VA-ORD GULF WAR RESEARCH : Research Program Overview

Presented to:
Research Advisory Committee on Gulf War Veterans’ Illnesses

VHA OFFICE OF RESEARCH AND DEVELOPMENT / Victor Kalasinsky and Robert Jaeger
April 20, 2017
Boston, MA
MISSION:
To discover knowledge and create innovations that advance health care for our Veterans and our Nation.

VISION:
To be the premier research organization leading our Nation’s efforts to enhance the health and well-being of Veterans by developing evidence-based clinical care and delivery systems improvements.

• 116 VAMCs have capacity for research
  – More than 90 are funded by VA at any time

• More than 2,400 Office of Research and Development (ORD)-funded projects

• Community of more than 3,000 VA researchers with a long history of significant research

• Broad, extensive research portfolio that balances the needs of all Veterans
Gulf War Research – Requests for Applications (RFAs)

**Biomedical Laboratory Research & Development (BLR&D):**
BX-17-011
Award for Research on Gulf War Veterans’ Illnesses (GWVI)
BX-17-012
Pilot Projects for Research on Gulf War Veterans’ Illnesses (GWVI)

**Clinical Science Research & Development (CSR&D):**
CX-17-011
Award for Research on Gulf War Veterans’ Illnesses (GWVI)
CX-17-012
Pilot Projects for Research on Gulf War Veterans’ Illnesses (GWVI)
CX-17-013
Award for Research on Treatments for Gulf War Veterans’ Illnesses (GWVI) – (clinical trial)

**Health Services Research & Development (HSR&D):**
HX-17-012
Targeted Solicitation for Service-Directed Research Award on Health Services Research on the Care of Gulf War Veterans
VA Office of Research and Development

• VA research is driven by improving health care for all Veterans
  – Investigator-initiated research (Clinician Researchers)
    • Pilot projects
    • Merit review
    • Clinical Trials
    • Career Development Awards
  – Service-directed research
  – Cooperative Studies Program (CSP)

• Public Access to Information about VA/ORD funded research
  – http://clinicaltrials.gov Information on current and past clinical trials
  – http://projectreporter.nih.gov/ Information on current and previously funded research projects
  – http://www.ncbi.nlm.nih.gov/pubmed Published results of research studies
VA Office of Research and Development Application Process

• The clinicians and researchers who treat and interact with ill Gulf War Veterans seeking care in VA Hospitals and Medical Centers are the best and most qualified individuals to propose the research that might be most beneficial to ill Gulf War Veterans.

• ORD invites VA intramural researchers to submit proposals for Gulf War research using the mechanism of “Requests for Applications” (RFAs).

• Since 2011, these RFAs have been issued by ORD twice per year on a consistent basis.

• VA/ORD has a specific Merit Review Panel, with expertise in Gulf War issues, to insure high quality, independent, and unbiased reviews of Gulf War research proposals submitted to ORD.
How ORD selects GWVI projects for funding

ORD sets priorities and communicates these: through Strategic Plan, Budget submission, and Requests For Applications (RFAs)

Average of 30 proposals submitted from researchers embedded in the field

ORD assigns to peer review committee

Proposal evaluated by Merit Review committees - typically ~ 30, largely non-VA, experts (incl. members recommended by RACGWVI)

Is it novel and non-duplicative?

Is it feasible?

Is it well-designed?

Are potential benefits to Veterans clearly delineated, plausible, and worthwhile?

ORD Service Directors analyze the proposals and peer-review critiques

Did peer-review committee feel it was meritorious?

Is it aligned with VA/VHA/ORD priorities?

Is it affordable and are funds available?

~20% of projects are selected for funding. Review panel scores are a major determinant, but ORD can pick projects out of order when needed to address key priorities and balance the portfolio
VA/ORD-Based FACA Committees (Federal Advisory Committee Act)

- **National Research Advisory Council (NRAC)**
  - To provide advice to the Under Secretary for Health and the Secretary of Veterans Affairs on research and development sponsored and/or conducted by the Veterans Health Administration, to include policies and programs of the Research and Development Office

- **Research Advisory Committee on Gulf War Veterans’ Illnesses (RACGWI)***
  - To provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research plans and strategies related to understanding and treating the health consequences of military service in the Southwest Asia theater of operations during the 1990 - 1991 Gulf War
  - Mandated by Congress in 1998; first chartered in January, 2002

