

Defense Health Program
Fiscal Year (FY) 2013 Budget Estimates
Exhibit R-2, DHP RDT&E Budget Item Justification

Appropriation/Budget Activity
Defense Health Program/BA: 2

DATE: February 2012
R1 Item Nomenclature: 6
Medical Technology Development
0603115HP

COST: (Dollars in Millions)

	2011 Actual	2012 Estimate	2013 Estimate	2014 Estimate	2015 Estimate	2016 Estimate	2017 Estimate
Total PE 0603115	723.324	703.313	239.110	282.441	290.422	289.094	290.613
CoE-Breast Cancer Center of Excellence (Army)	9.731	9.906	10.458	10.636	10.830	11.229	11.418
CoE-Gynecological Cancer Center of Excellence (Army)	8.502	8.655	9.138	9.293	9.463	9.811	9.977
CoE-Integrative Cardiac Health Care Center of Excellence (Army)	3.588	3.652	3.857	3.921	3.993	4.141	4.210
COE-Neuroscience Center of Excellence (USUHS)	1.345	1.845	1.948	1.981	2.017	2.053	2.088
CoE-Pain Center of Excellence (Army)	2.243	2.767	2.921	2.971	3.025	3.137	3.190
CoE-Prostate Cancer Center of Excellence (USUHS)	7.103	7.391	7.978	8.294	8.634	8.943	9.093
CSI-AFIRM (Army)	4.680	0.000	0.000	0.000	0.000	0.000	0.000

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CSI-Amyotrophic Lateral Sclerosis (ALS) (Army)	7.800	6.240	0.000	0.000	0.000	0.000	0.000
CSI-Autism Research (Army)	6.240	4.973	0.000	0.000	0.000	0.000	0.000
CSI-Blast Recovery Monitors (Army)	7.800	0.000	0.000	0.000	0.000	0.000	0.000
CSI-Bone Marrow Failure Disorder Research (Army)	3.900	3.120	0.000	0.000	0.000	0.000	0.000
CSI-EMF Blast Pulse Effects (Navy)	6.825	0.000	0.000	0.000	0.000	0.000	0.000
CSI-Global HIV/AIDS Prevention (Navy)	10.000	8.000	0.000	0.000	0.000	0.000	0.000
CSI-Gulf War Illness Peer Reviewed Research Programs (Army)	7.800	9.750	0.000	0.000	0.000	0.000	0.000
CSI-Joint Warfighter Medical Research (Army)	0.000	39.000	0.000	0.000	0.000	0.000	0.000
CSI-Multiple Sclerosis (Army)	4.680	3.705	0.000	0.000	0.000	0.000	0.000
CSI-Muscular Dystrophy Research (Army)	3.900	3.120	0.000	0.000	0.000	0.000	0.000

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CSI-Ovarian Cancer Research (Army)	19.500	15.600	0.000	0.000	0.000	0.000	0.000
CSI-Pain Management Task Force Research (Army)	3.900	0.000	0.000	0.000	0.000	0.000	0.000
CSI-Peer Reviewed Breast Cancer Research (Army)	146.250	117.000	0.000	0.000	0.000	0.000	0.000
CSI-Peer Reviewed Medical Research Program (Army)	48.750	48.750	0.000	0.000	0.000	0.000	0.000
CSI-Peer Reviewed Prostate Cancer Research (Army)	78.000	78.000	0.000	0.000	0.000	0.000	0.000
CSI-Peer-Restorative Transplant Research (Army)	0.000	14.625	0.000	0.000	0.000	0.000	0.000
CSI-Peer-Reviewed Alzheimer Research (Army)	14.625	11.700	0.000	0.000	0.000	0.000	0.000
CSI-Peer-Reviewed Cancer Research Program (Army)	15.600	12.480	0.000	0.000	0.000	0.000	0.000
CSI-Peer-Reviewed Hemorrhage Control Research (Army)	0.000	5.850	0.000	0.000	0.000	0.000	0.000

