Key Fields

Many data points from the Key Field sections of the CIBMTR forms appear again on other forms. This appendix contains instructions on how to answer the data fields located in the Key Field sections for all of the CIBMTR data collection forms (Pre-TED, Post-TED, and Comprehensive Report Forms).

On the paper forms, the Key Fields are generally found in the upper right-hand corner of the first page of the form. However, on the Pre- and Post-TED forms, the Key Fields are located in the left-hand column in the boxes titled *Center Identification* and *Recipient Identification*.

In the FormsNetTM2 application, the Key Fields are found on page one, or the "Key Page." A form cannot be entered into the database until all the Key Fields are complete and correct (i.e., error-free).

Accuracy of the Key Fields is essential for ensuring that:

- Data are being reported for the correct recipient.
- Transplant centers have access to their data.
- Data are being shared with the correct donor center, cord blood bank, cooperative registry, or other approved agency.

NOTE: Key Field Text

The key field terms are listed exactly as they appear on the data collection forms. In this appendix, the key field terms are arranged alphabetically.

Chronological number of this HSCT/DCI Field appears on: Post-TED Form 2450 and Selective Post-TED Form 2455

Enter the chronological number of this HSCT or Donor Cellular Infusion (DCI) event.

HSCT Event:

An HSCT event is defined as an infusion of mobilized peripheral blood stem cells (PBSC), bone marrow, or cord blood.

For recipients who have received a previous HSCT (prior to the HSCT for which this series of forms is being completed), the following are examples of how to calculate the chronological number of this HSCT.

Example 1:

A recipient was previously transplanted under a protocol that included an infusion of cells over multiple days: day 0, day +1 and day +2. This series of infusions is considered one HSCT event, as opposed to three HSCT events and should be counted as *HSCT Event #1*.

After receiving the infusion, the recipient had relapse of disease. The recipient is scheduled to receive a subsequent HSCT including a preparative regimen. This HSCT should be reported as *HSCT Event #2*.

Example 2:

A recipient previously received an allogeneic HSCT (*HSCT Event #1*). Then, due to delayed neutrophil recovery, the recipient received additional cyropreserved allogeneic mobilized PBSC from the original donor, without a preparative regimen (i.e., "boost" - *HSCT Event #2*).

After receiving the boost, the recipient had relapse of disease. The recipient is scheduled to receive a subsequent allogeneic HSCT with preparative regimen (*HSCT Event #3*).

Example 3:

A recipient previously received an autologous HSCT (*HSCT Event #1*). Then, due to delayed neutrophil recovery, the recipient received additional cyropreserved autologous cells without a preparative regimen (i.e., "boost" which is not counted as an HSCT event because the intent of the infusion is to treat the graft failure.).

The boost is successful, but a few years later the recipient develops a new malignancy. The recipient is scheduled to receive a subsequent autologous HSCT with preparative regimen (*HSCT Event #2*).

If the recipient receives an infusion due to the graft, count the infusion as a *subsequent HSCT*, not a DCI. The exception to this is autologous rescue. Autologous rescue is generally used to treat the recipient's poor graft response, rather than their disease. Autologous rescue **should not** be counted as a separate HSCT, but the data collection forms **will not** start over (i.e., the forms will continue from the previous HSCT).

Donor Cellular Infusion (DCI) Event:

A DCI is a form of cellular therapy that is commonly used to prevent and/or treat recurrent disease. The recipient does not receive a preparative regimen prior to receiving the cells. The types of cells used for a DCI include, but are not limited to: lymphocytes, peripheral blood mononuclear cells (both stimulated and unstimulated), dendritic cells from the original donor, and mesenchymal cells.

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A DCI should be reported for a recipient who receives cells (most often from the original donor) without a preparative regimen for **any reason** other than those pertaining to the original HSCT graft (i.e., do not report a DCI for no ANC recovery, partial or poor ANC recovery, loss of graft, or late graft failure).

Recipients may receive a DCI over several days or weeks. A single DCI event should include all infusions given within a 10-week period. The following example indicates how to calculate the chronological number of a DCI.

Example:

A recipient receives an HSCT on January 1, 2009. In the first four weeks after transplant, the recipient receives three DCIs (*DCI Event #1*). Twelve weeks after transplant, the recipient receives another DCI (*DCI Event #2*).

