ] Yes
- [ ] No

**Question 104**: Daunorubicin (Cerubidine)
- [ ] Yes
- [ ] No

**Question 105**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg

**Question 106**: Date started: __ __ __ __ - __ __- __ __

**Question 107**: Doxorubicin (Adriamycin)
- [ ] Yes
- [ ] No

**Question 108**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg

**Question 109**: Date started: __ __ __ __ - __ __- __ __

**Question 110**: Idarubicin (Idamycin)
- [ ] Yes
- [ ] No

**Question 111**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg

**Question 112**: Date started: __ __ __ __ - __ __- __ __

**Question 113**: Rubidazone
- [ ] Yes
- [ ] No

**Question 114**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg

**Question 115**: Date started: __ __ __ __ - __ __- __ __

**Question 116**: Other anthracycline
- [ ] Yes
- [ ] No

**Question 117**: Specify other anthracycline: ________________________

**Question 118**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg

**Question 119**: Date started: __ __ __ __ - __ __- __ __

**Question 120**: Bleomycin (BLM, Blenoxane)
- [ ] Yes
- [ ] No

**Question 121**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg

**Question 122**: Date started: __ __ __ __ - __ __- __ __

**Question 123**: Busulfan (Myleran)
- [ ] Yes
- [ ] No

**Question 124**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg

**Question 125**: Date started: __ __ __ __ - __ __- __ __

**Question 126**: Specify administration
- [ ] Oral
- [ ] IV
- [ ] Both

**Question 127**: Carboplatin
- [ ] Yes
- [ ] No

**Question 128**: Total dose: __ __ __ __ __ __ __ __ __ __ __ mg
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Center: CRID:

