



**National Marrow
Donor Program®**

Entrusted to operate the
C.W. Bill Young
Cell Transplantation Program

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November 17, 2008

Cdr. Elizabeth Montcalm-Smith
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 #N00014-08-1-0058 between the Office of
Naval Research and the National Marrow Donor Program

Dear Cdr. Montcalm-Smith:

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, 2008 to September 30, 2008.

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), letter
Dr. Robert J. Hartzman, CAPT, MC, USN (Ret): letter
Jennifer Ng, PhD – C.W. Bill Young Marrow Donor Recruitment and
DTIC (Ste 0944): letter and enclosure
J. Rike - DTIC (Ste 0944): letter
NRL (Code 5227): letter
Dennis Confer, MD, Chief Medical Officer, NMDP, letter only
Michelle Setterholm, NMDP letter only

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14. ABSTRACT <u>1. Contingency Preparedness:</u> Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan. <u>2. Rapid Identification of Matched Donors :</u> Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event. <u>3. Immunogenetic Studies:</u> Increase understanding of the immunologic factors important in HSC transplantation. <u>4. Clinical Research in Transplantation:</u> Create a platform that facilitates multicenter collaboration and data management.					
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Grant Award N00014-08-1-0058

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
JULY 01, 2008 to SEPTEMBER 30, 2008

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, 2008 through September 30, 2008**

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IIA. Contingency Preparedness – Hypothesis 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.1.1 Aim 1: Secure Interest of Transplant Physicians	Period 3 Activity: • During this period 323 Basic Radiation Training (BRT) exams were submitted by RITN centers; as of September 30, 2008 a total of 1,146 BRT exams had been submitted with a passing rate exceeding 95%. • During this period we initiated planning for a 2009 advanced training course for RITN centers to send staff to. The course is titled Advanced Radiation Medical Emergency training and will be conducted in Oakridge, TN at the Radiation Emergency Assistance Center/Training Site (REAC/TS). Class will be held on March 26 & 27. Course lessons included: ○ Basic Health Physics & Radiation Protection: Part I ○ A History of Serious Radiological Incidents: The Real Risk ○ Health Physics & Contamination Control: Part II ○ Radiation Detection, Monitoring & Protection Laboratory Exercise & Quiz ○ Diagnosis & Management of the Acute Radiation Syndrome (ARS) ○ Diagnosis & Management of Internal Contamination ○ Diagnosis & Management of Acute Local Radiation Injury & Case Review: Yanango Peru ○ Radiation Sources & Radiological Terrorism ○ Radiation Emergency Area Protocol Demonstration ○ Radiation Emergency Medical Management Drill ○ Radiation Dose Estimations – Problem Solving Session
IIA.1.2 Aim 2: GCSF in Radiation Exposure	Period 3 Activity: • No activity this period.

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IIA.1 3 Aim 3:

Patient Assessment
Guidelines and
System
Enhancements

Period 3 Activity:

In September CORD Link version 5.12 was released to support research completed by the CIBMTR for capturing the Cord Bank SCTOD required fields:

- Added “Bank did not test” option. Previously, the cord blood banks could not complete the form if they did not perform the test.
 - If the CBB does not have results captured for a particular test, checking the “Bank did not test” option will satisfy the field entry.
 - For cords that are shipped outside of the NMDP, and the Shipped to Other (SO) status is selected, entry of the Proposed Infusion Date, Transplant Center, and Recipient ID in the SCTOD form is now permitted.

To meet a regulatory requirement and increase product safety:

- Cord Blood Banks can send OCR forms that are scanned or hand entered by the NMDP. The data are populated into the CORD Link application. For scanned forms, a PDF is available in CORD Link. The scanned forms, when printed, now contain an ID number at the bottom of each page thus eliminating the risk of loss in chain-of-custody by linking the information to the cord blood unit.
- All import tools were modified to include the CMS question which is now required due to FDA regulations.

To increase cord blood bank efficiencies and allow users to quickly access and respond to important search information on a CBU:

- Email alerts generated by CORD Link now include a direct link to the NMDP’s connect page at “connect.nmdp.org”.

STAR Link and the **Do It Yourself (DIY)** application efforts were focused on simple project enhancements and preparation for future projects.

