2814: Indication for CRID Assignment

The Indication for CRID Assignment (Form 2814) collects information to initiate CIBMTR reporting on appropriate research or data collection forms. This form must be completed for the first indication requiring the individual to register for a CIBMTR Research ID (CRID). Subsequent interventions of the same indication – hematopoietic cellular transplant, non-transplant cellular therapy, marrow toxic injury, and non-cellular therapy – do not require an additional Form 2814; however, a subsequent, new indication may require completion of another Form 2814. Examples of an indication change that would require completion of another Form 2814 include:

- Transplant recipient becomes a marrow toxic injury RITN patient
- Cellular therapy recipient becomes a marrow toxic injury RITN patient
- Marrow toxic injury RITN patient receives cellular therapy or transplant
- Non-cellular therapy patient with any indication change

! Effective August 2021: Centers should now create an on demand indication form (2814) to report a subsequent infusion when there are NO follow up forms (F2100, F2450 or F4100) available to report this information. If follow-up forms are DUE in the forms grid, centers should NOT create a F2814, but report the subsequent infusion on the applicable follow-up form.

Manual Updates:
The most recent updates to the manual can be found below. Please note, the below updates were to the Forms Instruction Manual. All updates to the 2804 will now be documented in FormsNet3 Instructions.

Date	Manual Section	Add/ Remove/ Modify	Description
11/1/ 2021	2814: Indication for CRID Assignment	Update	Updated instructions to coincide with the Fall 2021 Release
8/3/ 2020	2814: Indication for CRID	Add	Provided instructions on generating an on demand F2814 Centers should now create an on demand indication form (2814) to report a subsequent infusion when there are NO follow up forms (F2100, F2450 or F4100) available to report

	Assignment		this information.
7/31/2020	2814: Indication for CRID Assignment	Add	Provided instructions in question 1 on which option to select if the infusion is gene therapy: If the infusion type is gene therapy, select “Hematopoietic cellular transplant.”
7/31/2020	2814: Indication for CRID Assignment	Add	Added the blue information box above question 1 notifying that if the infusion is gene therapy, the recipient will be placed on the HCT CRF track: Gene Therapy: If the infusion type is a gene therapy, the recipient will be placed on the HCT CRF track.
4/6/2020	2814: Indication for CRID Assignment	Add	Added sentence to question 5 providing guidance on when to select ‘no’.
1/29/2020	2814: Indication for CRID Assignment	Add	Added the following instruction for how to report the date of transplant for intrauterine transplants: **Intrauterine Transplants** For intrauterine transplants, report the date of birth as the date of transplant to avoid errors from occurring in FormsNet3^{SM}.
4/26/19	2814: Indication for CRID Assignment	Modify	Version 3 of the 2814: Indication for CRID Assignment section of the Forms Instructions Manual released. Version 3 corresponds to revision 3 of the Form 2814.

Last modified: Nov 01, 2021

Q1-2: Indication

Gene Therapy: If the infusion type is a gene therapy, the recipient will be placed on the HCT CRF track.

Question 1: What is the indication for CIBMTR Research ID (CRID) assignment?

Indicate whether the individual will be receiving hematopoietic cellular transplant (HCT), non-transplant cellular therapy, marrow toxic injury therapy, or non-cellular therapy.

Hematopoietic cellular transplant (HCT) 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. If the infusion type is gene therapy, select “Hematopoietic cellular transplant.”

Non-transplant cellular therapies 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; these are often referred to as cellular therapies for regenerative medicine (CTRM).

Marrow toxic injury should only be reported by Radiation Injury Treatment Network (RITN) centers in the event of mass casualty incident resulting in marrow toxic injury. Do not report marrow toxic injury for individuals receiving pre-transplant radiation therapy or for accidental, isolated exposures to radiation.

If you are completing this form for a patient at a RITN center and are uncertain if the patient’s data should be reported using the marrow toxic injury indication, submit a CIBMTR Center Support ticket or email RITN@nmdp.org.

Non-cellular therapy may include vaccine or immunomodulatory trials; report non-cellular therapy when the patient is enrolled on a trial or protocol requiring data submission to CIBMTR.

If the reported indication is:

- Hematopoietic cellular transplant, complete questions 2-3.
- Non-transplant cellular therapy, complete question 2
- Marrow toxic injury, complete question 2
- Non-cellular therapy, complete questions 4-6

Question 2: Event Date (or planned event date)

Report the planned date of transplant. An approximate date is fine to report if the date is not yet on the hospital schedule. When or if the approximated or planned date of infusion changes, the form should be updated in FormsNet3, as this data field is used to populate the date of infusion on the patient’s other data collection forms. If the recipient has a previous transplant already reported to CIBMTR, review previous

transplant follow-up forms and ensure the subsequent transplant is correctly reported on the follow-up forms, which will prompt appropriate follow-up forms to come due; a new or additional Form 2814 is not required.

> ! For intrauterine transplants, report the date of birth as the date of transplant to avoid error from occurring in FormsNet3SM.

Last modified: Mar 08, 2024

Q3: Hematopoietic Cellular Transplant (HCT)

Questions 3: Is the product genetically modified? For multiple products, report “Yes” if ANY of the products are genetically modified.

Genetically modified products include any product where the cells are manipulated via either:

- Gene transfer: A process by which copies of a gene are inserted into living cells in order to induce synthesis of the gene’s product; or
- Transduction: A process by which foreign DNA is introduced into a cell by a virus or viral vector These techniques alter its gene expression through the insertion of different genes or editing of genes. If more than one product is being infused, indicate if any of the products are genetically modified.

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Q4-6: Non-Cellular Therapy

Question 4: Specify the disease / study for which non-cellular therapy was given

Indicate if the individual is participating in the BMT CTN 17-02 study or receiving non-cellular therapy as treatment for MDS, multiple myeloma, myelofibrosis, sickle cell disease, or another disease. If the research participant is enrolled in a study or receiving therapy for a disease that is not captured in any of the above categories, specify in question 5

Question 5: Specify other disease / study

If you have indicated in question 4 ‘other disease/study’ please enter the disease or study patient has or will be given therapy for.

Question 6: Enrollment date (date of consent)

Report the date of consent for enrollment on non-cellular therapy protocol. Continue with the signature section of the form.

Signature Lines:

The FormsNet3SM 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.

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