

Product Identification (HPC, Cord Blood)

8. Cord Blood Registry: **Note: CB_Registry dropdown; Go to question 9 if other, 10 if NMDP or No Reg, 12 if not other, NMDP, or No Reg**
9. Specify other Cord Blood Registry: _____
10. Cord Blood Bank: **Note: CB_Bank dropdown; Req if NMDP or No Reg in Q8; Go to question 11 if other, 12 if not other**
11. Specify other Cord Blood Bank: _____
12. Cord Blood Unit ID on product bag: _____
13. NMDP Cord Blood Unit ID (CBUID): *(if applicable)* _____
Required if Registry (#8) = NMDP; At least one of Q13, 14, and 15 is required
14. Non-NMDP Registry Cord Blood Unit ID (Coop Reg CBUID): *(if applicable)* _____
15. Local Cord Blood Unit ID: *(if applicable)* _____ **Go to question 16 if answer, 17 if no answer**
16. Is the Local Cord Blood Unit ID also the ISBT-128 number?
 Yes
 No

Copy questions 12-16 to report additional bags of these products.

17. Was the CBU requested through the NMDP?
 Yes
 No
18. Is the CBU licensed by the U.S. Food and Drug Administration?
 Yes **Go to question 25**
 No **Go to question 19**

19. Specify the IND Sponsor:

NMDP sponsored Cord Blood IND **Go to question 25**

Other **Go to questions 20-21**

20. Specify IND Sponsor name: _____

21. Specify IND number: *(if known)* _____ **Go to question 25**

Donor Identification (HPC, Marrow; HPC, Apheresis; TC, Apheresis; TC, Whole Blood; Other)

22. ID on product bag: _____

23. NMDP Donor ID (DID): *(if applicable)* _____ — _____ — _____ **Note: At least one of Q23 and Q24 is required**

24. Non-NMDP Unrelated Donor ID (Coop Reg Donor ID): *(if applicable)* _____

Copy questions 22-24 to report additional bags of these products.

Product Complaint Information

25. Was the product bag cracked/broken?

Yes

No

26. Did the cryopreserved product arrive thawed?

Yes

No

Not applicable

27. Was there a problem with transport or handling?

Yes

No

28. Was there a problem with product labeling and/or accompanying records?

Yes

No

29. Was product contaminated?

- Yes
- No

30. Was there a problem with product appearance (e.g. clots, color, particulates)?

- Yes
- No

31. Was the cell count/viability significantly lower than expected or agreed upon?

- Yes
- No

32. Was there a problem of a nature not listed in questions 25–31?

- Yes
- No

33. When was problem/complaint discovered?

- Upon receipt (i.e. when your site inspected and took possession of the product) **Go to question 35**
- After receipt **Go to question 34**

34. Specify: _____

35. Describe problem/complaint and when and how it was discovered: _____

36. Describe immediate action taken: _____

37. Was product infused?

- Yes **Go to questions 38-39**
- No **Go to question 40**

To Be Completed By NMDP/CIBMTR Reviewer

Product Complaint: Failure/possible failure of a drug (includes biological products) to meet any of its specifications. This includes complaints that may potentially impact the safety, quality, identity, purity, or potency of the product.

44. Will NMDP/CIBMTR be initiating a product complaint investigation?

- Yes **Go to question 47**
- No **Go to questions 45-46**

45. Rationale:

- Licensed Cord Blood Unit
- Not on NMDP sponsored Cord Blood IND
- Product (Marrow, PBSC, Therapeutic Cells) not facilitated by NMDP
- Does not meet "product complaint" definition, but will be forwarded to appropriate NMDP department for follow-up
- Other

46. Comment: (text box; required if Q45 = other)

47. Will NMDP/CIBMTR be notifying the Cord Blood Bank? **Note: if yes must be cord in Q6**

- Yes
- No

48. Will NMDP/CIBMTR be notifying the non-NMDP Cord Blood IND Sponsor? **Note: if yes must be cord in Q6**

- Yes **Go to question 49**
- No **Go to question 50**

49. Non-NMDP Cord Blood IND Sponsor email: _____

50. Additional comments: (optional)

Person Completing Review Section of Form

51. First Name: **Note: auto-populated based on LDAP of user submitting review portion of form; don't show question #**

52. Last Name: **Note: auto-populated based on LDAP of user submitting review portion of form; don't show question #**

53. Date: **Note: auto-populated based on date review portion of form is submitted; don't show question #**

____ _ / ____ _ / ____ _
YYYY MM DD