- **Statistic:** DIY Online Donor Registration through www.marrow.org resulted in a **total of 6,063** between 1/1/08 – 10/06/08.

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IIA 1.4 Aim 4: National Data Collection Model	Period 3 Activity: - FormsNet v2.6.1 and v2.6.2 were released during the previous quarter including a number of bug fixes and enhancements including a major cleanup of forms tracking and internationalizations enhancements. - AGNIS has been released to production for forms 2900 and 2450 (death form and pre-TED). The data curation effort to register all 11,000 data elements in the caDSR is making steady progress with collaboration with a number of curators at the Minneapolis and Milwaukee campuses of CIBMTR and NCI.
IIA. Contingency Preparedness – Hypothesis 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.	
IIA.2.1 Aim 1: Contingency Response Network	Period 3 Activity: - Finalized agreements for the FY09 project period for RITN - Identified five transplant centers to invite to participate in RITN - Initiated planning for the 2009 RITN Educational Conference - Exercises: RITN centers continued to conduct self directed tabletop exercises based on the scenario provided to them by the NMDP and submit answers to key questions via the Internet once complete. - Meetings: Held three (3) conference calls with RITN centers to assist in completion of required tasks and to improve integration into the network. - Presented “Radiation Injury Treatment Network®: Hematology Physicians Preparing for a Mass Casualty Marrow Toxic Incident” at the Indo-US Workshop on Medical Countermeasures for Radiation Injury: Current and Evolving Technologies held from 17 – 20 August, 2008 in New Delhi, India. - RITN centers were identified as an asset to be called upon during both the Democratic National Convention in Denver, CO and the Republican National Convention in St. Paul, MN. - Local as well as regional centers were identified to respond to an incident.

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	Assistant Secretary of Preparedness and Response (DHHS) was provided with 24 hour contact information for the RITN Control Team in Minneapolis as well as contacts at each RITN center.
IIA.2.2 Aim 2: Sibling Typing Standard Operating Procedures	Period 3 Activity: No activity this period
IIA. Contingency Preparedness – Hypothesis 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
IIA.3.1 Aim 1: I.S. Disaster Recovery	Period 3 Activity: Began planning efforts to retro fit the coordinating center server room.
IIA.3.2 Aim 2: Critical Facility and Staff Related Functions	Period 3 Activity: Business Continuity Planning: - Emergency communications: - Satellite telephone connectivity issues continue to cause problems at all RITN center locations. Global Star (satellite phone service provider) states that many satellites are aging and being deactivated and that they will be replaced in the future. With-in the emergency communication sector hopes are not high that Global Star will be able to accomplish this with the economy in the current state it is in. - Completed the development of the Business Impact Analysis (BIA) with key NMDP operational departments, identifying critical areas that would have high impact to operations if rendered inoperable. - Conducted business continuity site visits to two (2) NMDP operated donor centers. Distributed Business Continuity Action Guides, reviewed procedures in place, and discussed methods to improve preparedness at each location. - Continued to develop a business continuity plan incorporating a Critical Staff Recovery Site (CSRS) with no initial cost to the organization

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IIB. Rapid Identification of Matched Donors – Hypothesis 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.

IIB.1.1 Aim 1: Increase Registry Diversity	Period 3 Activity: The NMDP will continue to focus on educating and motivating racial and ethnic minorities about the opportunity to save lives by joining the Registry and becoming a potential adult marrow donor for a patient in need. In support of this effort, we develop and produce a complete line of educational materials targeting multicultural communities. These materials are used by our adult donor recruitment teams to engage sponsors and potential Registry members in supporting our mission. Materials produced during this period included customizable posters used to create an emotional bond between potential Registry members and patients in need and promote recruitment drive events, as well as a reprint of the Chinese version of our consent form.
IIB.1.2 Aim 2: Evaluate HLA-DRB1 High Res typing	Period 3 Activity: This task is closed.
IIB.1.3 Aim 3: Evaluate HLA-C Typing of Donors	Period 3 Activity: This task is closed.
IIB.1.4 Aim 4: Evaluate Buccal Swabs	Period 3 Activity: No activity this period.
IIB 1.5 Aim 5: Enhancing HLA Data for Selected Donors	Period 3 Activity: No activity this period.
IIB 1.6 Aim 6: Maintain a Quality Control Program	Period 3 Activity: No activity this period.

