STEM CELL LABORATORY (STCL)

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Graft Characterization Form for CTN 1301 Protocol

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Blood and Marrow Transplant Clinical Trials Network CTN1301 Graft Evaluation Form (GRF)

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Note: Data is required for each product lot, defined as the CD34-enriched fraction from a single tubing set

1 How many lots were processed for this patient (TOTALLOTS) ____ Lots
For each lot record the following data: Use Q1 for skip logic

FINAL PRODUCT LOT #1

2 Record the nature of the lot. (NATLOT1)
Use selection for skip logic, if no pool skip questions for pool info

1 Entire product#1 one tubing set
2 Portion of product#1 (Split#1), Not pooled
3 Portion of product#1, remainder not CD34-enriched
4 Entire product#1 pooled with entire product#2
5 Entire product#1 pooled with partial product#2
6 Other, describe ____

Record start date of the CD34 selection procedure:
3 Selection#1 (Lot#1) (SELDATE1) ____ (mm/dd/yyyy)

Record the Donation Identification Number(s) (DIN) & Division Codes for the starting apheresis products used for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier. Leave Q4 blank if no second product.

4 DIN Start Apheresis #1 Lot#1: (DIN1START1) ____
5 Division Code Apheresis #1 Lot#1 (CODE1LOT1) ____
6 DIN Start Apheresis #2 Lot#1: (DIN2START1) ____
7 Division Code Apheresis #2 Lot#1 (CODE2LOT1) ____

Record the Donation Identification Number (DIN) for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier
8 DIN Lot #1: (DINLOT1) ____

Enter data for lot after selection and prior to final sampling and preparation for infusion, including:
Note: Values are absolute viable cell numbers only and are NOT cells per kg. Report to percision as indicated

9 Total number of nucleated cell recovered, Lot#1 (TNC1REC) ____ (xxx.x) x 10^7 cells
10 7-AAD flow viability Lot#1 (VIA1REC) ____ (xxx.x) %
11 CD34+ stem cells recovered, Lot#1 (CD34S1REC) ____ (xxx.x) x 10^7 cells
12 CD3+ T cells recovered, Lot#1 (CD3T1REC) ____ (xxx.x) x 10^4 cells
13 CD56+ NK cells recovered, Lot#1 (CD56NK1REC) ____ (xxx.x) x 10^4 cells
14 CD19 or CD20+ B cells recovered, Lot#1 (B1REC) ____ (xxx.x) x 10^5 cells
15 CD45bright/CD14bright Monocytes, Lot#1 (MO1REC) ____ (xxx.x) x 10^5 cells
16 CD34+ cell purity (% of TNC) (CD34S1PUR) ____ (xxx.x) %
17 CD34+ yield from start processed cells Lot#1 (CD341YLD) ____ (xxx.x) %
18 Log10 TCD from starting processed, Lot#1 (LOG1TCD) ____ xx.xx

Enter data for lot after sampling and preparation for infusion. Represents actual cells infused.
Note: Even if cells pooled for infusion enter data below for Lot#1 only.

19 Total # of viable nucleated cells infused, Lot#1 (TOT1INF) ____ (xxx.x) x 10^7 cells
20 Indicate reason if all cells were not infused:(LOT1REAS) ____
21 Gram stain results infused cells Lot#1 (GRS1RES) 1 Positive 2 Negative — Use response for skip logic
22 Endotoxin results infused cells, Lot#1 (ENDO1RES) 1 Positive 2 Negative — Use response for skip logic
23 If positive indicate EU/mL detected, Lot#1 (EUML1RES) ____ EU per mL Final Product
24 If negative indicate test sensitivity, Lot#1 (SENS1RES) ____ EU per mL Final Product
25 Day 14 Sterility results from last wash, Lot#1 (CUL1RES) 1 Positive 2 Negative — Use response for skip logic
26 If Sterility Culture positive indicate organism, Lot#1 (ORG1) ____
27 Was Lot#1 pooled for infusion? (1POOLTRES) 1 Yes 2 No
Use response for skip logic