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CSI-Peer-Reviewed Lung Cancer Research Program (Army)	12.480	9.945	0.000	0.000	0.000	0.000	0.000
CSI-Peer-Reviewed Orthopedic Research (Army)	23.400	29.250	0.000	0.000	0.000	0.000	0.000
CSI-Peer-Reviewed Spinal Cord Research Program (Army)	11.700	9.360	0.000	0.000	0.000	0.000	0.000
CSI-Peer-Reviewed Vision Research (Army)	3.900	3.120	0.000	0.000	0.000	0.000	0.000
CSI-Research in Alcohol and Substance Use Disorders (Army)	5.070	4.388	0.000	0.000	0.000	0.000	0.000
CSI-Traumatic Brain Injury/Psychological Health (TBI/PH) (Army)	57.266	83.850	0.000	0.000	0.000	0.000	0.000
CSI-Traumatic Brain Injury/Psychological Health (TBI/PH) (Navy)	12.247	0.000	0.000	0.000	0.000	0.000	0.000
CSI-Traumatic Brain Injury/Psychological Health (TBI/PH) (USUHS)	2.637	0.000	0.000	0.000	0.000	0.000	0.000

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CSI-Tuberous Sclerosis Complex (TSC) Research (Army)	6.240	4.972	0.000	0.000	0.000	0.000	0.000
Deployed Warfighter Protection (Army)	5.072	5.173	5.472	5.576	5.691	5.896	5.997
Enroute Care & Advanced Molecular Diagnostics Research & Development (Air Force)	0.000	3.264	6.000	4.800	4.500	4.200	4.400
Expeditionary Medicine, Directed Energy Research & Development (Air Force)	0.000	2.799	5.736	4.906	6.229	5.271	4.474
Force Health Protection, Advanced Diagnostics/Therapeut ics Research & Development (Air Force)	0.000	14.950	12.120	15.796	16.648	17.852	18.991
GDF-Medical Technology Development (GDF-MTD)	84.045	49.478	107.248	150.166	161.729	161.320	160.683
Hard Body Armor Testing (TMA)	0.000	0.829	0.607	0.000	0.000	0.000	0.000

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Human Performance Research & Development (Human Physiology, Evaluation & Optimization) Research (Air Force)	0.000	2.423	4.400	3.800	3.800	5.700	5.871
Medical Development (Lab Support) (Navy)	33.353	33.589	35.453	36.134	36.888	38.236	38.882
NMRC Bio Defense Research Directorate (BDRD) (Navy)	1.365	0.000	0.000	0.000	0.000	0.000	0.000
OCO-Body Blood Flow Monitor (TRF FROM JIEDDO)(Army)	8.775	0.000	0.000	0.000	0.000	0.000	0.000
Operational Medicine Research & Development (Air Force)	7.556	8.013	5.267	5.049	3.965	3.376	3.277
Regenerative Medicine (USUHS)	6.825	6.961	7.365	7.504	7.657	7.929	8.062
Underbody Blast Testing (TMA)	0.000	14.820	13.142	11.614	5.353	0.000	0.000
USAF Advanced Diagnostics & Therapeutics (Air Force)	6.728	0.000	0.000	0.000	0.000	0.000	0.000

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USAF Center for Advanced Molecular Diagnostics (CAMD) (Air Force)	4.333	0.000	0.000	0.000	0.000	0.000	0.000
USAF Directed Energy Injury/Human Effects (Air Force)	1.073	0.000	0.000	0.000	0.000	0.000	0.000
USAF Human Physiology, Systems Integration, Evaluation & Optimization Research (Air Force)	6.497	0.000	0.000	0.000	0.000	0.000	0.000

A. MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: For the Navy Bureau of Medicine and Surgery, this program element includes RDT&E,DHP funds for operating and miscellaneous support costs at RDT&E,DHP laboratories and other installations, facility and civilian personnel costs not directly chargeable to RDT&E,DHP projects. Also includes RDT&E, DHP funds for RDT&E, DHP laboratories and facilities for research, support, equipment and other investment and material support costs not directly chargeable to RDT&E, DHP projects. This excludes military manpower and related costs, non-RDT&E base operating costs, and military construction costs which are included in other appropriate programs.

Medical Development - Costs related to laboratory management and overhead or salaries of government employees are paid from science/research competitively awarded funding. The OCNIOUS laboratories conduct focused medical research on vaccine development for Malaria, Diarrhea Diseases, and Dengue Fever. In addition to entomology, HIV studies, surveillance and outbreak response under the GEIS program and risk assessment studies on a number of other infectious diseases that are present in the geographical regions where the laboratories are located. The CONUS laboratories conduct research on Military Operational Medicine, Combat Casualty Care, Diving and Submarine Medicine, Infectious Diseases, Environmental and Occupational Health, Directed Energy, and Aviation Medicine and Human Performance.