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IIB. Rapid Identification of Matched Donors – Hypothesis 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.

IIB 2.1 Aim 1: Collection of Primary Data	Period 3 Activity: - New versions of One Lambda/Luminex SSO kits were registered during the last quarter A, B, C, DRB1 kit revisions and the new high-definition HLA-A, -B and –DRB1 kits - A series of conference calls were held to discuss the SBT reporting format and provisions for using SBT for ambiguity resolution. We have a laboratory sending test messages and intend to be able to process their messages in the next quarter.
IIB 2.2 Aim 2: Validation of Logic of Primary Data	Period 3 Activity: This task is closed.
IIB 2.3 Aim 3: Reinterpretation of Primary Data	Period 3 Activity: This task is closed.
IIB 2.4 Aim 4: Genotype Lists & Matching Algorithm	Period 3 Activity: No activity this period.

IIB. Rapid Identification of Matched Donors – Hypothesis 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.3.1 Aim 1: Phase I of EM Haplotype Logic	Period 3 Activity: No activity specific to this Aim for this period.
IIB 3.2 Aim 2: Enhancement of EM Algorithm	Period 3 Activity: - A manuscript entitled “Re-creation of the Genetic Composition of a Founder Population” was accepted for publication in Human Genetics - A manuscript has been drafted entitled “The HLA genetics of Jewish populations” and has

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	undergone revision for submission during the next quarter Three abstracts were presented at the 15th IHIWS conference (“High resolution reconstruction of HLA haplotypes in Native Americans”, “HLA haplotype diversity in Brazil” and “Anthropological Insights from a Novel Visualization and Clustering Tool for HLA Haplotypes and Populations”
IIB 3.3 Aim 3: Optimal Registry Size Analysis	Period 3 Activity: - Study design work has progressed on the clinical validation of 8/8 matching including the development of statistical power computations. - A meeting was held with representatives from DKMS and they confirmed participation in the study which means we will be able to type all DoD, DKMS and NMDP donors with samples which represents the vast majority of donors on these searches.
IIB 3.4 Aim 4: Target Under- represented Phenotypes	Period 3 Activity: - Sent staff to annual GIS software (ESRI) user-group meeting - GIS software has been purchased and installed along with census resource databases - A prototype kernel density (heat) map was produced to show the geographical distribution of the most common African American broad HLA phenotype. - A full ZIP code update was performed on the geocoding database for use in ongoing ad-hoc analyses
IIB 3.5 Aim 5: Bioinformatics Web Site	Period 3 Activity: This task is closed.
IIB 3.6 Aim 6: Consultants to Improve Algorithm	Period 3 Activity: No activity this period.

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IIB. Rapid Identification of Matched Donors – Hypothesis 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.4.1 Aim 1: Expand Network Communications

Period 3 Activity:

Traxis Upgrade July 15, 2008

Traxis was upgraded on July 15th to address defects related to patient look ups and email notifications (sending them to NMDP Search Coordinators when a search request was processed).

SEARCH Link™ application upgrades

To aid the Search and Transplant Department in maintaining patient safety:

- Actions Codes were implemented for Cooperative Registry Donors and CBUs to improve operational efficiencies. These codes will function like the domestic donors and CBUs. Some Action Codes were retired.
- The Working TC Request tab no longer displays on the Request Detail screen for Rejected Electronic Workup requests.
- The Request Detail date fields for rejected requests are grayed out and made not editable to eliminate accidental changes.
- Requests for the same source in the search detail screen will continue to sort by date, with the most recent date displaying first. If there are multiple requests for the same source on the same day, the requests will sort in the following status order: 1.) Pending requests 2.) Open requests 3.) Resolved requests 4.) Closed requests 5.) Rejected requests.
- Functionality was restored to display a pop-up window indicating active sources exist on a search if a user attempts to cancel the search for a source type. The search will not be cancelled.

To improve operational efficiencies for the Search and Transplant Department:

- Find feature was implemented to easily filter patients with Coop action items.

