



CENTER FOR
MILITARY MEDICINE
RESEARCH



“DoD Funding Opportunities for Academic Investigators”

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Medicine

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University of Pittsburgh

12 June 2017

Western Pennsylvania & Pittsburgh



LEADERSHIP | 11/09/2012 @ 11:24AM | 9,156 views

The Best Places For Veterans

- **Pennsylvania:**
4th in the nation in
Veteran and
Military population

The Best Places For Veterans



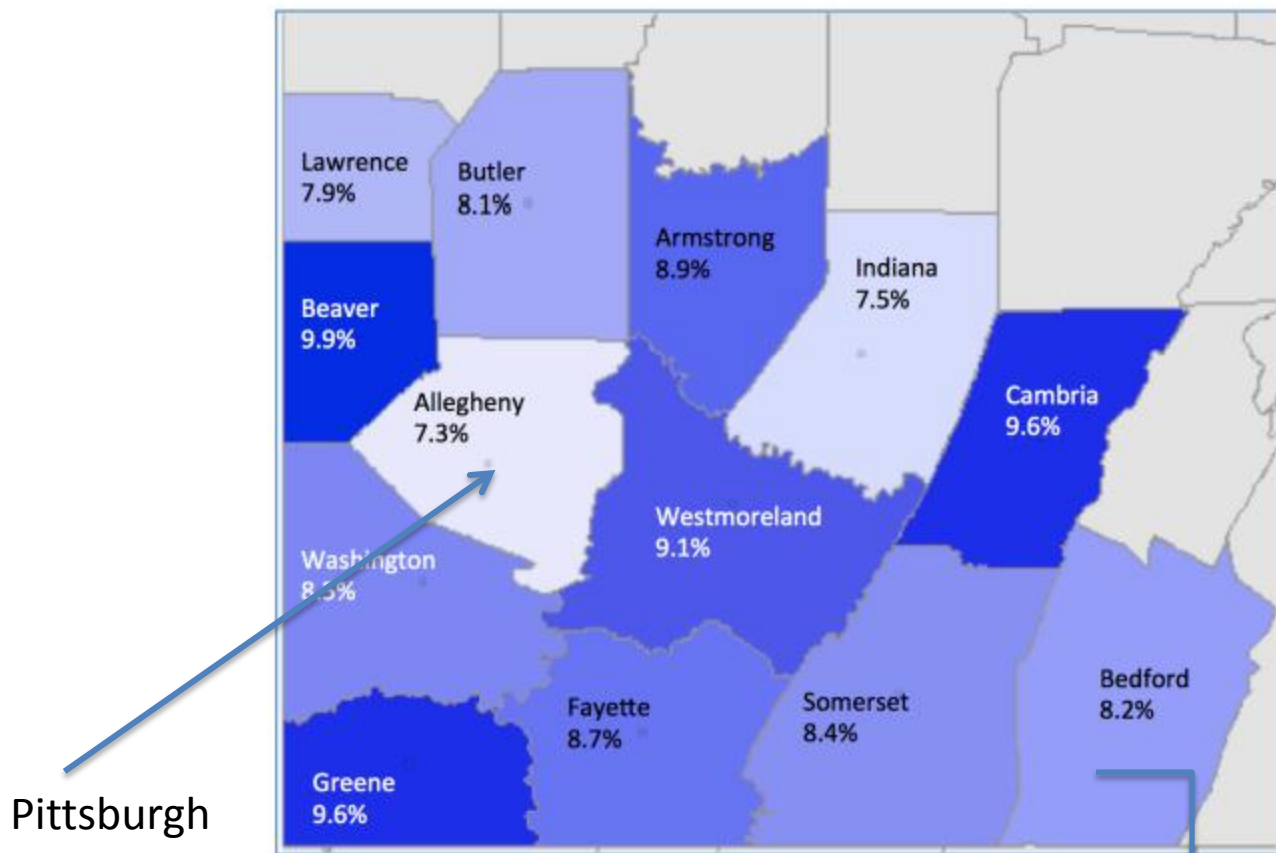
1. Pittsburgh

Population: 2.3 million

Median home price: \$106,500

Median 2BR rent: \$685

Density of Veterans Population Per County In Southwestern Pennsylvania – 13 County average: 8.6% (National average 6.7%)



SW Pennsylvania stands out as one of the densest veterans communities in the nation, with the densest populations existing in the area's rural counties outside of Pittsburgh and Allegheny county.

USUHS/WRNMMC is 230 miles from Pittsburgh



Formally established: June 12, 2012

Mission:

- Support medical research interests of the Departments of Defense and Veterans Affairs
- Organize collaboration among investigators at the University of Pittsburgh to promote forward planning of research initiatives in advance of award announcements to enhance readiness of the University to compete for federal funding
- Develop new research themes in collaboration with DoD investigators



University of Pittsburgh

www.cmmr.pitt.edu

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MEDICINE
RESEARCH**

Key Focus Areas

- **Medical Research**
- **Education**
- **Community Engagement**

CMMR Collaborators at the University of Pittsburgh

- McGowan Institute for Regenerative Medicine
 - Fox Vision Center
 - Safar Center for Resuscitation Research
 - School of Medicine (Neurosurgery; Plastics; Pulmonary; Ophthalmology)
 - School of Health & Rehabilitation Sciences
(Center for Assisted Technology; Neuromuscular Research Lab)
 - School of Nursing
 - Graduate School of Public Health
 - Western Psychiatric Institute and Clinic
 - Brain Institute
 - VA Pittsburgh Health System
- University of Pittsburgh Medical Center (UPMC)

CMMR Collaborators at the University of Pittsburgh

- School of Nursing (Caregiver Stress, Teaching Kids to Cope)
- School of Medicine (Neurosurgery; Plastics; Pulmonary; Ophthalmology)
- School of Health & Rehabilitation Sciences
(Center for Assisted Technology; Neuromuscular Research Lab)
- Graduate School of Public Health (Center for Vaccine Research)
- McGowan Institute for Regenerative Medicine
- Fox Vision Center
- Safar Center for Resuscitation Research
- Western Psychiatric Institute and Clinic
- Brain Institute
- University of Pittsburgh Medical Center (UPMC)



Pre-established Education & Research Agreements

- Navy Medical Research Center, Silver Spring, MD – Education Partnership Agreement (Regenerative Medicine, Rehabilitation & TBI)
- Uniformed Services University of the Health Sciences, Bethesda, MD - Research, Education & Partnership Agreement
- University of Pittsburgh School of Medicine Mini-elective course - “Joining Forces: Military Medicine from the Battlefield to Everyday Practice”
- Formal collaboration with the Institute for Surgical Research, Fort Sam Houston, TX (Combat Casualty Care)



Research Focus

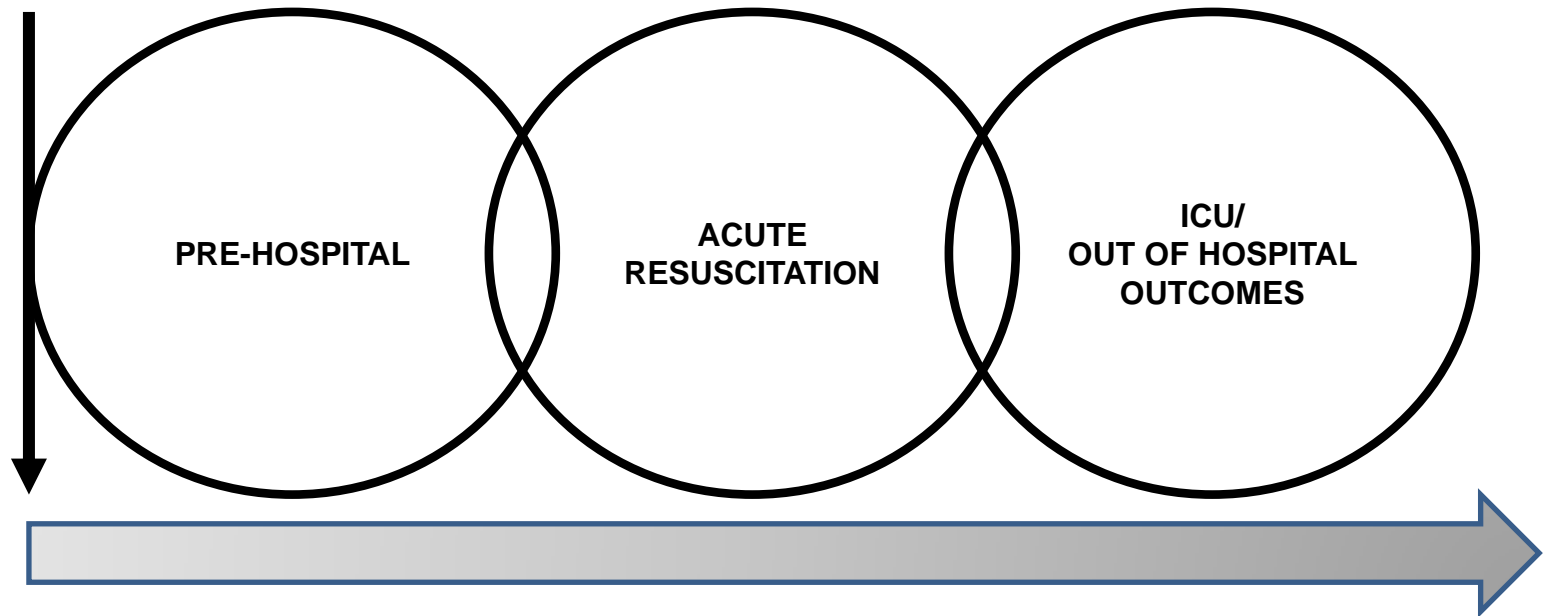
- Traumatic Brain Injury (basic & translational science)
- Human Performance/Injury Prevention
- Regenerative Medicine & Tissue Engineering
- Vision Restoration
- Reconstructive Surgery
- Transplantation Immunology (hand/face transplant)
- Neuroscience and Neuroimaging
- Pulmonary Medicine

