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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR DONOR HEALTH AND SAFETY
Orlando, FL
Wednesday, February 15, 2023, 1:00 – 3:00 pm

Co-Chair:	**Galen Switzer, PhD, University of Pittsburgh, Pittsburgh, PA; Telephone: 412-246-6564; E-mail: gswitzer@pitt.edu**
Co-Chair:	**Jack Hsu, MD, Shands HealthCare and University of Florida, Gainesville, FL; Telephone: 352-273-7539; E-mail: jack.hsu@medicine.ufl.edu**
Co-Chair:	**Sandhya Panch, MD, MPH, University of Washington and Seattle Cancer Care Alliance; Seattle, WA Telephone: 206-606-4336; E-mail: srpanch@uw.edu**
Scientific Director:	**Heather Stefanski, MD, PhD, Be The Match/NMDP, Minneapolis, MN; Telephone: 763-406-8495; E-mail: hstefans@nmdp.org**
Statistical Director:	**Brent Logan, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-955-8849; E-mail: blogan@mcw.edu**
Statistician:	**Stephanie Bo-Subait, MPH, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-8515; E-mail: sbosuba2@nmdp.org**

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1. **Introduction**
   a. 2022 Tandem DSWC session minutes (Attachment 1)

   The CIBMTR Donor Health and Safety Working Committee meeting was called to order by Dr. Galen Switzer at 1:10pm EST, on Wednesday, February 15th. The CIBMTR COI policy along with working committee leadership was introduced. Dr. Galen Switzer's departure was announced and Dr. Fotios (Frank) Michelis was appointed as the successor. Access to publicly available research datasets and the current patient reported outcome (PRO) protocol enrollment was illuminated. The processes of participating in the working committee, voting guidance, and rules of authorship were outlined.

2. **Accrual summary** (Attachment 2)

   The accrual summary can be found in the materials which were linked to the online Tandem agenda.

3. **Presentations, published or submitted papers**

   Recently published or summit worked from the committee were announced.

   a. **DS13-02** Murthy GSG, Logan BR, Bo-Subait S, Beitinjaneh A, Devine S, Farhadfar N, Gowda L, Hashmi S, Lazarus H, Nathan S, Sharma A, Yared JA, Stefanski HE, Pulsipher MA, Hsu JW, Switzer GE,

Panch SR, Shaw BE. Association of ABO mismatch with the outcomes of allogeneic hematopoietic cell transplantation for acute leukemia. ***Accepted to American Journal of Hematology.***

b. **DS19-02** Farhadfar N, Ahn KW, Bo-Subait S, Logan B, Stefanski HE, Hsu JW, Panch S, Confer D, Liu H, Badawy SM, Beitinjaneh A, Diaz MA, Hildebrandt GC, Kelkar AH, Lazarus HM, Murthy HS, Preussler JM, Schears RM, Sharma A, Poel M, Bruce JG, Pulsipher MA, Shaw BE, Wingard JR, Switzer GE. The impact of pre-apheresis Health Related Quality of Life on peripheral blood progenitor cell yield and donor?s health and outcome: Secondary analysis of Patient-Reported Outcome Data from the RDSafe and BMT CTN 0201 Clinical Trials. Transplantation and Cellular Therapy. 2022 Sep 1; 28(9):603.e1-603.e7. doi:10.1016/j.jtct.2022.05.042. Epub 2022 Jun 7. PMC9427696. ***Published.***

4. Studies in progress (Attachment 3)

The studies in progress can be found in the materials which were linked to the online Tandem agenda.

a. **DS20-01** Acute toxicities of bone marrow donation in donors with sickle cell trait (Nosha Farhadfar; John Wingard) **Data file preparation**

5. Review paper

a. Reducing the Risk of Transmission of Donor Derived Malignancy: Consensus Guidelines for Donor Genetic Screening Prior to Allogenic Stem Cell Transplant and Detection of Leukemia Origin in Relapse After Transplant (Lacey Scott Williams; Catherine Lai; Lucy Godley)

Dr. Jack Hsu introduced Lacey Williams, who gave an update on the review paper which aimed to complete a comprehensive review of donor derived malignancy (AML, ALL, MDS) to include donor sources, biology, treatment, and maintenance strategies. The second component of this proposal is to develop guidelines for increased screening of donors prior to allogeneic stem cell transplant to reduce the likelihood of relapse with donor derived malignancy where the PIs plan to convene a panel of 10-20 international experts to weight recommendation.

