

**NATIONAL
MARROW
DONOR
PROGRAM®**

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

April 29, 2011

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 #N00014-11-1-0339 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 January 1, 2011 to March 31, 2011.

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 at 612-362-3403 or at cabler@nmdp.org.

Sincerely,



Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

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REPORT DOCUMENTATION PAGE

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14. ABSTRACT <p>1. <u>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.</p> <p>2. <u>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.</p> <p>3. <u>Immunogenetic Studies</u>: Increase understanding of the immunologic factors important in HSC transplantation.</p> <p>4. <u>Clinical Research in Transplantation</u>: Create a platform that facilitates multicenter collaboration and data management.</p>					
15. SUBJECT TERMS Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes					
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Grant Award N00014-11-1-0339

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
JANUARY 01, 2011 to MARCH 31, 2011

Office of Naval Research

And

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

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Development of Medical Technology for Contingency Response to Marrow Toxic Agents
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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 1 Activity: <ul style="list-style-type: none"> No activity this quarter.
IIA.1 Task 2: GCSF in Radiation Exposure	Period 1 Activity: <ul style="list-style-type: none"> No activity this quarter.
IIA.1 Task 3: Patient Assessment Guidelines and System Enhancements	Period 1 Activity: <ul style="list-style-type: none"> No activity this quarter.

IIA 1 Task 4: National Data Collection Model – This task is closed.

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 1 Activity: <ul style="list-style-type: none"> The RITN Medical Advisor was prominently involved in the Scarce Resources for a Nuclear Detonation Project, which Department of Health and Human Services – Assistant Secretary for Preparedness and Response (DHHS-ASPR) led during 2010. This project sought to review the scope as well as to review in detail planning needs for many aspects of the response to such a large scale incident. Dr. David Weinstock co-authored eight of the 17 articles that were published in the Disaster Medicine and Public Health Preparedness journal supplement which was released in March 2011. Continued to maintain the operation of WebEOC for crisis management as the transition to HealthCare Standard software was completed. HealthCare Standard will replace WebEOC, access to this software is donated to RITN by the New England Center for Emergency Preparedness.
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IIA.2 Task 2: Sibling Typing Standard Operating Procedures	<p>Period 1 Activity:</p> <ul style="list-style-type: none"> No activity this quarter.
<p>IIA. Contingency Preparedness – Objective 3: NMDP’s critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.</p>	
IIA.3 Task 1: I.S. Disaster Recovery	<p>Period 1 Activity:</p> <ul style="list-style-type: none"> No activity this quarter.
IIA.3 Task 2: Critical Facility and Staff Related Functions	<p>Period 1 Activity:</p> <ul style="list-style-type: none"> No activity this quarter.
<p>IIB. 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.</p>	
IIB.1 Task 1: Increase Registry Diversity	<p>Period 1 Activity:</p> <p>Five contracted HLA testing laboratories performed HLA-A, B, DRB1 typing, two laboratories performed HLA-A, B, C, DRB1 typing, on a total of 80,764 newly recruited donors.</p> <ul style="list-style-type: none"> Blind quality control testing error rate was 0.01%, meeting the project requirement of $\leq 2.0\%$. On-time testing completion rate was 99.0%, meeting the project requirement of a minimum of 90% of typing results reported within 14 days of shipment of samples. <p>New Donor Queue Sorting</p> <p>To maximize the utilization of the HLA recruitment typing resources, a process was developed to strategically select samples from the newly recruited donor queue and direct these samples to specific laboratories. This process allows the NMDP to select donors, based on demographic data, and direct the testing to laboratories that provide the most complete and highest resolution HLA typing. The goal is to select the most valuable donors (young males, young females, and all minorities) and ensure they are listed on the registry with the most comprehensive typing available through the contract laboratory network.</p> <p>During this quarter:</p> <ul style="list-style-type: none"> 95% of males and females, 18-30 years of age were typed at HLA-A, B, C and DRB1

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IIB.1 Task 2: Evaluate HLA-DRB1 High Res typing – This task is closed.	
IIB.1 Task 3: Evaluate HLA-C Typing of Donors – This task is closed	
IIB.1 Task 4: Evaluate Buccal Swabs	Period 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.
IIB 1 Task 5: Enhancing HLA Data for Selected Donors – This task is closed.	
IIB 1 Task 6: Maintain a Quality Control Program	Period 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.
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 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.
IIB 2 Task 2: Validation of Logic of Primary Data – This task is closed.	
IIB 2 Task 3: Reinterpretation of Primary Data – This task is closed.	
IIB 2 Task 4: Genotype Lists & Matching Algorithm	Period 1 Activity: <ul style="list-style-type: none"> • 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 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.