Current Collaboration with DoD MTFs



DoD Funded (2016): Linking Investigations in Trauma and Emergency Services (LITES)

Point Of Injury (POI)



LITES

LITES Network



LITES Network Site Pls

TASK ORDER 0001 SITES

University of Pittsburgh
Jason Sperry, MD MPH

University of Colorado
Ernest Moore, MD

Oregon H & S University
Martin Schreiber, MD

University of Texas, Houston
John Holcomb, MD

Vanderbilt University
Rick Miller, MD

University of Arizona
Bellal Joseph, MD

University of Louisville
Brian Harbrecht, MD

Baylor College of Medicine
Robb Todd, MD

ALTERNATE SITES

University of Pennsylvania
Jeremy Cannon, MD

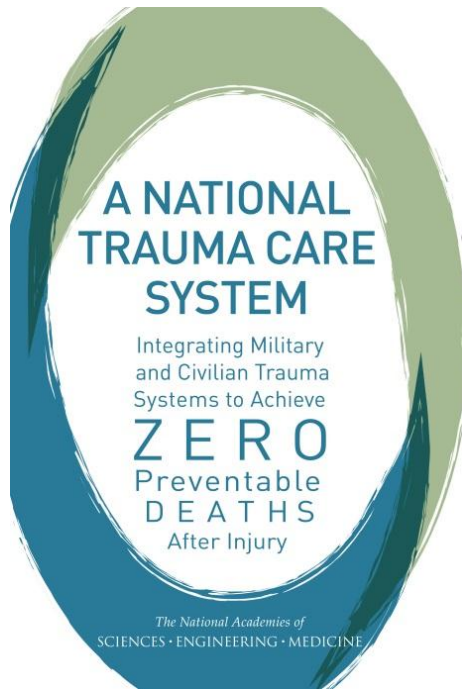
University of Utah
Raminder Nirula, MD

University of Florida
Fredrick Moore, MD

TBD sites

A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury

Report in Brief June 2016



NASEM to help insure lessons learned from the military's experiences in Afghanistan & Iraq are sustained and built on for future combat operations and translated into the civilian system.

Vision for a national trauma care system driven by the clear and bold aim of zero preventable deaths after injury

Opportunity for UPMC/Pitt to provide Trauma Surgery training experience to DoD Surgeons

Suggested citation: National Academies of Sciences, Engineering, and Medicine. 2016. *A national trauma care system: Integrating military and civilian trauma systems to achieve zero preventable deaths after injury*. Washington, DC: The National Academies Press.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE



How does a VA or academic investigator advance DoD research objectives?

Key points:

- DoD focus is the transition of medical technologies into deployed products (less mechanism of action)
- Acquiring DoD funding is a process built on understanding the DoD needs, performance, trust and sustained relationships
- DoD goal is to accelerate new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater or in the clinical facilities of the Military Health System

Military Medical Echelons of Care



Echelons of Care

- Level I
 - Battlefield to Battalion Aid Station
- Level II
 - Forward Surgical Team
 - Replaced the Mobile Army Surgical Hospital (MASH)
- Level III
 - Combat Surgical Hospital (CSH)
 - Air Force Theater Hospital (AFTH)
- Level IV
 - Landstuhl Regional Medical Center (LRMC)
- Level V
 - Stateside – WRAMC, NNMC, BAMC

Comparing Afghanistan

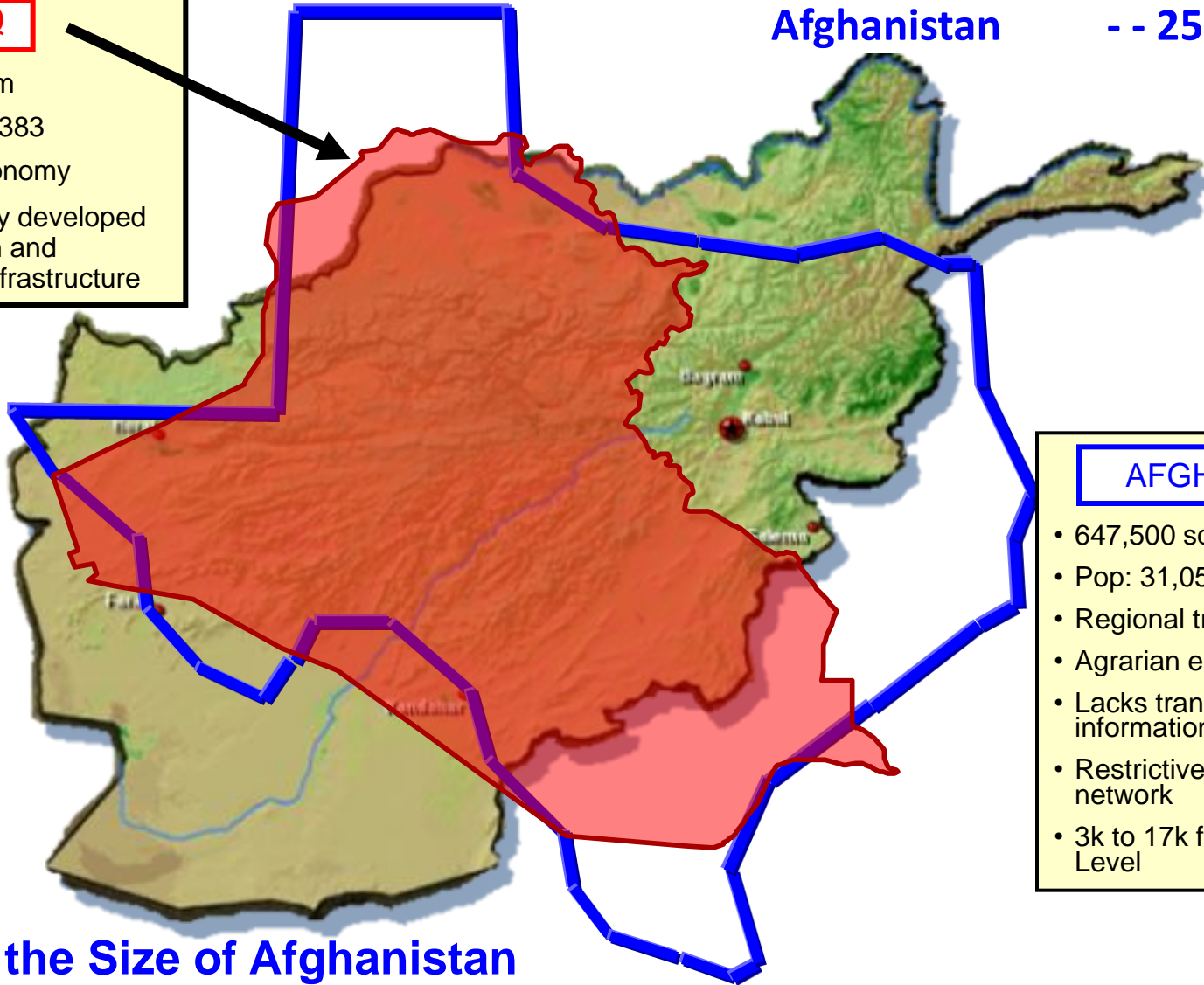
IRAQ

- 432,162 sq km
- Pop: 26,783,383
- Oil sector economy
- Comparatively developed transportation and information infrastructure

Texas
Afghanistan

- - 261,000 Sq Mi

- - 250,000 Sq Mi



AFGHANISTAN

- 647,500 sq km
- Pop: 31,056,947
- Regional tribal society
- Agrarian economy
- Lacks transportation and information infrastructure
- Restrictive terrain and road network
- 3k to 17k ft Above Sea Level

