7. Unique ID Assignment (CRID) & Protected Health Information (Form 2804) table of contents

NOTE:
The Unique ID (CRID) replaces the CIBMTR IUBMID# and the NMDP Recipient ID for data collection purposes. Additionally, the term CRID will replace the terms "Universal Recipient ID#" and "Unique ID Assignment" on the subsequent versions of the TED and Comprehensive Report Forms.

Transplant centers may assign an IUBMID for their own use. The NMDP will continue to assign a Recipient ID for use in the unrelated donor search process.

In order to create a universal unique ID system, the CIBMTR is collecting protected health information (**PHI**), including but not limited to identifiers such as name, social security number (**SSN**), mother's maiden name and birth information. This decision was made after careful consideration by a combination of CIBMTR staff, an external Data Advisory Group and representatives of the Health Resources and Services Administration (**HRSA**). Upon notification of a recipient's first HSCT, the CIBMTR will request the PHI needed to create a Unique ID (CRID). The Unique ID (CRID) is a lifelong ID used across the entire C.W. Bill Young Cell Transplantation Program. **Recipients existing in the CIBMTR or NMDP database as of December 2, 2007 have been assigned a Unique ID (CRID). Recipients who receive a HSCT on/or after December 3, 2007, must be assigned a Unique ID (CRID) using the Unique ID Assignment Form (Form 2804). Direct identifying information collected to establish the Unique ID (CRID) <u>will not be disclosed</u> to investigators for research purposes.**

The use of PHI to uniquely identify recipients who are included in the Program is needed for several reasons. First, the Program is required by HRSA to develop a system to uniquely identify recipients for center-specific outcomes reporting. The Unique ID (CRID) will avoid duplication of recipient records across transplant programs, particularly when situations exist where sequential HSCTs occur at different institutions. Additionally, the Unique ID (CRID) will facilitate knowledge of previous autologous HSCTs that may not be reported by a center performing an allogeneic HSCT, and therefore adjusting the expected outcome accordingly for center-specific outcome reporting. Second, uniquely identifying recipients will facilitate use of the National Death Index to determine completeness of recipient survival reporting, as well as establish lack of bias when reporting recipient deaths as *lost to follow-up* for center-specific analyses and other long-term follow-up studies. Similarly, collection of these data will allow CIBMTR to help centers re-establish contact with recipients who have been lost to follow-up but are not deceased, using databases available in the public and private sector. Data used to generate a Unique ID (CRID) may be used to increase the value of the SCTOD by acquiring matching data from other Federal government

databases for government reports or research about the Program. Third, generation of a Unique ID (CRID) is essential to determining that all allogeneic HSCT recipients in the United States are reported to the SCTOD. A recipient's SSN and date of birth have been routinely collected by the NMDP and the United States solid organ transplant program (UNOS) since the early 1990s. The information is used for purposes similar to those described above, in the context of their government reporting functions. Finally, in the event of a state law or IRB policy that supersedes federal statute, centers may opt out of providing some of these data. Date of birth and gender are considered essential. If a SSN is not provided, the full name of the recipient and the mother's maiden name are an alternative that will establish a Unique ID (CRID).

The Unique ID (CRID) system is able to assign an ID when a few identifying items are missing, however this increases the risk of creating a "fuzzy match" and therefore duplicate reporting of cases.

The items listed below highlight the important security concerns that have been addressed with regard to the collection of the PHI.

- CIBMTR and NMDP are designated Public Health Authorities in the capacity of collecting and using of data for the Stem Cell Therapeutics Outcomes Database (SCTOD) and addressing HIPAA privacy regulations.
- The electronic system that collects and houses the PHI is called FormsNet™2 (for more information regarding FormsNet™2, see section 8). The server holding the direct identifiers is very secure and is separate from the outcomes database. Access to these data is highly restricted within the CIBMTR. The electronic systems used for acquisition and generation of unique ID numbers have undergone rigorous certification and authorization from HRSA's Office of Information Technology and comply with all United States federal regulations relevant to security of electronic data in federal databases.
- Electronic transmission of the PHI from transplant centers using FormsNet™2 is protected by double authentication entry requirements (login/password and SecurID™ card) for all system users who enter the data. Electronic transmission is protected by SSL technology.
- When the paper Form 2804 is used to establish the Unique ID (CRID), the data are entered into FormsNet™2 at the CIBMTR. The transplant center will receive an e-mail containing the Unique ID (CRID), the recipient's year of birth, gender, disease and date of HSCT. The Form 2804 is then securely destroyed.
- Once the identifying data are entered into FormsNet™2 and a Unique ID (CRID) is assigned, the data are no longer visible to the transplant center or CIMBTR staff. Therefore, it is important that the information is accurate when

submitted. The PHI used to create the Unique ID (CRID) will not appear on any subsequent forms or correspondence. Centers wishing to confirm a Unique ID (CRID) will be able to re-enter data into one-way look-up tables, however PHI will not be displayed by the system. This security measure will prevent inappropriate revealing of PHI to unauthorized individuals.

Transplant centers need to take appropriate measures at their site to secure the PHI used to generate the Unique ID (CRID). However, data collected to establish the Unique ID (CRID) does not need to be maintained at the transplant center.

For more information regarding the Form 2804, see appendix D. For more information regarding the CIBMTR's Public Health Authority status, see appendix E.