CSI - Hyperbaric Oxygenation (HB02) for Chronic, Mild Traumatic Brain Injury (TBI) Clinical trial entails the development, initiation, operation, and analysis, including publication, from a multi-center, prospective, randomized controlled trial comparing multiple outcomes of enrolled subjects more than four months after mild to

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moderate traumatic brain injury, exposed to a series of daily hyperbaric oxygen sessions or to sham hyperbaric chamber exposures. The project will compare and assess the long-term benefit of hyperbaric oxygen therapy on service members with mild traumatic brain injury.

CSI - Global HIV/AIDS Prevention -The strategy for the FY 2011 CSI is to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at intramural and extramural research sites. The HIV/AIDS Prevention program conducts on-site visits to determine eligible areas for technical assistance and resource support. HIV/AIDS provides support to defense forces in the following areas: (1) HIV prevention, which includes training of medical personnel and peer educators, education of military members, provision of condoms and other prevention materials, provision of educational materials such as brochures, posters, and booklets (2) care for HIV-infected individuals and their families to include provision of electronic medical record programs, medications to treat HIV-related issues, physician education, and clinic infrastructure support, (3) treatment services including provision of laboratory services such as HIV test kits, and other laboratory equipment, and (4) Strategic Information including systems to collect information on the effectiveness of HIV treatment and prevention programs and generate databases of such information to guide treatment and prevention programs. Because of the CSI annual structure, out-year funding is not programmed.

OCO - EMF Blast Pulse Effects (TRF from JIEDDO)- (Breacher Injury Program (Navy) - The breacher injury program focuses on identifying occupational risks associated with exposure to repetitive low level blast, particularly that experienced by personnel who conduct explosive breaching, in both training and operational paradigms. Because highest degree of risk is currently indicated with chronic exposure (100s of events), this program also develops operationally relevant medical and blast exposure surveillance methodologies for transition to occupational medicine units with responsibility for breaching personnel.

Funding in this program element supports the Air Force Surgeon General's vision for medical modernization through a robust research & development program. It funds advanced technology development within the following research thrust/project areas: Expeditionary Medicine, En-Route Care, Force Health Protection, Operational Medicine, and Human Performance. For efforts supported by this program element, research is pursued with the intent to support solutions that answer Air Force specific needs. During this process, the efforts of other government agencies in those areas is assessed to avoid redundancy.

For the Army Medical Command, four Centers of Excellence (CoE) receive Medical Technology Development PE 0603115 funds to include:

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The Breast CoE (Army) provides a multidisciplinary approach as the standard of care for treating breast diseases and breast cancer.

The Gynecological CoE (Army) focuses on characterizing the molecular alterations associated with benign and malignant gynecologic disease and facilitates the development of novel early detection, prevention and novel biologic therapeutics for the management of gynecologic disease.

The Integrative Cardiac Health Project (ICHP) CoE (Army) uses cutting edge patient centric approaches for comprehensive cardiac event prevention as well as molecular research to detect cardiovascular disease at an early stage, to find new genes that significantly increase risk for heart attack in Service members, and identify molecular markers of obesity and weight loss.

The Pain CoE (Army) examines the relationship between acute and chronic pain and focuses on finding, implementing, and evaluating the most effective methods of relieving the acute pain caused by combat trauma and the effect this has throughout the continuum to rehabilitation and reintegration.

For the Army Medical Command, the Armed Forces Pest Management Board (AFPMB) Deployed Warfighter Protection project provides for the development of new or improved protection of ground forces from disease carrying insects.

The Army Medical Command received DHP Congressional Special Interest (CSI) directed research funding for FY11 and FY12. The strategy for the Congressionally directed research is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. Specific FY11 research efforts include the Armed Forces Institute of Regenerative Medicine (AFIRM); Amyotrophic Lateral Sclerosis (ALS); Autism Research; Blast Recovery Monitors; Bone Marrow Failure Research; Gulf War Illness Peer Reviewed Research; Multiple Sclerosis; Muscular Dystrophy; Ovarian Cancer Research; Pain Management Task Force; Peer Reviewed Breast Cancer Research; Peer Reviewed Medical Research Program; Peer Reviewed Prostate Cancer Research; Peer Reviewed Alzheimer Research; Peer Reviewed Cancer Research Program; Peer Reviewed Orthopedic Research; Peer Reviewed Spinal Cord Research; Peer Reviewed Vision Research; Research In Alcohol/Substance Use Disorders; Traumatic Brain Injury/Psychological Health (TBI/PH); and Tuberous Sclerosis Complex (TSC).

