Adverse Event Form Instructions

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

Key Field: 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.

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

Recipient Information

Question 1: CIBMTR Recipient ID (CRID):
The CRID is a lifelong ID assigned by the CIBMTR to each recipient. The CRID is generated using the CIBMTR Unique 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). This number should be in XXX-XXX-X format. This is the recipient identification number you use with the NMDP's search department, among others. The RID must be entered without dashes. This is an optional field.

Question 3: CIBMTR Center Number (CCN):
Enter your center's five-digit CIBMTR center number. This number should appear at the top of the FormsNet™2 screen next to your site name when you are logged in. If you are unfamiliar with this number, ask your center's data manager who completes the CIBMTR data collection forms.

Question 4: NMDP transplant center number (TC Code): *(if applicable)*
Enter your three-digit NMDP transplant center number. This is an optional field.

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.

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

Note: Questions 9-15 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.

Questions 9-10: NMDP Donor ID (DID): *(if applicable)* and **Non-NMDP Unrelated Donor ID (Coop Reg Donor ID): *(if applicable)***
Enter the NMDP Donor ID or the Non-NMDP Unrelated Donor ID. One of these fields is required if question 7 is not HPC, Cord Blood (Umbilical Cord Blood).

Question 11-15: 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 the other days.

Product Identification (HPC, Cord Blood)

Note: Questions 16-32 may only be completed if the Product type indicated in question 7 is HPC, Cord Blood (Umbilical Cord Blood).

Questions 16-19: 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 16-18 is required to be entered if question 7 is answered HPC, Cord Blood (Umbilical Cord Blood). The format for NMDP Cord Blood Unit ID, question 16 is XXXX-XXXX-X.

If question 18 is answered, then question 19 is also required to be answered.

Questions 20-23: 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 24-25: 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 25.

Questions 26-27: Cord Blood Bank: and **Specify other Cord Blood Bank:**

This question must be answered if question 24 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 26, specify cord blood bank in question 27.

Question 28: Was the CBU requested through the NMDP?

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

Question 29: 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 29, specify IND sponsor in question 30.

Questions 30-32: 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 30, specify IND Sponsor name and IND number in questions 31-32.

Adverse Event Information

Question 33: Date of infusion:

Enter the date the product was infused (in M/D/YYYY format). If there is more than one day of infusion enter the initial infusion date. This question is required for all products.

Question 34: Adverse event date of onset:

Enter the onset date for the adverse event (in M/D/YYYY format). 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 35: Date center became aware of the event:

Enter the date you became aware of the adverse event (in M/D/YYYY format). This question is required for all products.

Question 36: 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 37-38: Serious adverse event outcome: and **Specify other serious adverse event outcome:**

Select serious adverse event outcome if the response to question 36 is "Yes".

If "Other" is selected in question 37, specify other serious adverse event outcome in question 38.

Question 39: 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 please specify the relatedness for each unit in the event description.

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

Probable: 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.

Possible: 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 40: 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 41: 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 42: 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 43: 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.htm.

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 44: CTCAE Primary Event:

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

Question 45: CTCAE Grade (most severe):

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

Question 46: 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 47-49: 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 47, then enter the date of resolution and the type of resolution.

Question 50: 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 system. 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 55-64: 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.