

**NATIONAL
MARROW
DONOR
PROGRAM®**

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

April 26, 2012

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 #N00014-10-1-0204 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Parker:

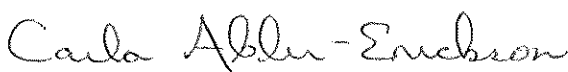
Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of January 1, 2012 to March 31, 2012.

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				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Service, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188) Washington, DC 20503. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 26-04-2012		2. REPORT TYPE Quarterly		3. DATES COVERED (From - To) Jan – Mar 2012	
4. TITLE AND SUBTITLE Development of Medical Technology for Contingency Response to Marrow Toxic Agents – Quarterly Performance/Technical Report for October 1, 2011 to December 31, 2011, Period 7				5a. CONTRACT NUMBER N/A	
				5b. GRANT NUMBER N00014-10-1-0204	
				5c. PROGRAM ELEMENT NUMBER N/A	
6. AUTHOR(S) Spellman, Stephen				5d. PROJECT NUMBER N/A	
				5e. TASK NUMBER Project 1, 2, 3, 4	
				5f. WORK UNIT NUMBER N/A	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) National Marrow Donor Program 3001 Broadway St., N.E., Ste. 500 Minneapolis, MN 55413				8. PERFORMING ORGANIZATION REPORT NUMBER N/A	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Office of Naval Research 875 N. Randolph St. Arlington, VA 22203				10. SPONSOR/MONITOR'S ACRONYM(S) ONR	
				11. SPONSORING/MONITORING AGENCY REPORT NUMBER N/A	
12. DISTRIBUTION AVAILABILITY STATEMENT Approved for public release; distribution is unlimited					
13. SUPPLEMENTARY NOTES N/A					
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.					
15. SUBJECT TERMS Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report		18. NUMBER OF PAGES 14
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	19a. NAME OF RESPONSIBLE PERSON Dennis L. Confer, MD – Chief Medical Office		
			19b. TELEPHONE NUMBER (Include area code) 612.362.3425		

Grant Award N00014-10-1-0204

DEVELOPMENT OF MEDICAL TECHNOLOGY
FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS
QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
JANUARY 01, 2012 to MARCH 31, 2012
PERIOD 8

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

January 01, 2012 through March 31, 2012

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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:

- No activity this period.

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 8 Activity:

- The web based learning management system (LMS) implementation continues with vendor SumTotal with a pilot launch scheduled for April 30, 2012
- Drafted the RITN Basic Radiation Training course for implementation in the LMS once launched

IIA.2.2 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:

- No activity this period.

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IIA.3 Task 2: Critical Facility and Staff Related Functions	Period 8 Activity: No activity this period.
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.	
IIB.1 Task 1: Increase Registry Diversity	Period 8 Activity: - During this quarter, 106 samples with a reported rare allele were sent to a contract laboratory for confirmation of the rare allele at HLA-A, -B, -C, or –DRB1. 59% of the samples came back with typing that differed from the previous typing. - An abstract detailing the results of the retyping project for DRB1*16:08 was submitted and accepted to the 2012 European Federation of Immunogenetics (EFI) meeting in May.
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 8 Activity: No activity this period.
IIB 1 Task 5: Enhancing HLA Data for Selected Donors	Period 8 Activity: AB only DRB1 typing project A poster abstract was presented at the 2012 ASBMT Tandem Meeting in February displaying the success rate for AB only typed donors matching searching patients with no 6/6 matched donors, reported in the previous period's report.
IIB 1 Task 6: Maintain a Quality Control Program – This task is closed.	

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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 period.

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 8 Activity:

- No activity this period.

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:

The following performance improvements to the HapLogic algorithm were achieved during this reporting period:

- Continued reduction in search run times
- Achieved median search run time of 35 seconds

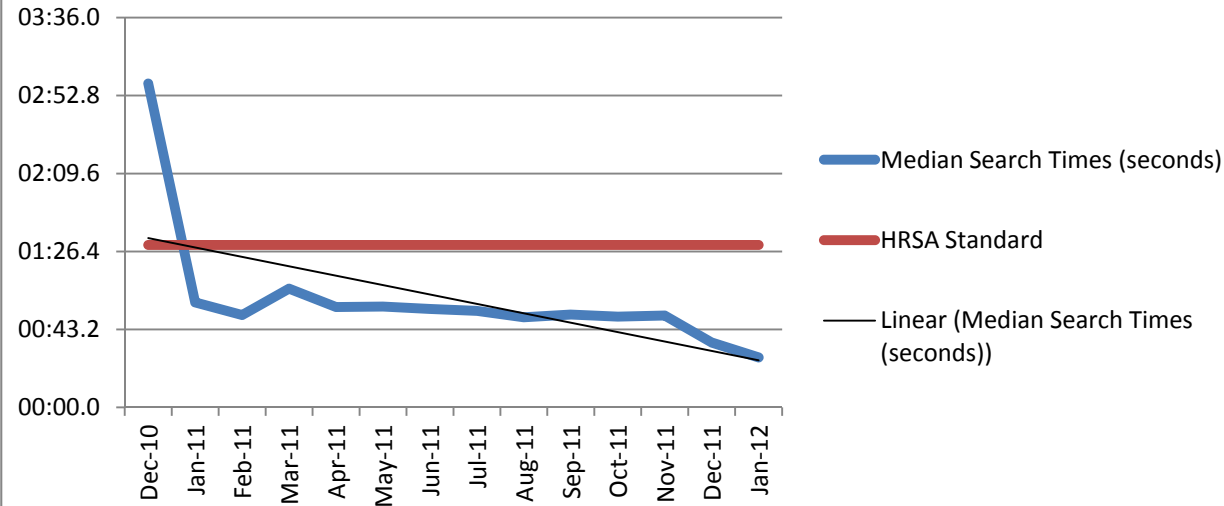
Graph below represents the search run times over the past year:

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Median Search Times (seconds)


IIB 3 Task 2:
 Enhancement of EM
 Algorithm
Period 8 Activity:

- Began processing of BMDW data in preparation for 5-locus BMDW haplotype frequency study.
- Continued development of a manuscript describing 6-locus haplotype frequency data utilized in HapLogic III.
- Calculated 5-locus high-resolution haplotype frequency for Canadian populations by detailed race
- Developed simulation framework for testing methods of generating synthetic haplotype frequencies to lower sampling error in population frequencies and submitted abstract to WMDA International Donor Registry Conference.
- Launched project to automate quarterly haplotype frequency updates to HapLogic.

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IIB 3 Task 3: Optimal Registry Size Analysis	Period 8 Activity: - Continued development of a Registry Models Physician-Oriented manuscript. - Drafted Registry Models Methods manuscript with an intended audience of bioinformaticians - Performed US Registry Model analysis for US cords for dose varying from 0.5 to 2.0 TNC/kg - Calculated HLA match rates for the Canadian registry.
IIB 3 Task 4: Target Under- Represented Phenotypes	Period 8 Activity: No activity this period.
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	Period 8 Activity: No activity this period.
IIB.4 Task 2: Central Contingency Management	Period 8 Activity: A draft manuscript describing the results of the 8/8 Donor Validation project was initiated. Donor testing was completed for the research project to analyze 10/10 high resolution matches (adding DQB1) on patients where an 8/8 match was identified. 234 donors were typed this quarter. Results were summarized for 10/10 match rate in the four main race groups (below). Approximately 24% of the donors included in the 8/8 analysis could not be assessed for 8/8 matching because no additional samples were

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available in the Repository.

These results are shown in the following table:

	CAU	HIS	API	AFA
10/10 HR Matched	209 (55%)	99 (32%)	96 (36%)	74 (19%)
Pending Further Testing; No Stored Sample	93 (25%)	84 (27%)	76 (28%)	74 (19%)
No 10/10HR Match	75 (20%)	124 (40%)	98 (36%)	242 (62%)
TOTAL	377	307	270	390

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.

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:

- No activity this period.

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

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

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:

Prospective Studies; RCI BMT

- During this reporting period, staff performed monitoring activities for the Adult Double Cord trial.
- Staff performed activities associated with the Long term Donor Follow up study including phone interviewing, data entry.

Cord Blood Research

- The Duke and St. Louis Cord Blood Bank (SLCBB) created and finalized training and validating the assay methodologies to ensure the generation of consistent results at both testing sites for the study investigating biomarkers associated with cord blood engraftment.
 - o Testing using this third laboratory, SLCBB, is under development to determine whether the poor reliability is due to center-specific or assay related issues.
 - o The effort to procure and place a flow cytometer with the correct lasers to perform the assays within the specifications of the manufacturer is on-going.

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

IID.1 Task 3:
Expand Immuno-
biology Research

Period 8 Activity:

The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies

- The IBWC held its annual meeting at the 2012 BMT Tandem meetings.
 - o 8 new proposals were reviewed and 6 accepted for analysis

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- One abstract was presented:
 - Fabio Giglio, et al., *KIR3DL1/S1 and HLA-B alleles combine to influence unrelated hematopoietic stem cell transplantation outcomes*. Oral presentation 2012 BMT Tandem Meetings.
- One abstract was accepted:
 - Carolyn Hurley, et al., *Impact of unidirectional mismatches on the outcome of unrelated donor hematopoietic stem cell transplantation*. Oral presentation 2012 IHIW/EFI/BSHI joint meetings.
- Four manuscripts were submitted:
 - John Horan, et al., *Evaluation of HLA matching unrelated hematopoietic stem cell transplantation for non-malignant disorders*. Submitted to Blood.
 - Effie Petersdorf, et al., *The role of major histocompatibility complex variation in unrelated donor hematopoietic cell transplantation*. Submitted to Science Translational Medicine.
 - Stephen Spellman, et al., *A perspective on the selection of unrelated donors and cord blood units for transplantation*. Submitted to Blood.
 - Sarah Cooley, et al., *The protective effect of unrelated donors with killer-cell immunoglobulin-like receptor (KIR) B genes is enhanced in recipients with HLA-C1 group ligands*. Submitted to Blood.
- Two manuscripts were published:
 - Katharina Fleischhauer, et al., *Non-permissive HLA-DPB1 T cell epitope mismatches increase mortality after unrelated donor hematopoietic cell transplantation*. Published in Lancet Oncology.
 - Kim Pearce, et al., *Analysis of non-HLA genomic risk factors in HLA-matched unrelated donor hematopoietic cell transplantation for chronic myeloid leukemia*. Published in Hematologica.

