

**NATIONAL
MARROW
DONOR
PROGRAM®**

Entrusted to operate the C.W. Bill Young Cell Transplantation Program,
including Be The Match Registry®

November 05, 2010

CDR Sheri Parker
Office of Naval Research (ONR 342)
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: Quarterly Performance/Technical Report of the National Marrow Donor Program®

Reference: Grant Award #N00014-08-1-1207 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Parker:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of July 1, 2010 to September 30, 2010.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at cabler@nmdp.org).

Sincerely,



Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

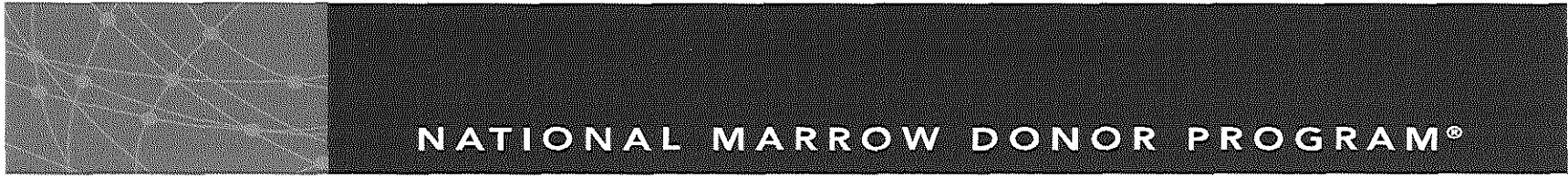
C: D. Ivery – ACO (ONR-Chicago)
Dr. Robert J. Hartzman, CAPT, MC, USN (Ret)
Jennifer Ng, PhD – C.W. Bill Young Marrow Donor Recruitment and Research Program
J. Rike - DTIC (Ste 0944)
NRL (Code 5227)
Dennis Confer, MD, Chief Medical Officer, NMDP
Michelle Setterholm, NMDP
Stephen Spellman, NMDP

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a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	Same as Report	18	Dennis L. Confer, MD - Chief Medical Office
					19b. TELEPHONE NUMBER (Include area code) 612.362.3425

The logo for the National Marrow Donor Program. It features a dark horizontal bar with a light-colored geometric pattern on the left side. The text "NATIONAL MARROW DONOR PROGRAM®" is written in white, uppercase letters across the bar.

NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-08-1-1207

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
JULY 01, 2010 to SEPTEMBER 30, 2010
PERIOD 8

Office of Naval Research

And

The National Marrow Donor Program
3001 Broadway Street N.E.
Minneapolis, MN 55413
1-800-526-7809

QUARTER PROGRESS REPORT**Development of Medical Technology for Contingency Response to Marrow Toxic Agents****July 01, 2010 through September 30, 2010**

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IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians

IIA.1. Task 1: Secure Interest of Transplant Physicians	Period 8 Activity: No activity this period.
IIA.1 Task 2: GCSF in Radiation Exposure	Period 8 Activity: No activity this period.
IIA.1. Task 3: Patient Assessment Guidelines and System Enhancements	Period 8 Activity: Donor Management tool application efforts were focused on prioritized enhancements for the Navy Contingency project. This project promotes electronic contact with donors via email and allows them to update their contact information and complete an online Health History Questionnaire (HHQ) from the Do It Yourself Donor online platform. Information provided by the donor is securely transferred to the donor's record in the tool used to manage Donor Activity; facilitating reporting, storage and review of this information in established donor management systems. Project Outcomes, related to the new versions of the tools used to manage Donor Activity, continue to show favorable results and strong user feedback: - Donors continue to be responsive to online tools. New Online Health History Questionnaire functionality resulted in: 8,471 "Completed" HHQs 470 "in process" HHQs between 10/1/09 – 09/30/10 - An overall time savings of 1,624 hours for completed HHQs due to the 50% reduction in processing time per Online HHQ.