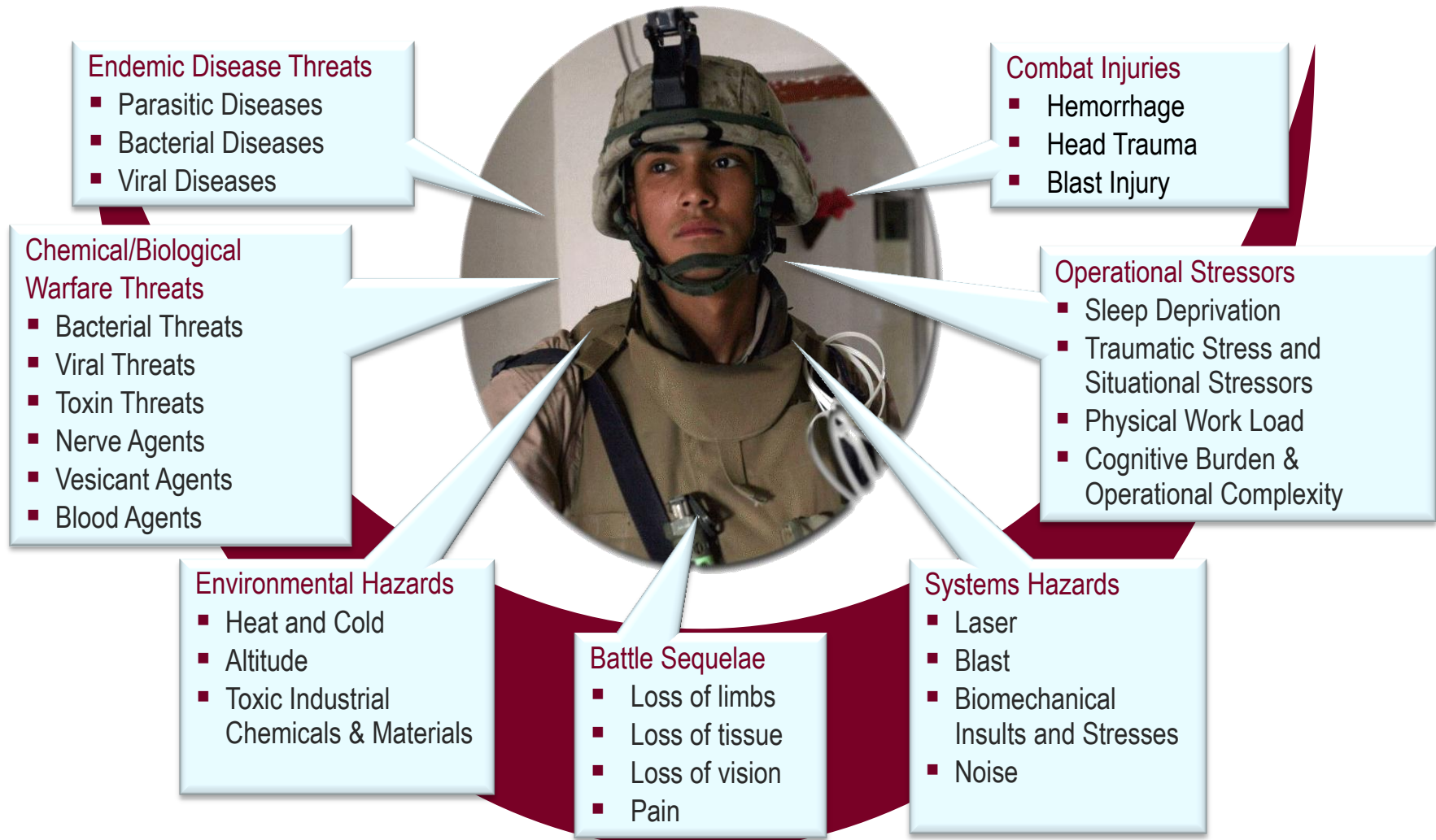
Iraq is 2/3 the Size of Afghanistan

Medical Research in the DoD

- Defense Health Program – largest funding sponsor in DoD
 - Centralized planning and programming of funds
 - Decentralized Execution
 - Leverage Services R&D Management & Science Infrastructure
 - Focus is Joint Force Health Protection
- Army-RDT&E – largest R&D management & science infrastructure
- Navy-RDT&E
- Defense Advanced Research Projects Agency-RDT&E
- Chemical and Biological Defense Program-RDT&E
- Defense-wide-RDT&E
- US Special Operations Command-RDT&E
- Air Force Human Systems-RDT&E

DoD Medical R&D Needs

“Immediate Warfighter Needs”



DoD Acronyms

- DoD – Department of Defense
- MHS – Military Health System
- DHP – Defense Health Program
- DHA – Defense Health Agency
- JPC – Joint Program Committee
- TRL – Technology Readiness Level
- OTA – Other Transaction Authority
- ONR – Office of Naval Research
- USAMRMC – US Army Medical Research & Materiel Command
- Services – Army, Navy, Air Force, Marines

Primary Points of Entry

- [FedBizOpps.Gov](https://www.fedbizopps.gov)
 - Existing Requests for Proposals
- [Grants.Gov](https://www.grants.gov)
 - Program Announcements and Broad Agency Announcements

USAMRMC Funding Opportunities

- Broad Agency Announcement
 - BAA 17-1, October 2016
 - USAMRAA: <http://www.usamraa.army.mil/>
 - FedBizOps: <http://fbo.gov> (keyword search: USAMRMC)
 - <http://www.grants.gov> (Funding No. W81XWH-17-R-BAA1)
 - Continuously Open through September 2017
 - Announcement lists topic areas of current interest
 - Pre-proposals submitted and evaluated continuously
 - Full Proposals undergo **external peer review**

Greatest chance for success is submitting a solicited proposal!



United States Army Medical Research Acquisition Activity USAMRAA

[PRODUCTS](#) | [CUSTOMERS](#) | [ORGANIZATION](#) | [BUSINESS](#) | [REFERENCES](#) | [COMMUNITY](#) | [TOOLS](#) | [LINKS](#) | [SITEMAP](#) |

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- [Assistance Advisory Notices](#)
- [Procurement Advisory Notices](#)
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- [BAA](#)
- [Customer Survey](#)
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- [PRWeb Help](#)

SITE SEARCH

IMPORTANT LINKS

[Center of Excellence](#)
[CMRA](#)
[PRCentral Training Presentations](#)
[HBCU-MI Briefing Presentations](#)
[Advanced Acquisition Forecast \(AAF\)](#)
[Trouble Accessing the USAMRAA website\(s\)](#)
[AbilityOne E-Commerce Website](#)
[\(USAMRMC Base Supply Program\)](#)
[Fort Detrick Contracting Community Portal](#)
[Sample Contract Supporting Documents](#)
[Contract Requirements Matrix](#)
[VCE-COR website](#)
[Vendor Day](#)
[General Guidelines for Awards Funded by the DOD](#)

NEWS

NOTICE TO CONTRACTORS



[Wiki-Leaks Sanitization Procedures](#)

ASSISTANCE AGREEMENT FORM POSTED

SF425 Federal Financial Report and Instructions were posted on 09/21/09.

PROGRAM ANNOUNCEMENT (PA) POSTINGS & UPDATES

For a complete listing of Assistance Agreement Funding Opportunities posted by the U.S. Army Medical Research Acquisition Activity, please see [Grants.gov](#) and perform a search using CFDA# 12.420.

NOTICE: Any assistance instrument awarded under these Funding Opportunities will be governed by the award terms and conditions, which conform to DoD's implementation of OMB circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

SOLICITATIONS POSTINGS & AMENDMENTS

For a complete listing of Solicitations posted by the U.S. Army Medical Research Acquisition Activity, please see [FedBizOpps](#) or the Army Single Face to Industry (ASFI) website and perform a search for W81XWH. Additionally, announcements with J&A's can be found on [FEDRIZOPPS](#) and [ASFI](#).



Federal Business Opportunities

s Opportunities: Home - Windows Internet Explorer

www.fbo.gov/



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Search more than **28,200*** active federal opportunities.

Posted Date:

Set-Aside Code:

Place of Performance: Type:

Keyword / Solicitation #: Agency:

Search

Additional criteria and multiple selections are available on the [advanced search form](#).

** Notices posted within the last 90 days.*



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Grants.gov

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Apply for Grants

Grants.gov provides an overview of the process to APPLY for federal grants. In order to apply for a grant, you and/or your organization must complete the Grants.gov registration process.

[Apply for Grant Opportunities »](#)



Grants.gov Updates:

GRANTS.GOV System Enhancement:
System Outage May 10-12, 2014
Release 12.3.4-SAM Integration & Minor Enhancements

For more information on scheduled maintenance outages and status updates, please visit the following:

[Grants.gov Calendar »](#)

[Grants.gov Blog »](#)

Did You Know?

Did you know that Grants.gov must receive verification of registration from SAM electronically before AORs can submit applications on Grants.gov? Please allow 24-48 hours from the date of the SAM email notification to complete the electronic process. To quickly and easily verify Grants.gov AOR status, [click here](#).

Financial Assistance

Grants.gov does not provide personal financial assistance. To learn where you may find personal financial assistance, please visit [USA.gov](#).