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IIB 3 Task 2: Enhancement of EM Algorithm	Period 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.
IIB 3 Task 3: Optimal Registry Size Analysis	Period 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.
IIB 3 Task 4: Target Under- Represented Phenotypes	Period 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.
IIB 3 Task 5: Bioinformatics Web Site – This task is closed.	
IIB 3 Task 6: Consultants to Improve Algorithm – This task is closed.	
IIB 3 Task 7: Population Genetics – This task is closed.	
IIB 3 Task 8: Haplotype Matching – This task is closed.	
IIB 3 Task 9: Global Haplotype/Benchmark – This task is closed.	
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 – This task is closed.	
IIB.4 Task 2: Central Contingency Management	Period 1 Activity: <ul style="list-style-type: none"> • No activity this quarter.
IIB.4 Task 3: Benchmarking Analysis – This task is closed.	
IIB.4 Task 4: Expand Capabilities of Collection and Apheresis Centers – This task is closed.	

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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 1 Activity:

In 1994 a retrospective D/R 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. Presence/absence typing of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1) has been included.

- Final results were received on the 175 cord/recipient pairs included in SG 27. All 175 pairs were typed for HLA and KIR.
- To date over 2100 pairs and 1180 additional donors have been typed for presence/absence of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1).

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 1 Activity:

- No activity this quarter.

IIC 2 Task 2: Related Pairs Research Repository – This task is closed.

IIC 2 Task 3: CIBMTR Integration – This task is closed.

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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 1 Activity:

- During this reporting period, database management and system updates were performed to the AdvantageEDC system being used for both the Double Cord and Revelimid trials.

NIH Transplant Center

- NMDP provided support for donor/cord blood unit identification, selection and collection for the NIH intramural unrelated donor transplant program. Activity in the last quarter was as follows:
 - 5 formal searches
 - 33 donor confirmatory typing blood sample and IDM testing requests
 - 14 cord blood unit confirmatory typing requests
 - 4 cord blood units
 - 5 PBSC collections

IID.1 Task 2: Research with NMDP Donors – This task is closed.

IID.1 Task 3:

Expand Immuno-
biology Research

Period 1 Activity:

- No activity this quarter.

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ACRONYM LIST

AABB	American Association of Blood Banks	HR	High Resolution
AFA	African American	HRSA	Health Resources and Services Administration
AGNIS	A Growable Network Information System	HSC	Hematopoietic Stem Cell
AML	Acute Myelogenous Leukemia	IBWC	Immunobiology Working Committee
ABD	Antigen Binding Domain	IDM	Infectious Disease Markers
API	Asian Pacific Islander	IHWG	International Histocompatibility Working Group
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IPR	Immunobiology Project Results
ASBMT	American Society for Blood and Marrow Transplantation	ICRHER	International Consortium for Research on Health Effects of Radiation
ASHI	American Society for Histocompatibility and Immunogenetics	IND	Investigational New Drug
B-LCLs	B-Lymphoblastoid Cell Lines	IS	Information Services
BARDA	Biomedical Advanced Research and Development Authority	IT	Information Technology
BBMT	Biology of Blood and Marrow Transplant	IRB	Institutional Review Board
BCP	Business Continuity Plan	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BCPeX	Business Continuity Plan Exercise	KIR	Killer Immunoglobulin-like Receptor
BMCC	Bone Marrow Coordinating Center	MDACC	MD Anderson Cancer Center
BMDW	Bone Marrow Donors Worldwide	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
BODI	Business Objects Data Integrator	MICB	MHC Class I-Like Molecule, Chain B
BRT	Basic Radiation Training	MKE	Milwaukee
C&A	Certification and Accreditation	MSKCC	Memorial Sloan-Kettering Cancer Center
CAU	Caucasian	MSP	Minneapolis
CBMTG	Canadian Blood and Marrow Transplant Group	MUD	Matched Unrelated Donor
CBB	Cord Blood Bank	NCBM	National Conference of Black Mayors

