



Congressionally Directed Medical Research Programs (CDMRP)

Overview of CDMRP and the Gulf War Illness Research Program

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GWIRP Program Manager, CDMRP

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¹ The views expressed in this presentation are those of the author and do not reflect the official policy of the Department of the Army, Department of Defense, or U.S. Government.



CDMRP Partnerships

Consumers

- ◆ Demonstrate need
- ◆ Participate at all levels
- ◆ Passion and perspective
- ◆ In touch with a network of other consumers

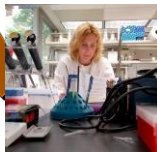


Congress

- ◆ Add funds to budget
- ◆ Targeted guidance
- ◆ Opportunity to leverage

Researchers

- ◆ Innovation and gaps
- ◆ Risk/Benefit
- ◆ Product-oriented



DOD

- ◆ Program management
- ◆ Regulatory and budget requirements
- ◆ Institute of Medicine (IOM) model

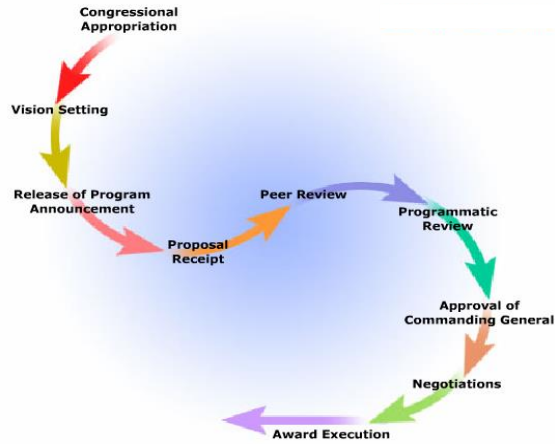
IMPROVE HEALTH (CURE)

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CDMRP Program Cycle



Fiscal Year 2013 (FY13) Funding

Program	Appropriations (\$M)
Amyotrophic Lateral Sclerosis Research Program (ALSRP)	\$7.5
Autism Research Program (ARP)	\$6.0
Bone Marrow Failure Research Program (BMFRP)	\$3.2
Breast Cancer Research Program (BCRP)	\$120
Duchenne Muscular Dystrophy Research Program (DMDRP)	\$3.2
Gulf War Illness Research Program (GWIRP)	\$20
Lung Cancer Research Program (LCRP)	\$10.5
Multiple Sclerosis Research Program (MSRP)	\$5.0
Neurofibromatosis Research Program (NFRP)	\$15
Ovarian Cancer Research Program (OCRP)	\$20
Peer Reviewed Cancer Research Program (PRCRP)	\$15
Peer Reviewed Medical Research Program (PRMRP)	\$50
Peer Reviewed Orthopaedic Research Program (PRORP)	\$30
Prostate Cancer Research Program (PCRP)	\$80
Spinal Cord Injury Research Program (SCIRP)	\$30
Tuberous Sclerosis Complex Research Program (TSCRCP)	\$6.0





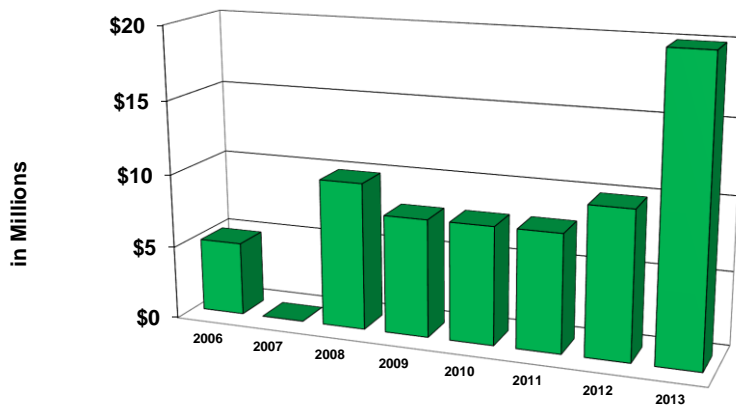
Gulf War Illness Research Program

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DOD Congressionally Directed Medical Research Programs



