Dear CIBMTR U.S. Center Medical Directors, Primary Contacts and Data Managers/Clinical Research Professionals:

This is a follow-up to the email sent on April 17, 2008 regarding the updated CIBMTR Public Health Authority (PHA) letter.

Several questions have arisen from centers that indicate some confusion regarding the submission of data, HIPAA and consent. Centers have asked whether this revised letter meant that submission of autologous data to CIBMTR was now required for the SCTOD. The new PHA letter does not represent a change – there is not an expectation to submit data for autologous patients with regard to the SCTOD. Submission of data for autologous recipients may be required for other programs, like CTN.

Centers can share whatever data they wish to with CIBMTR, in its capacity as a PHA. This is important, since if a center wants to share all of their data with us through FormsNet or StemSoft so that they get back a complete dataset, even for the patients who did not provide consent for research, this is possible. NOTE, the status of the CIBMTR as a PHA has not changed – it has been clarified as to the meaning. We will be taking steps soon to determine which centers may want to do this, so that our selection algorithm allows for this to happen. Once that is ready, we will communicate further with the centers as to how that will work.

Consent should still be requested for each patient whose data is sent to the CIBMTR regarding use for research. This will help establish whether CIBMTR is being requested to hold patient information on behalf of the center to fulfill a request for a complete dataset, or whether the patient’s data can be used for research purposes. So, consent is still necessary for us to determine whether or not a patient’s data can be used for a research purpose, but the center is able to share data with CIBMTR for any patient, without obtaining HIPAA authorization. So, for instance, if a center wants to send data on a patient who receives an autologous HCT on Feb 15, 2008 who did NOT consent for research, so that a future downloaded dataset from FormsNet is complete for all patients who underwent HCT at that center in 2008, the center can send that data, and CIBMTR can receive and hold that data. HOWEVER, it is crucial that the NO CONSENT for research box be checked so that that person’s data is not used for any research purpose.

Clinical Trials Network (CTN) centers will need to continue to submit data on all patients, using pre-TED and post-TED. Patients enrolled on CTN studies will require comprehensive Report Forms as has been described elsewhere.

A Data Transmission Agreement (DTA) is still necessary.

Thank you,

Carol Doleysh
Program Coordinator III - SCTOD
Center for International Blood and Marrow Transplant Research
Medical College of Wisconsin
9200 West Wisconsin Avenue, Suite C5500
Milwaukee, WI 53226
http://cibmtr.org/
Phone: 414-805-0644
Fax: 414-805-0714
Email: cdoleysh@mcw.edu