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	Navy Contingency Project Pilot Release 2 The Event Portal Workflow Management Application to manage contingency events (<i>initially for preliminary search event</i>), is in production for all Domestic NMDP Network Donor Centers, excluding the DoD, DKMS Americas, Gift of Life Registry and Caitlyn Raymond Registry. Key features included in this Release are the ability to: • Ability to track preliminary event donors in a central screen, for purposes of donor management. • Ability to import the preliminary event donors, as identified through the preliminary event daily report • Ability to export the preliminary event donors for purpose of supporting address validations, manual mail merges or automated letter merges Key statistics gathered to date for the Event Portal: • 5,197 Preliminary Search HHQs were completed • 2,141 Preliminary Search donors were activated • 7 days is the average close date on an Preliminary Search HHQ The Event Portal Workflow Management functionality has added to the productivity gains of donors screened using this method, in the following ways: • The capability to double the capacity to process an HHQ using the same number of staff resources. • The ability to scale for a contingency event requiring confirmation of the availability and suitability of a large number of donors.
IIA 1. Task 4: National Data Collection Model	Period 8 Activity: • No activity this period.

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IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.

IIA.2. Task 1:
Contingency
Response Network

Period 8 Activity:

- RITN Medical Advisor support activities included:
 - Conference calls with RITN Executive Committee
 - Reviewed for update the NMDP fact sheets; Fact Sheet for Health Care Professionals on Nerve Agents, Fact Sheet for Health Care Professionals on Radiation Injury and Stem Cell Transplantation, and Fact Sheet for Health Care Professionals on Mustard Agents (“Mustard Gas”).
 - Planning for projects to be completed during FY11.
 - Released (posted on RITN website) the updated RITN Acute Radiation Treatment Guidelines
- NMDP staff member attended the University of Kansas (July 11, 2010) tabletop exercise to observe, collect feedback to improve the FY11 tabletop exercise and provide support as requested to RITN center staff.

IIA.2. Task 2:
Sibling Typing
Standard Operating
Procedures

Period 8 Activity:

- No activity this period.

IIA. Contingency Preparedness – Objective 3: NMDP’s critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.

IIA.3. Task 1:
I.S. Disaster
Recovery

Period 8 Activity:

Disaster Recovery (DR):

- Completed reconciliation of existing or missing infrastructure and software in DR environment to support changes to external and internal production applications.
- Completed deployment and configurations of new NetApps 6080 and 2040 Storage units.

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	Disaster Recovery Test #19 scheduled to commence on October 1, 2010.
IIA.3. Task 2: Critical Facility and Staff Related Functions	Period 8 Activity: - High tensile strength security film was installed on the windows of the NMDP Repository Services building; this will strengthen the facility's exterior in case of severe weather (straight-line winds or tornado) as well as prevent accidental or purposeful breakage of the building's exterior glass. - Site visit was conducted at the NMDP operated donor center in Philadelphia (August 12, 2010) - At these site visits the Business Continuity Planner reviews the Business Continuity Action Guide with staff to better prepare each location for responding to incidents that interrupt operations ranging from power or Internet outages to severe weather.
II.B. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
II.B.1. Task 1: Increase Registry Diversity	Period 8 Activity: - Software development and testing was carried out under this aim toward the goal of accepting primary SBT data from recruitment typing HLA laboratories. This software is on track to be fully implemented in the next quarter. - Composed an HML Data Dictionary document which offers an overview and comparison of several versions of HML - Began adding SBT interpretation to the Star2 probe interpretation, and adding support for HML version 0.3.3 to Star2.
II.B.1. Task 2: Evaluate HLA-DRB1 High Res typing	Period 8 Activity: This task is closed.
II.B.1. Task 3: Evaluate HLA-C Typing of Donors	Period 8 Activity: This task is closed.

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IIB.1. Task 4: Evaluate Buccal Swabs	Period 8 Activity: Sample Storage Research Study (SSRS) 30 donor samples (frozen blood, blood spotted onto filter paper, and 2 buccal swabs for each donor) were sent to two laboratories for the 3 year time point of this study. Preliminary review of the data shows: • 100% accuracy in HLA typing • DNA extracted from the buccal swabs appears overall to be slightly degraded - 1 sample required the use of the second buccal swab • All sample types contained DNA of sufficient quality and quantity to accurately obtain HLA results at all loci tested
IIB 1. Task 5: Enhancing HLA Data for Selected Donors	Period 8 Activity: • No activity this period.
IIB 1. Task 6: Maintain a Quality Control Program	Period 8 Activity: • Forty four Research Repository samples with potential rare alleles were selected for possible inclusion in the quality control program. The samples were tested to confirm the presence of the rare allele prior to enrollment in the program. Thirty (66%) had a rare allele present. The remainders were confirmed as more common alleles.
IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
IIB 2. Task 1: Collection of Primary Data	Period 8 Activity: • No activity this quarter
IIB 2. Task 2: Validation of Logic of Primary Data	Period 8 Activity: • This task is closed.

