American Defense International, Inc.

**Federal Government Medical Research Funding: Strategies for Success**

VCOM Science Retreat
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Van Hipp, Chairman
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American Defense International
Total R&D by Agency, FY 2016

budget authority in billions of dollars

DOD, $72.2
HHS (NIH), $31.9
DOE, $12.5
NASA, $12.3
NSF, $6.3
USDA, $2.9
Commerce, $2.1
All Other, $6.2

Total R&D = $146.4 billion

Source: OMB R&D data, agency budget justifications, and other agency documents and data. R&D includes conduct of R&D and R&D facilities. © 2015 AAAS
Federal Funding Portfolio for Technology Development

...largely grants and contracts

Science & Technology $

DARPA

NIH

other federal agencies

SBIR/STTR

SBA

Venture Capital

Basic Research

Product Development

Angels

Service S&T
DoD in the Medical R&D Landscape

Over half of all federal R&D funding resides at the DoD; by comparison, NIH holds about 27% of all federal R&D. The DoD spends about $1 billion per year on medical R&D.

Division of labor among agencies that fund medical R&D:

- **DoD**: Mission-focused R&D expenditure driven by the needs of force health readiness/protection/health; relatively little basic science and a great deal of applied research. *Requirements-driven.*

- **Department of Veterans Affairs (VA)**: all intramural research; many shared interests with the DoD.

- **HHS**:
  - **NIH**: broad health mission; overlapping interest and collaboration in areas such as biodefense and traumatic brain injury (TBI). *By contrast with DoD, NIH research is generally investigator-initiated.*
  - **Biomedical Advanced Research and Development Agency (BARDA)**: advanced development of countermeasures against chemical, biological, radiological, and nuclear threats (CBRN); focus on therapeutics. DoD shares this interest but focuses on prophylaxis.
The DoD’s primary medical mission is to maintain the health and readiness of active duty service members in peacetime and during military operations.

To achieve this mission, the DoD:

- Provides clinical care to service members and beneficiaries at Medical Treatment Facilities (MTFs), clinics, and in the field. This ranges from the point of injury/exposure to definitive care.
- Supports R&D to advance the state of medical science/capability in areas of greatest need to achieve a ready and healthy force
  - Intramural programs (within the DoD’s own labs and clinics)
  - **Extramural Programs** (conducted by outside partners and funded by the DoD)
    - Can include projects with DoD collaborators with some portion of research done at a DoD lab/clinic

*Each service (Army, Navy, Marine Corps, Air Force) carries out its own care delivery and R&D activities, but many activities are “joint” (involving two or more services) or stretch across the entire DoD organization.*
Medical Research and Technology

Responds to Threats to Service Member Health and Performance

Endemic Disease Threats
- Parasitic Diseases
- Bacterial Diseases
- Viral Diseases

Chemical/Biological Warfare Threats
- Bacterial Threats
- Viral Threats
- Toxin Threats
- Nerve Agents
- Vesicant Agents
- Blood Agents

Environmental Hazards
- Heat and Cold
- Altitude
- Toxic Industrial Chemicals & Materials

Operational Stressors
- Sleep Deprivation
- Traumatic Stress and Situational Stressors
- Physical Work Load
- Cognitive Burden & Operational Complexity

Combat Injuries
- Hemorrhage
- Head Trauma
- Blast Injury

Systems Hazards
- Laser
- Blast
- Biomechanical Insults and Stresses
- Noise
Medical R&D activities in the DoD fall under the umbrella of the Defense Health Agency (DHA). However, there are both joint and service-specific programs.

**JOINT/DoD-WIDE:**
- U.S. Army Medical Research and Materiel Command (USAMRMC)
  - Responsible for the carrying out the JOINT Defense Medical R&D Program (DMRDP), and responsible for overseeing the Congressionally-Directed Medical Research Programs (CDMRP)
- Defense Advanced Research Projects Agency (DARPA)
- Defense Threat Reduction Agency (DTRA)

**SERVICE-SPECIFIC FUNDERS:**
- Office of Naval Research (ONR)
- Naval Health Research Center (NHRC)
- Air Force Office of Sponsored Research (AFOSR)
- Army Research Lab (ARL)
- Special Operations Command (USSOCOM)

**NON-DoD BUT IMPORTANT AND RELATED:**
- Veterans Health Administration (VHA)
Defense Medical R&D: High-Level Objectives

DoD Medical R&D aims to:

• Focus on advancing the state of medical science in areas of most pressing need directly relevant to battlefield injuries and other ailments that affect both Service members and their families.

