Product Complaint Form Instructions

NOTE: Product Complaint Definition: 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.

This form should be completed when a transplant center identifies problem(s) with the product as indicated in the definition above. The form should be completed as soon as possible after identifying the problem(s), but within three business days. The form should be completed for a single product (including all bags of that product). If more than one product is received that has the same problem(s), a separate Complaint form should be completed for each product.

Key Fields

Accuracy of the Key Fields is essential for ensuring that:

- Data are being reported for the correct recipient.
- Outcomes data accurately reflects appropriate transplant type and product for each transplant center.
- Data are being shared with the correct donor center, cord blood bank, cooperative registry, or other agency.

The Key Fields precede the form body and are automatically populated in the FormsNet3^{SM} application based on information provided on the CRID Assignment Form 2804. If errors are noted in the key fields, correct Form 2804 and then review it for accuracy. After Form 2804 has been corrected, verify data has been updated on all completed forms. If the data has not been updated automatically, centers will need to reprocess the completed forms to correct the key field data. If errors are noted in key fields for second or subsequent transplants, contact your CRC to make any necessary corrections to the transplant or product type.

Sequence Number: The system will auto-populate this field. Make note of the sequence number in any external tracking mechanism you have to easily locate the form again.

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Date Received: The system will auto-populate this field with the date the form is first processed.

CIBMTR Center Number (CCN): The system will auto-populate this field with your center's CIBMTR center number.

NMDP transplant center number (TC Code): Enter the center's NMDP transplant center number. This question is required.

NMDP secondary transplant center number (Secondary TC Code): ***(if applicable)*** This field is applicable for a small number of centers. If your center has a Secondary TC Code, please enter it here. For those at all other transplant centers, leave this question blank.

Product Complaint Information

Question 1: Date problem was discovered:
Indicate the date that the problem(s) reported with this product was first noticed (ISO date format YYYY/MM/DD). This field is required.

Question 2: NMDP Recipient ID (RID): ***(if applicable)***
Enter the NMDP-generated Recipient ID number (RID). The field has a built in format XXX-XXX-X and only the digits will need to be entered. This is the recipient identification number you use with the NMDP's search department, among others. This is an optional field.

Question 3: Local Recipient ID: ***(optional)***
If your center assigns an institution-specific ID for recipients, you may enter that here. This field is not required.

Question 4: Date product was received:
Enter the date that your center took responsibility of the product (ISO date format YYYY/MM/DD). If you are refusing to accept this product based on quality reasons, indicate the date that you inspected the product to determine its suitability. This field is required.

Question 5: Date of product collection:
Enter the date the product was collected (ISO date format YYYY/MM/DD). Collection date should be noted in the accompanying records sent with the product. This field is required.

Question 6: Product type received by transplant center:
Indicate the product for which this form is being completed. This field is required. Mark only one. If the product is not listed, check other and specify the product type in question 7. If the product was Cord Blood, continue with question 8. For all other products, continue with question 22.

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Questions 7: Specify other product type using ISBT-128 naming conventions: Indicate the other product type (required if question 6 is “Other”) and continue with question 22.

Product Identification (HPC, Cord Blood)

NOTE: Questions 8-21 may only be completed if the Product type indicated in question 6 is HPC, Cord Blood (Umbilical Cord Blood).

Questions 8-9: Cord Blood Registry: and **Specify other Cord Blood Registry:**

Select the appropriate Cord Blood Registry from the dropdown. If the bank that provided the product is not working through a registry, select “Bank doesn’t report through a registry.” If you do not see the appropriate registry listed, please select “Other” and specify the other registry in question 9.

Questions 10-11: Cord Blood Bank: and **Specify other Cord Blood Bank:**

This question must be answered if question 8 is answered “NMDP” or “Bank doesn’t report through a registry”. Select the appropriate cord blood bank from the dropdown list.

If “Other” is selected in question 10, specify cord blood bank in question 11.

Cord Blood Unit Identification – multiple section

Questions 12-16: Cord Blood Unit ID on product bag, NMDP Cord Blood Unit ID (CBUID): *(if applicable),* Non-NMDP Registry Cord Blood Unit ID (Coop Reg CBUID): *(if applicable),* Local Cord Blood Unit ID (if applicable), and **Is the Local Cord Blood Unit ID also the ISBT-128 number?**

Enter the cord blood unit ID in the appropriate question(s). Provide as many IDs as are known to facilitate investigation. One of questions 13-15 is required to be entered if question 6 is answered HPC, Cord Blood (Umbilical Cord Blood). The NMDP CBU ID is required if question 8 indicates that the unit was facilitated by the NMDP.

If question 15 is answered, then question 16 is also required to be answered.

NOTE: If there are multiple bags of this product, questions 12-16 can be repeated up to 5 times to report all bags of the product by clicking the Add multiple icon (orange +).

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Question 17: Was the CBU requested through the NMDP?

Select whether the cord blood unit was requested through the NMDP. This field is required.

