**National Marrow Donor Program®**

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

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May 11, 2009

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 #N00014-06-1-1207 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 January 1, 2009 to March 31, 2009.

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

Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

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1. Contingency Prepardness: 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.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** 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 | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
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NATIONAL MARROW DONOR PROGRAM®

*Creating Connections. Saving Lives.™*

# Grant Award N00014-08-1-1207

## QUARTERLY
## PERFORMANCE / TECHNICAL REPORT
## FOR
## JANUARY 01, 2009 to MARCH 31, 2009

Office of Naval Research

And

The National Marrow Donor Program
3001 Broadway Street N.E.
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# QUARTER PROGRESS REPORT

## Development of Medical Technology for Contingency Response to Marrow Toxic Agents

## January 01, 2009 through March 31, 2009

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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.1.1 Task 1:** Secure Interest of Transplant Physicians | **Period 2 Activity:**<br>• 26 RITN center staff members attended Advanced Radiation Medical Emergency training course and conducted in Oakridge, TN at the Radiation Emergency Assistance Center/Training Site (REAC/TS) on March 26 & 27, 2009. Course lessons included:<br>o Basic Health Physics & Radiation Protection: Part I<br>o A History of Serious Radiological Incidents: The Real Risk<br>o Health Physics & Contamination Control: Part II<br>o Radiation Detection, Monitoring & Protection Laboratory Exercise & Quiz<br>o Diagnosis & Management of the Acute Radiation Syndrome (ARS)<br>o Diagnosis & Management of Internal Contamination<br>o Diagnosis & Management of Acute Local Radiation Injury & Case Review: Yanango Peru<br>o Radiation Sources & Radiological Terrorism<br>o Radiation Emergency Area Protocol Demonstration<br>o Radiation Emergency Medical Management Drill<br>o Radiation Dose Estimations – Problem Solving Session<br>• During this period we continued to plan for the 2009 RITN conference "Nuclear Terrorism: Hematology/Oncology Center Preparedness" to be held in Bethesda, MD on May 18th (additional details of this conference are listed under AIM II A 2.1). |
| **IIA.1.2 Task 2:** GCSF in Radiation Exposure | **Period 2 Activity:**<br>• No activity this period. |

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|---|---|
| **IIA.1 3 Task 3:** Patient Assessment Guidelines and System Enhancements | **Period 2 Activity:**<br>In the last quarter, a new version of STAR Link was released to support the Navy Contingency project.<br>• Sample Tracking **–** Repository sample storage information is now sent to STAR Link Web. This information will be used to track receipt of returned donor recruitment sample kits. In addition, services have been deployed to send reminder emails back to the donors when they have not returned their kits. This functionality can be extended for contingency donors who have been requested to supply addition samples.<br>**Do It Yourself (DIY)** application efforts were focused on project enhancements and preparation for the Navy Contingency project including:<br>• Kit Requests – System automatically sends sample kit requests after DIY donors register on-line.<br>• Health History Questionnaire (HHQ) - Functionality to allow donors to enter on-line HHQ forms has been developed and is currently being tested.<br>• **Statistic:** DIY Online Donor Registration through www.marrow.org resulted in a **total of 22,011** between 1/1/09 – 3/31/09.<br>• Completed the following project initiation and analysis deliverables to support future releases on the Navy Contingency Project:<br>o Project scope/charter document<br>o Project Quality Assurance Plan<br>o Iteration 1 requirements/use case<br>o Iteration 2 requirements/use case<br>o Draft requirements/use case for iteration 3 (Voids)<br>o Began documenting requirements/use case for iteration 4 |
| **IIA 1.4 Task 4:** National Data Collection Model | **Period 2 Activity:**<br>• No activity this period. |

