REPORTING TO THE CENTER FOR INTERNATIONAL BLOOD AND MARROW TRANSPLANT RESEARCH (CIBMTR) DURING THE COVID-19 PANDEMIC

The CIBMTR is a research program operated by the Medical College of Wisconsin and the National Marrow Donor Program/Be The Match. It maintains a large outcomes registry of patients receiving hematopoietic stem cell transplants (HCTs) and other cellular therapies (CTs), primarily for hematologic malignancies and other life-threatening marrow disorders. Almost all US HCT and CT centers participate in this important research effort. **This non-interventional, National Institutes of Health and Health Resources and Services Administration-funded, Research Database Protocol is poised to collect invaluable information on the natural history of COVID-19 in HCT and CT patients and to rapidly disseminate information about incidence, risk factors and therapies.** In contrast to many areas of health care, where investigators are scrambling to set up registries to capture COVID information, the HCT and CT community can rapidly address the need for timely data using a well-developed infrastructure that has supported research and clinical decision-making for > 45 years.

Although many centers are temporarily suspending non-interventional research projects during the current pandemic, to protect patients and research staff from potential exposure and to conserve resources, **many investigators, institutions and the American Society for Transplantation and Cellular Therapy (ASTCT) consider CIBMTR's outcomes registry as exempt from this prohibition for the following reasons:**

1. There is **no additional risk** to patients, clinicians or study staff by participating in the CIBMTR outcomes registry during the COVID-19 pandemic.

2. There are **no required evaluations or appointment**s other than those done as part of standard of care. The source of data is the medical record and does not require contact between patients and research staff.

3. **The consent form is simple and usually administered by clinicians** at the time the patient signs the general consent for HCT or CT. A remote consent session is also allowed though a signed consent form is eventually required. The person conducting the remote consent session can ask for the patient's verbal consent by phone or video conference and document it in the patient's record. When the patient comes to the center for the transplant, the consent form can then be provided by a clinician for signature.

4. Once a patient signs a consent, **data submission can be delayed** if there are staff shortages. CIBMTR has suspended usual benchmarks for timely submission during the COVID-19 pandemic. However, for staff who have access to the medical record, reporting can continue – allowing staff to continue important research work while working remotely.

5. Obtaining consent at a later date (when the ban on non-interventional research is lifted, as some plan on doing) will not be possible for patients who die early after treatment (10-20% of HCT patients) which will lead to biased representation of patients in the CIBMTR our research data set. This could **adversely affect the scientific integrity** of investigations designed to understand the impact of COVID-19 on HCT/CT use and outcomes.

6. For many patients (all of those receiving allogeneic HCT), **these data *must* be submitted, with or without consent, to fulfill the federal reporting requirements** put in place by the Stem Cell Therapeutic and Research Act of 2005 and the Stem Cell Therapeutic and Research Reauthorization Acts of 2010 and 2015. However, without consent, the data can only be used for requirements of the C. W. Bill Young Cell Transplantation Program, greatly reducing its usefulness in informing our body of knowledge about HCT and CT outcomes.

Both the CIBMTR and the American Society for Transplant and Cellular Therapy urge you to allow continued consent and enrollment of HCT and CT patients in the CIBMTR's Database Protocol during the COVID-19 pandemic. This document has been approved by the National Marrow Donor Program Institutional Review Board.

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