Instructions for CIBMTR Recipient ID Assignment Form (Form 2804)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the CIBMTR Recipient ID Assignment Form.

E-mail comments regarding the content of the CIBMTR Forms Instruction Manual to: CIBMTRFormsManualComments@nmdp.org. Comments will be considered for future manual updates and revisions. For questions that require an immediate response, please contact your transplant center's CIBMTR CRC.

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CIBMTR Recipient ID Assignment

The CIBMTR Recipient ID (CRID) is a unique identifier assigned when an individual is registered with the CIBMTR as receiving a cellular therapy, including hematopoietic stem cell transplant (HCT). The CRID Assignment Form 2804 collects the information required to create a lifelong identification number specific to an individual, and certain data fields are used to ensure that the same individual does not inadvertently receive multiple CRID assignments.

By creating a unique identifier and ensuring cellular therapy recipients receive only a single CRID, the CIBMTR is better able to carry out its charge as a co-contractor of the C.W. Bill Young Transplantation Program with the responsibility for maintaining the Stem Cell Therapeutic Outcomes Database (SCTOD). The CRID is used to ensure the accuracy of center-specific outcomes by adjusting survival expectation for patients receiving multiple HCTs and allowing for verification of survival status within the National Death Index. Additionally, the CRID can be used to help re-establish contact with recipients who are lost to follow-up and to ensure that all allogeneic recipients in the United States, or who receive a product from the United States, are reported to the CIBMTR.

Completeness of the Form 2804 is important for ensuring that individuals are not assigned multiple CRIDs over their lifetime. The system is able to assign an identification number when some identifying fields are missing, but this increases the risk of duplicate reporting. Therefore, the following guidelines have been established:

- For autologous recipients who have not consented for research, report only the year of birth.

- For autologous recipients who have consented for research but not agreed to list all identifiers collected on the Form 2804, report only the information that the recipient has released.

- For all other recipients, complete the form as thoroughly as possible.

    - Date of birth and recipient's sex are considered essential.

    - If a social security number is not provided, the recipient's full name and mother's maiden name are considered a suitable alternative.

- In the event of a state law or IRB policy that supersedes federal statute, centers may opt out of providing some of these data.

The CIBMTR carefully ensures that identifying information is collected and stored in a secure manner. The electronic systems that generate CRIDs have undergone rigorous certification and authorization from HRSA's Office of Information Technology and they comply with all United States regulations relevant to security of data in federal databases.

Once the identifying data are entered into FormsNet3^{SM} and a CRID is assigned, the identifying data are no longer visible to the transplant center or CIBMTR staff. For that reason, it is important that the information is accurate when submitted. The identifying information used to create the CRID will not appear on any subsequent forms or correspondence.

Transplant centers need to take appropriate measures at their site to secure the identifying information used to generate the CRID.

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. Transplant and product type will not be automatically populated on product or donor specific forms (Forms 2004, 2005, and 2006) and will need to be manually reported.

> **NOTE:**
> This form only needs to be completed for patients who have not previously been assigned a CIBMTR Recipient ID (CRID).

Indication for CRID Assignment

Questions 1-2: What is the indication for CIBMTR recipient ID (CRID) assignment?

Indicate whether the recipient will be receiving hematopoietic cellular transplant (HCT), cellular therapy for regenerative medicine, non-transplant cellular therapy for MDS, or other indication. Hematopoietic cellular transplant is a transplant of bone marrow, peripheral blood stem cells, umbilical cord blood, or other cellular product containing CD34+ cells, also known as hematopoietic progenitor cells. Therapy given for regenerative medicine may be derived from a hematopoietic or non-hematopoietic tissue source and can be utilized for a broad range of indications, including autoimmune, cardiovascular, peripheral vascular, and neurologic diseases. Non-transplant therapy for MDS can include vaccine trials where tumor vaccines are derived from tissue sources; report only tissue-derived vaccine administration for myelodysplastic syndrome. Report any other tissue-derived vaccine administration or cellular therapy given for any other indication under "other indication" and specify in question 2.

If the reported indication is:

- Hematopoietic cellular transplant, complete questions 3-39.
    - For autologous recipients who have not given consent to allow their transplant data to be used for research, complete only questions 1-18 and 21 (year of birth only).
- Cellular therapy for regenerative medicine, complete questions 19-39 and 41-43.
- Non-transplant therapy for MDS, complete questions 19-40.
- Other indication, complete questions 2 and 19-39.

Hematopoietic Stem Cell Transplant (HCT)

> **NOTE:**
> If the patient is receiving products from more than one donor (e.g., a multiple cord blood unit transplant), answer questions 3-9 for each donor. Duplicate questions 3-9 as needed to record all product information.
>
> If a single donor gives two different product types, an instance of the donor and product information questions should be created for each product type (questions 3-9 and 13-18). It is critical to report the correct number of instances in order for the HCT and product information to be correctly auto-populated on other forms. It's just as important to report the correct number of instances of the donor & product information for the previous HCT in questions 13-18 to ensure accuracy.
>
> For example, if an unrelated donor gave both marrow and PBSC, two instances should be created. The HSC source for both instances should be reported as "Allogeneic, unrelated". The product type should be reported as bone marrow in one instance, and PBSC in the other.