- **Genomic Medicine Program Advisory Committee (GMPAC)**
  - To provide advice to the Secretary on the scientific and ethical issues related to the establishment, development, and operation of the Program in order to further VA’s medical research in providing Veterans with Medical care and treatment.
RAC 2016 Recommendations - Status

1. Update GWRSP for 2018 – 2022  
   (IN PROGRESS)

2. Establish coordinated system of centers within VHA  
   (UNDER REVIEW)

3. Seek strategic partnerships, collaboration with non-VA entities (IN PROGRESS)

4. Form a Work Group to identify challenges and solutions to recruitment  
   (IN PROGRESS)

5. Develop an approach to use ICD code(s) for GWI  
   (UNDER REVIEW)
1. Research and clinical sides of VA collaborate more interactively (IN PROGRESS)

2. VA physicians receive GWI training for uniformity of care (IN PROGRESS)

3. Make it easier for Veterans to volunteer for research studies and biobanks (IN PROGRESS)

4. Create a working group for a single case definition for GWI (IN PROGRESS)
5. Re-categorize deployed and non-deployed cohorts recognizing that Operation Desert Storm ended April 11, not March 1, 1991 (IN PROGRESS)

6. Undertake confirmation studies related to genomics (BChE variants; PON1, PON2, PON3; MVP; DoD serum; ALS) (UNDER REVIEW)

7. Follow Veterans closest to Khamisiyah and oil wells (IN PROGRESS for Khamisiyah)

8. Develop larger treatment trials from pilot studies (L-carnosine for IBS; CPAP treatment for GWI) (IN PROGRESS)
# VA-ORD Gulf War Research Funding (2007 – 2016)

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<thead>
<tr>
<th>Fiscal Year (FY)</th>
<th>VA Merit Review</th>
<th>UTSW Contract</th>
<th>FY Total</th>
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<td>2016</td>
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<td>$ 89.09 M</td>
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### Response Statistics for VA-ORD Gulf War Research Requests for Applications (RFAs)

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<tr>
<th>Season</th>
<th>Proposals Received</th>
<th>Projects Funded</th>
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<td>Spring 2017</td>
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<td>Jun 2017</td>
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Gulf War Research Projects Active in 2017 (slide 1 of 3)

Treatments/Clinical Trials

• Impact of exercise training on pain and brain function in Gulf War Veterans (5.1)
• Transcranial, Light-Emitting Diode (LED) Therapy to Improve Cognition in GWVI (5.1)
• Complementary Neurosteroid Intervention in Gulf War Veterans’ Illnesses (5.1)
• Cognitive Rehabilitation Therapy for Gulf War Veterans (5.1)
• Complementary and Alternative Medicine in Veterans with Gulf War Illnesses (5.1)
• RCT of Duloxetine and Pregabalin for the treatment of GWI in Veterans (5.1)
• Healthcare Utilization Patterns and Associated Costs for Gulf War I Era Veterans (5.1)
• WRIISC as a Model of Care for Chronic Multisymptom Illness (5.1)
• Novel Interventions for Gulf War Veterans’ Illnesses (5.1)
• Pilot Test of Telephone-Delivered Cognitive Behavioral Therapy for Insomnia for Veterans with Gulf War Illness (5.1)
• Randomized, Double-blind Placebo-controlled Phase III Trial of Coenzyme Q10 in Gulf War Illness (5.1)
• Evaluation of a Mindfulness-Based Intervention for Gulf War Illness (5.1)
Biomarkers/Mechanisms

- Examination of Cognitive Fatigue in Gulf War Illness Using fMRI (5.5)
- Longitudinal assessment of Gulf War veterans with suspected Sarin exposure (5.4, 5.5)
- Multimodal Biological Assessment of Gulf War Illness (5.5)
- National Health Survey of Persian Gulf Veterans and their Families (5.2)
- Somatic hypersensitivity in Veterans with IBS (5.1)
- Women vs. Men with GWI: Differences in Computational Models and Therapeutic Targets (5.1, 5.4)
- Genomics of Gulf War Illness in Veterans (5.4)
- Post Exertional Malaise in GWI: Brain Autonomic and Behavioral Interactions (5.5)
- A Translational Medicine Approach to Gulf War Illness: From Cells to Therapy (5.5, 5.8)
- Mechanisms of Gulf War Illness (5.1, 5.4)
Model Systems