| **IIA. Contingency Preparedness – Objective 2:** Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation. | |
|---|---|
| **IIA.2.1 Task 1:** Contingency Response Network | **Period 2 Activity:**<br>• Completed the development of the 2009 RITN Tabletop Exercise and distributed it to all RITN centers to complete prior to the end of July 2009.<br>• During this period we continued to plan for the 2009 RITN conference "Nuclear Terrorism: Hematology/Oncology Center Preparedness" to be held in Bethesda, MD on May 18, 2009.<br>o Based on current registrations we will have approximately 100 attendees<br>o During this period we secured as a key note opening address RADM W. Craig Vanderwagen (Assistant Secretary for Preparedness and Response)<br>o This conference will have a group session in the morning to provide a common operating picture then have three (3) interactive breakout workshops held three (3) times in the afternoon so that all attendees have the opportunity to participate.<br>o Morning sessions include:<br>▪ Threat Scenario Overview<br>▪ National Disaster Medical System<br>▪ Medical response expectations 10, 100, 1,000 miles from epicenter<br>▪ Altered Standards of Medical Care Overview<br>▪ NMDP Planning and data collection<br>o Afternoon interactive breakout workgroups include:<br>▪ Altered Standards of Care<br>▪ Logistical issues – bed mgmt, use of non-hospital loc, & staffing issues<br>▪ Provision of medical care – early and late care |

- The conference will culminate with a report of findings by the afternoon session moderators, with the intent of publishing these findings later in the year.

- **Meetings**:
  - 26 Committee members attended the RITN Steering Committee meeting at the 2009 ASBMT/CIBMTR Tandem meetings on February 11, 2009, the meeting agenda consisted of:
    - RITN accomplishments in 2008
    - 2009 expansion of RITN
    - 2009 RITN tasks and educational activities
    - New developments
    - RITN Tabletop Exercises Lessons Learned from 2006-2008 and a 2009 Tabletop Exercise Overview
    - Maintaining RITN's Momentum
  - Continued to plan for a RITN Steering Committee meeting to be held on May 19, 2009 following the RITN educational conference, tentative meeting agenda includes:
    - 2009 conference review
    - 2010 or 2011 conference planning
    - Update on tabletop Lessons Learned project
    - Coordination with HHS on triage of incident victims
    - Update on RITN-VA mapping project
    - Update on JCHO interaction
    - BARDA Presentation
    - Tour of HHS Secretaries Emergency Operations Center

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| **IIA.2.2 Task 2:** Sibling Typing Standard Operating Procedures | **Period 2 Activity:**<br>• 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.3.1 Task 1:** I.S. Disaster Recovery | **Period 2 Activity:**<br>• Additional hardware and software was purchased, installed and configured to support disaster recovery testing. Additional network segments were also added to support disaster recovery environment all for completing the upcoming test.<br>• Completed the disaster recovery smoke test for all Tier 1 applications in preparation for the disaster recovery exercise in April 2009. Also, preparations have begun for disaster recovery testing for Tier 2 through 5 applications which will be completed early summer, 2009. |
| **IIA.3.2 Task 2:** Critical Facility and Staff Related Functions | **Period 2 Activity:**<br>• Business Continuity Planning:<br>o Re-evaluated the necessity of and cancelled the installation of high tinsel strength security film on all windows of the NMDP Repository to harden the face of the storage facility in the event of a natural or man made disaster that could compromise the building structure.<br>o Began assembling NMDP operated donor center readiness kits to prepare these remote NMDP offices to better respond to incidents that impact their operations. |

| **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.1.1 Task 1:** Increase Registry Diversity | **Period 2 Activity:**<br>• Adult Donor Registry: To successfully serve all patients in need of cellular transplantation, the Marketing and Communications Department continues to focus on developing and executing strategies and tactics that increase awareness, education and engagement among target audiences. During January – March 2009, we focused on transitioning the first phase of our core English and non-English language educational materials to the new public-facing Be The Match (SM) brand name. Be The Match will help educate the general public about the need for unrelated marrow donors and motivate them to join the registry. |
| **IIB.1.2 Task 2:** Evaluate HLA-DRB1 High Res typing | **Period 2 Activity:**<br>• This activity is closed. |
| **IIB.1.3 Task 3:** Evaluate HLA-C Typing of Donors | **Period 2 Activity:**<br>• This activity is closed. |
| **IIB.1.4 Task 4:** Evaluate Buccal Swabs | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 1.5 Task 5:** Enhancing HLA Data for Selected Donors | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 1.6 Task 6:** Maintain a Quality Control Program | **Period 2 Activity:**<br>• No activity this period. |