The Army Medical Command FY12 Congressional Special Interest (CSI) directed research funding focuses on Amyotrophic Lateral Sclerosis (ALS); Autism Research; Bone Marrow Failure Research; Duchenne Muscular Dystrophy; Gulf War Illness Peer Reviewed Research; Multiple Sclerosis; Peer Reviewed Alzheimer Research; Peer Reviewed Breast Cancer Research; Peer Reviewed Cancer Research Program; Peer Reviewed Lung Cancer Research; Peer Reviewed Orthopedic Research; Peer

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Reviewed Ovarian Cancer Research; Peer Reviewed Vision Research; Peer Reviewed Prostate Cancer Research; Peer Reviewed Spinal Cord Research; Peer Reviewed Medical Research Program; Research In Alcohol and Substance Use Disorders; Tuberous Sclerosis Complex (TSC); Traumatic Brain Injury and Psychological Health; Peer Reviewed Hemorrhage Control Research; Peer Reviewed Restorative Transplantation Research; and Joint Warfighter Medical Research.

Because of the CSI annual structure, out-year funding is not programmed.

For the Uniformed Services University of the Health Sciences (USUHS), Medical Development programs include the Neuroscience Center of Excellence, the Prostate Cancer Center of Excellence, and the Center for Neuroscience and Regenerative Medicine.

For the Uniformed Services University of the Health Sciences (USUHS), the Neuroscience Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 2002 to conduct basic, clinical and translational research studies of militarily relevant neurological disorders affecting U.S. service members and military medical beneficiaries. The Center's mission is to improve prevention, diagnosis and treatment of neurological disorders that directly affect warfighters through a multi-site research program that collaborates broadly with military, civilian and federal medical institutions.

For the Uniformed Services University of the Health Sciences (USUHS), the Prostate Cancer Center of Excellence (CoE), formerly a Congressional Special Interest program, was chartered in 1992 to conduct basic, clinical and translational research programs to combat diseases of the prostate. The program's mission is fulfilled primarily through its three principal programs- the Clinical Translational Research Center, the Basic Science Research Program and the Tri-Service Multicenter Prostate Cancer Database which encompasses its clinical research work with other participating military medical centers. These affiliated sites contribute data and biospecimens obtained from prostate cancer patients and participate in clinical trials.

For the Uniformed Services University of the Health Sciences (USUHS), the Center for Neuroscience and Regenerative Medicine (CNRM) brings together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to traumatic brain injury (TBI) research. CNRM Research Programs emphasize aspects of high relevance to military populations, with a primary focus on patients at the Walter Reed National Military Medical Center.

Guidance for Development of the Force - Medical Technology Development provides funds for promising candidate solutions that are selected for initial safety and efficacy testing in small scale human clinical trials regulated

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by the U.S. Food and Drug Administration prior to licensing for human use. Research in this PE is designed to address the following: areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the strategy and initiatives described in the Quadrennial Defense Review. Program development and execution is peer-reviewed and fully coordinated with all of the Military Services, appropriate Defense Agencies or Activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established for the Defense Health Program, Research Development Test and Evaluation (RDT&E) funding. Research supported by this PE includes, polytrauma and blast injury, rehabilitation, diagnosis and treatment of brain injury, operational health and performance, psychological health and well-being for military personnel and families, decision support tools and physiological modeling, and medical simulation and training.

The Hard Body Armor project focuses on scientific study and evaluation of injuries related to blunt trauma events on cadavers. Preventing blunt trauma injury is one of the critical components of body armor design.

The Underbody Blast Testing project provides funds to establish a scientific and statistical basis for evaluating injuries to vehicle occupants during Underbody Blast (UBB) events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human tolerance limits and injury mechanisms needed to accurately predict injuries, including skeletal and soft tissues, to ground combat vehicle occupants caused by UBB events.

B. PROGRAM CHANGE SUMMARY:

	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>
FY13 Budget Estimate RDT&E	721.959	181.042	236.332	279.453
	0.000	0.000	0.000	0.000
Change Proposal	0.000	0.000	2.778	2.988
Congressional Special Interest	0.000	540.100	0.000	0.000
Realignment	0.000	0.000	0.000	0.000
Reprogramming	1.400	0.000	0.000	0.000
SBIR	-0.035	-17.829	0.000	0.000
FY13 Budget Submission RDT&E	723.324	703.313	239.110	282.441

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PROGRAM CHANGE SUMMARY EXPLANATION:

FY 2011: Congressional Special Interest increase to DHP RDT&E, PE 0603115-Medical Technology Development for NMRC Bio Defense Research Directorate (BDRD) (Navy) (+\$1.400 million).

