Adverse Event Form (Form 3001) Instructions

> **Note: Refer to the study protocol for specific instructions on when to use this form.**

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 CIBMTR center support to make any necessary corrections to the transplant or product type.

Sequence Number: This field will be auto-populated by the system. Make note of the sequence number in any external tracking mechanism you have to easily locate the form again.

Date Received: This field will be auto-populated by the system as the date the form is first processed.

Question 1: CIBMTR Research ID (CRID): This field will be auto-populated by the system. The CRID is a lifelong ID assigned by the CIBMTR to each recipient. The CRID is generated using the CIBMTR Research ID Assignment Form (Form 2804), and must be completed for all HSCT recipients.

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: CIBMTR Center Number (CCN): This field will be auto-populated by the system with your center's five-digit CIBMTR center number.

Question 4: NMDP transplant center number (TC Code): *(if applicable)*
This field will be auto-populated by the system with your center's three-digit NMDP transplant center number.

Question 5: 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.

Question 6: Local Recipient ID: *(optional)*
This is an optional field. Enter your local ID for the recipient.

Questions 7-8: Product type received by recipient: and **Specify other product type using ISBT-128 naming conventions:**
Enter the product type the recipient received. If the recipient has had more than one transplant, enter the product type that is associated with this Adverse Event.

If "Other" is chosen as the product type, specify the product type in question 8.

Adverse Event Information

Note: Questions 10-16 may only be completed if the Product type indicated in question 7 is HPC, Marrow or HPC, Apheresis or TC, Apheresis or TC, Whole Blood or Other.

Question 10-11: Registry Donor ID *(if applicable)* *and* **Global Registration Identifier for Donors (GRID)** *(if applicable)***:**

If the donor is from the NMDP, the GRID should be reported. If the donor is non-NMDP enter either the GRID or Registry Donor ID. Please note the GRID is preferred, but the Registry Donor ID can be used if the GRID is not available. One of these fields is required if question 7 is not HPC, Cord Blood (Umbilical Cord Blood).

HPC, Marrow; HPC, Apheresis; TC, Apheresis; TC, Whole Blood; Other Collection) – multiple section

Question 12-16: Date of Collection: and **ID on product bag, ID on product bag 2:** *(if applicable),* **ID on product bag 3:** *(if applicable),* **ID on product bag 4:** *(if applicable)* For each day of collection, complete the "Date of collection" and as many "ID on product bag" lines as needed. If there is more than one day of collection, add a multiple to enter

Product Identification (HPC, Cord Blood)-multiple section

Note: Questions 17-33 may only be completed if the Product type indicated in question 7 is HPC, Cord Blood (Umbilical Cord Blood).

Questions 17-20: NMDP Cord Blood Unit ID (CBUID): *(if applicable)* and **Non-NMDP Registry Cord Blood Unit ID (Coop Reg CBUID):** *(if applicable)* and **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. One of questions 17-19 is required to be entered if question 7 is answered HPC, Cord Blood (Umbilical Cord Blood). There is a built-in format for NMDP Cord Blood Unit ID, question 17 of XXXX- XXXX-X and you may only enter digits into the field.

If question 19 is answered, then question 20 is also required to be answered.

Questions 21-24: Cord Blood Unit ID on product bag 1: and **Cord Blood Unit ID on product bag 2:** *(if applicable)* and **Cord Blood Unit ID on product bag 3:** *(if applicable)* and **Cord Blood Unit ID on product bag 4:** *(if applicable)*

Enter the cord blood unit ID that is found on the product bag. The first ID is required and the rest are optional and must be completed if applicable.

Questions 25-26: 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 26.

Questions 27-28: Cord Blood Bank: and **Specify other Cord Blood Bank:**

This question must be answered if question 25 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 27, specify cord blood bank in question 28.

Question 29: Was the CBU requested through the NMDP?

Select whether the cord blood unit was requested through the NMDP.

Question 30: Is the CBU licensed by the U.S. Food and Drug Administration?
Select whether the cord blood unit is licensed by the FDA. If "No" is selected in question 30, specify IND sponsor in question 31.

Questions 31-33: 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 31, specify IND Sponsor name and IND number in questions 32-33.