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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 2.1 Task 1:** Collection of Primary Data | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 2.2 Task 2:** Validation of Logic of Primary Data | **Period 2 Activity:**<br>• This activity is closed. |
| **IIB 2.3 Task 3:** Reinterpretation of Primary Data | **Period 2 Activity:**<br>• This activity is closed. |
| **IIB 2.4 Task 4:** Genotype Lists & Matching Algorithm | **Period 2 Activity:**<br>• 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.3.1 Task 1:** Phase I of EM Haplotype Logic | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 3.2 Task 2:** Enhancement of EM Algorithm | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 3.3 Task 3:** Optimal Registry Size Analysis | **Period 2 Activity:**<br>• No activity this period. |

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| **IIB 3.4 Task 4:** Target Under- Repre-sented Phenotypes | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 3.5 Task 5:** Bioinformatics Web Site | **Period 2 Activity:**<br>• This activity is closed. |
| **IIB 3.6 Task 6:** Consultants to Improve Algorithm | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 3.7 Task 7:** Population Genetics | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 3.8 Task 8:** Haplotype Matching | **Period 2 Activity:**<br>• No activity this period. |
| **IIB 3.9 Task 9:** Global Haplotype/Benchmark | **Period 2 Activity:**<br>• 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.4.1 Task 1:** Expand Network Communications | **Period 2 Activity:**<br>In the last quarter, the effort for has been focused on the analysis and realization of request/fulfillment messaging and storage. This foundation (data model & integration) is a prerequisite for implementing improved electronic communication and parallel search stages.<br>• Analysis, vetting of request/fulfillment messaging structure through (peer-to-peer) P2P message realization.<br>• Analysis, vetting of request/fulfillment storage model. |

**Do It Yourself (DIY)** application project work efforts delivered the following functionality to allow Donor Centers and Recruitment Groups to use DIY as a recruitment tool:

- Automation of Drive request by DC/RG's – formerly, Recruiters filled out a drive request in SLW, and then faxed in the request. CSS would manually approve these drives.
- Ability to create single use promotional codes and create estimates for a drive.
- Ability to set up multiple funding sources in a single drive. Example: CMF donor paid in which donor pays $25.00, or CMF sponsor paid, in which a sponsor is billed and the donor responsibility is $0.
- Prioritization and automation of funding sources which allows recruiters to choose which funding type should be charged first.
- Added CSS functionality, including Stage Drive, Cancel Drive, Estimates Status and Date, View of actual against estimates via the Drive Estimates Grid.
- Setting Drive types: This allowed for automation of "Live" drives as well.
- Drive estimates automatically updating in FDR.
- Automated Status of donors including staged, newly entered, or duplicate.
- Create unique "single use codes" - ability to have SLW automatically generate X number of unique codes for a single drive, with the added functionality to export these promotional codes to a spreadsheet for mail merge.
- Drive max for Caucasian and overall drive totals.
- Automatic invoicing of newly entered donors.
- Automation of emails for kit returned, no kit received, and pending deletion due to incomplete registration in 45 and 60 days.
- UI Interface changes for Pending Donor and Pending Drive including new functionality of screens for additional edits.

**DIY 2 - Updated Functionality and User Interface**

- Automation of triggers to send emails to donor, email sent after 5, 10, and 15 days.
- Interface changes such as "Verisign" logo.

Reports that will allow tracking of donor recruitment and the supporting activities:

- Drive Activity Reports
- CSS Activity Reports

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| | • Drive Detail Report<br>**FDR**<br>• FDR will get new pushes of data from STAR Link via transactions. This new interaction will eliminate the need to send a Drive Detail report via email to the FDR user and will replace the "keying" of drive estimates.<br>• Changing the invoicing frequency due to length of drive. Drives longer than 12 days will invoice only monthly compared to the standard weekly. |
| **IIB.4.2 Task 2:** Central Contingency Management | **Period 2 Activity:**<br>A research project was developed to validate the 8/8 HLA high resolution match rate predictions for both Caucasian (CAU) and African American (AFA) patients. This study will validate previous registry benchmark analyses and supply valuable information regarding donor selection in the event of a contingency. During the past quarter:<br>• The study design was finalized and work began on the project.<br>• Study 'patients' were selected from the random pool of CAU and AFA donors previously high resolution HLA typed through ONR funded haplotype project and the genotypes used to run donor searches against the NMDP registry.<br>• Scientific Services search strategy staff started to perform donor selections on behalf of the study 'patients'. Beginning next quarter, donors with repository samples will be tested to identify the high resolution match rate for patients. |
| **IIB.4.3 Task 2:** Benchmarking Analysis | **Period 2 Activity:**<br>• No activity this period. |
| **IIB.4.4 Task 2:** Expand Capabilities of Collection and Apheresis Centers | **Period 2 Activity:**<br>• 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.1.1 Task 1:** Donor Recipient Pair Project | **Period 2 Activity:**<br>• 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 2.1 Task 1:** Analysis of non-HLA loci | **Period 2 Activity:**<br>• No activity this period. |
| **IIC 2.2 Task 2:** Related Pairs Research Repository | **Period 2 Activity:**<br>• No activity this period. |
| **IIC 2.3 Task 3:** CIBMTR Integration | **Period 2 Activity:**<br>• No activity this period. |
| **IID. Clinical Research in Transplantation – Objective 1:** Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response. | |
| **IID.1.1 Task 1:** Observational Research, Clinical Trials and NIH Transplant Center | **Period 2 Activity:**<br>• No activity this period. |
| **IID.1.2 Task 2:** Research with NMDP Donors | **Period 2 Activity:**<br>• No activity this period. |
| **IID.1.3 Task 3:** Expand Immuno-biology Research | **Period 2 Activity:**<br>• No activity this period. |