- Central Mechanisms Modulating Visceral Sensitivity (5.4, 5.6)
- Immunoregulation of Myelin Specific T Lymphocytes (5.4, 5.6)
- Neuroprotection and Myelin Repair Mechanisms in Multiple Sclerosis (5.4, 5.6)
- Sleep Neurobiology and Circuitry (5.4, 5.6)
- Understanding Pain of Gastrointestinal Origin in Women that Serve in OEF/OIF (5.5, 5.6)
- Identification of Plasma Biomarkers of Gulf War Illness Using "omic" Technology (5.5, 5.6)
- Gulf War Exposures and the Molecular Mechanisms of Paternal Reproductive Risk (5.6)
- Novel neurotrophic therapies in an optimized mouse model of GWVI (5.1, 5.6)
- Neuroinflammation, Oxidative Stress, and Hippocampal Defects in GWI (5.5, 5.6)
- Immune Basis for Hippocampal Cholinergic Deficits in Pyridostigmine-treated Rats (5.6)
- Gulf War neurotoxicants and acquired cognitive and neuropsychological dysfunction (5.6)
- Maintenance of Telomerase Activity as a Treatment for Gulf War Illness (5.1, 5.6)
Gulf War Research Projects
Selected for funding in 2017

- Treatments for Sleep Disorders in Gulf War Veterans (5.1)
- Treating Immune dysfunction in GWI (5.6)
- Gulf War Exposures and Neuroinflammation (5.6)
- Evaluating Treatments for Veterans with Chronic Multisymptom Illness (5.1)
Recently Competed Gulf War Research Projects

- Bacterial Overgrowth Associated with Chronic Multi-Symptom Illness Complex (5.1)
- Host Defense Mechanisms in Polyaromatic Hydrocarbon Carcinogenesis (5.5, 5.6)
- Prevention of Hippocampal Neurodegeneration Due to Age and Apnea (5.6)
- Epigenetic Mechanisms Relevant to the Pathogenesis of ALS (5.4, 5.6)
- Nanoparticle Coupled Antioxidants for Respiratory Illness in Veterans (5.1, 5.6)
- Memory and Mood Enhancing Therapies for Gulf War Illness (5.1, 5.6)
- MEG Synchronous Neural Interactions (SNI) in Gulf War Veterans (5.5)
- rTMS for the Treatment of Chronic Pain in GW1 Veterans (5.1)
- Diagnostic Utility of mtDNA Content and Exercise Challenge in Vets with GWI (5.1, 5.4)
- Vascular and Skeletal Muscle Function in Gulf War Veterans Illness (5.1, 5.4)
• **Gulf War Veterans’ Illnesses Biorepository (5.2, 5.4, 5.5)**
  – Began operations – July, 2012
  – Enrolling Veterans to obtain medical records
  – Brain and spinal cord tissue to be collected post-mortem
  – Review of pilot project in November, 2014

• **CSP #585 Gulf War Era Cohort and Biorepository (5.2, 5.4, 5.5)**
  – Deployed and non-deployed Veterans
  – Users of VA health care and non-users
  – Surveys and blood collection
  – September, 2014 – May 2016: enrolled 1276 participants
Gulf War Research Activities
National Academy of Medicine (NAM) Reports
(formerly, Institute of Medicine)

• **Assessment of the Department of Veterans Affairs Airborne Hazards and Open Burn Pit Registry**
  - Jan 2015 – Jan 2017 (First meeting Mar 13, 2015)
  - NAM report, Feb 28

• **Gulf War and Health, Volume 11: Generational Health Effects of Serving in the Gulf War**
  - Sep 2016 – Sep 2018 (First meeting Jan 12, 2017)
Gulf War Research – VA-DoD Coordination

- Regular briefings/updates between Gulf War Program Managers in VA/ORD and DoD/CDMRP
- Periodic review of proposals submitted/funded between agencies
- Annual Report to Congress (jointly with DoD)
- Joint VA/DoD Working Groups (Deployment Health and Medical)
- Participation in CFS Conference and GWI Workshop in Ft. Lauderdale, October 2016
• ILER - A complete record of every Service member’s occupational and environmental exposures over the course of their careers

• Pilot project – currently underway
  – Demonstrate feasibility
  – Develop a prototype

• Link DoD exposure databases to a Service member’s location and dates
  – Available to VA and DoD health care providers
  – Available to VBA adjudicators
QUESTIONS ?
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5.0 GULF WAR RESEARCH STRATEGIC OBJECTIVES 2013-2017
   5.1 Symptomatic and Specific Treatments
   5.2 Databases and Continued Surveillance
   5.3 Establish an Evidence-Based Case Definition …
   5.4 Genetics/Genomics/Systems Biology
   5.5 Biomarkers
   5.6 Animal Models
   5.7 Improve Coordination and Communication with Stakeholders
   5.8 Translate Research Findings to Practice
VA/ORD Gulf War Research Strategic Plan (2018-2022)