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- The *Email* field was implemented as required in the User Maintenance screen when adding a new user or making edits to an existing user.

To facilitate best matches for patients for transplant centers and the Search and Transplant Services department:

- Functionality was restored to display match grades for manually entered Cooperative Registry Donors and CBUs.
- Functionality was restored to set the status of Cooperative Registry Cords released as infused to NA.
- Functionality was restored to display Cooperative Registry Cord and Donor IDs, along with the Action Code descriptions, if applicable, in the Confirm multiple selection pop-up when multiple sources are released.
- Functionality was restored to prohibit an international transplant center to request a CBU from an international cord blood bank. Cord Blood Bank 191, StemCyte Taiwan National Cord Blood Center, is an exception to this rule.
- Two-day PBSC collections are shown as one donation on the Donor Info screen under Prev. Donations to lessen confusion.

STAR2 Application Upgrade

To increase operational efficiencies for the Search and Transplant Department:

Action codes that are no longer active/utilized were retired

To increase the reliability and timeliness of notifying network members of search activity:

Improvements were made in the functionality to send data to member centers. These improvements will increase the system capacity for handling large transaction volumes and detect data integrity issues (like incoming & outgoing duplicate transactions, gaps in sequence numbers).

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IIB.4.2 Aim 2: Central Contingency Management	Period 3 Activity: • The medical education department continued to execute education to referring physicians on the role and timing of transplantation. In this period, we issued a <i>Special edition of Advances in Transplantation</i> to 10,000 hematologists/oncologists. This issue covered key research presented at the 2008 European Blood and Marrow Transplantation meeting. By publishing this newsletter, NMDP brings the latest in transplant research and advances to the broader referral audience. • NMDP also continued the initiative to build awareness and use of the NMDP/ASBMT guidelines for <i>Recommended Timing for Transplant Consultation</i> and the <i>Post-Transplant Care Guidelines</i>. These two guidelines are now distributed in a tool kit, allowing referring physicians to understand both referral and post-transplant care recommendations, in order to provide optimal care to their patients. The post-transplant care kit also includes a highly regarded photo atlas for early assessment and diagnosis of GVHD. By recognizing GVHD symptoms early, care can be delivered to help prevent more extensive complications. In this period, 10,000 referring physicians were notified of the availability of the guidelines and were offered multiple ways to order the guidelines. Analysis of the result of the direct mail and e-mail campaign are underway.
IIB.4.3 Aim 2: Benchmarking Analysis	Period 3 Activity: • This task is closed.
IIB.4.4 Aim 2: Expand Capabilities of Collection and Apheresis Centers	Period 3 Activity: • No activity this period.

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IIC. Immunogenetic Studies – Hypothesis 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.1.1 Aim 1:
Donor Recipient Pair
Project

Period 3 Activity:

In 1994 a retrospective Donor/Recipient Pair HLA typing project to characterize class I and class II alleles of donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies.

- The contracts for SG21 (500 pairs) testing was awarded to four labs. SG21 contracts will include intermediate and high resolution HLA and also presence/absence testing for 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1).
- The project period for SG21 began September 1, 2008 and continues until December 31, 2008.

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

IIC 2.1 Aim 1:
Analysis of non-
HLA loci

Period 3 Activity:

Continued development of the IPR (Immunobiology Project Results) database occurred during the past quarter. This database will replace the existing HLA donor/recipient pairs database and have the capacity to process KIR, SNPs, or any other Immunobiological tests. For sample group twenty one (SG21), it will mirror HLA processing in the current system and incorporate KIR processing (which is not available in the current system).

- The Scientific Services and Bioinformatics departments continued to collaborate on the design and development of the IPR database application and tools to support immunogenetic testing projects
- A software-developer contractor has worked on implementing the acceptance, validation, storage of incoming data via Histoimmunogenetics Markup Language (HML). The next phase will develop