Gulf War Illness Research Program (GWIRP) Funding



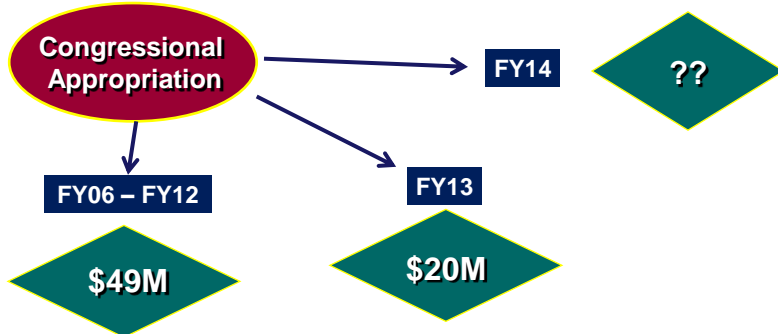
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GWIRP Synopsis



- ◆ 471 Pre-Applications Received
- ◆ 182 Full Submissions
- ◆ 57 Awards

- ◆ 5 Program Announcements released
- ◆ 11-12 awards anticipated

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FY08 National Defense Authorization Act

HR 1585 Conferees directed the Secretary of the Army to utilize the authorized funding... to undertake research on Gulf War Illnesses. Conferees also directed that activities under the Gulf War Illnesses program include:

- ◆ Studies of treatments for the complex of symptoms known as “Gulf War Illness”
- ◆ No studies based on psychiatric illness and psychological stress as the central cause
- ◆ Competitive selection and peer review to identify research with the highest technical merit and military value

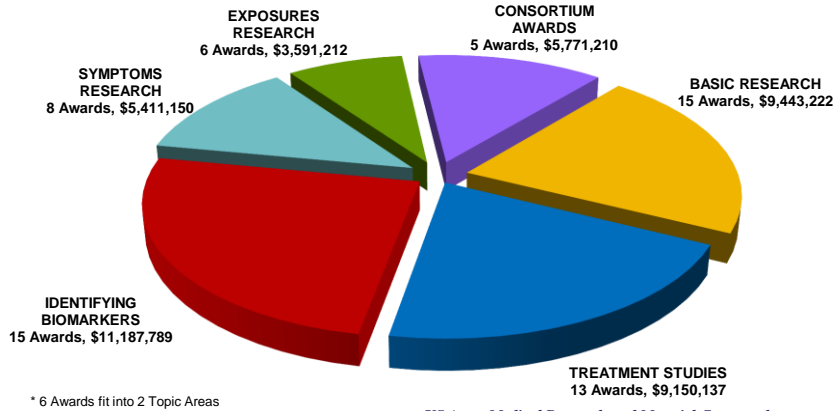
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GWIRP Portfolio

FY06-FY12 Funding by Topic Area (n = 62*)



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Basic Research

- ◆ GW080138, Shoffner, John, Georgia State University, IIRA, Mechanisms of Mitochondrial Defects in Gulf War Syndrome, \$440,674
- ◆ GW080152, Klimas, Nancy, VA Medical Center, Miami, FL, IIRA, The Use of Comprehensive Molecular Profiling with Network and Control Theory to Better Understand GWI and Model Therapeutic Strategies, \$715,456
- ◆ GW093005, Sopori, Mohan, Lovelace Biomedical & Environmental Research, IIRA, Neuroimmune Interactions, Low-Dose Sarin Inhalation, and Gulf War Syndrome, \$1,247,998

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Exposure Research

- ◆ **GW060012, Sullivan, Kimberly, Boston University School of Medicine, IIRA, Structural MRI and Cognitive Correlates in Pest-Control Personnel from Gulf War I, \$208,353**
- ◆ **GW060050, Morris, Mariana, Wright State University, IIRA, Autonomic Biomarkers and Treatment for Gulf War Illness, \$687,530**
- ◆ **GW080094, Crawford, Fiona, Roskamp Institute, IIRA, Identification of Biological Pathways Implicated in Hippocampal Dysfunction and Cognitive Impairment in Gulf War Illness, \$894,000**

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Identifying Biomarkers Research

- ◆ **GW080053, Baraniuk, James, Georgetown University, IIRA, Exercise-Induced Cerebrospinal Fluid Proteomic Biomarkers of Fatigue, \$921,000**
- ◆ **GW080080, Bach, Ronald, VA Medical Center, Minneapolis, MN, IIRA, Biomarkers of Gulf War Veterans' Illnesses: Tissue Factor, Chronic Coagulopathy, and Inflammation, \$653,460**
- ◆ **GW110044, Younger, Jarred, Stanford University IIRA, Identifying Immune Drivers of Gulf War Illness Using a Novel Daily Sampling Approach, \$900,642**

