Adverse Event Follow-up Form Instructions

Note: This form is used to report new information on a previously reported Adverse Event. Do not use this form for the original adverse event submission. It is helpful to have access to information from the original submission for completion of 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 FormsNet3SM 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: 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: Adverse Event Group ID:
The Adverse Event Group ID is the way the system distinguishes which Adverse Event goes with which Adverse Event Follow-up Form. The Group ID for the original Adverse Event can be found in the Recipient Forms grid. The Adverse Event Group ID for will be auto-populated.

Question 2: CIBMTR Recipient 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 Unique ID Assignment Form (Form 2804), and must be completed for all HSCT recipients.

Question 3: 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 4: CIBMTR Center Number (CCN):
This field will be auto-populated by the system with your center’s five-digit CIBMTR center number.

Question 5: Product type received by recipient:
Enter the product type the recipient received. If the recipient has had more than one transplant, enter the product type that is associated with the Adverse Event originally reported for which this follow-up form is being completed.

This question will be checked against the answer provided on the Adverse Event Form 3001 and an error will appear if they do not match.

Adverse Event Follow-up Information

Question 6: Does this adverse event now meet the regulatory definition of a serious adverse event when it previously did not?
Compare the adverse event status at the time of this report to the status of the adverse event at last report. Review the definition of a serious adverse event and select response.

If the adverse event has worsened from non-serious to serious, select “Yes” and go to question 7.
If the adverse event was not serious at last report and remains non-serious, select “No” and go to question 9.
If the adverse event has been previously reported as serious, select “Not applicable” and go to question 9.
Questions 7-8: Serious adverse event outcome: and Specify other serious adverse event outcome:
Select serious adverse event outcome if the response to question 6 is “Yes”.

If “Other” is selected in question 7, specify other serious adverse event outcome in question 8.

Question 9: Has the assessment of relatedness between this adverse event and the product changed?
Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response to indicate if there has been a change in relatedness between the adverse event and the product.

If “Yes” is selected, answer question 10.
If “No” is selected, continue to question 11.

Question 10: What is the relationship between the reported adverse event and the product?
Select response for the relationship between the adverse event and the product if the response to question 9 is “Yes”. If there was more than one cord blood unit infused please specify the relatedness for each unit in the event description update.

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.
Question 11: Has the assessment of a possible, probable, or definite product-related disease transmission changed?
Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response to indicate if this assessment has changed.

If “Yes” is selected, answer question 12.
If “No” is selected, continue to question 13.

Question 12: Is this adverse event a possible, probable, or definite disease transmission caused by the product?
Select response for the question of disease transmission if the response to question 11 is “Yes”.

Question 13: Has the CTCAE assessment for this adverse event changed?
Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response.
If “Yes” is selected, answer questions 14-16.
If “No” is selected, continue to question 17.

Question 14: CTCAE Primary Category:
Select the primary CTCAE category of the adverse event from the dropdown that best matches the adverse event at the time of this report if the response to question 13 is “Yes”.

Question 15: CTCAE Primary Event:
Select the primary CTCAE event for the adverse event at the time of this report from the dropdown if the response to question 13 is “Yes”.

Question 16: CTCAE Grade (most severe):
Select the most severe CTCAE Grade for the adverse event from the onset of the event to the time of this follow-up report if the response to question 13 is “Yes”.

Question 17: Has the assessment of expectedness for this adverse event changed?
Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response.

If “Yes” is selected, answer question 18.
If “No” is selected, continue to question 19.
Question 18: Does this adverse event meet the regulatory definition of “unexpected”?
Review the definition of unexpected provided on the form within the FormsNet 2 system and select response if the response to question 17 is “Yes”.

Question 19: Event description update since previous report of this adverse event:
Enter a description of the adverse event update. Include details since the last report. Specifically include any details that change / alter the event pertaining to the nature, seriousness, relatedness, or severity of the event. The previously reported description does not need to be repeated.

Question 20: Additional 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 or with the original submission. Include any subject details that are used to determine seriousness and relatedness of the event. This question is optional.

Questions 21-23: 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 21, then enter the date of resolution and the type of resolution.

Question 24: 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 FormsNet3SM 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.

**NMDP Review Section**

**Questions 25-29: To Be Completed By NMDP/CIBMTR Reviewer ONLY**
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 3003 for entry.

When Form 3003 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.