1. **Introduction**
   Dr. Stronccek called the meeting to order at 2:46 pm. Drs. Stronccek, Goldstein, and O’Donnell chaired the meeting. Attendees were welcomed and introductions of the Working Committee staff were made. Minutes from the February, 2012 meeting was approved.

   Dr. Stronccek welcomed new Co-Chair Bronwen Shaw, MD, PhD.

2. **Accrual summary**

   Dr. Confer briefly reviewed the accrual summary for the committee.

3. **Published/submitted papers and presentations**


4. **Studies in progress**
   a. **DS05-02** RDSafe: A multi-institutional study of HSC donor safety and quality of life (M Pulsipher)

   Dr. Pulsipher updated the committee on this study. This study has enrolled 1700 donors and about
50-60 donors per months. Enrollment is complete for older cohort (N>250) but younger cohort hasn’t met the accrual yet. It is going to continue to accrue and funding ends June 2014. Next steps will be informed by study results.

b. **DS08-01** The identification of cytogenetic abnormalities in donor derived hematopoietic cells after unrelated donor stem cell transplantation (N Frey)

Dr. Goldstein updated the status of the study. There are 6 cases indentified from 1998 – 2007. Willis Navarro will look up to 2012 data to indentify more cases.

c. **DS09-03** Effects of second donations on marrow and PBSC donors (D Stroncek)

Dr. Stroncek overviewed the study. The study aims to 1) compare the second donation experience in terms of baseline counts, hematologic recovery, collection yield and serious, life-threatening or adverse events and long-term pain or disability, 2) determine first donation results or characteristics which impact the risk of a poor outcome during a second donation, 3) determine donor characteristics which are predictive of a second donation. Suggestions from the committee are including marrow-marrow donation and expanding the data set up to the end of 2012. The protocol will be finalized and routed to the committee for review and comment.

d. **DS09-04** The effect of race, socioeconomic status, and donor center size on bone marrow and PBSC donor experiences (M Pulsipher)

Dr. Pulsipher presented the study. The same data set for the bone marrow versus peripheral blood stem cell donation Blood paper is used for this study. It includes over 10000 donors from 2005 to 2009. Challenges include determination of center effect based on donor center size and methodology of assessing social economic status. Zip codes are used to compute median household income but there are 19% missing in the data set. The preliminary analysis will be circulated soon.

e. **DS09-05b** PBSC versus bone marrow donor severe adverse events (M Pulsipher)

Dr. Pulsipher presented the preliminary results of this study. Previous studies by this committee reported a detailed comparison of the acute toxicities experienced by bone marrow (BM, n=2726) and peripheral blood stem cell (PBSC, n=6768) donors collected at National Marrow Donor Program (NMDP) centers between 2004 and 2009, concluding that although the donation experiences are similar, specific groups of donors (female, obese) were more likely to experience toxicities. Over 1,600 reported events to the NMDP were reviewed by a five physician panel. Serious adverse events fell into the following categories: 1) death, 2) life threatening events, 3) unplanned overnight hospitalization for expected (nausea, fainting, etc.) or unexpected events, 4) persistent or significant disability, 5) congenital anomaly, or 6) other. Overall rates of SAEs were significantly higher after BM donation (n=65, 2.38%) compared to PBSC donation (n=38, 0.56%; p<0.001). There were more life threatening events, unplanned overnight hospitalizations, and persistent or significant disabilities after BM donation compared to PBSC donation. Logistic regression models were built for SAE with or without expected hospitalizations. Multivariate analysis showed that although SAEs are uncommon, they are higher after BM compared with PBSC donation with or without expected hospitalization. In addition, women are at higher risk of SAEs with BM donation with expected hospitalization. Other SAEs of concern includes cancer and autoimmune diseases. Rates of cancer and autoimmune illness after BM vs. PBSC donation in this cohort were analyzed. There are no significant difference for incidence of cancer, autoimmune disease, and non-melanoma skin cancer after BM and PBSC donations. The study is currently in manuscript preparation.
f. **DS10-01** Effect of demographics on peripheral blood CD34+ counts and CD34+ yields in donors undergoing large volume leukapheresis (J Hsu / J Wingard)

Dr. Hsu updated the study. The study aims to determine the influence of race/ethnicity on the number of CD34+ cells collected. Suggestions from the committee include 1) adding recipient weight, apheresis volume and CVC insertion, 2) having primary endpoint just for collections on the 1st day, 3) removing the effect of race and ethnicity on graft composition since it is not collected, and 4) excluding dose of GCSF. The study protocol is currently in development.

