Overview of the CIBMTR and SCTOD

For New BMT Clinical Research Professionals

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- CIBMTR history and background
  - Research affiliation of NMDP (Minneapolis) and IBMTR/ABMTR (Milwaukee) began in 2004
  - Collaborates with CTN, EBMT
  - Seventeen working committees
    - Each has a specific area of interest, such as a type of disease (Acute Leukemia, Chronic Leukemia) or a general BMT issue (Infection, Graft Sources)
    - Determine studies done and prioritize the studies

- SCTOD overview
  - Explanation of the SCTOD contract:
    - Congress has legislated that outcomes data must be collected on all patients "who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor." This includes all allogeneic transplants, (related and unrelated) where either the donor or recipient resides in the U.S. The CIBMTR, as recipient of the SCTOD Contract, is responsible for the administration of this activity and the collection / analysis of the data.

  - How this affects CIBMTR data collection
    - Collaborative efforts will allow CIBMTR to meet the new challenges and requirements dictated by the Program. The two campuses are strategically adjusting internal procedures to implement the new contracts, including collecting data on a harmonized paper form and electronic data collection system. Once developed, the new Program will offer new research opportunities to the transplant community and streamline data collection. A combined continuous process improvement (CPI) and audit program is also in development.

  - When did this become effective?
    - The law was passed on December 19, 2005 and the SCTOD Contract was activated on September 27, 2006.
    - Articles about the SCTOD and the C. W. Bill Young Program can be found in the December 2006 CIBMTR Newsletter and the November 1, 2006 ASBMT eNews.

- Process for new centers
  - How they join
  - 5 digit center codes assigned by CIBMTR
  - Types of centers
    - Research vs. registering, Allo/Auto, CTN, etc.
  - CIBMTR campus assignment – Milwaukee or Minneapolis
    - One contact person for ALL correspondence for all types of transplant
  - Data Transmission Agreement

- Data submission process and timelines
  - 10 digit unique ID assignment
    - First step of data submission
    - Stays with patient forever
  - Data flow chart for U.S. transplant centers
  - New time points for CIBMTR forms: baseline, six months, death form

Time point	Reg	Research
Baseline	New for "TED" Not new for "Pre-REG"	New for Research
6 months	New for CIBMTR	New for CIBMTR
Death	Post-TED	Also send Follow-Up

  - Samples of new forms and recorded Summer 2007 training tele-conferences on www.cibmtr.org under 'data collection'
    - More opportunities for training at the upcoming February 2008 BMT Tandem Meeting in San Diego
  - Database protocols/consents
    - If 'no' to research, TED level data must still be submitted on allo infusions per government contract requirements
    - Data will not be used for research unless there is consent
  - Reimbursement for forms
    - Reimbursement rates
    - No TED level data is reimbursed

- Data submission methods
  - Current methods
    - Paper, disk, e-mail (StemSoft), TED on the Web, export from EBMT (TED level)
  - FormsNet 2 advantages
    - No interpretation by data entry staff
    - Immediate, no waiting for data entry
    - Center can make corrections, requested or unrequested
    - Forms due list and studies due

- Contact information for both campuses