## ACRONYM LIST

| | | | |
|---|---|---|---|
| AABB | American Association of Blood Banks | ICRHER | International Consortium for Research on Health Effects of Radiation |
| AGNIS | A Growable Network Information System | IS | Information Services |
| AML | Acute Myelogenous Leukemia | IT | Information Technology |
| ARS | Acute Radiation Syndrome (also known as Acute Radiation Sickness) | IRB | Institutional Review Board |
| ASBMT | American Society for Blood and Marrow Transplantation | JCAHO | Joint Commission on Accreditation of Healthcare Organizations |
| ASHI | American Society for Histocompatibility and Immunogenetics | KIR | Killer Immunoglobulin-like Receptor |
| B-LCLs | B-Lymphoblastoid Cell Lines | NCI | National Cancer Institute |
| BARDA | Biomedical Advanced Research and Development Authority | 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 | MDACC | MD Anderson Cancer Center |
| CBMTG | Canadian Blood and Marrow Transplant Group | MSKCC | Memorial Sloan-Kettering Cancer Center |
| CBB | Cord Blood Bank | MUD | Matched Unrelated Donor |
| CBC | Congressional Black Caucus | NEMO | |
| CBS | Canadian Blood Service | NCBM | National Conference of Black Mayors |
| CBU | Cord Blood Unit | NHLBI | National Heart Lung and Blood Institute |
| CHTC | Certified Hematopoeitic Transplant Coordinator | NIH | National Institutes of Health |
| CIBMTR | Center for International Blood & Marrow Transplant Research | NIMS | National Incident Management System |
| CLIA | Clinical Laboratory Improvement Amendment | NK | Natural Killer |
| 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 |

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|---|---|---|---|
| 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 |
| 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 |
| ERSI | Environment Remote Sensing Institute | RFP | Request for Proposal |
| FBI | Federal Bureau of Investigation | RFQ | Request for Quotation |
| FDA | Food and Drug Administration | RG | Recruitment Group |
| FDR | Fund Drive Request | RITN | Radiation Injury Treatment Network |
| Fst | Fixation Index | SBT | Sequence Based Typing |
| GETS | Government Emergency Telecommunications Service | SCTOD | Stem Cell Therapeutics Outcome Database |
| GCSF | Granulocyte-Colony Stimulating Factor (also known as filgrastim) | SG | Sample Group |
| GIS | Geographic Information System | SLW | STAR Link® Web |
| GvHD | Graft vs Host Disease | SSA | Search Strategy Advice |
| HCT | Hematopoietic Cell Transplantation | SSO | Sequence Specific Oligonucleotides |
| HHS | Health and Human Services | SSP | Sequence Specific Primers |
| HIPAA | Health Insurance Portability and Accountability Act | SSOP | Sequence Specific Oligonucleotide Probes |

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|---|---|---|---|
| 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 | UI | User Interface |
| IDM | Infectious Disease Markers | URD | Unrelated Donor |
| IHWG | International Histocompatibility Working Group | WGA | Whole Genome Amplification |
| IPR | Immunobiology Project Results | WMDA | World Marrow Donor Association |
| IND | Investigational New Drug | WU | Work-up |