Find Open Grant Opportunities

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Funding Opportunity Number	Opportunity Title	Agency
RFA-MD-14-004	NIMHD Social, Behavioral, Health Services, and Policy Research on Minority Health and Health Disparities (R01)	National Institutes of Health
RFA-MD-14-005	NIMHD Basic and Applied Biomedical Research on Minority Health and Health Disparities (R01)	National Institutes of Health
NNH14ZDA001N-MDAP	ROSES 2014: Mars Data Analysis Program	NASA Headquarters
L14AS00098	CESU, CCS, BLM Arizona, Relict Leopard Frog Conservation Implementation	Bureau of Land Management
USDA-AMS-FMPP-2014	2014 Farmers Market Promotion Program Grants	Agricultural Marketing Service

USAMRMC Funding Opportunities

- The Congressionally Directed Medical Research Programs (CDMRP)

▶ <http://cdmrp.army.mil>



- The Telemedicine and Advanced Research Center (TATRC)

▶ <http://www.tatrc.org>



Congressionally Directed Medical Research Programs (CDMRP)



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2016/2017 Program Announcements

Autism

Duchenne Muscular Dystrophy

Gulf War Illness

Lung Cancer

Neurofibromatosis

Peer Reviewed Medical

NEW Peer Reviewed Cancer

NEW Prostate Cancer

NEW Psychological

Health/Traumatic Brain Injury

Spinal Cord Injury

Tick-Borne Disease

Tuberous Sclerosis Complex

Latest News

PRMRP

Researchers Make a Key Discovery in How Malaria Evades the Immune System [↗](#)
PennState, June 06, 2016

PCRP

Imaging Biomarker Distinguishes Prostate Cancer Tumor Grade [↗](#)
UC San Diego Health, June 01, 2016

CDMRP

Vice President Biden and Dr. Jill Biden Address the Cancer Research Community at the AACR Annual Meeting 2016 [↗](#)
American Association for Cancer Research, April 26, 2016

[More News »](#)



For Investigators

[Open Funding Opportunities »](#)

[eBRAP: Start Pre-application »](#)

[How to Apply »](#)



Funded Research

[Search Awards & Publications »](#)

[Funded Investigators Guide »](#) [↗](#)



Program News & Highlights

[Upcoming Funding Opportunities »](#)

[Research Highlights/News »](#)

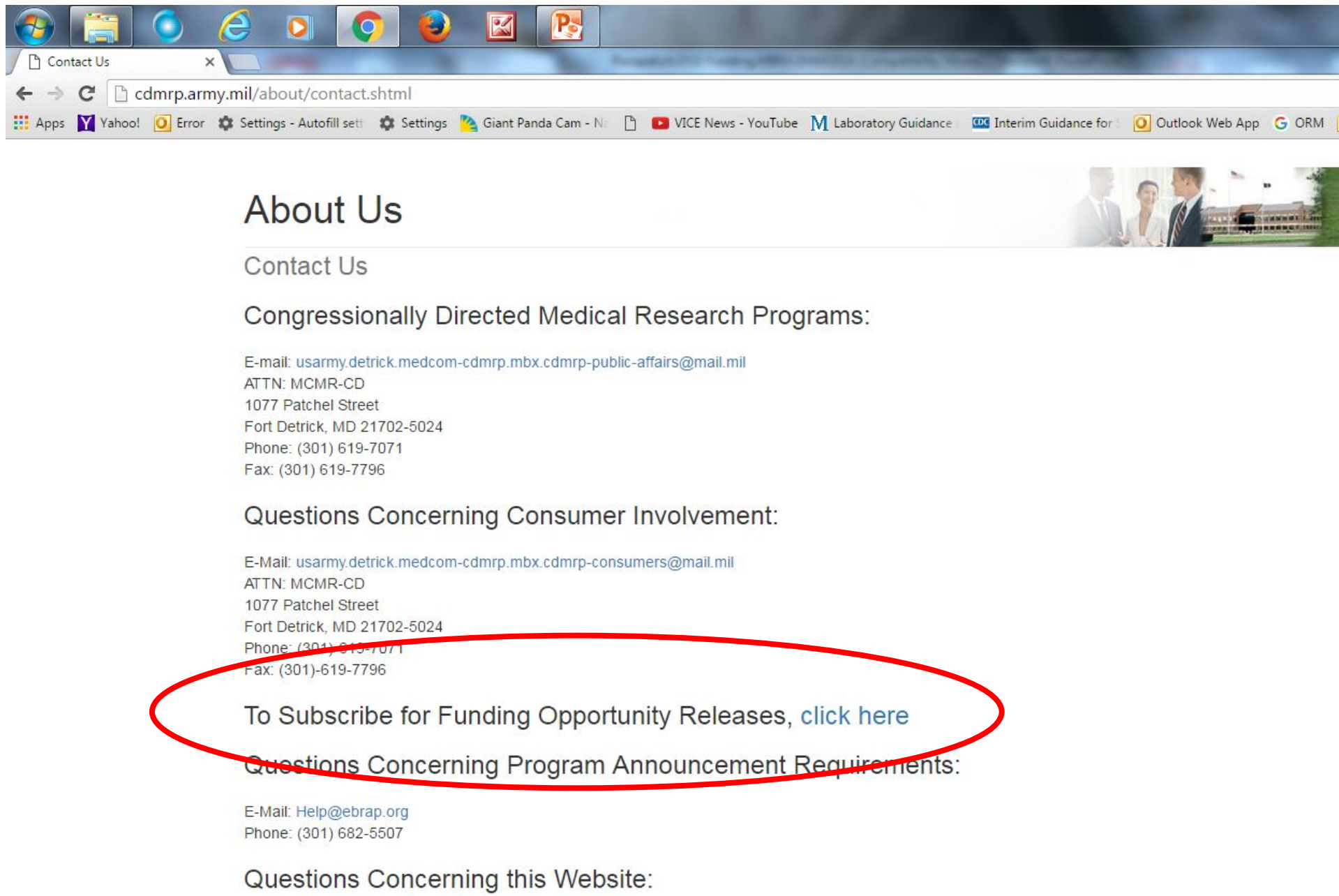
[CDMRP Milestones & Scientific Discoveries »](#)



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Congressionally Directed Medical Research Programs (CDMRP)



The screenshot shows a web browser window with the address bar displaying "cdmrp.army.mil/about/contact.shtml". The page title is "Contact Us". The main heading is "About Us". Below it, the section "Contact Us" is followed by "Congressionally Directed Medical Research Programs:". The contact information for the MCMR-CD is listed: E-mail: usarmy.detrick.medcom-cdmrp.mbx.cdmrp-public-affairs@mail.mil, ATTN: MCMR-CD, 1077 Patchel Street, Fort Detrick, MD 21702-5024, Phone: (301) 619-7071, Fax: (301) 619-7796. Below this, the section "Questions Concerning Consumer Involvement:" is followed by similar contact information: E-Mail: usarmy.detrick.medcom-cdmrp.mbx.cdmrp-consumers@mail.mil, ATTN: MCMR-CD, 1077 Patchel Street, Fort Detrick, MD 21702-5024, Phone: (301) 619-7071, Fax: (301)-619-7796. A red circle highlights the text "To Subscribe for Funding Opportunity Releases, [click here](#)". Below this, the section "Questions Concerning Program Announcement Requirements:" is followed by contact information: E-Mail: Help@ebrap.org, Phone: (301) 682-5507. The final section is "Questions Concerning this Website:".

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- [Amyotrophic Lateral Sclerosis](#)
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- [Bone Marrow Failure](#)
- [Breast Cancer](#)
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[Spinal Cord Injury](#)

[Tick-Borne Disease](#)

[Tuberous Sclerosis Complex](#)

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[Previously Funded Research Programs](#)

Research Programs (CSI) encompassing breast cancer research managed approximately over \$7.7 billion in research. Approximately 12,423 awards have been made to

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Research Programs

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- [Breast Cancer](#)
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Alcohol and Substance Abuse Disorders
Amyotrophic Lateral Sclerosis
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Defense Medical Research and Development
Duchenne Muscular Dystrophy
Epilepsy
Gulf War Illness
Joint Warfighter Medical
Lung Cancer
Military Burn
Multiple Sclerosis
Neurofibromatosis
Neurotoxin Exposure Treatment Parkinson's

Orthotics and Prosthetics Outcomes
Ovarian Cancer
Peer Reviewed Alzheimer
Peer Reviewed Cancer
Peer Reviewed Medical
Peer Reviewed Orthopaedic
Prostate Cancer
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Previously Funded Research Programs

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Peer Reviewed Medical Research Program

\$278.7M in play – FY16



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News & Highlights

Researchers Make a Key Discovery in How Malaria Evades the Immune System ([external link](#))

FY16 PRMRP Funding Opportunities Now Available!

FY15 PRMRP Recommended for Funding List

Guiding Therapeutic Decisions for Patients Using microRNA Biomarkers

Developing a Fingerprint for Renal Cell Carcinoma Progression

Making a difference in congenital heart disease

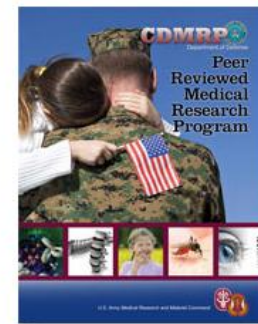
Peer Reviewed Medical



Vision - Improve the health and well-being of all military service members, veterans, and beneficiaries

The Peer Reviewed Medical Research Program (PRMRP), established in fiscal year 1999 (FY99), has supported research across the full range of science and medicine, with an underlying goal of enhancing the health and well-being of military Service members, Veterans, retirees, and their family members. Program oversight is provided by a program review panel with joint military service and interagency representation. Congressional appropriations for the PRMRP totaled \$1.092 billion through FY15 and have supported about 730 awards in more than 120 different topic areas. Congress appropriated \$278.7 million for the FY16 program to solicit proposals in 39 topic areas.

