1. Introduction
Nirali Shah welcomed all attendees and called the meeting to order at 2:46 pm. Drs. Switzer, Pulsipher, and Shah chaired the meeting; B Shaw, Scientific Director, D Confer, Ex Officio Senior Advisor, B Logan, Statistical Director, and P Chitphakdithai and D Kiefer, statisticians, were also present.

Goals and expectations of the meeting were discussed, the committee leadership noted that the advisory committee delivered a review of: outstanding to the Donor Health and Safety WC based on their achievement of metrics in 2015-2016. A reminder of the voting process, working committee membership and rules of authorship were summarized. The committee was reminded that it has been recommended that DSWC accept up to one proposal due to limited statistical hours.

Minutes from the 2016 Donor Health and Safety Working Committee Meeting held in Honolulu, HI were approved.

2. Accrual Summary
The accrual summaries (NMDP unrelated donors and RDSafe donors) were noted to be available online in the meeting materials.
3. Presentations, published or submitted papers
Galen Switzer provided recognition of the studies which were presented at national conferences and those studies submitted for publication in the past year. In particular, it was mentioned that DS05-02f was selected for a patient friendly summary available on the CIBMTR website.

4. Studies in Progress
It was noted that for more details regarding studies in progress to please refer to Attachment 3 available in the online meeting materials.

a. **DS05-02b, d, f, h** HRQoL RDSafe Studies (G Switzer)
Galen Switzer was invited to say a few words regarding the RDSafe HRQoL studies.

Galen acknowledged that the pediatric (DS05-02b) and older donor manuscripts (DS05-02f) have been published. The related vs. unrelated adult comparison (DS05-02d) has completed analysis, and is in the final stages of a draft manuscript. An additional pediatric manuscript (DS05-02h) looking specifically at parental thoughts on child’s age on the donation experience has been submitted and is under review. There is an RO1 grant submission to focus on pediatric related donors to study the effects of being a pediatric donor or a sibling in a family with an ill child.

There was a question as to if HRQoL differed for the donor dependent on whether their sibling was alive or had died. There was no difference, however the numbers were small with only 7 deaths in the pediatric HRQoL subset.

b. **DS05-02a, c, e, g** RDSafe Studies (M Pulsipher)
Mike Pulsipher was invited to say a few word regarding the RDSafe studies.

Mike noted that there has been extensive work around the RDSafe studies this past year regarding the comorbidities. A short summary of the main results was stated. All of the papers are in the process of being drafted for publication.

c. **DS16-S1** Evaluation of practice guidelines for the assessment and surveillance FU of pediatric HCT donors (L Wiener/G Switzer)
Nirali Shah was invited to say a few words regarding this upcoming survey which will look at practice guidelines, medical and psychosocial evaluations, and follow up for related donors. The survey is fully developed and will be out before this summer, please fill out if you’re a pediatric center.

5. New study proposals
a. **PROP 1611-32** The impact of donor body mass index on collection of G-CSF mobilized peripheral blood progenitor cells from unrelated donors (N Farhadfar/J Hsu/JR Wingard).

Dr. Nosha Farhadfar presented Proposal “The impact of donor body mass index on collection of G-CSF mobilized peripheral blood progenitor cells from unrelated donors”.

Dosing for GCSF is based on donor weight, variation in mobilization response is known to be affected by sex, age, GCSF dosing and timing, and ethnicity.
The hypothesis of the study is that BMI significantly influences the mobilization response to GCSF in NMDP unrelated donors. The endpoints for this study are the 1) number of MNCs and CD34+ cells collected on day 1 of apheresis, and 2) change of WBC and MNC from before the start of GCSF to after GCSF (prior to the first day of collection).

There are 5574 obese, 7379 overweight, 6428 normal and 136 underweight first time BMI donors identified for the study.

Comments and questions from discussion:

Question: Would we be able to look at dosing by BSA or ideal body weight?
Response: A proposal from a couple years ago did propose to look at dosing by ideal body weight however it was felt there was not enough variation for this to be feasible at the time.

Question: Are there data on biosimilars?
Response: There are no data as only original Filgrastim is used for URD in the US under the IND.