5. **Future / proposed studies**
   a. **PROP 1112-48** Retrospective examination of the role quantity of bone marrow harvests performed by a harvest center has on the overall quality of the harvested product. Assessment of the Potential impacts bone marrow product quality has on utilization of bone marrow as a cell source for transplant (N Prokopishyn)

Dr. Confer presented the proposal. The study aims to 1) examine the quantity (i.e. number) and relative quality (i.e. volume and total nucleated cell count of product harvested as compared to standard and minimal acceptable amounts) of bone marrow harvests performed by harvest centers from 1990 – 2012, 2) examine impact of number of harvests performed on achievement of harvest goals, 3) investigate the impact of harvest success on the utilization of bone marrow products by transplant centers to determine if there is a correlation between use of bone marrow as a cell source, overall quality of product received, number of harvests performed per year, and number of harvests performed by the harvesting centers. Comments from the committee include 1) using total nucleated cells per ml, 2) changing of bone marrow harvest process from 1990 - 2012 will make a difference, and 3) The fact that requests from transplant are not reported makes it difficult to compare requested versus received cell dose. In voting, the committee gave this proposal a rating of 2 on a scale of 1 (high scientific impact) to 9 (low scientific impact). The proposal was approved.

6. **Discuss development of new projects/studies**
   a. NMDP has observed a trend towards increased utilization of bone marrow for unrelated donor HCT. Bone marrow collections were up 30% in October-December 2012 versus October-December 2011. Should the committee consider development of projects/studies to improve marrow harvest safety and efficiency?

Dr. Shaw led a discussion about improving bone marrow harvest safety and efficiency. Bone marrow collections are growing twice of the rate of PBSC collections in October-December 2012 versus October-December 2011. It is a concern for many centers that the quality of marrow product and safety of marrow donors. One suggestion included trying to have some training program at next year council meeting.

7. **Other business**
   a. Dr. Confer provided an update on form revisions. Comments from last year meeting are: adding donor height and weight, pre-donation hematocrit and WBC especially for pediatric donors, anesthesia times and to make sure that graft/product data were collected at time of infusion to Form 2006. From 2006 hasn’t been revised by now. Suggestions from the committee include using the forms used in the RDSafe study as a guide for revising the From 2006 and looking at Tanya Pedersen’s file about gathering the minimum data set recommendation put forth by the Donor Outcome Workshops held in Berne and Leiden.

b. Dr. Stroncek raised the issue of serious adverse events (SAE) reporting. Forms that standardize the way measuring SAEs would be helpful. In anticipation of Cord Blood licensure in Oct 2011 a module was placed in FN2 for SAE collection. Transplant centers have been educated to use them.
SAE forms have been released for cord blood, bone marrow and PBSC for recipient SAEs. Donor SAEs are continuing to be reported on Form 701. There is a plan to migrate the donor SAEs to a more comprehensive system as the recipient SAEs.

The meeting was adjourned at 4:29 pm.

**Working Committee Overview Plan for 2013-2014**

a. **DS05-02** RDSafe: A multi-institutional study of HSC donor safety and quality of life. We are continuing to accrue until July 2014.

b. **DS08-01** The identification of cytogenetic abnormalities in donor derived hematopoietic cells after unrelated donor stem cell transplantation. We anticipate submitting the manuscript for peer-review by July 2013.

c. **DS09-03** Effects of second donations on marrow and PBSC donor. We anticipate developing the study protocol by July 2013. We anticipate submitting the manuscript for peer-review by December 2013.

d. **DS09-04** The effect of race, socioeconomic status, and donor center size on bone marrow and PBSC donor experiences. We anticipate developing the study protocol by March 2013. The analysis for this study will be completed by August 2013 and an abstract submitted for the 2013 meeting of the American Society of Hematology. We anticipate submitting the manuscript for peer-review by December 2013.

e. **DS09-05b** PBSC versus bone marrow donor severe adverse events. We anticipate submitting the manuscript for peer-review July 2013.

f. **DS10-01** Effect of demographics on peripheral blood CD34+ counts and CD34+ yields in donors undergoing large volume leukapheresis. We anticipate developing the study protocol by March 2013. The analysis for this study will be completed by August 2013 and an abstract submitted for the 2013 meeting of the American Society of Hematology. We anticipate submitting the manuscript for peer-review by December 2013.

g. **DS 13-01** Retrospective examination of the role quantity of bone marrow harvests performed by a harvest center has on the overall quality of the harvested product. We anticipate sending feedback to PI and requesting draft proposal by July 1, 2013. We anticipate developing the study protocol by December, 2014.

h. **DS 13-02** Retrospective analysis to understand the potential mechanisms underlying the clinical impact of ABO incompatibility. We anticipate finishing data file preparation by June 2013 and an abstract submitted for the 2013 meeting of the American Society of Hematology. We anticipate submitting the manuscript for peer-review by June 2014.
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<th>Work Assignments for Working Committee Leadership (February 2013)</th>
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