28 If yes indicate identity of second lot. (IDENT1) ____

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FINAL PRODUCT LOT #2

29 Record the nature of the lot. (NATLOT2)

1 Portion of product#1 (Split#2), Not pooled
2 Entire product#2 one tubing set
3 Portion of product#2 (Split#1), Not pooled
4 Portion of product#2 (Split#2), Not pooled
5 Portion of product#2, remainder not CD34-enriched
6 Partial Product#1 pooled with Entire product#2
7 Partial Product#1 pooled with partial product#2
8 Other, describe

Record date of the CD34 selection procedure:

30 Selection#2 (Lot#2) (SELDATE2) (mm/dd/yyyy)

Record the Donation Identification Number(s) (DIN) & Division Codes for the starting apheresis products used for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier. Leave Q30 & Q31 blank if no second product.

31 DIN Start Apheresis #1 Lot#2: (DIN1START2)
32 Division Code Apheresis #1 Lot#2 (CODE1LOT2)
33 DIN Start Apheresis #2 Lot#1: (DIN2START2)
34 Division Code Apheresis #2 Lot#2 (CODE2LOT2)

Record the Donation Identification Number (DIN) for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier

35 DIN Lot #2: (DINLOT2)

Enter data for lot after selection and prior to final sampling and preparation for infusion, including:
Note: Values are absolute viable cell numbers only and are NOT cells per kg. Report to percision as indicated

36	Total number of nucleated cell recovered, Lot#2 (TNC2REC)	(xxx.x) x 10^7 cells
37	7-AAD flow viability Lot#2 (VIA2REC)	(xxx.x) %
38	CD34+ stem cells recovered, Lot#2 (CD34S2REC)	(xxx.x) x 10^7 cells
39	CD3+ T cells recovered, Lot#2 (CD3T2REC)	(xxx.x) x 10^4 cells
40	CD56+ NK cells recovered, Lot#2 (CD56NK2REC)	(xxx.x) x 10^4 cells
41	CD29 or CD20+ B cells recovered, Lot#2 (B2REC)	(xxx.x) x 10^5 cells
42	CD45bright/CD24bright Monocytes, Lot#2 (MO2REC)	(xxx.x) x 10^5 cells
43	CD34+ cell purity (% of TNC) (CD34S2PUR)	(xxx.x) %
44	CD34+ yield from start processed cells Lot#2 (CD342YLD)	(xxx.x) %
45	Log20 TCD from starting processed, Lot#2 (LOG2TCD)	xx.xx

Enter data for lot after sampling and preparation for infusion. Represents actual cells infused.
Note: Even if cells pooled for infusion enter data below for Lot#2 only.

46 Total # of viable nucleated cells infused, Lot#2 (TOTL2INF) (xxx.x) x 10^8 cells
47 Indicate reason if all cells were not infused:(LOT2REAS)
48 Gram stain results infused cells Lot#2 (GRSL2RES)
1 Positive
2 Negative
49 Endotoxin results infused cells, Lot#2 (ENDOL2RES)
1 Positive
2 Negative
50 If positive indicate EU/mL detected, Lot#2 (EUMLL2RES) EU per mL Final Product
51 If negative indicate test sensitivity, Lot#2 (SENSL2RES) EU per mL Final Product
52 Day 14 Sterility results from last wash, Lot#2 (CULL2RES)
1 Positive
2 Negative
53 If Sterility Culture positive indicate organism, Lot#2 (ORGL2)
54 Was Lot#2 pooled for infusion? (L2POOLTRES)
1 Yes
2 No

55 If yes indicate identity of second lot. (IDENTL2)

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FINAL PRODUCT LOT #3

56 Record the nature of the lot. (NATLOT3)

1 Entire product#2 one tubing set
2 Portion of product#2 (Split#1), Not pooled
3 Portion of product#2 (Split#2), Not pooled
4 Portion of product#2, remainder not CD34-enriched
5 Entire product#2 pooled with partial product#1
6 Other, describe

Record date of the CD34 selection procedure:

57 Selection#3 (Lot#3) (SELDATE3) (mm/dd/yyyy)

Record the Donation Identification Number(s) (DIN) & Division Codes for the starting apheresis products used for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier. Leave Q56 & Q57 blank if no second product.