• Fund R&D spanning basic research through advanced clinical development, but with a strong emphasis on APPLIED and TRANSLATIONAL work.

• Discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, and communities.

• Accelerate transition of medical technologies into deployed products.

• Accelerate translation of advances in knowledge into 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 (MHS).
Major Capability Areas

- Medical Training and Health Information Sciences
- Military Infectious Diseases
- Military Operational Medicine
- Combat Casualty Care
- Clinical and Rehabilitative Medicine
Medical Simulation and Information Sciences

- Focused on improving military medical training through medical simulation, educational gaming, and objective training metrics. Objectives include:
  - Combat casualty training
  - Medical training methods, technologies, systems, and competency assessment tools for the attainment and sustainment of military medicine
- Aims to improve the use and sharing of health-related data for better strategic planning, process development, and software applications.
- Prominent military simulation facilities include:
  - The Walter Reed Medical Simulation Center (WRMSC)
  - Uniformed Services University for the Health Sciences (USUHS) Medical Simulation Center
Military Infectious Disease

- Antiparasitic drug discovery and development
- Vaccines for naturally occurring infectious diseases
- Prevention of diarrheal diseases
- Flavivirus (Dengue) vaccine research
- Diagnostic systems for infectious diseases
- HIV research - VACCINES
- Insect vector control – insecticides, repellents, and systems for vector identification
- Microbial sciences – wound infections, scrub typhus, and computational biology efforts
- Hantaviruses, viral hemorrhagic fevers, and other highly lethal viruses
- Disease areas of interest also include (among others): Norovirus and other viral diarrhea, Q fever, Crimean-Congo hemorrhagic fever, protozoal diarrhea, dengue, bacterial diarrhea
Operational Medicine
Focuses on physical and cognitive/psychological readiness

- Psychological health and suicide
- Sleep physiology and fatigue
- Bioenergetics, metabolism, and nutrition
- Injury prevention and protection
- Concussion dosimetry/mild brain injury assessment and interventions
- Standards and recovery strategies after neurosensory, musculo-skeletal, and thoracic injury
- Physical training interventions to reduce musculo-skeletal injuries
- Predictive models for heat and cold strain; hydration management; and altitude acclimatization
- Biomonitoring and other approaches to predict impact from occupational stressors and health hazards
Combat Casualty Care

Focuses on clinical needs at the point of injury and immediate post-injury

- The leading causes of death among Service members who die within the first hour of wounding are hemorrhage and traumatic brain injury (TBI).

Examples of relevant R&D interests:
- hemostatic agents for non-compressible hemorrhage, effective fluid resuscitation, improved blood related technology/products.
- Pre-hospital care documentation
- TBI acute and chronic therapies
- Organ support for the critically injured
- Mild traumatic brain injury (mTBI) objective diagnostics
- Improving wound outcomes by enhancing immune response
  - **Brooke Army Medical Center** – serves as the largest and most robust military healthcare organization within the Department of Defense (DOD)
  - **U.S. Army Institute for Surgical Research (ISR) Burn Center**
- mTBI/concussion definition and TBI-staging criteria
- Smart triage and decisional devices for forward areas
- Metabolic and tissue stabilization
Federal Coordination Efforts

- This resulted in the National Research Action Plan (NRAP), developed in collaboration by DoD, VA, NIH and the Department of Education in June, 2013. The NRAP brings together multiple federal agencies that have stakes in Traumatic Brain Injury and Psychological Health research, to include cooperative strategic planning and logistical support.
- In 2013, the President directed the initiation of the Brain Research Through Advancing Innovative Technologies (BRAIN) Initiative. The major goal of this multi-agency effort is to improve HOW we study the brain and behavior.
Clinical and Rehabilitative Medicine
Focuses on care 72 hours post-injury and beyond

- Management of pain
- Vision restoration
- Scarless wound healing and scar reduction
- Regeneration of tissue components (bone, muscle, nerve), craniofacial reconstruction, limb and digit regeneration, and genitourinary
- Improved outcomes from major extremity injury – limb salvage; rehabilitation strategies; prosthetics; prevention of bone, cartilage, and muscle loss
- Repair of burn injury – skin substitutes, prevention of burn injury progression
- Repair to auditory/vestibular systems
- Rehabilitation of dysfunction associated with traumatic brain injury
Congressionally-Directed Medical Research Programs (CDMRP)