The following table illustrates some of the differences between an HSCT and a DCI. For more information regarding counting HSCT and/or DCI events, contact your CIBMTR liaison.

| | HSCT | DCI |
|----------------------------|---|--|
| Purpose of infusion | Replace or repopulate recipient marrow and reconstitute immune system. | Prevent or treat recurrent disease by creating an immune effect within the recipient. |
| Composition of infusion | Must contain stem cells. | The cells of action are not stem cells, but the infusion may contain stem cells. Examples include, but are not limited to: lymphocytes, peripheral blood mononuclear cells (both stimulated and unstimulated), dendritic cells from the original donor, and mesenchymal cells. |
| Preparative regimen | A preparative regimen is typically used. Exceptions include, but are not limited to: Recipient's disease does not require preparative regimen (e.g., SCID, WAS, etc.) Subsequent HSCT for no ANC recovery, partial or poor ANC recovery, loss of graft, or late graft failure. | A preparative regimen is not used. However, therapy may be given to treat the recipient's disease between the HSCT and first DCI, or between DCIs. Examples of therapy include, but are not limited to: Rituximab, CHOP, 7 + 3, mylotarg, and steroids. |

Table 1. HSCT vs. DCI

CIBMTR Center Number Field appears on: all forms

Enter the five-digit CIBMTR center number. The CIBMTR center number replaces the three-digit CIBMTR team number and the three-digit NMDP TC Code.

CIBMTR Recipient ID Field appears on: all forms

This field is also known as the *Unique ID Number* or *CIBMTR Recipient ID* (CRID). The CRID is a lifelong ID assigned to each recipient. The CRID is generated using the Unique ID Assignment Form (Form 2804), and must be completed for all HSCT recipients receiving a first HSCT after December 2, 2007. Recipients existing in the CIBMTR or NMDP databases as of December 2, 2007, have been assigned a CRID.

In the FormsNetTM2 application, use **one** of the following options to look up a CRID:

- Enter the former NMDP Recipient ID (RID) in Patient Forms Due
- Enter the recipient IUBMID number and the former CIBMTR Team
 Number in Patient Forms Due

For more information regarding the CRID, see General Instructions, <u>Unique ID</u> Assignment (CRID) and Protected Health Information (Form 2804).

Consented for CIBMTR Specimen Repository? Field appears on: Pre-TED Form 2400

NOTE:

This question has been updated on the Pre-TED (Form 2400, revision 2) in the FormsNetTM2 online environment to reflect the collection of data relating to related and unrelated specimens submitted to CIBMTR repositories. This change is not reflected on the current paper version of the Pre-TED (Form 2400, version 2).

In the past, this question collected the recipient consent status for recipients at a small number of centers participating in a related CIBMTR Specimen Repository. Currently, centers should report the consent status for both allogeneic <u>related</u> (if your center is participating) and <u>unrelated</u> repository specimens on the Pre-TED. This change is necessary to capture the consent status for those unrelated HCT recipients that donated repository specimens that remain on the TED track.

When attempting to report the consent status for recipients receiving unrelated products in FormsNetTM2, it may be necessary to override errors to submit this data.

Answer "yes" if:

The recipient has consented to be part of the CIBMTR Research Specimen Repository.

Answer "no" if:

The recipient has not consented to be part of the CIBMTR Research Specimen Repository.

Consented for research?

Field appears on: Pre-TED Form 2400

Check the "yes" box if the recipient or legal guardian has signed the Observational Database consent form. If the recipient does not consent to participate in the Observational Database, check the "no" box. For more information regarding the Observational Database, see General Instructions, <u>Protocols and Consent Forms</u>.

Contact Person

Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

Enter the first and last names of the person completing the form.

On the paper form version of the Pre- and Post-TED, the intention of the "changed" box is to inform the CIBMTR of changes to the transplant center's contact information (e.g., contact person, phone number, fax number, and e-mail address). However, the CIBMTR encourages the transplant center's primary contact to make changes to contact information through the CIBMTR website.

https://network.nmdp.org/SHARED/CENTER_PERSONNEL/center_change_idx.pl

Cooperative Registry Donor ID Field appears on: Form 2000

Enter the donor identification number as assigned by the Cooperative Registry. This field should be used only for NMDP donors.

Cord Blood Unit ID Field appears on: Form 2000

Enter the identification number assigned to the cord blood unit. Both NMDP and non-NMDP cord blood unit IDs should be entered in this field. For more information regarding cord blood unit labeling, visit the ISBT 128 website at http://www.iccbba.org/index.html.

Date of Birth (recipient)

Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

Enter the recipient's date of birth as (YYYY/MM/DD).