129 Date started: __ __ __ __- __ __

130 Were pharmacokinetics performed to determine drug dosing?

☐ Yes ☐ No

131 Specify the target AUC: __________________________ mg/mL/minute

132 Cisplatin (Platinol, CDDP)

☐ yes ☐ no

133 Total dose: __________________________ mg

134 Date started: __ __ __ __- __ __

135 Cladribine (2-CdA, Leustatin)

☐ yes ☐ no

136 Total dose: __________________________ mg

137 Date started: __ __ __ __- __ __

138 Corticosteroids

☐ yes ☐ no

139 Methylprednisolone (Solu-Medrol)

☐ Yes ☐ No

140 Total dose: __________________________ mg

141 Date started: __ __ __ __- __ __

142 Prednisone

☐ Yes ☐ No

143 Total dose: __________________________ mg

144 Date started: __ __ __ __- __ __

145 Dexamethasone

☐ yes ☐ no

146 Total dose: __________________________ mg

147 Date started: __ __ __ __- __ __

148 Other corticosteroid

☐ Yes ☐ No

149 Specify other corticosteroid: __________________________

150 Total dose: __________________________ mg

151 Date started: __ __ __ __- __ __

152 Cyclophosphamide (Cytoxan)

☐ yes ☐ no

153 Total dose: __________________________ mg

154 Date started: __ __ __ __- __ __

155 Cytarabine (Ara-C)

☐ yes ☐ no

156 Total dose: __________________________ mg

157 Date started: __ __ __ __- __ __

158 Etoposide (VP-16, VePesid)

☐ yes ☐ no

159 Total dose: __________________________ mg

160 Date started: __ __ __ __- __ __

161 Fludarabine (Fludara)

☐ yes ☐ no

162 Total dose: __________________________ mg

163 Date started: __ __ __ __- __ __

164 Ifosfamide (Ifex)

☐ yes ☐ no

165 Total dose: __________________________ mg

166 Date started: __ __ __ __- __ __

167 Intrathecal therapy (chemotherapy)

☐ yes ☐ no

168 Intrathecal cytarabine (IT Ara-C)

☐ Yes ☐ No
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>169 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>170 Date started:</td>
<td></td>
</tr>
<tr>
<td>171 Intrathecal methotrexate (IT MTX)</td>
<td>Yes</td>
</tr>
<tr>
<td>172 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>173 Date started:</td>
<td></td>
</tr>
<tr>
<td>174 Intrathecal thiotepa</td>
<td>Yes</td>
</tr>
<tr>
<td>175 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>176 Date started:</td>
<td></td>
</tr>
<tr>
<td>177 Other intrathecal drug</td>
<td>Yes</td>
</tr>
<tr>
<td>178 Specify other intrathecal drug:</td>
<td></td>
</tr>
<tr>
<td>179 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>180 Date started:</td>
<td></td>
</tr>
<tr>
<td>181 Melphalan (L-PAM, Alkeran)</td>
<td>Yes</td>
</tr>
<tr>
<td>182 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>183 Date started:</td>
<td></td>
</tr>
<tr>
<td>184 Specify administration</td>
<td>Oral</td>
</tr>
<tr>
<td>185 Mitoxantrone (Novantrone)</td>
<td>Yes</td>
</tr>
<tr>
<td>186 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>187 Date started:</td>
<td></td>
</tr>
<tr>
<td>188 Monoclonal antibody (mAb)</td>
<td>Yes</td>
</tr>
<tr>
<td>189 Radio labeled mAb</td>
<td>Yes</td>
</tr>
<tr>
<td>190 Total dose of radioactive component:</td>
<td>mCi</td>
</tr>
<tr>
<td>191 Date started:</td>
<td></td>
</tr>
<tr>
<td>192 Tositumomab (Bexxar)</td>
<td>Yes</td>
</tr>
<tr>
<td>193 Ibritumomab tiuxetan (Zevalin)</td>
<td>Yes</td>
</tr>
<tr>
<td>194 Other radio labeled mAb</td>
<td>Yes</td>
</tr>
<tr>
<td>195 Specify other radio labeled mAb:</td>
<td></td>
</tr>
<tr>
<td>196 Alemtuzumab (Campath)</td>
<td>Yes</td>
</tr>
<tr>
<td>197 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>198 Date started:</td>
<td></td>
</tr>
<tr>
<td>199 Rituximab (Rituxan, anti CD20)</td>
<td>Yes</td>
</tr>
<tr>
<td>200 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>201 Date started:</td>
<td></td>
</tr>
<tr>
<td>202 Gemtuzumab (Mylotarg, anti-CD33)</td>
<td>Yes</td>
</tr>
<tr>
<td>203 Total dose:</td>
<td>mg</td>
</tr>
<tr>
<td>204 Date started:</td>
<td></td>
</tr>
<tr>
<td>205 Other mAb</td>
<td>Yes</td>
</tr>
</tbody>
</table>
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Center: CRID:

206 Specify other mAb: __________________________________________

207 Total dose: ____________________ mg

208 Date started: _____________

209 Nitrosourea
   ☐ Yes ☐ No

210 Carmustine (BCNU, Gliadel)
   ☐ yes ☐ no

211 Total dose: ____________________ mg

212 Date started: _____________

213 CCNU (Lomustine)
   ☐ Yes ☐ No

214 Total dose: ____________________ mg

215 Date started: _____________

216 Other nitrosourea
   ☐ Yes ☐ No

217 Specify other nitrosourea: __________________________________________

218 Total dose: ____________________ mg

219 Date started: _____________

220 Paclitaxel (Taxol, Taxotere)
   ☐ Yes ☐ No

221 Total dose: ____________________ mg

222 Date started: _____________

223 Teniposide (VM26)
   ☐ Yes ☐ no

224 Total dose: ____________________ mg

225 Date started: _____________

226 Thiotepa
   ☐ Yes ☐ No

227 Total dose: ____________________ mg

228 Date started: _____________

229 Treosulfan
   ☐ Yes ☐ No

230 Total dose: ____________________ mg

231 Date started: _____________

232 Tyrosine kinase inhibitors (TKI)
   ☐ yes ☐ no

233 Dasatinib (Sprycel)
   ☐ yes ☐ no

234 Total dose: ____________________ mg

235 Date started: _____________

236 Imatinib mesylate (STI571, Gleevec)
   ☐ yes ☐ no

237 Total dose: ____________________ mg

238 Date started: _____________

239 Nilotinib (AMN107, Tasigna)
   ☐ yes ☐ no

240 Total dose: ____________________ mg

241 Date started: _____________

242 Other tyrosine kinase inhibitor
   ☐ Yes ☐ No

243 Specify other tyrosine kinase inhibitor: ____________________________

244 Total dose: ____________________ mg

245 Date started: _____________

246 Other drug
   ☐ Yes ☐ No

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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.
Form 4000 R5.0: Cellular Therapy Essential Data Pre-Infusion Form

247 Specify other drug: __________________________________________________________________________

248 Total dose: __________________ mg

249 Date started: __ __ __ __ - __ __- __ __

Functional Status

Questions: 250 - 252

Specify the functional status of the recipient immediately prior to the cellular therapy:

250 What scale was used to determine the recipient’s functional status prior to the cellular therapy

- Karnofsky (recipient age ≥ 16 years)
- Lansky (recipient age ≥ 1 and < 16 years)

251 Karnofsky Scale (recipient age ≥ 16 years)

252 Lansky Scale (recipient age ≥ 1 and < 16 years)

Comorbid Conditions

Questions: 253 - 311

This section to be completed for malignant hematologic disorders and solid tumor indications.

