DATE: September 28, 2011

TO: CIBMTR Data Managers

FROM: Marie Matlack; CIBMTR Senior Manager-Data Management
       Janet Brunner, PA-C; CIBMTR Program Director-Data Operations

RE: FormsNet Release on September 28, 2011

The FormsNet release on September 28 included the release of two new forms that are located in unscheduled forms. The forms are Adverse Event (Form 3001) and Product Complaint (Form 3010). The forms were developed to collect real-time reporting of adverse events and product issues in conjunction with the implementation of the 10-CBA protocol, which is a multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications.

These forms should be completed:

Based on the adverse reporting requirements listed in the 10-CBA study protocol. (Information regarding 10-CBA protocol and licensure can be found at: http://marrow.org/HD/MedEd/Cord_Blood_Licensure/US_Transplant_Centers/U_S__Transplant_Center_Information.aspx).

Based on the instructions provided by the National Marrow Donor Program. (At this time you may continue to use your current process for reporting of non-CBA events for unrelated transplants to the NMDP. Use of these forms for non-CBA events is optional until further notice.)

These forms should not be completed for:
  Recipients that underwent an autologous HCT.
  Recipients that underwent a related-donor HCT.

For questions concerning the 10-CBA protocol, please contact Amy Hays (ahays@nmdp.org or 612.884.8559). Amy has a presentation on the 10-CBA protocol at the 2011 Clinical Research Professionals/Data Management Conference on Wednesday, November 2 at 1:45 pm.

For questions concerning adverse event reporting, please contact Ruth Bakken (rbakken@nmdp.org or 612-627-5812).