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IIB 2. Task 3: Reinterpretation of Primary Data	Period 8 Activity: This task is closed.
IIB 2. Task 4: Genotype Lists & Matching Algorithm	Period 8 Activity: No activity this quarter
IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.	
IIB.3. Task 1: Phase I of EM Haplotype Logic	Period 8 Activity: - Enhanced the technology port of the Search Server matching algorithm in order to increase stability and performance of the algorithm. - Hired replacement business analyst to continue working on business and system requirements for HapLogic Phase III
IIB 3. Task 2: Enhancement of EM Algorithm	Period 8 Activity: No activity this period.
IIB 3. Task 3: Optimal Registry Size Analysis	Period 8 Activity: During the past quarter the manuscript “Genetic Differentiation of Jewish Population” was published in Tissue Antigens.
IIB 3. Task 4: Target Under- Repre- sented Phenotypes	Period 8 Activity: No activity this period.
IIB 3. Task 5: Bioinformatics Web Site	Period 8 Activity: This task is closed.
IIB 3. Task 6: Consultants to Improve Algorithm	Period 8 Activity: No activity this period.

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IIB 3. Task 7: Population Genetics	Period 8 Activity: No activity this period.
IIB 3. Task 8: Haplotype Matching	Period 8 Activity: No activity this period.
IIB 3. Task 9: Global Haplotype/Benchmark	Period 8 Activity: No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
IIB.4. Task 1: Expand Network Communications	Period 8 Activity: Extended the Business to Business (B2B) Services to support the new alleles and allele combinations expressed as allele codes. Also provided: - Limited Support for WHO approved P codes - Full support of WMDA approved codes – XXXX, NNNN, UUUU, NEW. - Support in external tools for user queries of allele code information - Preparation for expansion of allele code information - Support for new nomenclature vendor DNA typing kits NMDP has initiated development on a B2B implementation of a Cord Blood Unit inventory exchange model. The following have been completed: - Development of modifications to B2B database schema to support inventory sharing - Development of new B2B Gateway database schema to support transaction sharing - Began development of the components required to share NMDP cord blood unit inventory with strategic partners, and to keep it updated.

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	• Exchanged test cord blood inventory messages with several partners. • Documented semantics describing the messages and process flow to exchange inventory. • Documented fields that each will be sending in the inventory exchange. • Shared house rules for searching based on CBU status, no differences or concerns. • Agreed that since ownership of data resides with the source registry, the mirroring registry will only update a CBU's search antigens when a CBU change is received from the source registry; the search antigens will not be updated by the non-owner when lab results are received.
IIB.4. Task 2: Central Contingency Management	Period 8 Activity: Donor Testing Donor testing continued for a research project to validate the "actual" HLA-A, B, C and DRB1 (8/8) high resolution match rates for CAU, AFA, HIS, and API patients and supply valuable information regarding donor selection in the event of a contingency. Donors are being tested in rounds of priority for cost efficiency. Final testing for the four race group's 8/8 match rate continues. A poster abstract summarizing the CAU and AFA data to date was presented at the ASHI annual meeting in Sept. 2010. • In this period, donor testing was performed on 1671 loci total for 1292 donors and results compiled for the analysis.
IIB.4. Task 3: Benchmarking Analysis	Period 8 Activity: • No activity this period.
IIB.4. Task 4: Expand Capabilities of Collection and Apheresis Centers	Period 8 Activity: • No activity this period.

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IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.

IIC.1. Task 1:
Donor Recipient Pair
Project

Period 8 Activity:

- No activity this period.

IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.

IIC 2. Task 1:
Analysis of non-HLA
loci

Period 8 Activity:**KIR**

In 2005 a pilot study to perform high resolution KIR gene typing was launched. The primary objectives of the study were to move technology forward from the current practice of locus level typing to high resolution typing, disseminate information and protocols in an open source mechanism and develop reference lines for use in individual laboratories.

- All 46 novel alleles have been submitted and names received. Publication of the new IPD database containing these alleles is expected within the next year. A publication is in development to describe the typing of the new alleles.
- Preparation continued on the KIR Typing Project manuscript.
- 1180 donors were typed for presence/absence of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1) under the Donor/Recipient Pair Project in support of a CIBMTR retrospective study investigating the role of KIR in reduced intensity conditioning transplants for hematological malignancies.