Date of HSCT for this follow-up Field appears on: Post-TED Form 2450 and Selective Post-TED Form 2455

Enter the HSCT infusion start date for this follow-up (**YYYY/MM/DD**). If the infusion occurs over more than day, report the first day of the infusion. This date must match the date reported on the Pre-TED (question 2 – *Date of this HSCT*). If the HSCT date has changed since submitting the Pre-TED, then a paper Error Correction Form must be submitted for the Pre-TED.

Date of HSCT for which this form is being completed Field appears on: all forms <u>except</u> Pre-TED 2400, Post-TED Form 2050, and Selective Post-TED Form 2455

Enter the HSCT infusion start date for which this form is being completed (**MM/DD/YYYY**). If the infusion occurs over more than day, report the first day of the infusion.

Date of this Report Field appears on: all forms

Enter the date the paper form is sent to the CIBMTR, or the date the form is electronically submitted to the CIBMTR using the FormsNetTM 2 application (**YYY/MM/DD**). If this date is entered incorrectly, then a paper Error Correction Form must be submitted.

Did the recipient receive a subsequent HSCT since the date of contact from the last report?

Field appears on: Post-TED Form 2450 and Selective Post-TED Form 2455

Indicate whether or not the recipient received a subsequent HSCT since the date of contact from the last report. If the recipient is on the TED track and receives a

subsequent HSCT (autologous or allogeneic) due to the relapse of disease, has a planned subsequent for a new malignancy, or has an allogeneic HSCT for a reason pertaining to the graft, the reporting process will begin again with another Pre-TED. However, the reporting process will not start over if the recipient receives a subsequent **autologous** HSCT due to a failure to engraft, failed or poor neutrophil recovery, or loss of graft (graft failure).

Disease

Field appears on: Post-TED Form 2450

Indicate the recipient's diagnosis as reported on the Pre-TED Disease Classification Sheet.

Donor Date of Birth Field appears on: IDM Form 2004, HLA Form 2005, and INF Form 2006

Enter the donor's date of birth (MM/DD/YYYY). If the donor's date of birth is provided, then the donor gender field must also be completed. Although this field is only required if a donor ID is not provided, the CIBMTR would like to collect this data for as many donors as possible.

Donor Gender

Field appears on: IDM Form 2004, HLA Form 2005, and INF Form 2006

Indicate the donor's biological gender (sex) as *male* or *female*. If this field is completed, the donor date of birth field must also be completed. Although this field is only required if a donor ID is not provided, the CIBMTR would like to collect this data for as many donors as possible.

Donor ID

Field appears on: INF Form 2006

Enter the identification number assigned to the donor. This ID can be an NMDP ID or a non-NMDP ID.

Donor Type

Field appears on: Post-TED Form 2450

Indicate the donor type as *autologous* or *allogeneic*. On the Pre-TED Form 2400, there is an additional donor type to choose from; *multiple donors*. For definitions of these terms, see <u>Appendix B – Glossary of Terms</u>.

EBMT Code (CIC) Field appears on: Pre-TED Form 2400, Post-TED Form 2450, and Selective Post-TED Form 2455

Enter the EBMT Center Identification Code (CIC #). Non-EBMT centers leave this field blank.

E-mail

Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

Enter the e-mail address of the person completing the form.

On the paper form version of the Pre- and Post-TED, the intention of the "changed" box is to inform the CIBMTR of changes to the transplant center's contact information (e.g., contact person, phone number, fax number, and e-mail address). However, the CIBMTR encourages the transplant center's primary contact to make changes to contact information through the CIBMTR website.

https://network.nmdp.org/SHARED/CENTER_PERSONNEL/center_change_idx.pl

Ethnicity Field appears on: Pre-TED Form 2400

Indicate the recipient's ethnicity. Reporting ethnicity is optional for non-US centers that participate in the CIBMTR as *TED Only* centers. However, non-US centers that participate in the CIBMTR as Comprehensive Report Form centers **must** complete the fields designated as "optional for non-US centers." For more information regarding non-US centers, see General Instructions, <u>EBMT Centers</u>.

The United States Office of Management and Budget (OMB) has defined ethnicity as culturally or geographically determined. The distinction between Hispanic and non-Hispanic is for the purpose of the United States census and reporting of SCTOD data. According to the OMB, "Hispanic" is an ethnic designation based upon where someone (his or her ancestors) was raised (e.g., "Latin America"). Hispanic people can be white, black/African American, and/or native. The CIBMTR recognizes regional differences with regard to the interpretation of ethnicity throughout the world. Transplant centers should use their best judgment when completing this section, and may develop a data collection tool that allows the recipient to self-report their ethnicity. For more information regarding ethnicity, see <u>Appendix I</u>.