Question 34: Date of infusion:
Enter the date the product was infused (ISO date format YYYY/MM/DD) or you may select the date from the calendar icon. If there is more than one day of infusion enter the initial infusion date. This question is required for all products.

Question 35: Adverse event date of onset:
Enter the onset date for the adverse event (ISO date format YYYY/MM/DD) or you may select the date from the calendar icon. If the exact date is unknown enter the date the investigator determined the adverse event to meet the adverse event reporting criteria (i.e.: serious). This question is required for all products.

Question 36: Date center became aware of the event:
Enter the date you became aware of the adverse event (ISO date format YYYY/MM/DD) or you may select the date from the calendar icon. This question is required for all products.

Question 37: Does this adverse event meet the regulatory definition of a serious adverse event?
Review the definition of a serious adverse event and select response. This question is required for all products.

Questions 38-39: Serious adverse event outcome: and **Specify other serious adverse event outcome:**
Select serious adverse event outcome if the response to question 37 is "Yes".

If "Other" is selected in question 38, specify other serious adverse event outcome in question 39.

Question 40: What is the relationship between the reported adverse event and the product?

Select response for the relationship between the adverse event and the product based on the following definitions. If there was more than one cord blood unit infused, specify the relatedness for each unit in the event description.

Definitely: Adverse event is clearly related to study treatment/procedure.

Probably: Adverse event is likely related to study treatment/procedure. Adverse event is not likely to be caused by underlying medical condition or concomitant therapy, and nature of the adverse event or temporal relationship between the onset of the adverse event and the study treatment/procedure leads the investigator to believe there is a reasonable chance of causal relationship.

Possibly: Adverse event may be related to study treatment/procedure. Adverse event could be attributed to underlying medical condition or other concomitant therapy, but nature of the adverse event or temporal relationship between the onset of the adverse event and study treatment/procedure leads the investigator to believe that there could be a causal relationship.

Unlikely: Adverse event is doubtfully related to study treatment/procedure.

Unrelated: Adverse event is clearly NOT related to study treatment/procedure. Adverse event is most plausibly explained by underlying medical condition or concomitant therapy, or adverse event has no plausible relationship to the study treatment/procedure, or adverse event has no plausible biological relationship to the study treatment/procedure.

This question is required for all products.

Question 41: Is this adverse event being reported because of possible, probable, or definite disease transmission caused by the product?

Select response for the question of disease transmission. This question is required for all products.

Question 42: Event Description:

Enter a description of the adverse event. Include such details as pertinent signs and symptoms, laboratory values, radiographic or pathology findings, and any other procedures/actions taken. This question is required for all products.

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

Enter any other relevant findings that have not been collected elsewhere on the form. Include any subject details that are used to determine seriousness and relatedness of the event. This field is optional for all product types.

Question 44: CTCAE Primary Category:

The Common Terminology Criteria for Adverse Events (CTCAE) version 4 is used to classify the adverse events. More information on the CTCAE can be found on the National Cancer Institute website (http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc).

Select the primary CTCAE category of the adverse event from the dropdown that best matches the adverse event. This question is required for all products.

Question 45: CTCAE Primary Event:

Select the primary CTCAE event for the adverse event from the dropdown. This question is required for all products.

Question 46: CTCAE Grade (most severe):

Select the most severe CTCAE Grade for the adverse event. This question is required for all products.

Question 47: Does this adverse event meet the regulatory definition of "unexpected"?

Review the definition of unexpected and select response. This question is required for all products.

Questions 48-50: Has this adverse event resolved at the time of this report? and **Date of resolution:** and **Type of resolution:**

Select response for adverse event resolution at the time the form is being completed.

If "Yes" is selected in question 48, then enter the date of resolution and the type of resolution.

Question 51: Additional comments: *(optional)*

Enter any additional comments on the adverse event. This question is optional.

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 FormsNet3^{SM} application. There is no action required by the user. These questions will populate each time the form is opened and saved.

Date:

This question 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 on the form or the adverse event that is being reported. This question is required.

NMDP Review Section

Questions 52-58: 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.

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 3001 for entry.

When Form 3001 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. Once the form has been reviewed by NMDP/CIBMTR the form will go to 'Complete' status.

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