Throughout history, military medical personnel have pioneered breakthroughs in reconstructive surgery, the use of antibiotics, intensive care, burn care, and kidney dialysis in response to war time needs, benefitting Service members and civilians alike. Medical research supported by the PRMRP to address near-term military needs continues this tradition. Millions of nondeployed personnel, their dependents, military retirees, and veterans receive military medical services, creating a critical need to support research on a broad spectrum of medical issues affecting these diverse populations that include children and the elderly. The PRMRP is committed to funding research with the potential to profoundly impact the development and implementation of medical devices, drugs, and clinical practice guidelines that will enhance the



» Click on Image to View Program Booklet

DoD FY16 PRMRP (\$278.7M) will solicit research applications for the following 39 topics areas:

- Acute Lung Injury
- Antimicrobial Resistance
- Chronic Migraine and Post-Traumatic Headaches
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Emerging Infectious Diseases
- Focal Segmental Glomerulosclerosis
- Fragile X Syndrome
- Hepatitis B
- Hereditary Angioedema
- Hydrocephalus
- Inflammatory Bowel Disease
- Influenza
- Integrative Medicine
- Interstitial Cystitis
- Lupus
- Malaria
- Metals Toxicology
- Mitochondrial Disease
- Nanomaterials for Bone Regeneration
- Nonopioid Pain Management
- Pancreatitis
- Pathogen-Inactivated Dried Plasma
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Psychotropic Medications
- Pulmonary Fibrosis
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Tinnitus
- Tuberculosis
- Vaccine Development for Infectious Disease
- Vascular Malformations
- Women's Heart Disease

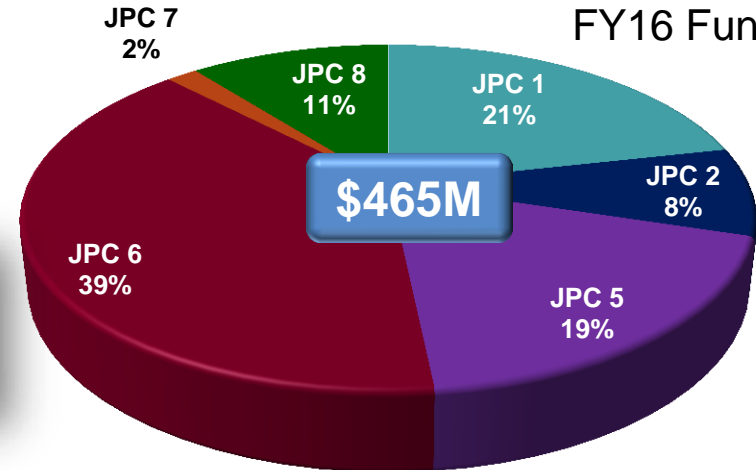
Military Relevance: Relevance to the healthcare needs of the military Service members, Veterans, and beneficiaries is a key feature of each FY16 PRMRP award mechanism.

Joint Program Committees (JPC's)

Tri-service funded & managed



FY16 Funding



\$465M

Medical Training and Health Information Sciences (JPC 1)

- Medical Information Technology Development
- Accelerated Transition of Modeling and Simulation Technology for Medical Training/Education/ Treatment

Military Infectious Diseases (JPC 2)

- Rapid Screening of Fresh Whole Blood
- Antimicrobial Countermeasures
- Wound Infection Prevention & Management
- Diagnostic Systems for Infectious Diseases



Military Operational Medicine (JPC 5)

- Military Family & Community Health and Resilience
- Psychological Health and Resilience
- Deployment Related Psychol. Health Problems
- Suicide Prevention
- Post Deployment Health Risks/PTSD



Combat Casualty Care (JPC 6)

- Hemorrhage Control
- Bone and Soft Tissue Trauma
- Blast Injury Models
- Traumatic Brain Injury
- Casualty Extraction and Life Support
- Evacuation Practices
- Ground and Aeromedical Transport



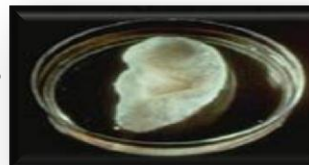
Radiation Health Effects (JPC 7)

- Biomedical Technology for Radiation Countermeasures
- Radiation Biology Modeling
- Internal Contamination

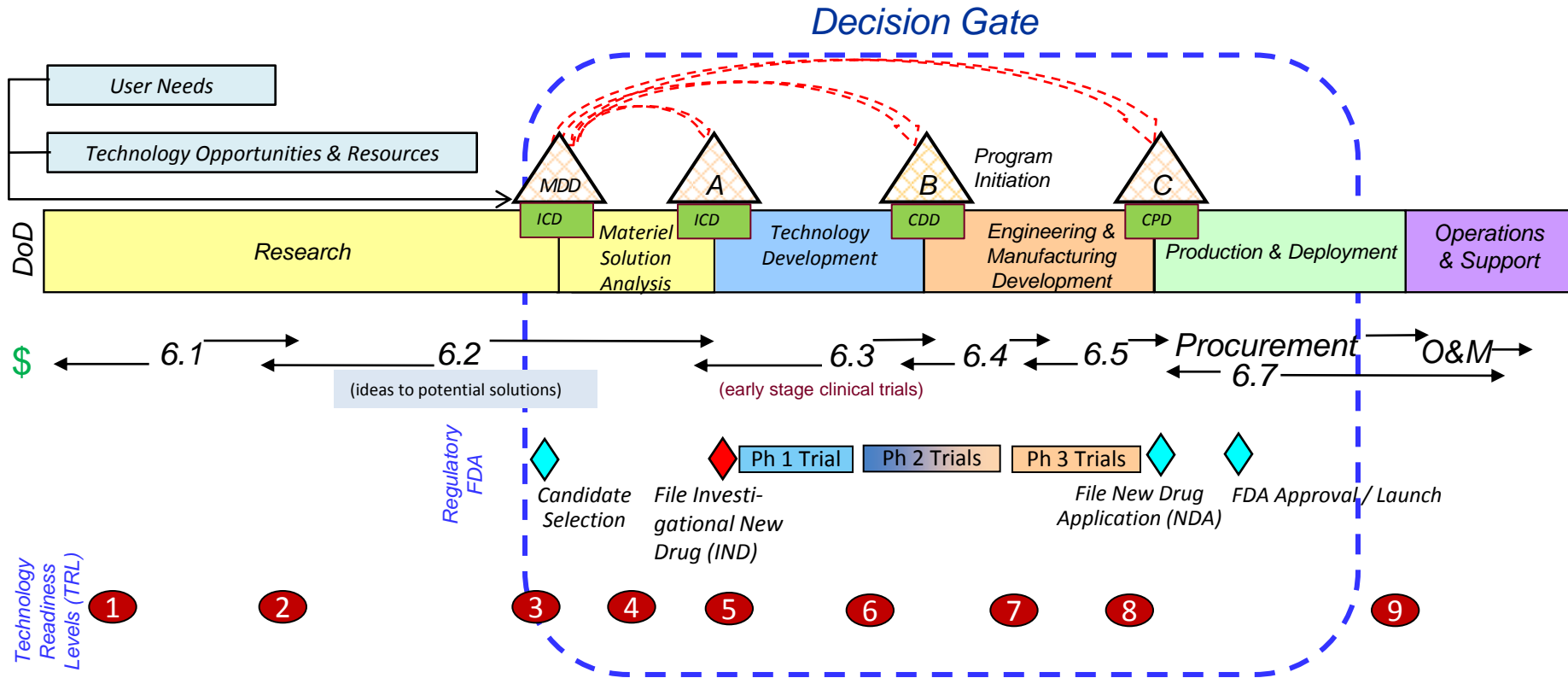


Clinical & Rehabilitative Medicine (JPC 8)

- Sensory System Traumatic Injury
- Regenerative Medicine
- Neuromusculoskeletal Injuries
- Scar Contracture
- Pain Management



DoD Medical Product Development



TRL 3: Drugs/Pharmaceuticals – Initial Proof of Concept (PoC) for candidate constructs demonstrated in vitro/vivo.
Devices – Initial PoC for candidates demonstrated in lab models/animal studies.

TRL 6: Drugs/Pharmaceuticals – Phase 1 data meets safety requirements; supports proceeding to Phase 2 studies.
Devices – Initial clinical data meets safety requirements; supports proceeding to efficacy trials.
 For 510(k), *equivalency to predicate established*; supports testing in military environment.

What is the DoD R&D process?

How does it compare to NIH?

Specific to:

- Requirements
- Nature of research
- Contracts - Cooperative Agreements
- Research priorities

Requirement vs Capability

Requirement

- Problem to be solved
- Determined by the funding organization
- More requirements than money
- Prioritization is key
- Not determined by research community
- Priorities may shift

Capability

- Solution to a problem
- Not always the solution that works in the lab
- Not the solution that works once
- Solution has to work at scale under operational conditions

Fundamental Nature of Research

Hypothesis Driven

- Researcher's bright ideas
- Knowledge focused
- Stable long-term funding
- Must answer the question and determine mechanism
- Publication & presentations are the coin of the realm

Requirements Driven

- Customer specified
- Acquisition model
- Problem focused
- Solve problem with fewest resources
- Empiric problem solving accepted
- Publications, presentations are by-products

Requirements driven & sponsored research are synonymous.