Several other comments included:
We know that increased BMI is a factor for increased pain at donation. We know that females experience more pain, and that dose reduction can happen. We will be assessing total dose for the study. There would be a need to measure and correct for the efficiency of the apheresis machine by AC. This can easily be done. Is there information of GCSF receptors or stem cells in adipose tissue – very little.

In general, this proposal was well received and many members felt this question of BMI and dosing continues to be one of interest to the community at large, particularly if obese donors are being given a higher dose of GCSF than is required to meet the necessary yield.

b. PROP 1611-31 The Impact of Pre-Operative Collection of Autologous Blood for Bone Marrow Harvest on Donor Health and Outcome (N Farhadfar/JR Wingard/H Murthy).

Dr. Nosha Farhadfar presented Proposal 1611-31 “The Impact of Pre-Operative Collection of Autologous Blood for Bone Marrow Harvest on Donor Health and Outcome”.

There are many known disadvantages of auto blood transfusion after bone marrow harvest, including risk of misidentification of unit, possible bacterial contamination of unit, and high cost associated with auto blood transfusion, among others.

The hypothesis of this study is that autologous blood transfusion after bone marrow harvest may be unnecessary and can compromise bone marrow donor’s health.

The primary endpoints of this study are to 1) study the impact of autologous blood transfusion on donor health and outcome after bone marrow harvest and 2) identify factors that can predict the need for blood transfusion after marrow harvest.

This study would clarify whether routine auto blood transfusion after bone marrow harvest is required in unrelated donors and provide an opportunity to harmonize clinical policies across the US regarding auto blood collection and transfusion after bone marrow harvest.
There were 7117 first time bone marrow NMDP donors identified for this study.

At the time of preparing the data for this proposal it was thought that we would not be able to retrieve the actual donor level data on whether autologous units were drawn.

After Dr. Farhadfar’s proposal presentation Dr. Dennis Confer presented information on possible sources of auto unit collection and a variety of data split by receipt of auto unit post-harvest that has already been compiled.

The NMDP 700 Series (donor forms) does not ask for number of auto units collected pre-harvest, only if any (and number of) transfused after harvest. While billing data has this information, it is unreliable for research purposes. StarLink, an NMDP application, does capture the planned dates of auto blood collection. This data has been requested and will be quality checked once received.

Dennis noted that other groups, including AABB, and ASBMT, are interested in the topic of autologous donations as well.

Comments and questions from discussion:

Data related to D-R weight pairs is available it should be used as well to look into this question.

A previous limitation was the lack of knowing the number of units collected, if that’s attainable data and accurate then that drawback is removed. Key toxicity measures and recovery can be studies regardless, but are stronger with knowing number of units collected.

It was asked if NMDP collects information related to iron supplements after harvest; iron supplement information not collected.

Question: How would it be possible to control for time between auto unit collection and harvest?  
Response: If the StarLink data are deemed reliable we would have date of auto until collection to control for time between auto unit collection and harvest.

Question: Are there literature recommendation for thresholds to transfuse at due to hematology levels?  
Response: Yes, and according to the hematocrit levels presented by Dennis very few of these donors would have been below the threshold to transfuse. A follow up question was posed regarding healthy-volunteer donor’s QoL and to be able to quickly resume daily activities (college athletes or others with strenuous work responsibilities). A question was raised about whether the rate of drop was important.

There was a discussion as to whether or not a short survey to centers to understand their current practices would be useful. Results from an AABB survey with a 50% response rate indicated that the majority of centers collect and transfuse auto units (of which half routinely gave the units back regardless of other factors), 20% don’t collect auto units, and very few centers have a written policy. Of the responding centers there were 11 that indicated they never collect auto units, 7 of these centers gave permission to be contacted for follow-up. Some centers mentioned that they discussed this with the donor as to what their preference was.
The committee was interested in this study proposal to promote harmonization of practice and protect donors. The interest of other external groups was noted, as well as the fact that significant preparatory work (from multiple sources) has already gone into this topic.

At the conclusion of the proposals being presented the co-chairs reminded members to vote on a scale of 1 (high scientific impact) to 9 (low scientific impact) and to turn in both their ballets and evaluation forms.