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	and test the extension of the process to genotype lists (of immediate importance for KIR data) and the reporting of the whole process. It is scheduled for completion late next quarter. [The development of genotype lists also requires enhancements of NDMP databases/software on which IPR depends.] • Another software-developer contractor has worked on a implementing a web-browser-based application which will allow users to view typing results as stored in the database. It is scheduled for completion next quarter. • Analysis of processing rules (lab-to-lab comparison, ambiguity analysis, data audits) has been put on hold until data-loading development is completed. It is scheduled to resume early 2009. • Specifications are being written to transfer data from the old system to IPR. They are scheduled for completion next quarter. • Work continued on a prototype project to recreate informational data stores.
IIC 2.2 Aim 2: Related Pairs Research Repository	Period 3 Activity: • No activity this period.
IID. Clinical Research in Transplantation – Hypothesis 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
IID.1.1 Aim 1: Observational Research, Clinical Trials and NIH Transplant Center	Period 3 Activity: • No activity this period.
IID.1.2 Aim 2: Research with NMDP Donors	Period 3 Activity: • No activity this period.
IID.1.3 Aim 3: Expand Immuno- biology Research	Period 3 Activity: • No activity this period.

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AABB	American Association of Blood Banks	IND	Investigational New Drug
AML	Acute Myelogenous Leukemia	ICRHER	International Consortium for Research on Health Effects of Radiation
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	KIR	Killer Immunoglobulin-like Receptor
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	NCI	National Cancer Institute
BRT	Basic Radiation Training	MHC	Major Histocompatibility Complex
C&A	Certification and Accreditation	MICA	MHC Class I-Like Molecule, Chain A
CBMTG	Canadian Blood and Marrow Transplant Group	MICB	MHC Class I-Like Molecule, Chain B
CBB	Cord Blood Bank	MUD	Matched Unrelated Donor
CBC	Congressional Black Caucus	NCBM	National Conference of Black Mayors
CBS	Canadian Blood Service	NIH	National Institutes of Health
CBU	Cord Blood Unit	NIMS	National Incident Management System
CHTC	Certified Hematopoietic Transplant Coordinator	NK	Natural Killer
CIBMTR	Center for International Blood & Marrow Transplant Research	NMDP	National Marrow Donor Program
CLIA	Clinical Laboratory Improvement Amendment	NRP	National Response Plan
CME	Continuing Medical Education	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
COG	Children's Oncology Group	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CREG	Cross Reactive Groups	OIT	Office of Information Technology
CT	Confirmatory Testing	OMB	Office of Management and Budget
CTA	Clinical Trial Application	ONR	Office of Naval Research

QUARTER PROGRESS REPORT

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

July 01, 2008 through September 30, 2008

DIY	Do it yourself	PBMC	Peripheral Blood Mononuclear Cells
DKMS	Deutsche Knochenmarkspenderdatei	PBSC	Peripheral Blood Stem Cell
DMSO	Dimethylsulphoxide	PCR	Polymerase Chain Reaction
DNA	Deoxyribonucleic Acid	PSA	Public Service Announcement
D/R	Donor/Recipient	QC	Quality control
EBMT	European Group for Blood and Marrow Transplantation	RCC	Renal Cell Carcinoma
EM	Expectation Maximization	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
EMDIS	European Marrow Donor Information System	REAC/TS	Radiation Emergency Assistance Center/Training Site
FBI	Federal Bureau of Investigation	RFP	Request for Proposal
FDA	Food and Drug Administration	RFQ	Request for Quotation
Fst	Fixation Index	RITN	Radiation Injury Treatment Network
GETS	Government Emergency Telecommunications Service	SBT	Sequence Based Typing
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SCTOD	Stem Cell Therapeutics Outcome Database
GvHD	Graft vs Host Disease	SG	Sample Group
HHS	Health and Human Services	SSP	Sequence Specific Primers
HIPAA	Health Insurance Portability and Accountability Act	SSOP	Sequence Specific Oligonucleotide Probes
HLA	Human Leukocyte Antigen	STAR®	Search, Tracking and Registry
HML	Histoimmunogenetics Mark-up Language	TC	Transplant Center
HR	High Resolution	TED	Transplant Essential Data
HRSA	Health Resources and Services Administration	TNC	Total Nucleated Cell
HSC	Hematopoietic Stem Cell	TSA	Transportation Security Agency
IBWC	Immunobiology Working Committee	URD	Unrelated Donor
IDM	Infectious Disease Markers	WMDA	World Marrow Donor Association
IHWG	International Histocompatibility Working Group	WU	Work-up