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Symptom Research

- ◆ GW080156, Zuraw, Bruce, Veterans Medical Research Foundation San Diego, IIRA, Epithelial Cell TRPV1-Mediated Airway Sensitivity as a Mechanism for Respiratory Symptoms Associated with Gulf War Illness, \$842,400
- ◆ GW093043, Tuteja, Ashok, VA Medical Center, Salt Lake City, Utah, IIRA, Probiotic (Bifidobacterium Infantis) for Gulf War Illness, \$466,260
- ◆ GW093049, Oaklander, Anne Louise, Massachusetts General Hospital, IIRA, Undiagnosed Small Fiber Polyneuropathy: Is It a Component of Gulf War Illness?, \$929,224

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Treatment Research

- ◆ GW080059, Conboy, Lisa, New England School of Acupuncture, Inc., CTA, Effectiveness of Acupuncture in the Treatment of Gulf War Illness, \$1,015,733
- ◆ GW080064, Meggs, William, East Carolina University, CTA, Trial of Naltrexone and Dextromethorphan for Gulf War Veterans' Illness, \$1,063,641
- ◆ GW100054, Rabago, David, University of Wisconsin, Madison, ITEA, Nasal Irrigation for Chronic Rhinosinusitis and Fatigue in Patients with Gulf War Syndrome, \$668,072

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GWIRP FY12 Award Mechanisms

- ◆ **Clinical Trial Award (CTA)**
 - ❖ Supports substantive clinical trials focusing on GWI treatments
 - ❖ CTA with Multiple PI Option supports up to 3 collaborating PIs
- ◆ **Consortium Award (CA)**
 - ❖ Supports multi-institutional consortium for GWI research
- ◆ **Innovative Treatment Evaluation Award (ITEA)**
 - ❖ Supports exploratory or small-scale studies evaluating treatments not previously studied in GWI
- ◆ **Investigator-Initiated Research Award (IIRA)**
 - ❖ Supports new ideas in basic and clinical developmental research



FY12 GWIRP Awards – Consortium



Kimberly Sullivan, Ph.D.
Boston University Medical Campus
Brain-Immune Interactions as the Basis of Gulf War Illness (GWIC)

Mariana Morris, Ph.D.
NOVA Southeastern University
Understanding Gulf War Illness: An Integrative Modeling Approach





FY12 GWIRP Awards – IIRAs

Michelle Block, Ph.D.
Virginia Commonwealth University

Brian Cooper, Ph.D.
University of Florida

Beatrice Golomb, M.D., Ph.D.
University of California, San Diego

Lisa Pierce, Ph.D.
Tripler Army Medical Center.



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GWIRP FY13 Proposed Priority Areas

- ◆ Identification of effective treatments for GWI
- ◆ Improved diagnostic testing for GWI
- ◆ Improved understanding of GWI pathobiology



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FY13 GWIRP Investment Strategy

Award Mechanism	Award Value	Award Duration	Anticipated Number of Awards
Clinical Trial Development Award	\$100,000	1 year	1 - 2
Investigator-Initiated Research Award	\$600,000	3 years	3 - 5
Innovative Treatment Evaluation Award	\$450,000	3 years	3
Clinical Trial Award	\$1,500,000	4 years	2 - 3
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CTA w/Multiple PI Option	\$4,500,000 (max)	4 years	1

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FY13 GWIRP Integration Panel Members

Gudrun Lange, Ph.D., Chair
U.S Department of Veterans Affairs

Rogene Henderson, Ph.D.
Lovelace Respiratory Institute

Roberta F. White, Ph.D., Chair Emeritus,
Boston University

Major Carlos Maldonado, Ph.D.
David Grant USAF Medical Center

Daniel Havlicek, M.D.
University of Michigan

K. Jeffrey Myers, M. D.
U.S. Department of Veterans Affairs

Anthony Hardie
Veterans of Modern Warfare

David Winnett
Veterans for Common Sense

Suzanne Vernon, Ph.D.
CFIDS Association of America

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Questions?

