



**RDSafe: A Multicenter Study of Hematopoietic Stem Cell Donor
Safety and Quality of Life**

**CIBMTR PROTOCOL 06-DON
DRAFT Version 7.0**

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Center for International Blood and Marrow Transplant Research (CIBMTR)**

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PROTOCOL SYNOPSIS – CIBMTR PROTOCOL 06-DON

RDSafe: A Multicenter Study of Hematopoietic Stem Cell Donor Safety and Quality of Life

Principal Investigator: Michael A. Pulsipher, M.D.

Study Design:

This is a multicenter, observational, prospective study comparing acute stem cell donation toxicities and psychosocial effects in related and unrelated marrow and peripheral blood stem cell (PBSC) donors.

Primary Objectives:

- 1) Compare the incidence of grades III-IV Common Toxicity Criteria (CTC) adverse events in related bone marrow and PBSC donors defined by three age groups (<18, 18 to 60, >60) versus unrelated bone marrow and PBSC donors ages 18 to 60.
- 2) Compare the perceived physical and psychosocial difficulty with donation between related bone marrow and PBSC donors defined in three age groups as in (1) versus unrelated donors ages 18 to 60.

Secondary Objectives:

- 1) Compare the incidence of serious and/or life-threatening toxicities in pediatric bone marrow and PBSC donors < age 18 and adult donors > age 60 with the younger adult related and unrelated bone marrow and PBSC donors.
- 2) Compare the incidence of vascular complications (stroke, MI, etc.), splenic rupture, and new onset or flares of autoimmune illnesses within six months of donation in related and unrelated bone marrow and PBSC donors treated with and without filgrastim prior to donation.
- 3) Compare the pre-donation risk factor profiles of related and unrelated bone marrow and PBSC donors.
- 4) Correlate the type and number of pre-donation risk factors of related and unrelated BM and PBSC donors with the incidence of CTC adverse events, serious unexpected or life threatening toxicities, and possible rare G-CSF toxicities (vascular events, splenic rupture, or autoimmune illness).
- 5) Describe donation-related psychosocial experiences of participating related and unrelated BM and PBSC donors from pre-donation through one year follow-up.
- 6) Compare the donation-related psychosocial experiences and status of related and unrelated BM and PBSC donors.
- 7) Examine the effect of pre-donation psychosocial variables (e.g., ambivalence, medical concerns) on post-donation outcomes, including perceived physical and psychological difficulty with donation.

Eligibility Criteria

A. Related BM and PBSC donors

- 1) Donors of any age
- 2) Meet donation criteria per institution policies and procedures.
- 3) Willing to receive phone follow up from the NMDP call center at 1 and 6 months

B. Unrelated BM and PBSC donors

This cohort will include all unrelated donors collected at NMDP centers from the initiation through the completion of accrual to the related donor cohort.

C. Psychosocial/Quality of Life (QOL) Cohort

- 1) Eligible and consented to the trial by the inclusion criteria listed in 5.2.2.3.1.
- 2) Competent to answer the psychological assessment questions by themselves (adult cohort) or with the assistance of a parent (pediatric cohort).
- 3) English speaking (the psychosocial instruments have not been validated in other languages)
- 4) Access available to a telephone for interviews.
- 5) Willing to participate if chosen in pre-donation, 1 month and 1 year follow up interviews as shown by checking a box on the study consent form.

Donor Exclusion Criteria

- 1) Center-specific donor exclusion criteria as outlined per policies and procedures at participating transplant institutions.

Study Description:

Any donor medically suitable to donate in accordance with standards established at participating centers will be considered eligible to participate in this study.. Participating centers will be required to attempt to enroll all eligible donors on this study. Donors will be approached to participate in all aspects of the study. Donors who decline to participate in the QOL portion of the study may still participate in the other components. Of those willing to participate in the QOL cohort, a subset of donors will be randomly assigned to the psychosocial portion of the study. Centers will complete a baseline donor evaluation form, a collection day form for each day collected, and adverse event forms as needed for donors enrolled on the study. Subsequently, all donors on the study will undergo telephone follow-up at one and six months post donation to ascertain donation-related acute toxicities and filgrastim-related autoimmune and vascular toxicities. Donors randomized to the QOL cohort will undergo psychosocial evaluations by telephone through the Survey Research Program at the University of Pittsburgh at pre-donation, one month and one year, in addition to the toxicity assessments described above.

Accrual Objective: 2800 related donors. The comparator cohort of unrelated donors enrolled through the NMDP during this time period will consist of approximately 6500 donors.

Accrual Period: The estimated accrual period is four years.

Study Duration: All donors will be followed for acute toxicities up to six months after donation. Donors randomized to the QOL cohort will complete their final psychological assessment one year after study entry.