• SECTION 1: EXECUTIVE SUMMARY
• SECTION 2: INTRODUCTION AND BACKGROUND
• SECTION 3: GOALS AND OBJECTIVES (or Vision and Mission)
• SECTION 4: PROGRESS, CHALLENGES and OPPORTUNITIES
• SECTION 5: CORE RESOURCES (Cohorts; Data use and management; Technology)
• SECTION 6: CROSS-CUTTING OBJECTIVES (Partnerships; Communication)
• SECTION 7: SCIENTIFIC APPROACHES
  – Genetics/genomics
  – Molecular and cellular mechanisms
  – Systems biology and biological circuits
  – Animal models, physiology, and behavior
  – Clinical research
  – Epidemiology/Continued surveillance
• SECTION 8: CONCLUSIONS
• SECTION 3: GOALS AND OBJECTIVES (or Vision and Mission)

  – Goals (or Vision)
    • Improve the health and well-being of Gulf War Veterans.
    • Utilize emerging knowledge to prevent similar war-related illnesses in the future.

  – Objectives (or Mission)
    • Develop effective treatments for ill Gulf War Veterans
    • Identify biomarkers and improve diagnosis for conditions affecting Gulf War veterans
    • Continue surveillance/health monitoring
• SECTION 7: SCIENTIFIC APPROACHES (or Research Goals) - each with Background, Objectives/Aims (and sub-Aims, if needed), Strategies, Targets/Metrics, and relevant Cross-cutting Objectives/Goals.

  – Genetics/genomics
  – Molecular and cellular mechanisms
  – Systems biology and biological circuits
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## VA/ORD Gulf War Research Strategic Plan (2018-2022)
### Structure Crosswalk

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<td>Epi. missing in old structure, combining w/ surveillance</td>
</tr>
<tr>
<td><strong>VI. Conclusions</strong></td>
<td>Conclusions</td>
<td></td>
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GENERAL TEMPLATE for SECTION 7: SCIENTIFIC GOALS AND OBJECTIVES

A. Select one scientific area from Section 7 (Highlight your selected area):

- Genetics/Genomics
- Molecular and Cellular Mechanisms
- Systems Biology and Biological Circuits
- Animal Models, Physiology, and Behavior
- Clinical Research
- Epidemiology/Continued Surveillance

B. Progress:
What progress has been made in this scientific area as it relates to Gulf War research? Focus attention to recent years and advances since the current GWRSP.

- 

C. Challenges:
What research-related challenges have hampered progress to-date and/or what challenges pose an impediment to future progress in this scientific area?

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D. Opportunities:
What research directions offer the greatest opportunity to make progress in this scientific area as it relates to the GWRSP? Take into consideration timeframe and potential impact, as well as partnerships that may be needed.

- 

E. Scientific Goal(s) and/or Objectives
What are the top goal(s) for your selected scientific area that are achievable by 2022?

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What might be some supporting objectives for each goal? Consider specific outcomes that are actionable and measurable.

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DRAFT TIMELINE

- Apr 11-19    Establish Writing Teams
- Apr 20       Briefing for RAC
- May          First drafts from Writing Teams
- Jun          Second drafts from Writing Teams
- Jul          Combine and edit draft GWRSP
- Jul 24-28    Work Group discuss GWRSP
- Aug          Briefing for RAC
- Aug-Sep      Finalize and submit to VHA
• SECTION 1: EXECUTIVE SUMMARY
• SECTION 2: INTRODUCTION AND BACKGROUND
• SECTION 3: GOALS AND OBJECTIVES (or Vision and Mission)
• SECTION 4: PROGRESS, CHALLENGES and OPPORTUNITIES
• SECTION 5: CORE RESOURCES (Cohorts; Data use and management; Technology)
• SECTION 6: CROSS-CUTTING OBJECTIVES (Partnerships; Communication)
• SECTION 7: SCIENTIFIC APPROACHES
  – Genetics/genomics
  – Molecular and cellular mechanisms
  – Systems biology and biological circuits
  – Animal models, physiology, and behavior
  – Clinical research
  – Epidemiology/Continued surveillance
• SECTION 8: CONCLUSIONS
QUESTIONS?