Currently, donor derived malignancies are screened for in many ways and may be a challenge with this proposal. An important aspect of this study would be to inform on how we should be screening for this within the donor, but also to focus on instances where the recipient relapses to see if that is DDM. It could also help the field know when to report DDM to NMDP, and how to report it. The writing committee was considering the Journal of Clinical Oncology (JCO) for submission.

6. Future/proposed studies

a. **PROP 2210-205** Unrelated donor collection efficiency and adverse events during the COVID-19 pandemic (Matthew Seftel; David Allan) (Attachment 4)

Matthew Seftel presented this proposal which aims to compare unrelated donor PBSC and BM collections prior to and during the COVID-19 pandemic era. The pandemic was hypothesized to

impact the target population by prompting higher cell dose requests, increased collection yields, and elevated incidences of donor adverse events. Results from this study may edify registries/collection centers on proper management of high cell dose requests, provide insight on donor counselling as cryopreservation continues, and optimize HPC dose targets with ongoing use of planned cryopreservation.

Concerns regarding the use of donor adverse event data were raised in consideration of the unfavorable data retention methods, though the importance of identifying potential trends of AEs justified the efforts required to retrieve data from spreadsheets. Isolating hospitalization from adverse events amongst donors was also advised. PIs were suggested to examine bone marrow transplants as a separate cohort and recognize COVID-19 as a potential confounder by stratifying on year of transplant. Acknowledgement of circumstances requiring donors to be prepped for fresh cell collection when cell count yield was too low from cryopreservation efforts would provide valuable insight for this protocol.

Proposals dropped due to feasibility or overlap with existing studies

a. **PROP 2210-143** Understanding the fates of cryopreserved unrelated stem cell grafts since the start of the COVID-19 pandemic (Joshua A. Fein; Alexandra Gomez Arteaga)
b. **PROP 2210-150** Evaluation of Hematopoietic Stem Cell Donor Characteristics and Factors Associated with Donor Adverse Outcomes in This Era (Kehinde Adekola; Oluwatobi Odetola)
c. **PROP 2210-204** Implications of umbilical cord blood-derived pathogenic mutations revealed by pre- and-post transplant genomics assessment (Satyajit Kosuri; Gregory Roloff)

7. Other business

a. **Additional business items** As needed and as time allows for discussion

Dr. Heather Stefanski introduced NMDP's new process for communicating genetic mutation findings identified in a patient's post-transplant appointment. Prior to the policy change enacted on 1/30/23, inconsistencies regarding donor disclosure and proper handling techniques were observed. Centers not being required to report genetic mutation findings raised concerns, but NMDP's efforts to encourage participation amongst centers will support this new research opportunity.

Dr. Galen Switzer introduced a new feasibility study for psychosocial, ethical, and clinical decisions regarding incidental diagnosis of clonal hematopoiesis among healthy, unrelated, hematopoietic stem cell donors. The qualitative examination of donors confirmed to have the CH+ genetic mutation will inform future research studies about study design feasibility and best practices of informing patients with incidental medical findings.

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Working Committee Overview Plan for 2023-2024		
Study number and title	**Current status**	**Chairs' priority**
DS20-01 Acute Toxicities of Bone Marrow Donation in Donors with Sickle Cell Trait	Data file preparation	*1*
DS23-01 Unrelated Donor Collection Efficiency and Adverse Events During the COVID-19 Pandemic	Protocol Pending	*2*