Grants vs Cooperative Agreements

Grants

- No pre-specified deliverables
- Major risk is to next grant
- Other than reports, the gov't is hands off
- Used extensively by NIH

Cooperative Agreement

- Specific deliverables
- Periodic reviews can result in loss of funds
- Gov't is a participant in planning work
- Used by DoD

Contracts (DARPA) are the most prescriptive.

Core Program vs Congressional Special Interest (CSI)

Core program

- Money requested by DoD in Pres. Budget
- Enduring military requirement
- Money available over a number of years (aka programmatic funding)
- Plans cover multiple years
- Intramural expertise

CSI

- Money not requested by DoD
- Money added by Congress
- Not a military requirement (priority)
- No assurance of money in subsequent years
- Very little goes inside DoD

CSI:\$\$ with disease attached.

Earmark:\$\$ with Zipcode attached.

DoD Research Priorities

Core programs

- Behavioral health
- TBI, Cognition
- Suicide prevention
- Infectious diseases (malaria, dengue, diarrhea, HIV)
- Orthopedics
- Combat casualty care

Congressional Special Interest (CSI)

- Breast cancer
- Prostate cancer
- Ovarian cancer
- ALS
- Spinal cord injury
- Autism

CSI programs much more like civilian priorities.

Scientific vs Programmatic Review

Scientific Review

- Much like NIH processes
- Usually done outside the DoD (AIBS)
- Done by subject matter experts when available
- Objective –criteria known
- Pick the best projects

Programmatic Review

- Unique to DoD
- Done by group inside DoD
- Criteria are more subjective
- Pick the best group of projects based on a plan (program)

Important: Need both scientific and programmatic support to get funded!

PA vs BAA

Program Announcement

- Boundary conditions specified
- Relatively specific
- Money has been allocated and will be awarded

Broad Agency Announcement

- Trolling for good ideas
- Fewer constraints
- Boundaries may be vague
- No dollar limit
- May be little (or no) money to spend

All will appear on grants.gov

DoD Pre-proposal vs Proposal

Pre-proposal

- Short
- Focused – easy to read
- Screened – not necessarily by SME's
- Can someone reading this quickly understand its relevance?

Full Proposal

- More detailed
- Focused – easy to read
- Scientific and programmatic reviews
- Will appeal to SME's and have obvious relevance

DoD Project vs Program

Project

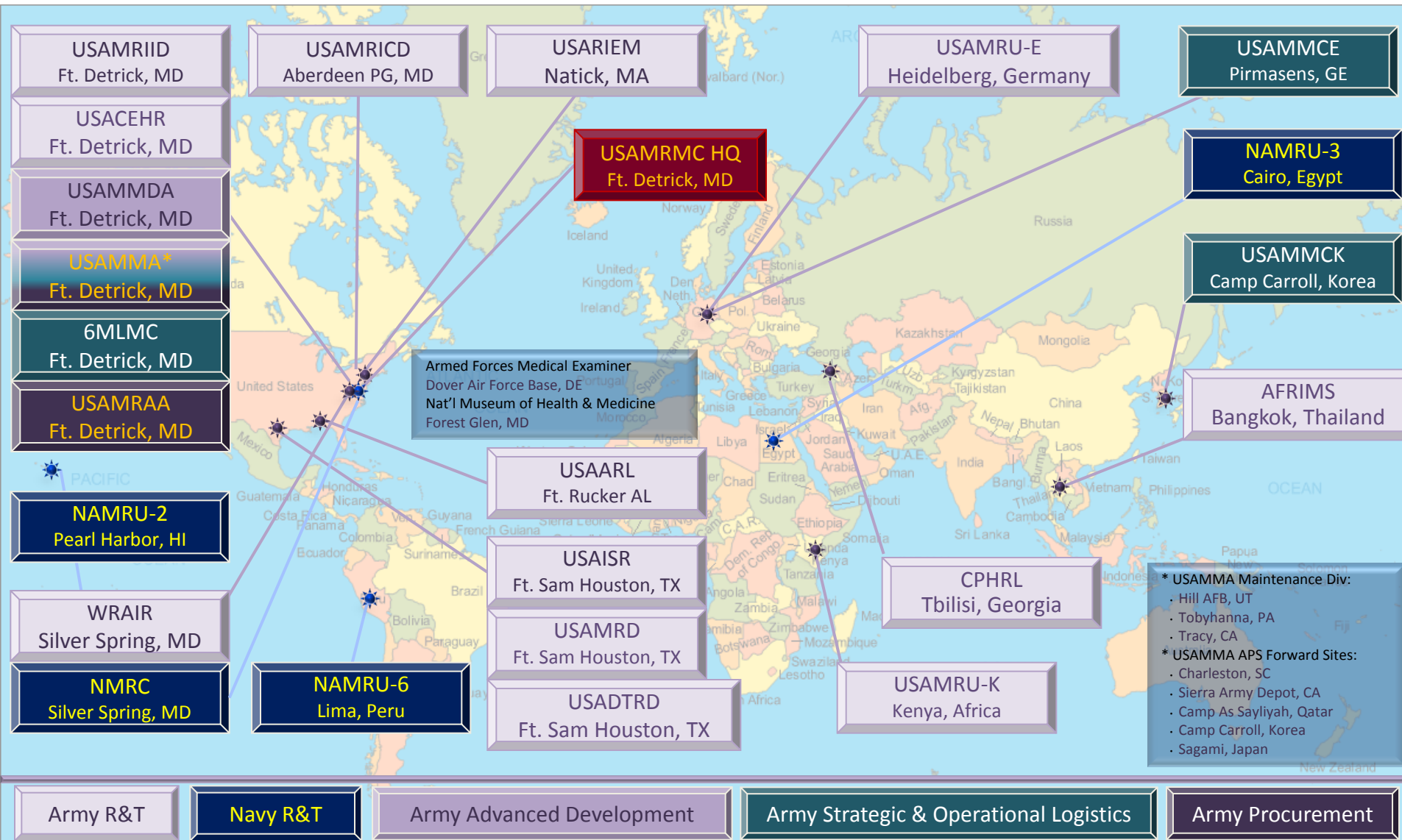
- Stand alone effort
- If designed well, can answer important questions
- Works well for simple problems, incremental benefit
- Requires assurances of money before beginning
- Linear, stepwise, each step complete before next one starts

Program

- Group of projects
- Must be arranged in proper sequence – some processes in parallel, others in sequence
- Usually required for complex problems
- Multi-year funding profile
- Completing a group of projects in non-linear fashion to achieve results while conserving resources

Understanding DoD's programs is paramount for success.
The most expensive resource is time.

US Army Medical Research & Materiel Command



USAMRMC Core S & T Programs

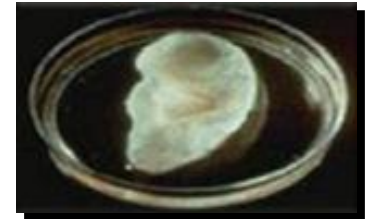
Military Infectious Diseases (RAD 1)

- Medical readiness
- Vaccines
- Biotechnology
- Prophylaxis/treatment drugs
- Diagnostics/prognostics
- Vector control
- Medical C4ISR
- HIV countermeasures



Clinical and Rehabilitative Medicine (RAD 5)

- Neuromusculoskeletal Rehabilitation
- Regenerative Medicine and Transplants
- Vision Restoration
- Pain Management



Combat Casualty Care (RAD 2)

- Lightweight medical equipment
- Medical C4ISR
- Trauma care
- Health monitoring & diagnostic technology



Military Operational Medicine (RAD 3)

- Soldier selection & sustainment
- Soldier performance
- Warrior system modeling
- Health hazards protection
- Diagnostics/prognostics
- Health monitoring



Medical Chemical Biological Defense

- Medical management of CW casualties
- Medical readiness
- Drug prophylaxes/pretreatments
- Diagnostics/therapeutics
- Vaccines/therapies
- Field-portable diagnostic systems
- Medical readiness
- Biotechnology



Defense Health Agency



DHA Background

Formed

October 1, 2013

Headquarters

Falls Church, Virginia

Website

tricare.mil/tma

Purpose: consolidate the Services Medical R&D into one joint military organization

DHA – 10 Shared Services

1. Facilities
2. Medical Logistics
3. Health Information Technology
4. TRICARE – managed care program
5. Pharmacy
6. Budget & Resource Management
7. Contracting/Procurement
- 8. Research Development Acquisition-established**
June 2014
9. Medical Education & Training
10. Public Health

DHA

- Agency of the United States Department of Defense that forms a key component of the U.S. Military Health System (MHS).
- Replaces the Tricare Management Activity (TMA) as the U.S. military entity responsible for providing TRICARE.
- TMA had provided TRICARE services since 1996
- All tri-service DOD medical research (>\$400M/year) – i.e. Joint Program Committee (JPC's) will be managed out of the DHA