58 DIN Start Apheresis #1 Lot#3: (DIN1START3)
59 Division Code Apheresis #1 Lot#3 (CODE1LOT3)
60 DIN Start Apheresis #2 Lot#3: (DIN2START3)
61 Division Code Apheresis #2 Lot#3 (CODE2LOT3)

Record the Donation Identification Number (DIN) for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier

62 DIN Lot #3: (DINLOT3)

Enter data for lot after selection and prior to final sampling and preparation for infusion, including:
Note: Values are absolute viable cell numbers only and are NOT cells per kg. Report to percision as indicated

63	Total number of nucleated cell recovered, Lot#3 (TNC3REC)	(xxx.x) x 10^7 cells
64	7-AAD flow viability Lot#3 (VIA3REC)	(xxx.x) %
65	CD34+ stem cells recovered, Lot#3 (CD34S3REC)	(xxx.x) x 10^7 cells
66	CD3+ T cells recovered, Lot#3 (CD3T3REC)	(xxx.x) x 10^4 cells
67	CD56+ NK cells recovered, Lot#3 (CD56NK3REC)	(xxx.x) x 10^4 cells
68	CD39 or CD20+ B cells recovered, Lot#3 (B3REC)	(xxx.x) x 10^5 cells
69	CD45bright/CD34bright Monocytes, Lot#3 (MO3REC)	(xxx.x) x 10^5 cells
70	CD34+ cell purity (% of TNC) (CD34S3PUR)	(xxx.x) %
71	CD34+ yield from start processed cells Lot#3 (CD343YLD)	(xxx.x) %
72	Log30 TCD from starting processed, Lot#3 (LOG3TCD)	xx.xx

Enter data for lot after sampling and preparation for infusion. Represents actual cells infused.
Note: Even if cells pooled for infusion enter data below for Lot#3 only.

73 Total # of viable nucleated cells infused, Lot#3 (TOTL3INF) (xxx.x) x 10^8 cells
74 Indicate reason if all cells were not infused:(LOT3REAS)
75 Gram stain results infused cells Lot#3 (GRSL3RES)
1 Positive
2 Negative
76 Endotoxin results infused cells, Lot#3 (ENDOL3RES)
1 Positive
2 Negative
77 If positive indicate EU/mL detected, Lot#3 (EUMLL3RES) EU per mL Final Product
78 If negative indicate test sensitivity, Lot#3 (SENSL3RES) EU per mL Final Product
79 Day 14 Sterility results from last wash, Lot#3 (CULL3RES)
1 Positive
2 Negative
80 If Sterility Culture positive indicate organism, Lot#3 (ORGL3)
81 Was Lot#3 pooled for infusion? (L3POOLTRES)
1 Yes
2 No

82 If yes indicate identity of second lot. (IDENTL3)

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FINAL PRODUCT LOT #4

83 Record the nature of the lot. (NATLOT4)

1 Portion of product#2 (Split#2), Not pooled
2 Partial Product#1 pooled with partial product#2
3 Other, describe

Record date of the CD34 selection procedure:

84 Selection#4 (Lot#4) (SELDATE4) (mm/dd/yyyy)

Record the Donation Identification Number(s) (DIN) & Division Codes for the starting apheresis products used for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier.

