Form 3001 R3.0: Adverse Event Form

Center: CRID:

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)* _____

7 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

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

Adverse Event Information

Questions: 9 - 51

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

9 NMDP Donor ID (DID): *(if applicable)* _____

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

11 Global Registration Identifier for Donors (GRID) *(if applicable)* _____

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

Questions: 12 - 16

12 Date of Collection: __ __ __ __ - __ __- __ __

13 ID on product bag: _____

14 ID on product bag 2: *(if applicable)* _____

15 ID on product bag 3: *(if applicable)* _____

16 ID on product bag 4: *(if applicable)* _____

Product Identification (HPC, Cord Blood) (1)

Questions: 17 - 33

17 NMDP Cord Blood Unit ID (CBUID): *(if applicable)* _____

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

19 Local Cord Blood Unit ID: *(if applicable)* _____

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

○ Yes ○ No

21 Cord Blood Unit ID on product bag 1: _____

22 Cord Blood Unit ID on product bag 2: *(if applicable)* _____

23 Cord Blood Unit ID on product bag 3: *(if applicable)* _____

24 Cord Blood Unit ID on product bag 4: *(if applicable)* _____

25 Cord Blood Registry: _____

26 Specify other Cord Blood Registry: _____

27 Cord Blood Bank: _____

28 Specify other Cord Blood Bank: _____

29 Was the CBU requested through the NMDP?

○ Yes ○ No

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

○ Yes ○ No

31 Specify the IND Sponsor:

- ○ NMDP sponsored Cord Blood IND
- ○ Other

32 Specify IND Sponsor name: _____

33 Specify IND number: *(if known)* _____

34 Date of infusion: __ __ __ __ - __ __- __ __

35 Adverse event date of onset: __ __ __ __ - __ __- __ __

36 Date center became aware of the event: __ __ __ __ - __ __- __ __

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Center: CRID:

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

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

Yes No

57 Non-NMDP Cord Blood IND Sponsor email: _____

58 Additional comments: *(optional)*

_____

Person Completing Review Section of Form

First Name: _____ Last Name: _____

Date: __ __ __ __ - __ __ - __ __