DoD Medical R&D Consortia

- **Medical Product Research Development** (\$500M/5 years)
- **Medical Technology Enterprise Consortium** (no funding ceiling)
- **Medical CBRN Defense Consortium** (\$10B/20 years)
- All managed out of the US Army Medical Research & Materiel Command (USAMRMC), Fort Detrick, MD
- Established in 2016
- Focus: products & solutions for the warfighter
- Keys to success:
 - Teaming
 - Industry partners
 - Cost-sharing
 - Commercial plan

Medical Technology Enterprise Consortium (MTEC)

Mission and Scope of Activities

- **MTEC Mission:** Assist the U.S. Army Medical Research and Materiel Command by providing cutting-edge technologies and effective materiel life cycle management to transition medical solutions to industry that protect, treat, and optimize Service Members' health and performance across the full spectrum of military operations.
- **Scope of activities anticipated:** Stand up and operate a 501c3 organization (MTEC) that will engage in
 - biomedical research and prototyping;
 - **capitalization of private sector technology opportunities;**
 - **technology transfer;**
 - **commercialization of Government intellectual property; and**
 - follow-on production for the U.S. Army Medical Research and Materiel Command
- **This opportunity represents a “first of its kind” construct that combines the “traditional” Government-funded prototype project work with requirements to raise and execute private sector funding streams that could support not only the individual projects, but also the companies who will execute those projects**

Rationale for using an OT

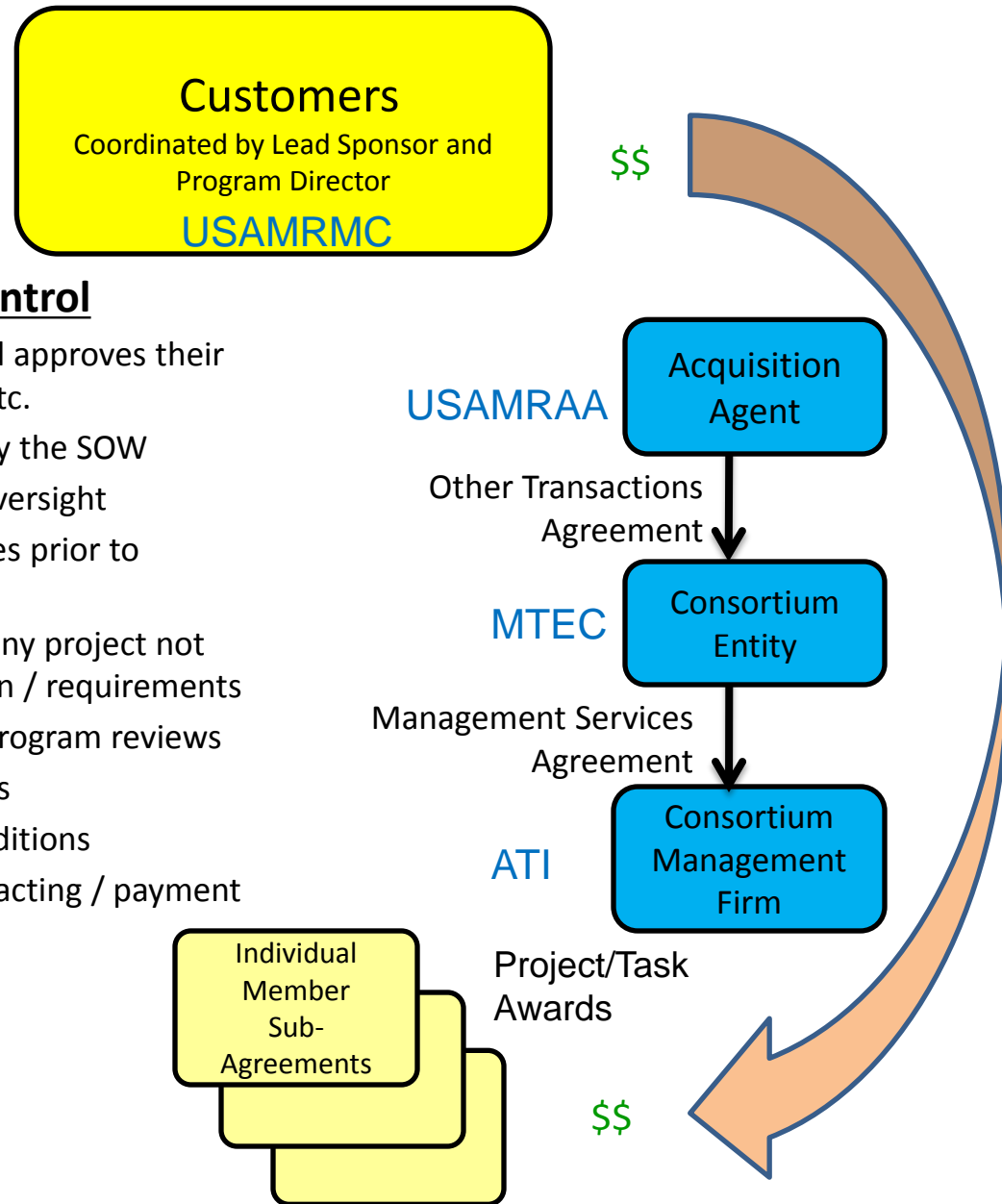
- Government needs to obtain leading edge R&D (and prototypes) from commercial sources, but some companies (and other entities/non-traditionals) are unwilling **or unable** to comply with the Government's procurement regulations.
 - The Government's procurement regulations and certain procurement statutes do not apply to OTs, and other transaction authority gives agencies the flexibility necessary to develop agreements tailored to a particular transaction.
- By using an OT instead of a contract, an agency and its partners are able to develop a flexible arrangement tailored to the project and the needs of the participants:
 - “Other Transactions are meant to present the Government and contractor with a **‘blank page’** from which to begin when negotiating such instruments.”
 - **OTs promote “a more collaborative working relationship,”** which can be more conducive to R&D than the type of relationship established by a contract.

Source: L. Elaine Halchin - CRS Report to Congress, July 2011

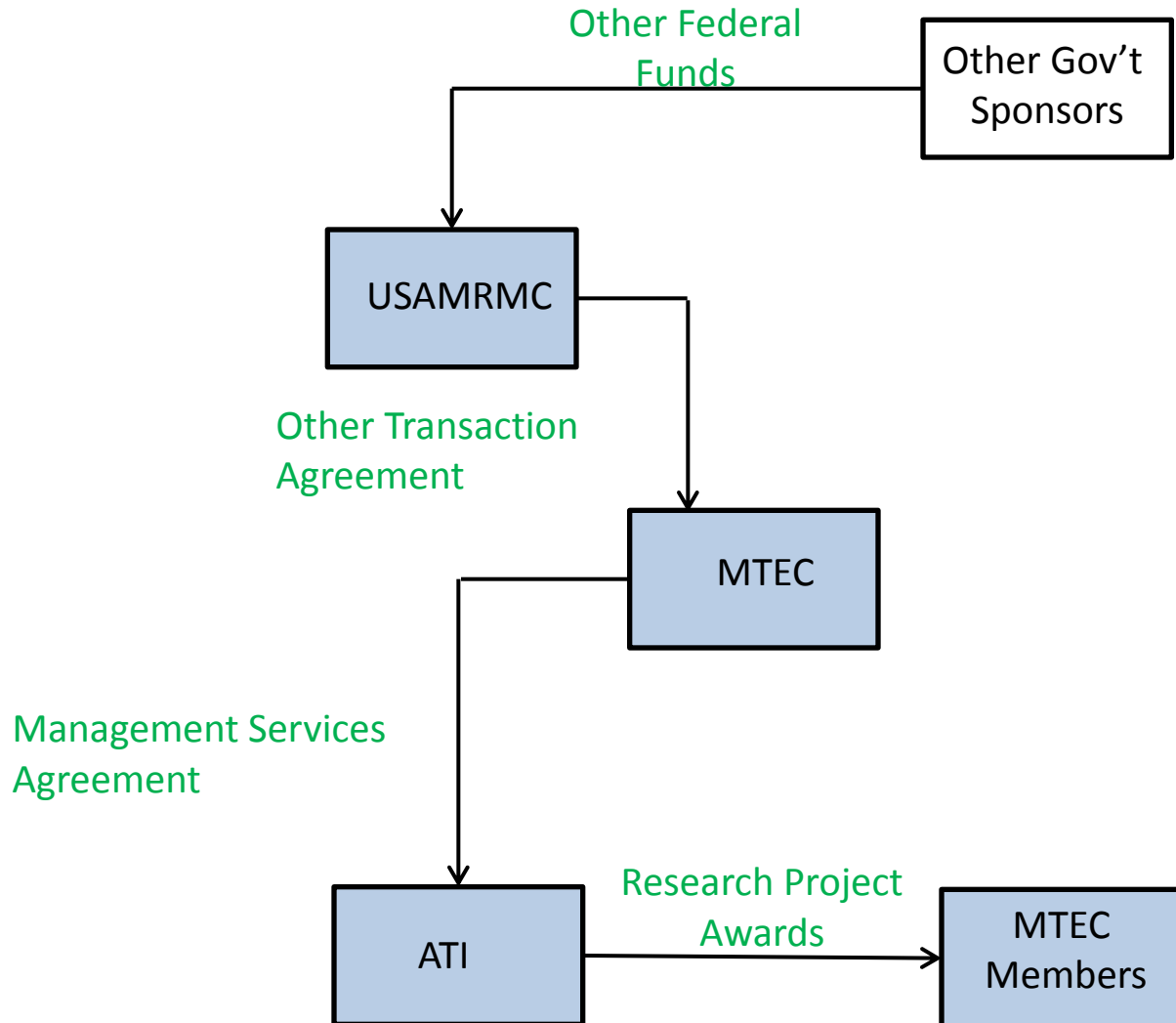
The OT-Consortium Business Model

- An “enterprise partnership” between the Government and a consortium of technology developers/providers in a specific domain where....
 - The “Government” partner can be a single sponsor (program executive officer) or multiple sponsors coordinated through a lead agency
 - The “Consortium” partner is a group of for-profit, not-for-profit and/or non-profit companies, universities and other academic research organizations having competence in the technical domain of interest
- The parties are connected through a binding “contract-like” instrument called an “Other Transaction” that operates outside the normal Federal Acquisition Regulations (FAR)