Fax Number Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

Enter the fax number of the person completing the form.

On the paper form version of the Pre- and Post-TED, the intention of the "changed" box is to inform the CIBMTR of changes to the transplant center's contact information (e.g., contact person, phone number, fax number, and e-mail address). However, the CIBMTR encourages the transplant center's primary contact to make changes to contact information through the CIBMTR website.

https://network.nmdp.org/SHARED/CENTER_PERSONNEL/center_change_idx.pl

Follow-up Field appears on: Post-TED Form 2450 and Selective Post-TED Form 2455

Indicate the follow-up time point for this form as *day 100, 6 month, or annual.* If annual is selected, enter the number of year(s) post HSCT for which this follow-up is occurring.

Forms such as the Form 2450 and 2455 are expected at multiple time points. The follow-up field corresponds to the time point post-HSCT.

The FormsNet[™]2 application uses this field to determine the difference between two forms with the same form number. The CIBMTR uses this number to track the forms due for each recipient.

The follow-up visit ID should be calculated based on the HSCT anniversary date. For example, if the HSCT occurred on March 26, 2004, and the recipient is seen by a physician for a follow-up visit on April 1, 2009, then the follow-up visit ID should be reported as "annual, 5" as this represents the five-year anniversary of the recipient's HSCT.

Follow-up visit (years after transplant) Field appears on: Form 2300

Indicate the follow-up time point for this form by specifying the number of years after HSCT this form is being completed.

Gender (recipient) Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

Indicate the recipient's biological gender (sex) as male or female.

HSCT Type

Field appears on: all forms <u>except</u> Pre-TED Form 2400, Post-TED Form 2450, and Selective Post-TED Form 2455

Indicate the type of HSCT performed as either autologous, allogeneic unrelated, allogeneic related, or syngeneic (identical twin).

Hospital

Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

Enter the hospital or transplant center name.

ID Assigned by

Field appears on: Pre-TED Form 2400

Check the "CIBMTR" box if the ID is assigned using either the paper Form 2804, or FormsNetTM 2. Do not use the "EBMT" or "Other" boxes.

NMDP Cord Blood Unit ID Field appears on: Form 2000 and INF 2006

Enter the cord blood unit identification number as assigned by the NMDP.

NMDP Donor ID Field appears on: Form 2000

Enter the donor identification number (e.g., 0000-0000-0) as assigned by the NMDP. If the donor is not an NMDP donor, check the "Non-NMDP donor or cord blood unit" box.

Non-NMDP Cord Blood Unit ID Field appears on: Form 2000, IDM Form 2004, HLA Form 2005, and INF Form 2006

On the Baseline Form 2000 and the INF Form 2006, check the "Non-NMDP donor or cord blood unit" box and continue with donor demographic questions as indicated on the form.

On the IDM Form 2004 and the HLA Form 2005, enter the identification number assigned to the cord blood unit.

Non-NMDP Donor ID Field appears on: Form 2000, IDM Form 2004, and HLA Form 2005

Examples of non-NMDP donor registries include, but are not limited to: St. Louis Cord Blood Bank, Anthony Nolan, and StemCyte International Cord Blood Center.

If the non-NMDP donor does not have an ID number, this field may be left blank as long as the donor's date of birth and gender are completed.

Phone Number Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

Enter the telephone number of the person completing the form.

On the paper form version of the Pre- and Post-TED, the intention of the "changed" box is to inform the CIBMTR of changes to the transplant center's contact information (e.g., contact person, phone number, fax number, and e-mail address). However, the CIBMTR encourages the transplant center's primary contact to make changes to contact information through the CIBMTR website.

https://network.nmdp.org/SHARED/CENTER_PERSONNEL/center_change_idx.pl

Product Type

Field appears on: all forms <u>except</u> Pre-TED Form 2400, Post-TED Form 2450, and Selective Post-TED Form 2455

Indicate the product type used as *marrow*, *PBSC*, *cord blood*, *multiple cord blood units infused*, *or other product*. If using multiple cords, only select "Multiple cords." If "other product" is selected, specify the product type.

