FormsNet™ Product Complaint Form

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number (CCN): ___ ___ ___ ___ ___ **(FN unable to pre-populate but number at top of screen)**

NMDP transplant center number (TC Code): ___ ___ ___

NMDP secondary transplant center number (Secondary TC Code): *(if applicable)* ___ ___ ___ ___

All fields required unless otherwise indicated.

1. Date problem was discovered: ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

Recipient Information

2. NMDP Recipient ID (RID): *(if applicable)* ___ ___ ___ — ___ ___ — ___

3. Local Recipient ID: *(optional)* _____

Product Information

4. Date product was received: ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

5. Date of product collection: ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

6. Product type received by transplant center:
   - ☐ HPC, Marrow (Bone Marrow) ***Go to questions 22-24***
   - ☐ HPC, Apheresis (Peripheral Blood Stem Cells) ***Go to questions 22-24***
   - ☐ HPC, Cord Blood (Umbilical Cord Blood) ***Go to questions 8, 10, 12-15, and 17-18***
   - ☐ TC, Apheresis (Therapeutic Cells) ***Go to questions 22-24***
   - ☐ TC, Whole Blood (Therapeutic Cells) ***Go to questions 22-24***
   - ☐ Other - ***Go to questions 7 and 22-24***

7. Specify other product type using ISBT-128 naming conventions: _____ ***Go to question 22***

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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***

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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

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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***

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38. Date of infusion: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

39. Was there a serious recipient adverse event caused by, or probably caused by, the product?

☐ Yes – Complete an Adverse Event form to report details

☐ No

Person Completing Form

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

_____

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

_____

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

___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

43. Preferred method of contact: *(phone number or e-mail address)* **Note: don't show question #**

_____

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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

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