

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: _____

Form 3010 R3.0: Product Complaint Form

Center:

CRID:

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)
- Vivotec 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 (Taipei, 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 (Taipei, 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

Form 3010 R3.0: Product Complaint Form

Center: _____

CRID: _____

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: ____ - ____ - ____