- Primary role is to execute funding in research areas directed by Congress.
- CDMRP is the “execution management agency” for the extramural programs in the capability areas outlined above, as well as other programs – some not obviously militarily-relevant – when the funding has been directed by Congress.
- The programs CDMRP executes are distinct mainly in:
  - How they are reviewed
  - Who makes the ultimate funding decisions
  - Whether it is possible to discuss ideas in advance of proposal submission
- **ALL PROPOSALS GET A PEER REVIEW REGARDLESS OF PROGRAM.**
- The Department of Defense Peer Reviewed Orthopaedic Research Program (PRORP) was established by Congress in fiscal year 2009 (FY09) to support military-relevant, peer-reviewed orthopaedic research. The program has been continued each year through FY16, with congressional appropriations totaling **$278.5 million (M)**.
CDMRP-executed programs where the decision-makers are primarily MILITARY, and where relationships with the program office are available and can have influence:

• "DMRDP"
• Psychological Health & TBI
• Spinal Cord Injury
• Peer-reviewed Orthopaedic
• Vision
• Other programs not listed in right-hand column
• To a lesser degree, Peer-Reviewed Medical (PRMRP)

CDMRP-executed programs where no substantive dialogue with program managers is available in advance:

• Breast, ovarian, prostate, lung, and Peer-Reviewed Cancer
• Duchenne Muscular Dystrophy
• Tuberous Sclerosis Complex
• ALS
• Autism
• Gulf War Illness
• Neurofibromatosis
• Bone Marrow Failure
• Multiple Sclerosis
Office of Naval Research (ONR) Warfighter Performance Department

Three portfolios are important to highlight:

- **Applied Instructional Research:** Training for medical skills proficiency; particular focus on metrics for learning effectiveness
- **Force Health Protection:** Capabilities relating to combat casualty care
- **Undersea Medicine:** Focus on preventing/mitigating adverse health effects that negatively impact submarine and diving operations
  - Long-range Broad Agency Announcement (BAA) #N00014-16-R-BA-01 now open (appears on grants.gov)
  - Special Notices are posted periodically on specific topics

Naval Health Research Center (NHRC)

- Department of Defense's (DoD) premier deployment health research center tasked with optimizing the operational health and readiness of the nation's armed forces
- Sets the standards in joint ventures, innovation, and practical application
Air Force Medical R&D Activities

- **Air Force Office of Scientific Research (AFOSR)**
  - Plans, coordinates, and executes the Air Force Research Laboratory's (AFRL) basic research program in response to technical guidance from AFRL and requirements of the Air Force.
  - Fosters, supports, and conducts research within Air Force, university, and industry laboratories in areas that offer significant and comprehensive benefit to national warfighting and peacekeeping capabilities.
  - Post annual BAA with some medical/life science thrust areas (performance, cognitive science, etc.)

- **Air Force Research Laboratory (AFRL)**
  - Human performance (sleep, nutrition, etc.)

- **Air Force Medical Support Agency (AFMSA)**
  - Policy, programmatic, and operational support for ground and air expeditionary medical capabilities.

Currently open announcements include:
Research Interests of the Air Force Office of Scientific Research (AFOSR), BAA-AFRL-AFOSR-2015-0001 (on grants.gov)
SOF medical personnel place a premium on medical equipment that is small, lightweight, ruggedized, modular, multi-use, and designed for operation in extreme environments. The equipment must be easy to use, require minimum maintenance, and have low power consumption. Drugs and biologics should not require refrigeration or other special handling. Research projects may apply existing scientific and technical knowledge for which concept and/or patient care efficacy have already been demonstrated to meet SOF requirements. 2016 Research Areas of Interest:

- Medical Simulation and Training Technologies
- Damage Control Resuscitation
- Force Health Protection and Environmental Medicine
- Human Operational Performance
- Prolonged Field Care
- Portable Lab Assays and Diagnostics
- Canine Medicine

Technology & Industry Liaison Office (TILO) (http://www.socom.mil)

The Technology & Industry Liaison Office (TILO) is the conduit to present information on capabilities to the various USSOCOM Program Executive Offices, Directorates and others. It is our duty to match your company’s product/service/capability to the appropriate personnel within the command and schedule discussions or demonstrations if there is sufficient interest at the headquarters. This is an opportunity to submit Advanced Development proposals (TRL 6.5 and above). Areas of interest are:

- Aviation Systems
- Biometrics and Forensics
- Command, Control, Communications, and Computers
- Cyberspace Operations
- Intelligence, Surveillance, and Reconnaissance
- Irregular Warfare
- Medical
- Mobility
- Power and Energy
- Soldier Systems
- Weapons and Electronic Attack

