**Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form**

**Center:**

**CIBMTR CRID:**

---

### 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. **Study ID number:**

8. **Specify corporate / industry sponsor name:**

9. **Specify EudraCT number:**

10. **Specify UMIN number:**

11. **Specify other sponsor:**

12. **Specify the ClinicalTrials.gov identification number:**

---

*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 R4.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

### Key Fields
- **Sequence Number:**
- **Date Received:**
- **CIBMTR Center Number:**
- **CIBMTR Research ID:**
- **First Name:**
- **Last Name:**
- **E-mail address:**

### Cellular Therapy and HCT History

#### Questions 15 - 29

15. Is this the first application of cellular therapy (non-HCT)?
   - Yes
   - No

16. Were all prior cellular therapies (non-HCT) reported to the CIBMTR?
   - Yes
   - No
   - Unknown

17. Specify the number of prior cellular therapies:

### Prior Cellular Therapies (1)

#### Questions 18 - 23

18. Date of the prior cellular therapy: __ __ __ __ - __ __- __ __
   - Date estimated

19. Was the cellular therapy performed at a different institution?
   - Yes
   - No

20. Specify the institution that performed the prior cellular therapy:
   - Name:
   - Address:
   - City:
   - State:
   - Country:

21. Specify the indication for the prior cellular therapy:
   - Promote stem cell engraftment (e.g. co-infusion with HCT)
   - Suboptimal donor chimerism (post-HCT)
   - Immune reconstitution (post-HCT)
   - GVHD prophylaxis (with HCT)
   - GVHD treatment (post-HCT)
   - Prevent disease relapse (post-HCT)
   - Relapsed, persistent or progressive disease (post-HCT)
   - Infection treatment
   - Infection prophylaxis
   - B cell lymphoproliferative disorder (PTLD, EBV lymphoma)
   - Autoimmune disease
   - Cardiovascular disease
   - Musculoskeletal disorder
   - Neurologic disease
   - Ocular disease
   - Pulmonary disease
   - Solid tumor
   - Malignant hematologic disorder
   - Non-malignant disorder
   - Unknown
   - Other indication

22. Specify other indication: ____________________________
23 What was the cell source for the prior cellular therapy? (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

HCT History
24 Has the recipient ever had a prior HCT?
- Yes
- No
- Unknown
25 Were all prior HCTs reported to the CIBMTR?
- Yes
- No
- Unknown

Prior HCTs (1)

Specify the institution that performed the prior HCT:
28 Name: __________________________
City: __________________________
State: __________________________
Country: __________________________

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

Planned Infusions

Specify the total number of planned infusions: (per protocol) (as part of this course of cellular therapy)

30 Is the product genetically modified?
- Yes
- No

Donor Information for this Infusion (1)

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

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

34 Was this donor used for any prior cellular therapies or HCT? (for this recipient)
- Yes
- No
- Unknown

35 Does this product contain cytotoxic T lymphocytes (CTLs)?
- Yes
- No
Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form

Planned HCT

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

37 Specify the HCT type
- Autologous
- Allogeneic

38 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

39 What was the indication for performing treatment with cellular therapy?
- Suboptimal donor chimerism (post-HCT)
- Immune reconstitution (post-HCT)
- GVHD prophylaxis (with HCT)
- GVHD treatment (post-HCT)
- Prevent disease relapse (post-HCT)
- Relapsed, persistent or progressive disease (post-HCT)
- Malignant hematologic disorder - Also complete CIBMTR Form 2402
- Non-malignant disorder - Also complete CIBMTR Form 2402
- B cell lymphoproliferative disorder (PTLD, EBV lymphoma)
- Cardiovascular disease
- Musculoskeletal disorder
- Neurologic disease
- Ocular disease
- Pulmonary disease
- Infection treatment
- Infection prophylaxis
- Other indication

40 Date of diagnosis: __ __ __ __ ___ __ __

Cardiovascular disease

41 Specify cardiovascular disease
- AML, 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)

42 Specify other cardiovascular disease: ______________________

43 Specify other peripheral vascular disease: ______________________

Musculoskeletal

44 Specify musculoskeletal disorder
- Avascular necrosis of femoral head (721)
- Osteoarthritis (722)
- Osteogenesis imperfecta (723)
- Traumatic joint injury (724)
- Other musculoskeletal disorder (729)
### Neurologic Disease