IIC 2. Task 2: Related
Pairs Research
Repository

Period 8 Activity:

- No activity this period.

IIC 2. Task 3:
CIBMTR Integration

Period 8 Activity:

- During this period the subject areas for Match Grades, Match Grade Variables, and Infectious Disease Markers were added to the Immunobiology Integrated Database in order to continue

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	joining NMDP and CIBMTR data.
IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
IID.1. Task 1: Observational Research, Clinical Trials and NIH Transplant Center	Period 8 Activity: Observational Research - Staff continued work on various observational studies within the area of Immunobiology, GVHD and Graft Sources Working Committees. Five abstracts were submitted and accepted to the American Society of Hematology annual meetings during this reporting period. Prospective Studies; RCI BMT - During this report period, follow up activities continued for donors participating in the PBSC vs. Marrow clinical trail. Staff continue to support this activity including monitoring. - Adult Double Cord trial activity during this period included two patients being enrolled for a total of thirty eight patients accrued to this study, giving us a 69% completion rate. Staff continues to coordinate and complete monthly PI and coordinator calls, manage data collection and monitor sites. - Revlemid trial activity continued during this period. Sites continued to enroll patients onto this study using the EMMES developed data capture forms. Minor revisions to the data capture system have been identified and have or are currently being revised. NIH Transplant Center - NMDP provided support for donor identification, selection and collection for the NIH intramural unrelated donor transplant program. Activity in the last quarter was as follows: 14 formal searches 46 donor confirmatory typing blood sample and IDM testing requests 40 cord blood unit confirmatory typing requests 11 PBSC collections 4 cord blood shipments

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IID.1. Task 2: Research with NMDP Donors	Period 8 Activity: • The survey research team continues to develop processes and add staff to support studies requiring their expertise. • Staff continued support of a Donor Ethnicity study with Dr. Galen Switzer from the University of Pittsburgh. • Staff continued to collaborate on a COG KIR study. Activities include facilitating the collection of a donor blood sample and shipment to the study lab. • Staff continued to work on identifying and streamlining the operational processes needed to implement the protocol for long-term donor follow-up.
IID.1. Task 3: Expand Immunobiology Research	Period 8 Activity: The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies • The co-scientific director attended the Center-specific Outcome Analysis forum in Milwaukee, WI • Three manuscripts were accepted for publication: ○ Ann Woolfrey, et al., HLA-C antigen mismatches are associated with worse outcomes in unrelated donor peripheral blood stem cell transplantation. BBMT 2010 Sept 23 [Epub ahead of print] ○ Peter Shaw, et al., Outcomes of pediatric BMT for leukemia and myelodysplasia using matched sibling, mismatched related or matched unrelated donors. Blood 2010 July 29 [Epub ahead of print] ○ David Valcarcel, et al., One antigen mismatched related vs. HLA-matched unrelated donor HCT in adults with acute leukemia: CIBMTR results in the era of molecular typing. BBMT 2010 July 29 [Epub ahead of print]. • One manuscript was submitted for publication: ○ Lujia Dong, et al., The outcomes of family haploidentical hematopoietic stem cell transplantation in hematological malignancies are not associated with patient age. Rejected by Blood. Submitted to BBMT. • One abstract was submitted to the 2010 ASH Annual Meeting

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- | | |
|--|---|
| | <ul style="list-style-type: none">• Bronwen Shaw, et al., Permissive HLA-DPB1 mismatching compared to a non-permissive mismatching significantly improves overall survival following allogeneic transplantation in patients with both 10/10 and 9/10 matched unrelated donors. ASH Annual Meeting 2010. |
|--|---|