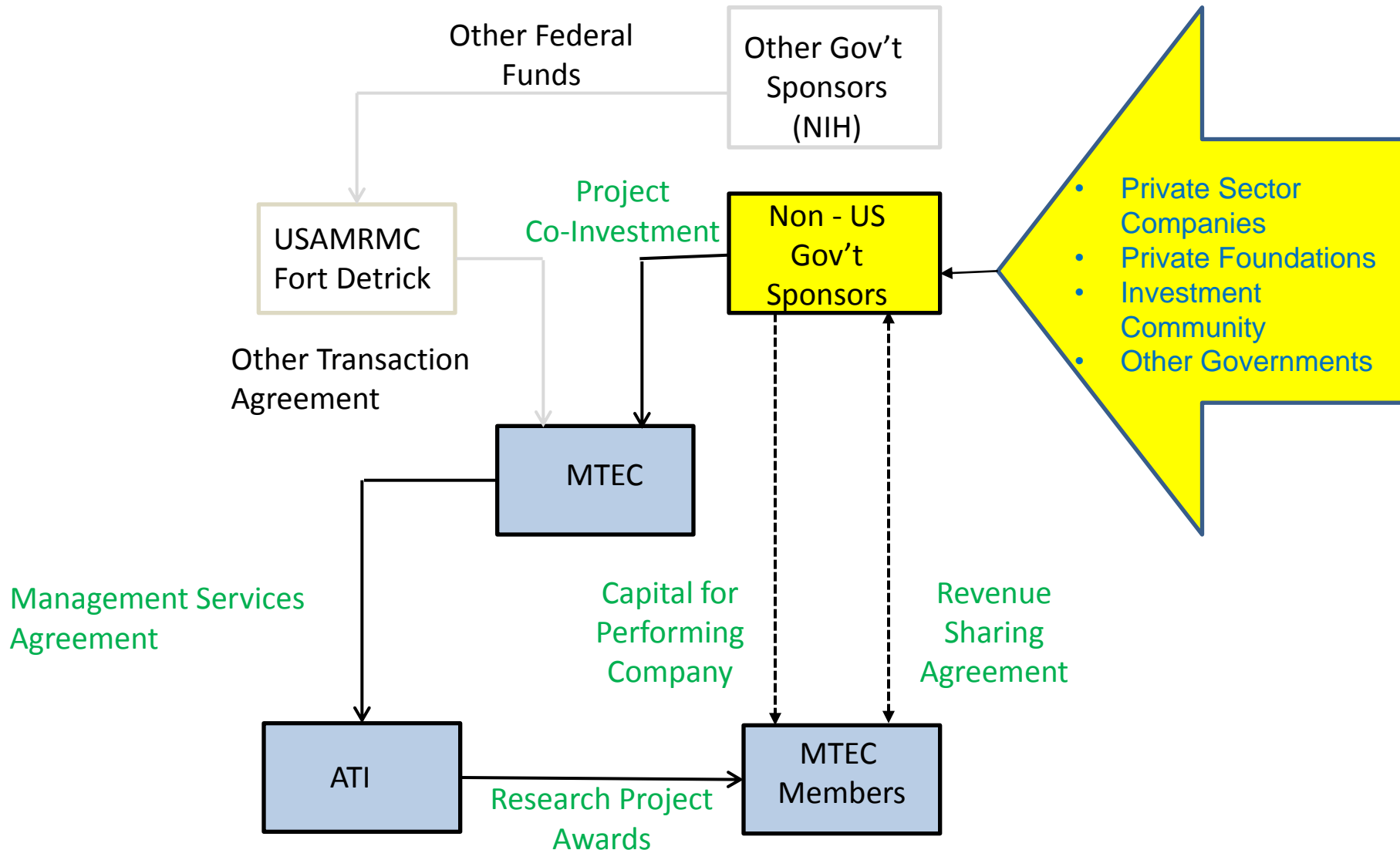
Technical and Financial Management



Funding Flows – “Traditional Research Operations”



Additional Funding flows – the MTEC Model



Mutual Benefits from using the Model

U.S. Government

- Reduced Acquisition lead time
- One-stop technology shopping
- Access to broad spectrum of traditional and non-traditional contractors
- Full and open competition throughout
- Source selection integrity preserved
- Full control over use of sponsor's funds
- Ability to fund projects incrementally
- Open dialogue with Contractor is permitted up until proposal submittal
- Technically acceptable proposals placed in basket awaiting funding for 2 years

Industry and Academia

- Relief from FAR provisions
- Enables industry/academia planning for technology development and/or Internal R&D (IRAD) investments
- Enhanced collaboration between the Government, Industry and Academia during white paper and proposal preparation processes
- Higher visibility into USG requirements
- Open dialogue with the Government is permitted up until proposal submittal
- Technically acceptable proposals placed in basket awaiting funding for 2 years

- Project must fall within the prescribed areas of military need which has a manufacturing component aspect to continue its development



MCDC
Medical CBRN
Defense Consortium
Prevent | Diagnose | Treat

- **Medical CBRN Defense Consortium (MCDC)**
- **previously the National Chemical & Biological Defense Consortium (NCBDC)**
- **www.MedCBRN.org**

Medical CBRN Defense Consortium

- Sponsor: **Joint Project Manager for Medical Countermeasure Systems (JPM-MCS)**
- Advanced development efforts to support the DoD medical pharmaceutical and diagnostic requirements as related to counter Chemical Biological Radiological & Nuclear (CBRN) threats.
- Major product areas:
 - **Detection:** Systems and devices to identify CBRN agents and assist in making medical decisions
 - **Prevention:** Prophylaxis, pretreatment, and post-exposure prophylaxis
 - **Treatment:** Therapeutics (post-exposure, post-symptomatic)
 - **Chemical:** Medical protection against use of chemical agents
- Manager: Advanced Technology International (formerly SCRA)
- Award type: Other Transaction Agreement (OTA)
- Funding amount: \$10B over 20 years

Medical CBRN Defense Consortium

- Examples of medical countermeasures
 - one-threat-one-drug: smallpox vaccine
 - many-threats-one-drug: broad-spectrum capability against gram-negative bacteria
 - Bioscavenger prophylactic for protection against chemical nerve agents
- Pitt is a member of the consortium and the Chair of the Formation Committee
- Status: Award made February 2016 to ATI
- Web site: <http://www.medcbrn.org>

Medical CBRN Defense Consortium (MCDC)

Request for Prototype Proposal 1 (RPP1)

- Development of Monoclonal Antibody Medical Countermeasures against Aerosolized Botulinum Toxin Serotypes A and B
- Fill/Finish of Venezuelan Equine Encephalitis (VEE) virus like particles (VLP) Bulk Drug Product

Request for Prototype Proposal 2 (RPP2)

- Development of a Dual Drug Delivery Device (D4)
- Lyophilized Formulation and Final Product Manufacturing Process for Western/Eastern/Venezuelan Equine Encephalitis (WEVEE) Vaccine
- VEE Monovalent VLP Phase 1 Clinical Study
- Eastern Equine Encephalitis Vaccine (EEEV) Prototypes
- Definitive Efficacy Studies of Pyridostigmine Bromide (PB)

Summary

1. Understand the unique needs of DoD medical research (Note: this is a process, not an easy read!)
 - work to fill capability gaps
 - develop products and solutions (not mechanisms of action)
 - unique needs across each echelons of care
 - dedicated personnel needed to develop competitive DoD proposals
2. Familiarize yourself with:
 - CDMRP web site – enroll for research proposal announcements
 - Grants.gov
 - FedBizOps.gov
 - SBIR/STTR topic announcements (DoD, HHS, NASA, etc)
3. Develop collaborative relationships with DoD/VA investigators
(attend MHSRS meeting – every August in Florida!)
4. Establish Partnership Agreements with DoD lab organizations
5. Understand the unique DoD lexicon (OTA, TRL, P6, JPC, DHA)
6. Realize there are new models of DoD programs for academia to consider
(Consortium/OTA)



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