CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

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CIBMTR Guidance for Reporting Autologous Cellular Therapies

Please consider the following guidance when determining whether to report a cellular therapy to the CIBMTR. The scope of this document covers autologous cellular therapies only.

Reporting Autologous Cellular Therapy Data to the CIBMTR

Reporting of autologous cellular therapy data to the CIBMTR remains voluntary at this time, with the exception of cellular therapy received after an allogeneic HCT. Reporting of the infusion date is strongly encouraged and form completion remains voluntary.

Consent Status for Cellular Therapy

The CIBMTR encourages centers to approach all patients for consent to participate in the Observational Research Database. When a patient consents to participate in the Observational Database, their data are stored in the CIBMTR's Observational Research Database and may be used for research. The primary purpose of the Observational Research Database is to have a comprehensive source of data that can be used to study cellular therapy and hematopoietic cellular transplantation (HCT). The consent form applies to both HCT and cellular therapy. Per CIBMTR, a patient only needs to be consented once to participate in the Observational Research Database, however, you should follow the guidance of your local IRB. The most recent consent status reported to CIBMTR is the consent applied to the entire patient record.

Below are the scenarios describing when autologous cellular therapy data can be collected in the context of patient consent for research:

1. **Autologous cellular therapy**: For any cellular therapy (e.g., CAR T-cells) that uses an autologous donor/product and is given as a stand-alone therapy (not associated with an HCT)
    - *Reporting these infusions is voluntary at this time*. When consent for research is not obtained, these infusions should <u>not</u> be reported to the CIBMTR. **In these cases, please make sure that the patient consents for data sharing with the CIBMTR <u>before</u> assigning a CRID.**
    - If consent for research is later obtained for a subsequent infusion, cellular therapy infusions that occurred prior to obtaining consent to participate in the Observational Database are not be required to be retroactively reported.
2. **Autologous cellular therapy given after HCT**: for any cellular therapy infusion (e.g. co-infusion, DLI/DCI, CAR-T) given after a patient has already had an HCT, please follow the table below for requirements:

First Infusion type	Consent for research is obtained for HCT	Second Infusion type	Consent for research is obtained for CT	Report that the CT event occurred?	Complete the F4000 series?	How to report
Auto HCT	Yes	auto cellular therapy	Yes/Not approached (prior consent status is valid)	Yes	Voluntary form completion	CT infusion reported on appropriate HCT follow up form to trigger F4000
			Declined	Yes	No	CT infusion reported on the appropriate HCT form as occurring but F4000 would be made NRQ
	No	auto cellular therapy	Yes	Yes	Voluntary form completion	Would create new F2814 Indication form to trigger F4000
			No/Not approached	No	No	Do not report to CIBMTR
Allo HCT	Yes	auto cellular therapy	Yes/Not approached (prior consent status is valid)	Yes	Voluntary form completion or *limited data collection	CT infusion reported on appropriate HCT follow up form to trigger F4000
			Declined	Yes	*limited data collection	The CT is reported on the HCT form as occurring, but the CT forms would be abbreviated
	No	auto cellular therapy	Yes	Yes	Voluntary form completion or *limited data collection	CT infusion reported on appropriate HCT follow up form to trigger F4000
			No/Not approached	Yes	*limited data collection	The CT is reported on the HCT form as occurring, but the CT forms would be abbreviated

*limited data collection in progress

Please submit all questions via CIBMTR Center Support (https://nmdp.service-now.com/csm)