Question 3: Specify HSC source

Indicate if the recipient will be receiving cells from an autologous, related allogeneic, or unrelated allogeneic source. If the recipient will be receiving cells from an autologous source, continue with question 4; for all allogeneic options, continue with question 5.

Question 4: Has the recipient signed an IRB-approved consent form for submitting research data to the NMDP/CIBMTR?

This question should be answered for autologous recipients only. Indicate if the recipient consented to participate in the research database.

- If the autologous recipient was asked for consent and consented in accordance with your transplant center's IRB requirements, indicate "yes" and complete all applicable fields on this form.

- If the recipient was asked but declined to participant, answer "no" and complete only questions 1-18 and 21 (year of birth only) on this form.

- If the recipient was not asked for consent to the research database, indicate "not applicable" and complete only questions 1-18 and 21 (year of birth only) on this form.

- If the recipient consents to submit research data after the CRID is initially assigned, submit an error correction form to update the form with the additional information used for patient identification.

Questions 5-9: Specify the planned product type(s)

Indicate if the recipient will be receiving a bone marrow, peripheral blood stem cell (PBSC), or single cord blood product according to their transplant plan. If the recipient is receiving multiple product types from the same donor, report all product types in questions 5-9. If the recipient will be receiving any other product, indicate "other product" and specify in question 9.

Question 10: What was the primary disease for which the HCT was performed?

From the list provided, specify the primary disease (as determined at the time of form submission) for which the patient will be receiving the transplant. For example, if the recipient was initially diagnosed with myelodysplastic syndrome (MDS) that transformed to acute myelogenous leukemia (AML), report AML. If the recipient has two hematologic or lymphoid malignancies that are not the result of transformation, the transplant physician should specify the primary disease for which the recipient will receive HCT. If both diseases are active and considered primary indications for transplant, indicate "other disease."

Question 11: Is this the first HCT for this recipient?

Indicate if the planned HCT will be the first HCT for this recipient. Do not include other previous cellular therapies that are not considered hematopoietic cellular transplant. If "yes," continue with question 19; if "no," continue with question 12.

Question 12: Date of the last HCT (just before current HCT)

Report the date of the recipient's previous HCT. If the recipient has had multiple prior HCTs, report only the date of the most recent.

NOTE:

Questions 13-18 should be duplicated for each donor utilized in the patient's last HCT. If the patient received products from more than one donor (e.g., a multiple cord blood unit transplant), copy and complete questions 13-18 to reflect all product information.

If a single donor gives two different product types, an instance of the donor and product information questions should be created for each product type (questions 3-9 and 13-18). It is critical to report the correct number of instances in order for the HCT and product information to be correctly auto-populated on other forms. It's just as important to report the correct number of instances of the donor & product information for the previous HCT in questions 13-18 to ensure accuracy.

For example, if an unrelated donor gave both marrow and PBSC, two instances should be created. The HSC source for both instances should be reported as "Allogeneic, unrelated". The product type should be reported as bone marrow in one instance, and PBSC in the other.

Question 13: Specify HSC source for the last HCT
Indicate the cell source for the recipient's most recent previous HCT: autologous, related allogeneic, or unrelated allogeneic.

Questions 14-18: Specify product type(s) for the last HCT
Indicate the product type for the recipient's most recent previous HCT: bone marrow, peripheral blood stem cells (PBSCs), or single cord blood unit. If the recipient received multiple product types from the same donor, report all product types in questions 14-17. If the recipient received any other product, indicate "other product" and specify in question 18.

Recipient Data

For autologous recipients who have not given consent to allow their transplant data to be used for research, only complete questions 1-18 and 21 (year of birth only). For all other recipients, complete as many data fields as possible.

Questions 19-20: First Name, Last Name
Report the recipient's complete legal first name in question 19 and complete legal last name in question 20. If you are unable to report the full legal name, reporting initials or partial name can reduce duplicate CRIDs.

Question 21: Date of birth
Reporting the recipient's date of birth is *required for all Form 2804* submissions. For autologous recipients who have not given consent to allow their transplant data to be used for research, only report year of birth.

Questions 22-24: Location of birth
Report the recipient's country of birth in question 22. If applicable, specify city and state of birth in questions 23-24, respectively.

Question 25: Sex
Report the recipient's biological sex; *required for allogeneic HCT recipients*.

Questions 26-27: Is the recipient's social security number provided?
Specify if the recipient provided a social security number. If yes, continue with question 27 and report the recipient's social security number.

If the recipient declined to provide a social security number or is not a United States citizen, indicate "no" or "not applicable" and continue with question 28.