Race Field appears on: Pre-TED Form 2400

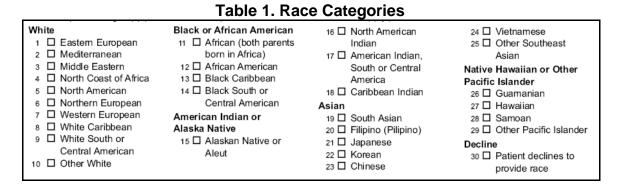
Indicate the recipient's race. Reporting race is optional for non-US centers that participate in the CIBMTR as *TED Only* centers. However, non-US centers that participate in the CIBMTR as Comprehensive Report Form centers **must** complete the fields designated as "optional for non-US centers." For more information regarding non-US centers, see General Instructions, <u>EBMT Centers</u>.

The United States Office of Management and Budget (OMB) has defined race as inherited genetic characteristics. Race groupings were created by the OMB for the purpose of collecting census data. Race data is collected in order to analyze

recipient access to HSCT. If the recipient is from more than one race group, check all that apply. For consistency of data collection, assign the major race category according to the subcategories listed on the Baseline Form 2000. Table 1 (see below) provides the detailed list of major and sub-categories from the Baseline Form 2000. The CIBMTR recognizes regional differences with regard to the interpretation of race throughout the world. Transplant centers should use their best judgment when completing this section, and may develop a data collection tool that allows the recipient to self-report their race(s). For more information regarding race, see <u>Appendix I</u>.

If the recipient's race is unknown, leave this field blank in the FormsNetTM2 application and override the error with the "UK" error code. On the paper version of the form, write in "unknown" in the margin of the form.

If the recipient declines to answer, leave this field blank in the FormsNet[™]2 application and override the error with the "UA" error code. On the paper version of the form, write "declined to answer."



Study ID Field appears on: Pre-TED Form 2400

Currently, the CIBMTR is tracking only BMT-CTN and RCI-BMT study numbers (e.g., BMT-CTN 0601, check the "BMT-CTN" box and report "0601" in the "Study ID" field). Study ID numbers from organizations and/or companies other than those listed should not be reported. If a recipient is enrolled on more than one study and a paper form is submitted, list the additional study number(s) in the margin of the form, matching the study ID(s) to the appropriate organization(s). The FormsNet[™] 2 application will allow multiple entries.

Any recipient who receives an allogeneic (related or unrelated) HSCT where either the stem cell donation or the transplant occurs within the United States is considered part of the SCTOD. There are no current SCTOD studies.

Today's Date

Field appears on: all forms <u>except</u> Pre-TED Form 2400, Post-TED Form 2450, and Selective Post-TED Form 2455 (see "date of report" for these forms)

Enter the date the paper form is sent, or the form is electronically submitted to the CIBMTR using the FormsNet[™] 2 application (MM/DD/YYYY).

Unit

Field appears on: Pre-TED Form 2400 and Post-TED Form 2450

NOTE: Unit

EBMT Centers that have multiple CIBMTR Center numbers, and allow transmission of MED-A data to the CIBMTR, **must** use the "unit" field on the MED-A in order to ensure that the data is mapped into the correct recipient file in the CIBMTR database.

The purpose of this field is to allow transplant centers the ability to differentiate between data reporting programs within the institution. This should be considered a tool to help track recipients in your center when more than one type of recipient is transplanted under your CIBMTR Center Number (CCN).

Indicate the letter that corresponds to the hospital unit in which the recipient received their transplant (A = adult, H = hematology, O = oncology, P = pediatric). Only one unit may be reported per recipient, even if more than one option applies. This field may be left blank if hospital unit distinction is not necessary at your institution.

Universal Recipient ID: Field appears on: Pre-TED Form 2400

See "CIBMTR Recipient ID"

Visit

Field appears on: Form 2200, all Post-HSCT Disease Specific Forms, Fungal Infection Form 2046, Hepatitis Serology Form 2147, and HIV Form 2148

Indicate the follow-up time point for this form as:

- Form 2200: 6 months, 1 year, or 2 years
- Post-HSCT disease-specific forms, Form 2147, and Form 2148: 100 day, 6 month, 1 year, 2 years, or >2 years, specify
- Fungal Infection Form 2046: baseline, 100 days, 6 months, 1 year, 2 years, or > 2 years, specify

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Forms such as the Form 2450 and 2455, are expected at multiple time points. The visit field corresponds to the time point post-HSCT.

The FormsNet[™]2 application uses this field to determine the difference between two forms with the same form number. The CIBMTR uses this number for tracking the forms due for each recipient.

The visit ID should be calculated based on the HSCT anniversary date. For example, if the HSCT occurred on March 26, 2004, and the recipient is seen by a physician for a follow-up visit on April 1, 2009, then the visit ID should be reported as "annual, 5" as this represents the five-year anniversary of the recipient's HSCT.

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