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AABB	American Association of Blood Banks	IBWC	Immunobiology Working Committee
AFA	African American	IDM	Infectious Disease Markers
AGNIS	A Growable Network Information System	IHWG	International Histocompatibility Working Group
AML	Acute Myelogenous Leukemia	IPR	Immunobiology Project Results
ABD	Antigen Binding Domain	ICRHER	International Consortium for Research on Health Effects of Radiation
API	Asian Pacific Islander	IND	Investigational New Drug
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IS	Information Services
ASBMT	American Society for Blood and Marrow Transplantation	IT	Information Technology
ASHI	American Society for Histocompatibility and Immunogenetics	IRB	Institutional Review Board
B-LCLs	B-Lymphoblastoid Cell Lines	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BARDA	Biomedical Advanced Research and Development Authority	KIR	Killer Immunoglobulin-like Receptor
BCPeX	Business Continuity Exercise	MDACC	MD Anderson Cancer Center
BBMT	Biology of Blood and Marrow Transplant	MDS	Myelodysplastic Syndrome
BMT	Bone Marrow Transplantation	MHC	Major Histocompatibility Complex
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MICA	MHC Class I-Like Molecule, Chain A
BRT	Basic Radiation Training	MICB	MHC Class I-Like Molecule, Chain B
C&A	Certification and Accreditation	MKE	Milwaukee
CAU	Caucasian	MSKCC	Memorial Sloan-Kettering Cancer Center
CBMTG	Canadian Blood and Marrow Transplant Group	MSP	Minneapolis
CBB	Cord Blood Bank	MUD	Matched Unrelated Donor
CBC	Congressional Black Caucus	NCBM	National Conference of Black Mayors
CBS	Canadian Blood Service	NCI	National Cancer Institute
CBU	Cord Blood Unit	NEMO	N-locus Expectation-Maximization using

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			Oligonucleotide typing data
CHTC	Certified Hematopoietic Transplant Coordinator	NHLBI	National Heart Lung and Blood Institute
CIBMTR	Center for International Blood & Marrow Transplant Research	NIH	National Institutes of Health
CIT	CIBMTR Information Technology	NIMS	National Incident Management System
CLIA	Clinical Laboratory Improvement Amendment	NK	Natural Killer
CME	Continuing Medical Education	NLE	National Level Exercise
CMF	Community Matching Funds	NMDP	National Marrow Donor Program
COG	Children's Oncology Group	NRP	National Response Plan
CREG	Cross Reactive Groups	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CSS	Center Support Services	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CT	Confirmatory Testing	OIT	Office of Information Technology
CTA	Clinical Trial Application	OMB	Office of Management and Budget
DC	Donor Center	ONR	Office of Naval Research
DHHS-ASPR	Department of Health and Human Service – Assistant Secretary Preparedness and Response	P2P	Peer-to-Peer
DIY	Do it yourself	PBMC	Peripheral Blood Mononuclear Cells
DKMS	Deutsche Knochenmarkspenderdatei	PBSC	Peripheral Blood Stem Cell
DMSO	Dimethylsulphoxide	PCR	Polymerase Chain Reaction
DoD	Department of Defense	PSA	Public Service Announcement
DNA	Deoxyribonucleic Acid	QC	Quality control
D/R	Donor/Recipient	RCC	Renal Cell Carcinoma
EBMT	European Group for Blood and Marrow Transplantation	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
EM	Expectation Maximization	REAC/TS	Radiation Emergency Assistance Center/Training Site
EMDIS	European Marrow Donor Information System	RFP	Request for Proposal
ENS	Emergency Notification System	RFQ	Request for Quotation
ERSI	Environment Remote Sensing Institute	RG	Recruitment Group
FBI	Federal Bureau of Investigation	RITN	Radiation Injury Treatment Network

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FDA	Food and Drug Administration	SBT	Sequence Based Typing
FDR	Fund Drive Request	SCTOD	Stem Cell Therapeutics Outcome Database
Fst	Fixation Index	SG	Sample Group
GETS	Government Emergency Telecommunications Service	SLW	STAR Link® Web
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SSA	Search Strategy Advice
GIS	Geographic Information System	SSO	Sequence Specific Oligonucleotides
GvHD	Graft vs Host Disease	SSP	Sequence Specific Primers
HCT	Hematopoietic Cell Transplantation	SSOP	Sequence Specific Oligonucleotide Probes
HEPP	Hospital Emergency Preparedness Program	STAR®	Search, Tracking and Registry
HHQ	Health History Questionnaire	TC	Transplant Center
HHS	Health and Human Services	TED	Transplant Essential Data
HIPAA	Health Insurance Portability and Accountability Act	TNC	Total Nucleated Cell
HIS	Hispanic	TSA	Transportation Security Agency
HLA	Human Leukocyte Antigen	UI	User Interface
HML	Histoimmunogenetics Mark-up Language	URD	Unrelated Donor
HR	High Resolution	WGA	Whole Genome Amplification
HRSA	Health Resources and Services Administration	WMDA	World Marrow Donor Association
HSC	Hematopoietic Stem Cell	WU	Work-up