6. Other business
   a. No additional business items were discussed.

7. Closing remarks
   Co-chairs thanked members for their attendance and encouraged them to continue their participation in DSWC studies. The meeting was adjourned at 4:08 pm.
Working Committee Overview Plan for 2017-2018

a. **DS05-02a** RDSafe-a: Older adult related donors compared to adult related donors
   This study is currently in manuscript preparation, we anticipate this study to be submitted to Blood by July 2017.

b. **DS05-02c** RDSafe-c: Acute toxicities of related adult donors compared to unrelated adult donors
   This study is currently in manuscript preparation, we anticipate this study to be submitted by July 2017.

c. **DS05-02d** RDSafe-d: QoL for related adult donors compared to unrelated adult donors
   The study is in the final stages of draft manuscript. We anticipate that this study will be submitted by July 2017.

d. **DS05-02e** RDSafe-e: Acute toxicities for pediatric related donors compared to adult related donors
   This study is currently in manuscript preparation, we anticipate this study to be submitted to Blood by July 2017.

e. **DS05-02g** RDSafe-g: Late toxicities and SAE for related donors
   This study is currently in analysis, we anticipate this study will be submitted by July 2017.

f. **DS05-02h** RDSafe-h: Parent v child donor perceptions of the bone marrow donation experience
   This study is currently under peer-review, we anticipate this study will be accepted shortly.

g. **DS09-03** Effects of second donation on marrow/PBSC donors
   Currently this study is in manuscript preparation, we anticipate this study to be submitted by July 2017.

h. **DS13-01** Assessment of the potential impacts BM product quality on HCT
   We are currently preparing the data file for this study; there have been 180 statistical hours allocated for this study from 03/01/2017 to 06/30/2017 and another 70 statistical hours from 07/01/2017 to 06/30/2018. We anticipate this study will be in manuscript prep by July 2017.

i. **DS13-02** Clinical impact of ABO incompatibility on alloHCT
   This study is currently in protocol development. We anticipate this study will be in data file preparation by July 2017.

j. **DS16-01** One vs two day apheresis in URD
   This study is currently protocol development; there have been 10 statistical hours allocated for this study from 03/01/2017 to 06/30/2017 and another 180 statistical hours from 07/01/2017 to 06/30/2018. We anticipate this study will be in data file preparation by June 2017.

k. **DS16-S1** Evaluation of practice guidelines for the assessment and surveillance FU of pediatric HCT donors. This study is a collaboration between University of Pittsburgh and the NIH, with statistical analysis done at University of Pittsburgh. This survey for this study is finalized and is awaiting distribution. We anticipate conducing the survey over the course of spring/early summer 2017.

l. **DS16-S2** Survey of the screening and management for clonal disorders of hematopoiesis in related allogeneic donors.
This study will use minimal statistical hours. This study is currently in protocol and survey development. We anticipate conducting the survey over the course of summer 2017, with results published by June 2018.

m. **DS17-01** Impact of donor BMI on collection of G-CSF mobilized PBSC from URD
   This study is currently pending a protocol; there have been 60 statistical hours allocated for this study from 07/01/2017 to 06/30/2018. We anticipate this study will be in data file preparation by June 2018.

n. **DS17-02** Impact of pre-operative collection of auto blood for BM harvest on donor health and outcome
   This study is currently in protocol development. We anticipate this study will be in data file preparation by July 2017.
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<th>Oversight Assignments for Working Committee Leadership (March 2017)</th>
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<td>Bronwen Shaw</td>
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<td>Dennis Confer</td>
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| Galen Switzer | DS05-02  d, h  RDSafe  
DS16-S2  Evaluation of practice guidelines for the assessment and surveillance FU of pediatric HCT donors |
| Michael Pulsipher | DS05-02a, c, e, g  RDSafe  
DS09-03  Effects of second donation on marrow/PBSC donors  
DS16-S1  Survey of the screening and management for clonal disorders of hematopoiesis in related ALLO donors  
DS17-01  The impact of donor body mass index on collection of G-CSF mobilized peripheral blood progenitor cells from unrelated donors |
| Nirali Shah | DS13-01  Assessment of the potential impacts BM product quality on HCT  
DS16-01  One vs two day apheresis in URD  
DS17-02  The Impact of Pre-Operative Collection of Autologous Blood for Bone Marrow Harvest on Donor Health and Outcome  [Statistical Center Study] |