85 DIN Start Apheresis #1 Lot#4: (DIN1START4)
86 Division Code Apheresis #1 Lot#4 (CODE1LOT4)
87 DIN Start Apheresis #2 Lot#4: (DIN2START4)
88 Division Code Apheresis #2 Lot#4 (CODE2LOT4)

Record the Donation Identification Number (DIN) for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier

89 DIN Lot #4: (DINLOT4)

Enter data for lot after selection and prior to final sampling and preparation for infusion, including:
Note: Values are absolute viable cell numbers only and are NOT cells per kg. Report to percision as indicated

90 Total number of nucleated cell recovered, Lot#4 (TNC4REC) (xxx.x) x 10^7 cells
91 7-AAD flow viability Lot#4 (VIA4REC) (xxx.x) %
92 CD34+ stem cells recovered, Lot#4 (CD34S4REC) (xxx.x) x 10^7 cells
93 CD3+ T cells recovered, Lot#4 (CD3T4REC) (xxx.x) x 10^4 cells
94 CD56+ NK cells recovered, Lot#4 (CD56NK4REC) (xxx.x) x 10^4 cells
95 CD49 or CD20+ B cells recovered, Lot#4 (B4REC) (xxx.x) x 10^5 cells
96 CD45bright/CD44bright Monocytes, Lot#4 (MO4REC) (xxx.x) x 10^5 cells
97 CD34+ cell purity (% of TNC) (CD34S4PUR) (xxx.x) %
98 CD34+ yield from start processed cells Lot#4 (CD344YLD) (xxx.x) %
99 Log40 TCD from starting processed, Lot#4 (LOG4TCD) xx.xx

Enter data for lot after sampling and preparation for infusion. Represents actual cells infused.
Note: Even if cells pooled for infusion enter data below for Lot#4 only.

100 Total # of viable nucleated cells infused, Lot#4 (TOTL4INF) (xxx.x) x 10^8 cells
101 Indicate reason if all cells were not infused:(LOT4REAS)
102 Gram stain results infused cells Lot#4 (GRSL4RES)
1 Positive
2 Negative
103 Endotoxin results infused cells, Lot#4 (ENDOL4RES)
1 Positive
2 Negative
104 If positive indicate EU/mL detected, Lot#4 (EUMLL4RES) EU per mL Final Product
105 If negative indicate test sensitivity, Lot#4 (SENSL4RES) EU per mL Final Product
106 Day 14 Sterility results from last wash, Lot#4 (CULL4RES)
1 Positive
2 Negative
107 If Sterility Culture positive indicate organism, Lot#4 (ORGL4)
108 Was Lot#4 pooled for infusion? (L4POOLTRES)
1 Yes
2 No

109 If yes indicate identity of second lot. (IDENTL4)

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FINAL PRODUCT LOT #5

110 Record the nature of the lot. (NATLOT5)

1 Partial Product#1 pooled with partial product#2 ☐
2 Other, describe ☐

Record date of the CD34 selection procedure:

111 Selection#5 (Lot#5) (SELDATE5) ☐ (mm/dd/yyyy)

Record the Donation Identification Number(s) (DIN) & Division Codes for the starting apheresis products used for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier.

112 DIN Start Apheresis #1 Lot#5: (DIN1START5) ☐
113 Division Code Apheresis #1 Lot#5 (CODE1LOT5) ☐
114 DIN Start Apheresis #2 Lot#5: (DIN2START5) ☐
115 Division Code Apheresis #2 Lot#5 (CODE2LOT5) ☐

Record the Donation Identification Number (DIN) for this lot:
Note: If ISBT128 labeling not used, indicate unique product identifier

116 DIN Lot #5: (DINLOT5) ☐

Enter data for lot after selection and prior to final sampling and preparation for infusion, including:
Note: Values are absolute viable cell numbers only and are NOT cells per kg. Report to percision as indicated