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

Select whether the cord blood unit is licensed by the FDA. This field is required.

If "No" is selected in question 18, specify IND sponsor in question 19.

Questions 19-21: Specify the IND Sponsor: and **Specify IND Sponsor name:** and **Specify IND number:** ***(if known)***

If the cord blood unit was not licensed by the FDA, indicate whether shipment was facilitated under the NMDP IND or another Sponsor's IND.

If "Other" is selected in question 19, specify IND sponsor name and IND number in questions 20-21.

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

Note: Questions 22, 24-25 must be completed if the product listed in question 6 is anything other than Cord Blood.

Question 22: ID on product bag:
Enter the ID on the product bag.

Question 24: Registry Donor ID: ***(if applicable)*****:**
Enter the Registry Donor ID.

Question 25: Global Registration Identifier for Donors (GRID) ***(if applicable)*****:**
Enter the GRID on the product bag.

NOTE: If there are multiple bags of this product, questions 22, 24-25 can be repeated up to 5 times to report all bags of the product by clicking ADD NEW.

Product Complaint Information

For Questions 26-33, report all issues that apply to this complaint. Each question must be answered either "yes" or "no".

Question 26: Was the product bag cracked/broken?
Indicate if the product bag was damaged. This field is required.

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Question 27: Did the cryopreserved product arrive thawed?

If the product was intended to be frozen upon arrival, indicate if it arrived thawed. If the product was not intended to arrive frozen (e.g., fresh PBSC or Marrow), indicate “not applicable.” This field is required.

Question 28: Was there a problem with transport or handling?

Indicate if there was a problem with transport or handling of the product. This field is required.

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

Indicate if there was a problem with product labeling or the records that accompany the product at shipment. This field is required.

Question 30: Was the product contaminated?

Indicate if the product was contaminated. Describe the nature of the contamination in question 36 (e.g., positive sterility result). This field is required.

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

Indicate if there was a problem with the appearance of the product. Describe the appearance in question 36. This field is required.

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

Indicate if the cell count or viability was significantly lower than expected or agreed upon. This field is required.

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

If there was another problem that was not listed in any of the above fields, indicate “yes” here and describe the problem in question 36.

Questions 34-35: When was the problem/complaint discovered?

Indicate whether the problem was discovered when the product was received or after receipt (e.g., at product thaw). If after thaw, indicate at what point the problem was discovered in Q35. This field is required.

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

Enter a description of the problem and impact to the transplant center, transplant schedule, and/or recipient. Include details such as location and approximate size of crack, color, temperature data, preliminary culture results, etc., as applicable to the problem, and describe how the problem was discovered. Do not repeat information that was already entered elsewhere in the form. This question is required for all products.

Note that this field is limited to 1000 characters, so the description should be as succinct as possible, while still describing the event in enough detail so that a reviewer can determine the severity of the incident.

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Question 37: Describe immediate action taken:

Describe any immediate action taken to contain or correct the problem. This question is required for all products. If no action was taken, “none” is an acceptable response. Note that this field is limited to 1000 characters, so the description should be as succinct as possible, while still describing the event in enough detail so that a reviewer can determine the severity of the incident.

Question 38: Was product infused?

Indicate if the product was infused. This field is required.

Question 39: Date of infusion:

Enter the date the product was infused (ISO date format YYYY/MM/DD). This question is required for all products that were infused. If the product was infused overnight, indicate the date the infusion started as the date of infusion.

Question 40: Was there a serious recipient adverse event caused by, or probably caused by, the product?

Indicate whether this product may have caused a serious recipient adverse event. If yes, also complete a Form 3001 – Adverse Event Form.

Person Completing Form

First Name: and **Last Name:**

The First Name and Last Name of the person logged in to complete the form will be populated by the system. There is no action required by the user. These questions will populate each time the form is opened and saved.

Date:

This will be populated by the system each time the form is opened and saved. There is no action required by the user.

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

Enter information for the best way to contact the person completing the form. This information will be used if there are questions about the product complaint that is being reported. This question is required for all products.

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Queries Review and Form Processing

Once the Preferred method of contact field has been completed, proceed to the Queries Review page. Answer any queries and process the form. The “Process” button will submit the form and display a form process page. The “Process/Next” button will submit the current form and will open a new Form 3010 for entry.

NMDP Review Section

Questions 41-47: To Be Completed By NMDP/CIBMTR Reviewer

This section will be completed by NMDP/CIBMTR. Do not enter any information into this section. The form cannot be processed if any of the fields have been completed.

When Form 3010 is processed by a user at the transplant center and there are no errors, the form will go to ‘Review’ status. NMDP will review your submission and document the results of the review on the same form, should you wish to maintain it in your files. Once the form has been reviewed by NMDP/CIBMTR the form will go to ‘Complete’ status. At this time, an email will be sent to the cord blood bank, and to the IND sponsor notifying them of this complaint.

In the event the form is in ‘Complete’ status and data is changed by the transplant center and the form is saved or processed, the information contained in the review section will be removed by the system.

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