253 Were there clinically significant co-existing diseases or organ impairment at time of patient assessment prior to preparative regimen? Source: Blood, 2005 Oct 15;106(8):2912-2919

- yes                   - no                   - Unknown

254 Arrhythmia - For example, any history of atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias requiring treatment

- yes                   - no                   - Unknown

255 Cardiac - Any history of coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), congestive heart failure, myocardial infarction, OR ejection fraction ≤ 50% on the most recent test

- yes                   - no                   - Unknown

256 Cerebrovascular disease - Any history of transient ischemic attack, subarachnoid hemorrhage or cerebrovascular accident

- yes                   - no                   - Unknown

257 Diabetes - Requiring treatment with insulin or oral hypoglycemics in the last 4 weeks but not diet alone

- yes                   - no                   - Unknown

258 Heart valve disease - Except asymptomatic mitral valve prolapse

- yes                   - no                   - Unknown

259 Hepatic, mild - Chronic hepatitis, bilirubin > upper limit of normal to 1.5 x upper limit of normal, or AST/ALT > upper limit of normal to 2.5 x upper limit of normal at the time of transplant OR any history of hepatitis B or hepatitis C infection

- yes                   - no                   - Unknown

260 Hepatic, moderate/severe - Liver cirrhosis, bilirubin > 1.5 x upper limit of normal, or AST/ALT > 2.5 x upper limit of normal

- yes                   - no                   - Unknown

261 Infection - For example, documented infection, fever of unknown origin, or pulmonary nodules requiring continuation of antimicrobial treatment after day 0

- yes                   - no                   - Unknown

262 Inflammatory bowel disease - Any history of Crohn’s disease or ulcerative colitis requiring treatment

- yes                   - no                   - Unknown

263 Obesity - Patients with a body mass index > 35 kg/m² prior to the start of conditioning

- yes                   - no                   - Unknown

264 Peptic ulcer - Any history of peptic ulcer confirmed by endoscopy and requiring treatment

- yes                   - no                   - Unknown

265 Psychiatric disturbance - For example, depression, anxiety, bipolar disorder or schizophrenia requiring psychiatric consult or treatment in the last 4 weeks

- yes                   - no                   - Unknown

266 Pulmonary, moderate - Corrected diffusion capacity of carbon monoxide and/or FEV₁ 66-80% or dyspnea on slight activity at transplant

- yes                   - no                   - Unknown

267 Pulmonary, severe - Corrected diffusion capacity of carbon monoxide and/or FEV₁ ≤ 65% or dyspnea at rest or requiring oxygen at transplant

- yes                   - no                   - Unknown

268 Renal, moderate/severe - Serum creatinine > 2 mg/dL or > 177 µmol/L or on dialysis at transplant, OR prior renal transplantation

- yes                   - no                   - Unknown

269 Rheumatologic - For example, any history of systemic lupus erythmatosis, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica requiring treatment (DO NOT include degenerative joint disease, osteoarthritis)

- yes                   - no                   - Unknown
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270 Solid tumor, prior - Treated at any time point in the patient’s past history, excluding non-melanoma skin cancer, leukemia, lymphoma or multiple myeloma
   yes  no  Unknown

271 Breast cancer
   yes  no

272 Year of diagnosis:

273 Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)
   yes  no

274 Year of diagnosis:

275 Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)
   yes  no

276 Year of diagnosis:

277 Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)
   yes  no

278 Year of diagnosis:

279 Lung cancer
   yes  no

280 Year of diagnosis:

281 Melanoma
   yes  no

282 Year of diagnosis:

283 Oropharyngeal cancer (tongue, buccal mucosa)
   yes  no

284 Year of diagnosis:

285 Sarcoma
   yes  no

286 Year of diagnosis:

287 Thyroid cancer
   yes  no

288 Year of diagnosis:

289 Other co-morbid condition
   yes  no  Unknown

290 Specify other co-morbid condition:

291 Was there a history of malignancy (hematologic or non-melanoma skin cancer) other than the primary disease for which this infusion is being performed?
   yes  no

Specify which malignancy(ies) occurred:

292 Acute myeloid leukemia (AML / ANLL)
   yes  no

293 Year of diagnosis:

294 Other leukemia, including ALL
   yes  no

295 Year of diagnosis:

296 Specify leukemia:

297 Clonal cytogenetic abnormality without leukemia or MDS
   yes  no

298 Year of diagnosis:

299 Hodgkin disease
   yes  no

300 Year of diagnosis:

301 Lymphoma or lymphoproliferative disease
   yes  no

302 Year of diagnosis:

303 Was the tumor EBV positive?
   yes  no
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Center: CRID:

304 Other skin malignancy (basal cell, squamous)
   yes no
   Year of diagnosis:

306 Specify other skin malignancy:
   yes no
   Year of diagnosis:

307 Myelodysplasia (MDS) / myeloproliferative (MPN) disorder
   yes no
   Year of diagnosis:

309 Other prior malignancy
   yes no
   Year of diagnosis:

311 Specify other prior malignancy:

First Name: __________________________
Last Name: __________________________
E-mail address: _______________________
Date: ________ - ________ - ________

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