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ACRONYM LIST

AABB	American Association of Blood Banks	HLA	Human Leukocyte Antigen
AFA	African American	HML	Histoimmunogenetics Mark-up Language
AGNIS	A Growable Network Information System	HR	High Resolution
AML	Acute Myelogenous Leukemia	HRSA	Health Resources and Services Administration
ABD	Antigen Binding Domain	HSC	Hematopoietic Stem Cell
API	Asian Pacific Islander	IBWC	Immunobiology Working Committee
AQP	Ancestry Questionnaire Pilot	IDM	Infectious Disease Markers
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IHWG	International Histocompatibility Working Group
ASBMT	American Society for Blood and Marrow Transplantation	IPR	Immunobiology Project Results
ASHI	American Society for Histocompatibility and Immunogenetics	ICRHER	International Consortium for Research on Health Effects of Radiation
B-LCLs	B-Lymphoblastoid Cell Lines	IND	Investigational New Drug
BARDA	Biomedical Advanced Research and Development Authority	IS	Information Services
BBMT	Biology of Blood and Marrow Transplant	IT	Information Technology
BCP	Business Continuity Plan	IRB	Institutional Review Board
BCPeX	Business Continuity Plan Exercise	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BMCC	Bone Marrow Coordinating Center	KIR	Killer Immunoglobulin-like Receptor
BMDW	Bone Marrow Donors Worldwide	MDACC	MD Anderson Cancer Center
BMT	Bone Marrow Transplantation	MDS	Myelodysplastic Syndrome
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MHC	Major Histocompatibility Complex
BODI	Business Objects Data Integrator	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	MRD	Minimal Residual Disease
CBMTG	Canadian Blood and Marrow Transplant Group	MSKCC	Memorial Sloan-Kettering Cancer Center

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CBB	Cord Blood Bank	MSP	Minneapolis
CBC	Congressional Black Caucus	MUD	Matched Unrelated Donor
CBS	Canadian Blood Service	NAC	Nuclear Accident Committee
CBU	Cord Blood Unit	NCBM	National Conference of Black Mayors
CHTC	Certified Hematopoietic Transplant Coordinator	NCI	National Cancer Institute
CIBMTR	Center for International Blood & Marrow Transplant Research	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CIT	CIBMTR Information Technology	NHLBI	National Heart Lung and Blood Institute
CLIA	Clinical Laboratory Improvement Amendment	NIH	National Institutes of Health
CME	Continuing Medical Education	NIMS	National Incident Management System
CMF	Community Matching Funds	NK	Natural Killer
COG	Children's Oncology Group	NLE	National Level Exercise
ConOps	Concept of Operations	NMDP	National Marrow Donor Program
CREG	Cross Reactive Groups	NRP	National Response Plan
CSS	Center Support Services	NST	Non-myeloablative Allergenic Stem Cell Transplantation
CT	Confirmatory Testing	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CTA	Clinical Trial Application	OIT	Office of Information Technology
CWD	Common and Well Documented	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
DHHS-ASPR	Department of Health and Human Services – Assistant Secretary for Preparedness and Response	QC	Quality control
DNA	Deoxyribonucleic Acid	RCC	Renal Cell Carcinoma
DR	Disaster Recovery	RCI BMT	Resource for Clinical Investigations in Blood and

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			Marrow Transplantation
D/R	Donor/Recipient	REAC/TS	Radiation Emergency Assistance Center/Training Site
EBMT	European Group for Blood and Marrow Transplantation	RFP	Request for Proposal
EDC	Electronic Data Capture	RFQ	Request for Quotation
EFI	European Federation of Immunogenetics		
ELISpot	Enzyme-Linked Immunosorbent Spot	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	SSA	Search Strategy Advice
FDR	Fund Drive Request	SSO	Sequence Specific Oligonucleotide
FLOCK	Flow Cytometry Analysis Component	SSP	Sequence Specific Primers
Fst	Fixation Index	SSOP	Sequence Specific Oligonucleotide Probes
GETS	Government Emergency Telecommunications Service	STAR®	Search, Tracking and Registry
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	TC	Transplant Center
GIS	Geographic Information System	TED	Transplant Essential Data
GvHD	Graft vs. Host Disease	TNC	Total Nucleated Cell
HCS	HealthCare Standard	TSA	Transportation Security Agency
HCT	Hematopoietic Cell Transplantation	UI	User Interface
HEPP	Hospital Emergency Preparedness Program	UML	Unified Modeling Language
HHQ	Health History Questionnaire	URD	Unrelated Donor
HHS	Health and Human Services	WGA	Whole Genome Amplification
HIPAA	Health Insurance Portability and Accountability Act	WMDA	World Marrow Donor Association
HIS	Hispanic	WU	Work-up