Questions 28-29: Does the recipient have a Recipient NMDP ID?
Specify if the recipient has previously been assigned a recipient ID (RID) by the National Marrow Donor Program (NMDP). If the recipient has had an NMDP RID assigned, continue with question 29 and report the recipient's seven-digit RID.

If the recipient has not been assigned an NMDP RID, indicate "no" and continue with question 30.

Questions 30-31: Does the recipient have a Recipient EBMT ID?
Specify if the recipient has previously been assigned a recipient ID (RID) by the European Group for Blood and Marrow Transplantation (EBMT). If the recipient has had an EBMT RID assigned, continue with question 31 and report the recipient's eight-digit RID.

If the recipient has not been assigned an EBMT RID, indicate "no" and continue with question 32.

Questions 32-33: Does the recipient have an EBMT CIC?
Specify if the recipient is associated with an EBMT center. If the recipient is associated with an EBMT center, continue with question 33 and report the four- to five-digit Centre Identification Code (CIC) identifying the transplant center.

If the recipient is not associated with an EBMT CIC, indicate "no" and continue with question 34.

Questions 34-35: Does the recipient have an IUBMID?
Specify if the recipient was previously assigned an International Bone Marrow Transplant Registry (IBMTR) identification number (IUBMID), which was the precursor to the current CRID system. If the recipient has an IBMTR ID number, continue with question 35 and report the six-digit IUBMID.

If the recipient was never assigned an IUBMID, indicate "no" and continue with question 36.

Questions 36-37: Does the recipient have a Team ID?
Specify if the recipient was previously associated with an IBMTR transplant center identified by a Team ID, which was the precursor to the current CIBMTR center number (CCN) system. If the recipient was previously assigned an IUBMID, they were associated with an IBMTR transplant center identified by a Team ID. Report the four-digit team ID in question 37.

If the recipient was never assigned an IBMTR team ID, indicate "no" and continue with question 38.

Question 38: Recipient's mother's maiden name (optional for non-U.S. centers)
Report the recipient's mother's maiden name. This field may be left blank if the recipient's mother's maiden name is unknown, the autologous recipient declined to release mother's maiden name, or your transplant center is located outside the United States. If the indication for CRID assignment is non-transplant therapy for

MDS, continue with question 40. For all other indications, continue with question 39.

Question 39: Planned infusion date

Report the planned date of cellular infusion. This field is required for all Form 2804 submissions. If the planned date of infusion changes, the electronic form should be updated in FormsNet3^{SM}, as this data field is used to populate the date of infusion on the patient's other case report forms. If indication for CRID assignment is cellular therapy for regenerative medicine, continue with question 41. For all other indications, continue with the signature line.

Question 40: Enrollment date

This question should only be answered for recipients receiving non-transplant therapy for MDS. Report the date of enrollment on study.

Cellular Therapy for Regenerative Medicine

Questions 41-42: Indication for cellular therapy

From the list provided, specify the disease classification for which the patient will be receiving cellular therapy. Examples include:

Autoimmune disease: Crohn's disease, ulcerative colitis, diabetes mellitus type I, rheumatoid arthritis, systemic lupus erythematous, systemic sclerosis

Cardiovascular and peripheral vascular disease: acute myocardial infarction, chronic coronary artery disease (ischemic, cardiomyopathy), heart failure (non-ischemic etiology), limb ischemia, thromboangiitis obliterans

Musculoskeletal disease: avascular necrosis of femoral head, osteoarthritis, osteogenesis imperfecta, traumatic joint injury

Neurologic disease: acute cerebral vascular ischemia, amyotrophic lateral sclerosis, Parkinson's disease, spinal cord injury, cerebral palsy, congenital hydrocephalus, multiple sclerosis, myasthenia gravis

Report any other indication for cellular therapy for regenerative medicine under "other disease" and specify in question 42.

Question 43: Is this the first application of cellular therapy for this indication?

Indicate "yes" if the planned therapy will be the first cellular therapy (for regenerative medicine) for this recipient for this indication. Indicate "no" if the recipient has previously received cellular therapy (for regenerative medicine) for the same indication.

Signature
The FormsNet3^{SM} application will automatically populate the signature data fields, including name and email address of person completing the form and date upon submission of the form.

Manual Change History

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
1.1	01/15/2015	Add	Added explanatory text to informational boxes before questions 3 and 13. *If a single donor gives two different product types, an instance of the donor and product information questions should be created for each product type (questions 3-9 and 13-18). It is critical to report the correct number of instances in order for the HCT and product information to be correctly auto-populated on other forms. It's just as important to report the correct number of instances of the donor & product information for the previous HCT in questions 13-18 to ensure accuracy.* *For example, if an unrelated donor gave both marrow and PBSC, two instances should be created. The HSC source for both instances should be reported as "Allogeneic, unrelated". The product type should be reported as bone marrow in one instance, and PBSC in the other.*
1.1	01/15/2015	Modify	Updated formatting of manual to meet brand standards