All medical related activities are coordinated and managed by the SOCOM Office of the Chief Surgeon
These programs all coordinate with and complement one another:

- **Defense Threat Reduction Agency (DTRA)**
  - Lead DoD agency for countering WMD threats – large basic and applied research program
  - CBRN defense portfolio: WMD sensing and recognition; containment, decontamination
  - **Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD)** is the Joint Services single focal point for research, development, acquisition, fielding and life-cycle support of chemical, biological, radiological and nuclear (CBRN) defense equipment and medical countermeasures. **Headquartered in Aberdeen, MD.**
  - Joint Staff (J-8) Advisor/Director of the Joint Requirements Office for CBRN Defense

- **USAMRMC Medical Biological Defense Research**
  - Vaccines
  - Broad-spectrum and novel therapeutics
  - Small molecule therapies
  - Next-generation diagnostics
  - Biosurveillance/emerging infectious diseases
  - Animal model development (FDA animal rule)

- **USAMRMC Chemical Defense Research**
  - Nerve agent prophylaxes
  - Therapeutics for nerve and vesicant agents
  - Non-Traditional Agent (NTA) research
  - Diagnostic assays/technologies
The Defense Advanced Research Projects Agency (DARPA) was established in 1958 to prevent strategic surprise from negatively impacting U.S. national security and to create strategic surprise for U.S. adversaries by maintaining the technological superiority of the U.S. military.

- DARPA works in all areas of defense
- DARPA’s mission is “to maintain the technological superiority of the U.S. military and prevent technological surprise from harming our national security by sponsoring revolutionary, high-payoff research that bridges the gap between fundamental discoveries and their military use.”
  - No intramural research – DARPA is not a lab
  - Program managers have autonomy in setting research priorities and making funding decisions.
  - DARPA programs are very forward-thinking with a science fiction-like feel – only the most cutting edge work is supported
- DARPA’s interests lie in transitioning new technology into military use as quickly as possible. Faculty researchers are well-advised to team with defense industry or defense lab researchers when proposing new research.
DARPA Program Areas

Biological Technologies Office (BTO)

- Recently established (April 2014)
- Focus on the intersection of biology with engineering and the physical sciences
- Combines some programs previously under the Defense Sciences Office (DSO) and the Microsystems Technology Office (MTO) but will also include new opportunities

Thrust areas:

- Restore/maintain warfighter abilities – advanced prosthetics, neural interfaces, etc.
- Harness biological systems – apply capabilities of biological systems to new novel products
- Apply biological complexity at scale

Examples of programs:

- Systems-Based Neurotechnology for Emerging Therapies (SUBNETS)
- Hand Proprioception and Touch Interfaces (HAPTIX)
- Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT)
VA research is different from research sponsored by other federal research agencies in that:

• VA Research is the only research program focused entirely on Veterans' needs.

• VA Research is intramural, meaning only VA employees can serve as PI on research under VA's sponsorship. However, it is common for VA researchers to collaborate with academic institutions and other extramural partners.

• More than 60 percent of VA researchers are also clinicians who provide direct patient care.

VA Research is conducted by the **Office of Research and Development**

- Small Project Innovative Research Evaluation (SPIRE) – 2 years, $100K/year. Must be innovative; can be used to get pilot data
- Topics include: **rural health care/quality**, suicide risk and/or prevention, osteoarthritis, etc.
The NIH should not be thought of as one organization, but rather 27 individual fiefdoms, each with a culture and set of practices.

Part of the NIH mission is to “find and fund the best science with the least administrative burden”. It is a Program Official/Director’s job to help you understand the system and present your ideas in the best light.

In tight budget times, folks hunker down. Conservatism rules, but reviewers and staff are eager to be “wowed.”

Know where to go for your grant.

Know whom to contact in Grants Management and Review.

Follow Directions.

Allow 2 days to get the grant submitted into Grants.gov.

The National Center for Advancing Translational Sciences (NCATS) strives to develop innovations to reduce, remove or bypass costly and time-consuming bottlenecks in the translational research pipeline, so that new treatments and cures for disease can be delivered to patients faster.

Dr. Chuck Peterson (former Director at NHLBI, has chaired many NIH review panels) is a Senior Advisor for ADI’s Health and Life Sciences Team, and is available to advise on strategy and/or answer questions related to NIH.
Developing an FDA regulatory strategy requires a clear definition of the intended use, potential risks, potential benefits, users, and complete description of any device.

Do not approach the FDA until you have a clear understanding your device approval path. If seeking 510(k), clearly identify a predicate device and provide evidence supporting the equivalence.