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CBC	Congressional Black Caucus	NCI	National Cancer Institute
CBS	Canadian Blood Service	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CBU	Cord Blood Unit	NHLBI	National Heart Lung and Blood Institute
CHTC	Certified Hematopoietic Transplant Coordinator	NIH	National Institutes of Health
CIBMTR	Center for International Blood & Marrow Transplant Research	NIMS	National Incident Management System
CIT	CIBMTR Information Technology	NK	Natural Killer
CLIA	Clinical Laboratory Improvement Amendment	NLE	National Level Exercise
CME	Continuing Medical Education	NMDP	National Marrow Donor Program
CMF	Community Matching Funds	NRP	National Response Plan
COG	Children's Oncology Group	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CREG	Cross Reactive Groups	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CSS	Center Support Services	OIT	Office of Information Technology
CT	Confirmatory Testing	OMB	Office of Management and Budget
CTA	Clinical Trial Application	ONR	Office of Naval Research
DC	Donor Center	P2P	Peer-to-Peer
DHHS-ASPR	Department of Health and Human Service – Assistant Secretary Preparedness and Response	PBMC	Peripheral Blood Mononuclear Cells
DIY	Do it yourself	PBSC	Peripheral Blood Stem Cell
DKMS	Deutsche Knochenmarkspenderdatei	PCR	Polymerase Chain Reaction
DMSO	Dimethylsulphoxide	PSA	Public Service Announcement
DoD	Department of Defense	QC	Quality control
DHHS-ASPR	Department of Health and Human Services – Assistant Secretary for Preparedness and Response	RCC	Renal Cell Carcinoma
DNA	Deoxyribonucleic Acid	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
DR	Disaster Recovery	REAC/TS	Radiation Emergency Assistance Center/Training Site

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D/R	Donor/Recipient	RFP	Request for Proposal
EBMT	European Group for Blood and Marrow Transplantation		
EDC	Electronic Data Capture	RFQ	Request for Quotation
EFI	European Federation of Immunogenetics	RG	Recruitment Group
EM	Expectation Maximization	RITN	Radiation Injury Treatment Network
EMDIS	European Marrow Donor Information System	SBT	Sequence Based Typing
ENS	Emergency Notification System	SCTOD	Stem Cell Therapeutics Outcome Database
ERSI	Environment Remote Sensing Institute	SG	Sample Group
FBI	Federal Bureau of Investigation	SLW	STAR Link® Web
FDA	Food and Drug Administration		
FDR	Fund Drive Request	SSA	Search Strategy Advice
FLOCK	Flow Cytometry Analysis Component	SSO	Sequence Specific Oligonucleotides
Fst	Fixation Index	SSP	Sequence Specific Primers
GETS	Government Emergency Telecommunications Service	SSOP	Sequence Specific Oligonucleotide Probes
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	STAR®	Search, Tracking and Registry
GIS	Geographic Information System		
GvHD	Graft vs Host Disease	TC	Transplant Center
HCS	HealthCare Standard	TED	Transplant Essential Data
HCT	Hematopoietic Cell Transplantation	TNC	Total Nucleated Cell
HEPP	Hospital Emergency Preparedness Program	TSA	Transportation Security Agency
HHQ	Health History Questionnaire	UI	User Interface
HHS	Health and Human Services	UML	Unified Modeling Language
HIPAA	Health Insurance Portability and Accountability Act	URD	Unrelated Donor
HIS	Hispanic	WGA	Whole Genome Amplification
HLA	Human Leukocyte Antigen	WMDA	World Marrow Donor Association
HML	Histoimmunogenetics Mark-up Language	WU	Work-up