### Key Fields

**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)*

#### Product type received by recipient:

- HPC, Marrow (Bone Marrow)
- HPC, Apheresis (Peripheral Blood Stem Cells)
- HPC, Cord Blood (Umbilical Cord Blood)
- TC, Apheresis (Therapeutic Cells)
- TC, Whole Blood (Therapeutic Cells)
- Other

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

### Adverse Event Information

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

8. NMDP Donor ID (DID): *(if applicable)*
9. Non-NMDP Unrelated Donor ID (Coop Reg Donor ID): *(if applicable)*
10. Global Registration Identifier for Donors (GRID): *(if applicable)*

#### HPC, Marrow; HPC, Apheresis; TC, Apheresis; TC, Whole Blood; Other Collection Information (1)

11. Date of Collection: __-__-__
12. ID on product bag 1: __-__-__
13. ID on product bag 2: *(if applicable)*
14. ID on product bag 3: *(if applicable)*
15. ID on product bag 4: *(if applicable)*

### Product Identification (HPC, Cord Blood) (1)

16. NMDP Cord Blood Unit ID (CBUID): *(if applicable)*
17. Non-NMDP Registry Cord Blood Unit ID (Coop Reg CBUID): *(if applicable)*
18. Local Cord Blood Unit ID: *(if applicable)*
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:
25. Specify other Cord Blood Registry:
26. Cord Blood Bank:
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
   - No
30. Specify the IND Sponsor:
   - NMDP sponsored Cord Blood IND
   - Other
31. Specify IND Sponsor name:
32. Specify IND number: *(if known)*

### Adverse Event Information

33. Date of infusion: __-__-__
34. Date of onset: __-__-__
35. Adverse event date of onset: __-__-__
36. Date center became aware of the event: __-__-__

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**Adverse Event Form**

**Questions: 9 - 51**

**Questions: 12 - 16**

**Questions: 17 - 33**

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CIBMTR Form 3001 revision 3.0 last updated Wednesday, October 10, 2018

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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 Does this adverse event meet the regulatory definition of a serious adverse event?
   - Yes
   - No

38 Serious adverse event outcome:
   - Death
   - Life-threatening adverse event
   - Inpatient hospitalization or prolongation of existing hospitalization
   - Persistent or significant disability/incapacity
   - Congenital anomaly/birth defect
   - Other

39 Specify other serious adverse event outcome: __________________________

40 What is the relationship between the reported adverse event and the product?
   - Unrelated
   - Unlikely
   - Possibly
   - Probably
   - Definitely

41 Is this adverse event being reported because of possible, probable, or definite disease transmission caused by the product?
   - Yes
   - No

42 Event Description: __________________________

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

44 CTCAE Primary Category: __________________________

45 CTCAE Primary Event: __________________________

46 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.

47 Does this adverse event meet the regulatory definition of “unexpected”?
   - Yes
   - No

48 Has this adverse event resolved at the time of this report?
   - Yes
   - No

49 Date of resolution: __ __ __ - __ __ __

50 Type of resolution:
   - Complete recovery from adverse event
   - Resolved, but with residual effects
   - Fatal adverse event
   - Death unrelated to this adverse event

51 Additional comments: (optional)

Person Completing Form
First Name: __________________________ Last Name: __________________________

Date: __ __ __ - __ __ __

Preferred method of contact: (phone number or email address) __________________________

To Be Completed By NMDP/CIBMTR Reviewer

Questions: 52 - 58

52 Will NMDP/CIBMTR be initiating an adverse event investigation?
   - Yes
   - No

53 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

54 Comment: __________________________

55 Will NMDP/CIBMTR be notifying the Cord Blood Bank?
   - Yes
   - No
**Form 3001 R3.0: Adverse Event Form**

**Center:**

**CRID:**

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56 Will NMDP/CIBMTR be notifying the non-NMDP Cord Blood IND Sponsor?

- [ ] Yes  
- [x] No

57 Non-NMDP Cord Blood IND Sponsor email: __________________________

58 Additional comments: (optional)

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**Person Completing Review Section of Form**

First Name: ___________________________  Last Name: ___________________________

Date: __ __ __ __ __ __ __ __ __ __

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