46 Specify neurologic disease:
- Acute cerebral vascular ischemia (731)
- ALS, amyotrophic 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)

47 Specify other neurologic disease: ____________________________

### Ocular

48 Specify ocular disease: ____________________________

### Pulmonary

49 Specify pulmonary disease: ____________________________

### Other

50 Specify other indication: ____________________________

### Infection

Questions: 51 - 57

Specify organism code(s):

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>51</td>
<td></td>
<td></td>
</tr>
<tr>
<td>52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>53</td>
<td></td>
<td></td>
</tr>
<tr>
<td>54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

57 Specify other organism: ____________________________

### Disease Assessment at Last Evaluation Prior to Cellular Therapy

Questions: 58 - 83

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.

58 Was the disease assessed prior to the cellular therapy?
  - ✔ Yes  ☐ No

59 Was the disease status assessed by molecular testing? (e.g. PCR)
  - ✔ Yes  ☐ No  ☐ Not Applicable

60 Date sample collected: ____________________________

61 Was disease detected?
  - ✔ Yes  ☐ No

62 Was the status considered a disease relapse or progression?
  - ✔ Yes  ☐ No

63 Was the disease status assessed via flow cytometry? (immunophenotyping)
  - ✔ Yes  ☐ No  ☐ Not Applicable

64 Date sample collected: ____________________________

65 Was disease detected?
  - ✔ Yes  ☐ No

66 Was the status considered a disease relapse or progression?
  - ✔ Yes  ☐ No
Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form

Key Fields

Sequence Number:

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

CIBMTR Center Number:

CIBMTR Research:

Specify radio labeled mAb:

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

CIBMTR Form 4000 revision 4 last updated Monday, July 24, 2017 Copyright(c) 2012 National Marrow Donor Program and The Medical College of Wisconsin, Inc. All rights reserved.
**Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form**

**Center:** 
**CRID:** 

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>94</td>
<td>Daunorubicin (Cerubidine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>97</td>
<td>Doxorubicin (Adriamycin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>98</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>Idarubicin (Idamycin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>101</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>102</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>103</td>
<td>Rubidazole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>104</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>105</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>106</td>
<td>Other anthracycline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>107</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>108</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>109</td>
<td>Specify other anthracycline:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>110</td>
<td>Bleomycin (BLM, Bleomixane)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>111</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>112</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>113</td>
<td>Busulfan (Myleran)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>114</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>115</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>116</td>
<td>Specify administration</td>
<td>Oral</td>
<td>N</td>
</tr>
<tr>
<td>117</td>
<td>Carboplatin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>118</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>119</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>120</td>
<td>Were pharmacokinetics performed to determine drug dosing?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>121</td>
<td>Specify the target AUC:</td>
<td>mg/mL/minute</td>
<td></td>
</tr>
<tr>
<td>122</td>
<td>Cisplatin (Platinol, CDDP)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>123</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>124</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>125</td>
<td>Cladribine (2-CdA, Leustatin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>126</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>127</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>128</td>
<td>Corticosteroids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>129</td>
<td>Methylprednisolone (Solu-Medrol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>130</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>131</td>
<td>Date started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>132</td>
<td>Prednisone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>133</td>
<td>Total dose:</td>
<td>mg</td>
<td></td>
</tr>
</tbody>
</table>
### Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>134</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>135</strong> Dexamethasone</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>136</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>137</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>138</strong> Other corticosteroid</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td><strong>139</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>140</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>141</strong> Specify other corticosteroid:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>142</strong> Cyclophosphamide (Cytoxan)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>143</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>144</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>145</strong> Cytarabine (Ara-C)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>146</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>147</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>148</strong> Etoposide (VP-16, VePesid)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>149</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>150</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>151</strong> Fludarabine (Fludara)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>152</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>153</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>154</strong> Ifosfamide (Ifex)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>155</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>156</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>157</strong> Intrathecal therapy (chemotherapy)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>158</strong> Intrathecal cytarabine (IT Ara-C)</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td><strong>159</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>160</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>161</strong> Intrathecal methotrexate (IT MTX)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>162</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>163</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>164</strong> Intrathecal thiopeta</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>165</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>166</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>167</strong> Other intrathecal drug</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td><strong>168</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>169</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>170</strong> Specify other intrathecal drug:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>171</strong> Melphalan (L-PAM, Alkeran)</td>
<td>[ ] yes</td>
</tr>
<tr>
<td><strong>172</strong> Total dose:</td>
<td>[ ] mg</td>
</tr>
<tr>
<td><strong>173</strong> Date started:</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>174</strong> Specify administration</td>
<td>Oral</td>
</tr>
</tbody>
</table>

---

Mail, fax or email this form to Minneapolis. Fax: 612-527-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.

CIBMTR Form 4000 revision 4 last updated Monday, July 24, 2017 Copyright(c) 2012 National Marrow Donor Program and The Medical College of Wisconsin, Inc. All rights reserved.
175 Mitoxantrone (Novantrone)
   - yes  no

176 Total dose: ______________________________ mg

177 Date started: __ __ __ __ - __ __- __ __

178 Monoclonal antibody (mAb)
   - Yes  No

179 Radio labeled mAb
   - Yes  No

180 Total dose of radioactive component: ______________________________   mCi  MBq

181 Date started: __ __ __ __ - __ __- __ __

Specify radio labeled mAb:

182 Tositumomab (Bexxar)
   - yes  no

183 Ibritumomab tiuxetan (Zevalin)
   - yes  no

184 Other radio labeled mAb
   - Yes  No

185 Specify other radio labeled mAb: ______________________________

186 Alemtuzumab (Campath)
   - yes  no

187 Total dose: ______________________________ mg

188 Date started: __ __ __ __ - __ __- __ __

189 Rituximab (Rituxan, anti CD20)
   - yes  no

190 Total dose: ______________________________ mg

191 Date started: __ __ __ __ - __ __- __ __

192 Gemtuzumab (Mylotarg, anti-CD33)
   - yes  no

193 Total dose: ______________________________ mg

194 Date started: __ __ __ __ - __ __- __ __

195 Other mAb
   - yes  no

196 Total dose: ______________________________ mg

197 Date started: __ __ __ __ - __ __- __ __

198 Specify other mAb: ______________________________

199 Nitrosourea
   - Yes  No

200 Carmustine (BCNU, Gliadel)
   - yes  no

201 Total dose: ______________________________ mg

202 Date started: __ __ __ __ - __ __- __ __

203 CCNU (Lomustine)
   - Yes  No

204 Total dose: ______________________________ mg

205 Date started: __ __ __ __ - __ __- __ __

206 Other nitrosourea
   - Yes  No

207 Total dose: ______________________________ mg

208 Date started: __ __ __ __ - __ __- __ __

209 Specify other nitrosourea: ______________________________

210 Paclitaxel (Taxol, Yotax)
   - Yes  No

211 Total dose: ______________________________ mg
**Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form**

**Center:**

**CRID:**

---

212 Date started: __________ - __________

213 Teniposide (VM26)

☐ yes ☐ no

214 Total dose: ______________ mg

215 Date started: __________ - __________

216 Thiopela

☐ Yes ☐ No

217 Total dose: ______________ mg

218 Date started: __________ - __________

219 Treosulfan

☐ Yes ☐ No

220 Total dose: ______________ mg

221 Date started: __________ - __________

222 Tyrosine kinase inhibitors (TKI)

☐ yes ☐ no

223 Dasatinib (Sprycel)

☐ yes ☐ no

224 Total dose: ______________ mg

225 Date started: __________ - __________

226 Imatinib mesylate (STI571, Gleevec)

☐ yes ☐ no

227 Total dose: ______________ mg

228 Date started: __________ - __________

229 Nilotinib (AMN107, Tasigna)

☐ yes ☐ no

230 Total dose: ______________ mg

231 Date started: __________ - __________

232 Other tyrosine kinase inhibitor

☐ Yes ☐ No

233 Total dose: ______________ mg

234 Date started: __________ - __________

235 Specify other tyrosine kinase inhibitor: ________________________________

236 Other drug

☐ Yes ☐ No

237 Total dose: ______________ mg

238 Date started: __________ - __________

239 Specify other drug: ________________________________

---

**Functional Status**

Questions: 240 - 242

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

240 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)

241 Karnofsky Scale (recipient age ≥ 16 years)

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

---

First Name: __________________________

Last Name: __________________________

E-mail address: __________________________

Date: __________ - __________

---

Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.