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

Reporting a subsequent transplant using the indication form is not allowed. Report the subsequent transplant on the latest follow up form for the most recent transplant.

Another Form 2814 would not be required for interventions such as subsequent transplant or subsequent round of cellular therapy.

Q1: Indication

Q2-5: Hematopoietic Cellular Transplant

Q6: Cellular Therapy

Q7: Marrow Toxic Injury

Q8-10: Non-Cellular Therapy

Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below.

Date	Manual Section	Add/Remove/Modify	Description
7/26/16	2814: Indication for CRID Assignment	Modify	Version 2 Released

Q1: Indication

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.

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, contact your CIBMTR CRC 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 2-5.
- Non-transplant cellular therapy, complete question 6
- Marrow toxic injury, complete question 7
- Non-cellular therapy, complete questions 8-10.

Q2-5: Hematopoietic Cellular Transplant (HCT)

Questions 2-4: Specify the planned cell source(s) for this HCT

Indicate if the recipient will be receiving cells from an autologous, related allogeneic, or unrelated allogeneic source. Indicate all that apply; if the recipient is receiving multiple products, ensure all product sources are specified. Report only the sources for the current hematopoietic cellular transplant; do not report cellular sources for previous hematopoietic cellular transplant(s), co-infusions, or planned subsequent hematopoietic cellular transplant(s).

Question 5: Planned HCT date

Report the planned date of transplant; this should be the first date of transplant reported to CIBMTR for this recipient. If the planned date of infusion changes, the electronic form should be updated in FormsNet3SM, as this data field is used to populate the date of infusion on the patient's other case report 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. Continue with the signature section of the form.

Q6: Cellular Therapy

Question 6: Planned infusion date

Report the planned date of cellular infusion. If the planned date of infusion changes, the electronic form should be updated in FormsNet3SM, as this data field is used to populate the date of infusion on the patient's other case report forms. Continue with the signature section of the form.

Q7: Marrow Toxic Injury

Question 7: Event date

Report the date the patient was exposed to radiation. This should be the same as the date of the mass casualty event resulting in marrow toxic injury. A Radiation Injury Treatment Network (RITN) center should only report marrow toxic injury 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. Continue with the signature section of the form.

Q8-10: Non-Cellular Therapy

Questions 8-9: Specify the disease for which non-cellular therapy was given

Indicate if the individual is receiving non-cellular therapy as treatment for MDS, multiple myeloma, myelofibrosis, sickle cell disease, or another disease. If the research participant is receiving therapy for a disease that is not captured in any of the above categories, specify in question 9.

Question 10: 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.