SBIR Transfer from DHP RDT&E, PE 0603115-Medical Technology Development (-\$0.035 million) to DHP RDT&E, PE 0605502 - Small Business Innovation Research (SBIR) program (+\$0.035 million).

FY 2012: Congressional Special Interest increases to DHP RDT&E, PE 0603115 - Medical Technology Development (total of +\$540.100 million) as follows: Peer-Reviewed Amyotrophic Lateral Sclerosis (ALS) (+\$6.400 million); Peer-Reviewed Autism Research (+\$5.100 million); Peer-Reviewed Bone Marrow Failure Disease Research Program (+\$3.200 million); Peer-Reviewed Duchenne Muscular Dystrophy (+\$3.200 million); Peer-Reviewed Gulf War Illness Research Program (+\$10.000 million); Peer-Reviewed Multiple Sclerosis (+\$3.800 million); Peer-Reviewed Alzheimer Research (+\$12.000 million); Peer-Reviewed Breast Cancer Research Program (+\$120.000 million); Peer-Reviewed Cancer Research Program (+\$12.800 million); Peer-Reviewed Lung Cancer Research Program (+\$10.200 million); Peer-Reviewed Orthopedic Research Program (+\$30.000 million); Peer-Reviewed Ovarian Cancer Research Program (+\$16.000 million); Peer-Reviewed Vision Research (+\$3.200 million); Peer-Reviewed Prostate Cancer Research Program (+\$80.000 million); Peer-Reviewed Spinal Cord Research Program (+\$9.600 million); Peer-Reviewed Medical Research Program (+\$50.000 million); Peer-Reviewed Research in Alcohol and Substance Use Disorders (+\$4.500 million); Peer-Reviewed Tuberous Sclerosis Complex (TSC) (+\$5.100 million); Peer-Reviewed Traumatic Brain Injury and Psychological Health (+\$86.000 million); Peer-Reviewed Hemorrhage Control Research (+\$6.000 million); Peer-Reviewed Restorative Transplantation Research (+\$15.000 million); Joint Warfighter Medical Research (+\$40.000 million); and Global HIV/AIDS Prevention (+\$8.000 million).

SBIR Transfer from DHP RDT&E, PE 0605013 - Information Technology Development (-\$17.829 million) to DHP RDT&E, PE 0605502 - Small Business Innovation Research (SBIR) program (+\$17.829 million).

FY 2013: Change Proposal for inflation adjustment to DHP RDT&E, PE 0603115-Medical Technology Development (+\$2.778 million).

FY 2014: Change Proposal for inflation adjustment to DHP RDT&E, PE 0603115-Medical Technology Development (+\$2.988 million).

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C. OTHER PROGRAM FUNDING SUMMARY:

	<u>FY 2011</u> <u>Estimate</u>	<u>FY 2012</u> <u>Estimate</u>	<u>FY 2013</u> <u>Estimate</u>	<u>FY 2014</u> <u>Estimate</u>	<u>FY 2015</u> <u>Estimate</u>	<u>FY 2016</u> <u>Estimate</u>	<u>FY 2017</u> <u>Estimate</u>
DHP Operation & Maintenance	18.400	19.544	20.134	20.743	21.370	22.015	22.555
BA-1, PE 0806721	8.000	8.244	8.495	8.755	9.022	9.297	9.455
BA-1, PE 0807714	10.400	11.300	11.639	11.988	12.348	12.718	13.100

D. ACQUISITION STRATEGY: Mature and demonstrate safety and effectiveness of medical procedures, medical devices, and drug and vaccine candidates intended to prevent or minimize effects from battlefield injuries, diseases, and extreme or hazardous environments. Milestone A packages will be developed to transition promising products into advanced development.

E. PERFORMANCE METRICS:

Prostate Cancer Center of Excellence: Performance is judged on the amount of extramural funding received, the number of active protocols, the number of articles that appear in peer reviewed journals, and the number of contact hours in support of the training of residents and fellows in the Military Health System.

Center for Neuroscience and Regenerative Medicine: In FY10 through FY12, identify, design protocols, perform scientific and program reviews, and conduct research in Clinical Core activities such as Phenotyping, Imaging and Imaging Analysis, to aid in patient diagnosis and evaluation.

The benchmark performance metric for transition of research conducted with Medical Technology Development funding will be the attainment of maturity level that is typical of TRL 6 or the equivalent for knowledge products.