Date: September 7, 2011

To: CIBMTR Medical Directors and Data Managers / Clinical Research Professionals

From: Mary Horowitz, MD, MS and Douglas Rizzo, MD, MS

RE: CIBMTR Data Reporting and consent information for BMT CTN patient

This memo addresses CIBMTR data reporting requirements for Blood and Marrow Transplant Clinical Trials Network (BMT CTN) patients and provides details regarding CIBMTR research consent status.

The BMT CTN was established in October 2001, with an aim to create an infrastructure to address important issue in hematopoietic stem cell transplantation by conducting large, multi-institutional clinical trials. The current funding cycle for the grant that supports the BMT CTN ended on July 31, 2011. Requests for Proposals were released by NIH in 2010 for the Data and Coordinating Center (DCC) and Core Center participation in a new, six-year funding cycle. Applications were reviewed in March 2011 and Core Centers were notified of their awards in July 2011. Effective August 1, 2011, the composition of the Steering Committee changed by virtue of Core Center selection. The new infrastructure consists of:

- Twenty Core Clinical Centers (some of which are consortia of two or more centers);
- Affiliate Centers;
- The Data and Coordinating Center, made up of three organizations (CIBMTR, The EMMES Corporation and NMDP) that work together to provide administrative, logistic, scientific and informatics support;
- Protocol Teams;
- Technical Administrative and Scientific Advisory Committees

Reporting requirements for BMT CTN patient data using FN2 are listed below.

- Centers participating in BMT CTN trials must provide at least TED-level data to the CIBMTR on all (i.e. autologous & allogeneic) consecutive hematopoietic stem cell transplants performed at their institution during the period they are actively enrolling patients.

- Patients providing consent for BMT CTN clinical protocols are inherently consenting to the treatment specified as well as the data collection necessary for the clinical protocol. In nearly all cases, data collection on CIBMTR observational database forms is required as one component of the data being collected to support the clinical protocol. The second component is collection of data in the EMMES Advantage EDC system. All patients who participate in BMT CTN clinical trials must provide consent for the protocol and data collection as a condition of enrollment. All patients SHOULD be approached at the same time to provide consent for the CIBMTR observational database, as this increases the usefulness of their data for other research without increasing the data submission burden.
Unless otherwise specified in the BMT CTN protocol, any patient participating in a BMT CTN protocol where enrollment occurs “pre-transplant” must have Comprehensive Report Form (CRF) data submitted, regardless of the center’s designated status for reporting other CIBMTR data (i.e. if a center only reports CRF-level data for allo_MUD and TED-level data for related allo & auto transplants, this reporting status limitation does not apply to BMT CTN patients).

Any patient participating in a BMT CTN protocol where enrollment occurs “post-transplant” will stay on the data reporting track assigned by the CIBMTR randomization process at the time of Pre-TED Form (2400) completion (i.e. TED or CRF track). An example is the randomized trial for treatment of GVHD (protocols 0801 & 0802), where patients were not eligible or enrolled until the post transplant event occurred.

Any patient participating in a BMT CTN “Pre-transplant” enrollment protocol for an autologous transplant must answer “yes” to the consent for CIBMTR Research question on the CIBMTR Recipient ID Assignment Form (2804). If the question is answered “no”, the Pre-TED Form (2400) will not come due for the patient.

If you have any questions regarding CIBMTR data reporting for BMT CTN patients, please contact Kavita Bhavsar, BMT CTN Program Coordinator (CIBMTR Data), at kavitab@mcw.edu or your center liaison.

Additional BMT CTN and CIBMTR information may be found at: www.bmtctn.net or www.cibmtr.org

Thank you.