FormsNet™ Adverse Event Form

Registry Use Only

Sequence Number:

Date Received:

Recipient Identification

1. CIBMTR Recipient ID (CRID):

   ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

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

   ____ ____ ____ - ____ ____ ____ - ____

3. CIBMTR Center Number (CCN):

   ____ ____ ____ ____ ____

4. NMDP transplant center number (TC Code): *(if applicable)*

   ____ ____ ____

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

   ____ ____ ____ ____

6. Local Recipient ID: *(optional)*

   _____

7. Product type received by recipient:

   ☐ HPC, Marrow (Bone Marrow) ***Go to questions 9-15***
   ☐ HPC, Apheresis (Peripheral Blood Stem Cells) ***Go to questions 9-15***
   ☐ HPC, Cord Blood (Umbilical Cord Blood) ***Go to questions 16-18, 20-24, 26, and 28-29***
   ☐ TC, Apheresis (Therapeutic Cells) ***Go to questions 9-15***
   ☐ TC, Whole Blood (Therapeutic Cells) ***Go to questions 9-15***
   ☐ Other ***Go to questions 8-15***

   8. Specify other product type using ISBT-128 naming conventions: _____

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

9. NMDP Donor ID (DID): *(if applicable)* **Note: at least one of Q9 or Q10 (Donor ID) is required**

   ____ ____ ____ ____ - ____ ____ ____ ____ - ____

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

    _____

Note: question 11-15 will be a group multiple to collect all bag IDs associated with all days of collection

11. Date of Collection:

    ___ ___ ___ ___ - ___ ___ - ___ ___
    YYYY MM DD

12. ID on product bag:

    _____

13. ID on product bag 2: *(if applicable)*

    _____

14. ID on product bag 3: *(if applicable)*

    _____

15. ID on product bag 4: *(if applicable)* ***Go to question 33***

    _____

Product Identification (HPC, Cord Blood)

Note: questions 16-32 will be a group multiple to collect all the data if multiple CBUs are transplanted

16. NMDP Cord Blood Unit ID (CBUID): *(if applicable)* **Note: at least one Q16, Q17, Q18 is required**

    ____ ____ ____ ____ - ____ ____ ____ ____ - ____

17. Non-NMDP Registry Cord Blood Unit ID (Coop Reg CBUID): *(if applicable)*

    _____

18. Local Cord Blood Unit ID: *(if applicable)* ***Go to question 19 if answered, 20 if not answered***

    _____

    19. Is the Local Cord Blood Unit ID also the ISBT-128 number?

        ☐ Yes
        ☐ No

20. Cord Blood Unit ID on product bag 1:

    _____

21. Cord Blood Unit ID on product bag 2: *(if applicable)*

    _____

22. Cord Blood Unit ID on product bag 3: *(if applicable)*

    _____

23. Cord Blood Unit ID on product bag 4: *(if applicable)*

_____

24. Cord Blood Registry: **Note: CB_Registry dropdown; If NMDP then Q16 must be answered; *Go to question 25 if other, 26 if NMDP or No Reg, 28 if not other, NMDP or No Reg***

25. Specify other Cord Blood Registry: _____

26. Cord Blood Bank: **Note: CB_Bank drpdwn; Req if NMDP or No Reg in Q24; *Go to question 27 if other, 28 if not other***

27. Specify other Cord Blood Bank: _____

28. Was the CBU requested through the NMDP?

☐ Yes
☐ No

29. Is the CBU licensed by the U.S. Food and Drug Administration?

☐ Yes ***Go to question 33***
☐ No ***Go to question 30***

30. Specify the IND Sponsor:

☐ NMDP sponsored Cord Blood IND ***Go to question 33***
☐ Other ***Go to questions 31-32***

31. Specify IND Sponsor name: _____

32. Specify IND number: *(if known)* _____

33. Date of infusion:

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

34. Adverse event date of onset:

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

35. Date center became aware of the event:

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

36. Does this adverse event meet the regulatory definition of a serious adverse event?

☐ Yes ***Go to question 37***
☐ No ***Go to question 39***

An adverse event is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes listed in question 37 below.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition (use other option in question 37).

37. Serious adverse event outcome:

☐ Death ***Go to question 39***
☐ Life-threatening adverse event ***Go to question 39***
☐ Inpatient hospitalization or prolongation of existing hospitalization ***Go to question 39***
☐ Persistent or significant disability/incapacity ***Go to question 39***
☐ Congenital anomaly/birth defect ***Go to question 39***
☐ Other ***Go to question 38***

38. Specify other serious adverse event outcome: _____

39. What is the relationship between the reported adverse event and the product?

☐ Unrelated
☐ Unlikely
☐ Possibly
☐ Probably
☐ Definitely

40. Is this adverse event being reported because of possible, probable, or definite disease transmission caused by the product?

☐ Yes
☐ No

41. Event Description:

42. Relevant Medical Clinical Findings (e.g., pre-existing conditions, lab results, concomitant medications, procedures, etc.): *(optional)*

43. CTCAE Primary Category: **Note: dropdown of CTCAE version 4.0 categories with filters for Q44**

44. CTCAE Primary Event: **Note: dropdown of CTCAE version 4.0 events**

45. CTCAE Grade (most severe):

☐ Grade 1
☐ Grade 2
☐ Grade 3
☐ Grade 4
☐ Grade 5

An adverse event is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application.

46. Does this adverse event meet the regulatory definition of “unexpected”?

☐ Yes
☐ No

47. Has this adverse event resolved at the time of this report?

☐ Yes ***Go to questions 48-49***
☐ No ***Go to question 50***

48. Date of resolution:

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

49. Type of resolution:

☐ Complete recovery from adverse event
☐ Resolved, but with residual effects
☐ Fatal adverse event
☐ Death unrelated to this adverse event

50. Additional comments: *(optional)*

Person Completing Form

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

_____

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

_____

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

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

54. Preferred method of contact: *(phone number or email address)* **Note: don’t show question #**

_____

To Be Completed By NMDP/CIBMTR Reviewer

55. Will NMDP/CIBMTR be initiating an adverse event investigation?

☐ Yes ***Go to question 58*** **Note: trigger Adverse Event Medical Monitor Form**
☐ No ***Go to questions 56-57*** **Note: DO NOT trigger Adverse Event Medical Monitor Form**

56. Rationale:

☐ Licensed Cord Blood Unit
☐ Not on NMDP sponsored Cord Blood IND
☐ Product (Marrow, PBSC, Therapeutic Cells) not facilitated by NMDP
☐ Not reported as a serious adverse event
☐ Other

57. Comment: **Note: required if other in Q56, acceptable if filled in for any other option in Q56**

58. Will NMDP/CIBMTR be notifying the Cord Blood Bank? **Note: if yes must be cord in Q7**

☐ Yes
☐ No

59. Will NMDP/CIBMTR be notifying the non-NMDP Cord Blood IND Sponsor? **Note: if yes must be cord in Q7**

☐ Yes ***Go to question 60***
☐ No ***Go to question 61***

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

61. Additional comments: *(optional)*

Person Completing Review Section of Form

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

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

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

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD