Date: October 28, 2010

To: CIBMTR Data Managers / Clinical Research Professionals

From: Douglas Rizzo, MD, MS

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

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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.

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. This infrastructure consists of:

- Sixteen Core Clinical Centers;
- Affiliate Centers;
- The Data and Coordination Center (DCC), 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 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 (protocol 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.

**A patient at my center consented to participate in a BMT CTN trial, but not for CIBMTR observational research as outlined in the observational database protocol. What should I do?**

This scenario can occur in two ways.

In the first case, the patient was approached for consent to the observational database protocol and declined. In this case, all patients enrolled on BMT CTN “Pre-Transplant” enrollment protocols are assigned to the CIBMTR Comprehensive Report Form (CRF) track. However, their data will only be used for BMT CTN protocol analysis and not for any CIBMTR observational research study if a consent has not been given to participate in research. The same applies to patients enrolled on BMT CTN “Post-Transplant” enrollment protocols.

In the second case, the patient was approached for consent for the BMT CTN, but never approached for consent for observational research. In this case, as above, the patient’s data submitted to the CIBMTR will only be used for purposes of BMT CTN studies. However, if the patient is still alive, the center is encouraged to approach the patient and request consent for research in the observational database protocol. This will require signature of the existing CIBMTR observational research database consent form available at [http://www.cibmtr.org/DataManagement/ProtocolConsent/ObservationalData/index.html](http://www.cibmtr.org/DataManagement/ProtocolConsent/ObservationalData/index.html)
If the patient is deceased and did not consent for CIBMTR research: Since consent for BMT CTN and related data collection is required to participate in a BMT CTN protocol, the patient has consented to the collection of data for BMT CTN.

If the patient was registered with CIBMTR prior to the implementation of FormsNet, please complete CRF-level forms and send an e-mail to kavitab@mcw.edu with patient details, including CRID #, IUBMID # (if available), CIBMTR Center Number (CCN), Date of Birth, Transplant Date and BMT CTN protocol #. This patient’s data will only be used for BMT CTN research and not for other CIBMTR observational research.

If the patient was registered with CIBMTR using the current FormsNet™2 web application:

- Auto/ Allo transplant: Centers must check the BMT CTN tick box on the Pre-TED Form (2400) and check “No” to “Consent for Research”. In this case, “consent for research” is meant to apply to the CIBMTR observational database protocol. This will put the patient on the CRF track, as required, and research level data will only be used for BMT CTN purposes and not for other CIBMTR studies.

If this patient is alive and did not sign the consent for CIBMTR research:

CIBMTR strongly encourages centers to request patients who are enrolled on a BMT CTN trial to also sign the consent to participate in CIBMTR research. Participants should be informed that additional long term follow-up forms are not required.

If the patient agrees to participate in CIBMTR Research, please update the box on the Pre-TED Form (2400) “Consent for Research” to “Yes”. This patient data may then be used for other CIBMTR observational research studies. If this patient had an autologous transplant, please send an e-mail to kavitab@mcw.edu with patient details, so that the Pre-TED Form (2400) and follow-up forms can be made due for completion.

- If the patient did not consent to participate in CIBMTR Research, please verify that the Pre-TED Form (2400) “Consent for Research” is checked “No” so that this patient data will only be used for BMT CTN purposes.

If you have any questions on CIBMTR data reporting for BMT CTN patients, feel free to contact your liaison or BMT CTN Data Program Coordinator, Kavita Bhavsar, at kavitab@mcw.edu.