117 Total number of nucleated cell recovered, Lot#5 (TNC5REC) ☐ (xxx.x) x 10^7 cells
118 7-AAD flow viability Lot#5 (VIA5REC) ☐ (xxx.x) %
119 CD34+ stem cells recovered, Lot#5 (CD34S5REC) ☐ (xxx.x) x 10^7 cells
120 CD3+ T cells recovered, Lot#5 (CD3T5REC) ☐ (xxx.x) x 10^4 cells
121 CD56+ NK cells recovered, Lot#5 (CD56NK5REC) ☐ (xxx.x) x 10^4 cells
122 CD59 or CD20+ B cells recovered, Lot#5 (B5REC) ☐ (xxx.x) x 10^5 cells
123 CD45bright/CD54bright Monocytes, Lot#5 (MO5REC) ☐ (xxx.x) x 10^5 cells
124 CD34+ cell purity (% of TNC) (CD34S5PUR) ☐ (xxx.x) %
125 CD34+ yield from start processed cells Lot#5 (CD345YLD) ☐ (xxx.x) %
126 Log50 TCD from starting processed, Lot#5 (LOG5TCD) ☐ xx.xx

Enter data for lot after sampling and preparation for infusion. Represents actual cells infused.
Note: Even if cells pooled for infusion enter data below for Lot#5 only.

127 Total # of viable nucleated cells infused, Lot#5 (TOTL5INF) ☐ (xxx.x) x 10^8 cells
128 Indicate reason if all cells were not infused:(LOT5REAS) ☐
129 Gram stain results infused cells Lot#5 (GRSL5RES)
1 Positive ☐
2 Negative ☐
130 Endotoxin results infused cells, Lot#5 (ENDOL5RES)
1 Positive ☐
2 Negative ☐
131 If positive indicate EU/mL detected, Lot#5 (EUMLL5RES) ☐ EU per mL Final Product
132 If negative indicate test sensitivity, Lot#5 (SENSL5RES) ☐ EU per mL Final Product
133 Day 14 Sterility results from last wash, Lot#5 (CULL5RES)
1 Positive ☐
2 Negative ☐
134 If Sterility Culture positive indicate organism, Lot#5 (ORGL5) ☐
135 Was Lot#5 pooled for infusion? (L5POOLTRES)
1 Yes ☐
2 No ☐

136 If yes indicate identity of second lot. (IDENTL5) ☐

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SUM OF ALL CD34-ENRICHED CELLS INFUSED

Note: All cells processed on a single tubing set is considered to be a lot

137 Total number of Lots Infused:(TOTLOTINF) [ ]

Enter data for lot after sampling and preparation for infusion. Represents actual cells infused.

Note: Values are absolute viable cell numbers only and are NOT cells per kg. Report to percision as indicated

138 Total number of nucleated cells, All Lots (TNCALLINF)	[ ]	(xxx.x) x 10^7 cells
139 7-AAD flow viability ALL Lots (VIAALLINF)	[ ]	(xxx.x) %
140 CD34+ stem cells, All Lots (CD34SALLINF)	[ ]	(xxx.x) x 10^7 cells
141 CD3+ T cells, All Lots (CD3TALLINF)	[ ]	(xxx.x) x 10^4 cells
142 CD56+ NK cells, All Lots (CD56NKALLINF)	[ ]	(xxx.x) x 10^4 cells
143 CD19 or CD20+ B cells, All Lots (BALLINF)	[ ]	(xxx.x) x 10^5 cells
144 CD45bright/CD14bright Monocytes, All Lots (MOALLINF)	[ ]	(xxx.x) x 10^5 cells
145 CD34+ cell purity (% of TNC) (CD34ALLPUR)	[ ]	(xxx.x) %
146 CD34+ yield from starting processed cells (CD34ALLYLD)	[ ]	(xxx.x) %
147 Log10 TCD from all start processed (LOGALLTCD)	[ ]	xx.xx

148 Record patients's weight at time of infusion (PRWTINF) [ ] (xxx.x) kg

Note: This data will be used to compute cells infused per kg. Weight should be obtained at time according to local SOP

149 Was the Certificate of Analysis for each lot complete for lot release requirements at time of infusion? (COACOMPL)

1 Yes
2 No

[ ]

Signature Manifest

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Title: Graft Characterization Form for CTN 1301 Protocol

All dates and times are in Eastern Time.

STCL-PROC-015 FRM5 Graft Characterization Form for CTN 1301 Protocol

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