

# Form 3010 R3.0: Product Complaint Form

Center:

CRID:

## Key Fields

Sequence Number \_\_\_\_\_

Date Received: \_\_\_\_-\_\_\_\_-\_\_\_\_

CIBMTR Center Number (CCN): \_\_\_\_\_

NMDP transplant center number (TC Code): \_\_\_\_\_

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

## Product Complaint Information

Questions: 1 - 40

1 Date problem was discovered: \_\_\_\_-\_\_\_\_-\_\_\_\_

### Recipient Information

2 NMDP Recipient ID (RID): *(if applicable)* \_\_\_\_\_

3 Local Recipient ID: *(optional)* \_\_\_\_\_

### Product Information

4 Date product was received: \_\_\_\_-\_\_\_\_-\_\_\_\_

5 Date of product collection: \_\_\_\_-\_\_\_\_-\_\_\_\_

6 Product type received by transplant center:

- ☐ 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: \_\_\_\_\_

### Product Identification (HPC, Cord Blood)

8 Cord Blood Registry:

- |  |   |
|--|---|
| <input type="radio"/> National Marrow Donor Program (United States)                  | <input type="radio"/> Korea Cord Blood Bank (Korea)   |
| <input type="radio"/> INCUCAI - Argentine CPH Donors Registry (Argentina)            | <input type="radio"/> Mexican Bone Marrow Donor Registry (Mexico)                               |
| <input type="radio"/> Australian Bone Marrow Donor Registry (Australia)              | <input type="radio"/> Europdonor Foundation (Netherlands)                                       |
| <input type="radio"/> Austrian Cord Blood Registry (Austria)                         | <input type="radio"/> Poltransplant (Polish Central)  |
| <input type="radio"/> Belgium Cord Blood Registry                                    | <input type="radio"/> Unrelated CB Registry (Poland)  |
| <input type="radio"/> Redome-Brasil (Brazil)   | <input type="radio"/> Spanish Cord Blood Registry (Spain)                                       |
| <input type="radio"/> Chinese Marrow Donor Program (China)                           | <input type="radio"/> Tobias Registry of Swedish Bone Marrow Donors - CORD BLOOD (Sweden)       |
| <input type="radio"/> OneMatch Stem Cell and Marrow Network                          | <input type="radio"/> Swiss Blood Stem Cells - CORD BLOOD (Switzerland)                         |
| <input type="radio"/> Czech Stem Cells Registry (CSCR) - CORD BLOOD (Czech Republic) | <input type="radio"/> Buddhist Tzu Chi General Hospital Stem Cells Center - CORD BLOOD (Taiwan) |
| <input type="radio"/> Finnish Cord Blood Registry (Finland)                          | <input type="radio"/> Ankara University Unrelated Blood and Marrow (Turkey)                     |
| <input type="radio"/> The French Cord Blood Registry (France)                        | <input type="radio"/> British Bone Marrow Registry - Cord Blood (United Kingdom)                |
| <input type="radio"/> ZKRD - CORD BLOOD (Germany)                                    | <input type="radio"/> Anthony Nolan Trust (United Kingdom)                                      |
| <input type="radio"/> Hadassah BMDR (Israel)   | <input type="radio"/> Other Registry - (specify below)  |
| <input type="radio"/> Italian Cord Blood Bank Network (Italy)                        | <input type="radio"/> Bank doesn't participate through a Registry                               |

9 Specify other Cord Blood Registry: \_\_\_\_\_

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## 10 Cord Blood Bank:

- ☐ LifeSouth Community Blood Centers (Gainesville, FL)
- ☐ New York Blood Center (Long Island City, NY)
- ☐ Ashley Ross Cord Blood Program (San Diego, CA)
- ☐ Vivocell Biosolutions GmbH & Co KG (Graz, Austria)
- ☐ St. Louis Cord Blood Bank (St Louis, MO)
- ☐ ITxM Cord Blood Services (Rosemont, IL)
- ☐ Reliance Life Science (Navi Mumbai, India)
- ☐ Eurocord- Slovakia (Bratislava, Slovakia)
- ☐ Bonfils Cord Blood Services (Denver, CO)
- ☐ Texas Cord Blood Bank (San Antonio, TX)
- ☐ BIONET/BabyBanks (Taipai, Taiwan)
- ☐ Bangkok Cord (Bangkok, Thailand)
- ☐ Children's Hospital of Orange County (CHOC) CBB (Orange, CA)
- ☐ Community Blood Services (Camden, NJ)
- ☐ Tokyo Cord Blood Bank (Tokyo, Japan)
- ☐ Celgene Cord Blood Bank (Cedar Knolls, NJ)
- ☐ Michigan Blood Cord Blood Bank (Grand Rapids, MI)
- ☐ Héma-Québec public cord blood bank (Montreal, Canada)
- ☐ Bloodworks (Seattle, WA)
- ☐ StemCyte Inc. (Covina, CA)
- ☐ Hellenic Cord Blood Bank (Athens, Greece)
- ☐ J.P. McCarthy Cord Stem Cell Bank (Detroit, MI)
- ☐ LeuvenCord (Belgium)
- ☐ Carolinas Cord Blood Bank (Durham, NC)
- ☐ Other Bank - (specify below)
- ☐ Lifeforce Cryobanks (Altamonte Springs, FL)
- ☐ New Jersey Cord Blood Bank (Allendale, NJ)
- ☐ M.D. Anderson Cord Blood Bank (Houston, TX)
- ☐ CORD:USE Cord Blood Bank (Orlando, FL)
- ☐ Gift of Life Bone Marrow Foundation, Inc. (Boca Raton, FL)
- ☐ University of Colorado Cord Blood Bank (Aurora, CO)
- ☐ StemCyte Taiwan National Cord Blood Center (Linkou, Taiwan)
- ☐ Singapore Cord Blood Bank, Ltd. (Singapore, Singapore)
- ☐ Sheba Cord Blood Bank (Tel Hashomer, Israel)
- ☐ Cleveland Cord Blood Center (Warrensville Heights, OH)
- ☐ Düsseldorf Cord Blood Bank (Dusseldorf, Germany)
- ☐ Healthbanks Biotech Co., Ltd (Taipai, Taiwan)

11 Specify other Cord Blood Bank: \_\_\_\_\_

## Cord Blood Unit Identification (1)

Questions: 12 - 16

**This section is designed to capture all bags of a cord blood product, if applicable. Report information for each product bag as a separate instance of the multiple.**

- 12 Cord Blood Unit ID on product bag: \_\_\_\_\_
- 13 NMDP Cord Blood Unit ID (CBUID): *(if applicable)* \_\_\_\_\_
- 14 Non-NMDP Registry Cord Blood Unit ID (Coop Reg CBUID): *(if applicable)* \_\_\_\_\_
- 15 Local Cord Blood Unit ID: *(if applicable)* \_\_\_\_\_
- 16 Is the Local Cord Blood Unit ID also the ISBT-128 number?
- ☐ Yes ☐ No

17 Was the CBU requested through the NMDP?

- ☐ Yes ☐ No

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

- ☐ Yes ☐ No

19 Specify the IND Sponsor:

- ☐ NMDP sponsored Cord Blood IND
- ☐ Other

20 Specify IND Sponsor name: \_\_\_\_\_

21 Specify IND number: *(if known)* \_\_\_\_\_

## Donor Identification (HPC, Marrow; HPC, Apheresis; TC, Apheresis; TC, Whole Blood; Other) (1)

Questions: 22 - 25

**This section is designed to capture all bags of a product, if applicable. Report information for each product bag as a separate instance of the multiple.**

- 22 ID on product bag: \_\_\_\_\_
- 24 Registry Donor ID: *(if applicable)* \_\_\_\_\_
- 25 Global Registration Identifier for Donors (GRID) *(if applicable)* \_\_\_\_\_

## Product Complaint Information

26 Was the product bag cracked/broken?

- ☐ Yes ☐ No

27 Did the cryopreserved product arrive thawed?

- ☐ Yes ☐ No ☐ Not applicable

28 Was there a problem with transport or handling?

- ☐ Yes ☐ No

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

☐ Yes ☐ No

30 Was product contaminated?

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

33 Was there a problem of a nature not listed in questions 26-32?

☐ Yes ☐ No

34 When was problem/complaint discovered?

- ☐ Upon receipt (i.e. when your site inspected and took possession of the product)
- ☐ After receipt

35 Specify: \_\_\_\_\_

36 Describe problem/complaint and when and how it was discovered:

37 Describe immediate action taken:

38 Was product infused?

☐ Yes ☐ No

39 Date of infusion: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

40 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

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

Preferred method of contact: (*phone number or email address*) \_\_\_\_\_

## To Be Completed By NMDP/CIBMTR Reviewer

Questions: 41 - 47

**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.**

41 Will NMDP/CIBMTR be initiating a product complaint investigation?

☐ Yes ☐ No

42 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

43 Comment:

44 Will NMDP/CIBMTR be notifying the Cord Blood Bank?

☐ Yes ☐ No

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

☐ Yes ☐ No

46 Non-NMDP Cord Blood IND Sponsor email: \_\_\_\_\_

47 Additional comments: (*optional*)

## Person Completing Review Section of Form

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_