Define your pre-clinical and clinical evaluations and ask the FDA to comment.

Do not ask the FDA for suggested models, methods of statistical analysis or clinical protocols.

The drug and device approval processes require planning, careful attention to detail and an early start.

Requirements for the approval influence the entire process of device design, development, testing and marketing.

FDA risk can be managed through careful analysis of regulatory pathways and compliance with regulatory requirements.

Dr. Warren Grundfest (currently serves on the FDA Science Advisory Board) is a Senior Advisor for ADI’s Health and Life Sciences Team, and is available to advise on strategy and/or answer questions related to FDA.
The mission of the Biomedical Advanced Research and Development Authority (BARDA) is to develop and procure medical countermeasures that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases.

BARDA supports the advanced development and procurement of vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures that are considered priorities for national health security.

BARDA funding bridges the “valley of death” characterizing the late stages of product development. BARDA’s support ensures continuity of funding at a critical point for medical countermeasures developed by industry or emerging from the basic research and preclinical development activities sponsored by the NIH.

In procuring medical countermeasures for the Strategic National Stockpile, BARDA enhances the capabilities of the Centers for Disease Control and Prevention (CDC) to organize an effective response.
Program Divisions:

Division of Chemical, Biological, Radiological and Nuclear Medical Countermeasures

- Develops and procures the CBRN medical countermeasures (MCMs) required by the U.S. Department of Health and Human Services (HHS) to mitigate the adverse health effects arising from public health emergencies.

Influenza Division

- The National Strategy for Pandemic Influenza (November 2005) designated the HHS as the lead agency for public health preparedness and medical response to a probable or actual influenza pandemic.

Division of Regulatory & Quality Affairs

- Develops strategies to facilitate the regulatory development pathway and to anticipate product lifecycle issues. It applies quality and regulatory best practices to the life cycle management of MCMs ultimately needed for stockpiling, delivery, and use.

Strategic Science and Technology

- Identifies and supports the advancement of platform technologies that enhance capabilities for the development and manufacturing of MCMs.
U.S. Southern Command (SOUTHCOM), located in Doral, Fla., is one of nine unified Combatant Commands (COCOMs) in the Department of Defense.

SOUTHCOM is responsible for providing contingency planning, operations, and security cooperation in its assigned Area of Responsibility which includes:

- Central America
- South America
- The Caribbean (except U.S. commonwealths, territories, and possessions)

Oversight for force protection and all medical readiness spending in all Areas of Responsibility.

Highly opportunistic alignment for VCOM clinics in El Salvador, Dominican Republic, and Honduras.
National Guard Bureau Office of the Joint Surgeon General (NGB-JSG)

- NGB Joint Surgeon's Office mission is to develop, coordinate, communicate and implement National Guard medical policies, procedures and operational responses in collaboration with state and federal interagency and international medical partners, and to develop and coordinate guidance for medical operations conducted by National Guard CBRN Enterprise medical elements.

- First Responder Medicine is a critical component of the NG mission.

- Each state in the United States has a senior military officer, as the state adjutant general (TAG), who is de facto commander of a state's military forces, including the National Guard, the naval militia, and any state defense forces.

  - **Major General Perry G. Smith** – Alabama TAG (resides in Auburn)
National Science Foundation (NSF)

- The National Science Foundation (NSF) is an independent federal agency created by Congress in 1950 "to promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense..."
- With an annual budget of $7.5 billion (FY 2016), NSF is the funding source for approximately 24 percent of all federally supported basic research conducted by America's colleges and universities.
- In many fields such as mathematics, computer science and the social sciences, NSF is the major source of federal backing.
National Rural Health Association (NRHA)

- The National Rural Health Association (NRHA) is a national nonprofit membership organization with more than 20,000 members.
- The association’s mission is to provide leadership on rural health issues through advocacy, communications, education and research.
- NRHA membership consists of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health.
Developing and maintaining key congressional “champions” is imperative to positively influencing the oversight and regulatory environment impacting the budgets and markets.

**Virginia Delegation**

- **Senator Tim Kaine**
  - Committee on Health, Education, Labor and Pension (oversight of all NIH spending)
  - Armed Services Committee
    - Subcommittee on Readiness and Management Support
      - Oversight of RDT&E Support program spending
    - Subcommittee on Seapower
      - Oversight of Navy and Marine Corps RDT&E spending

- **Senator Mark Warner**
  - Senate Budget Committee

- **Representative Morgan Griffith**
  - House Energy and Commerce Committee, Health Subcommittee
    - Oversight of NIH, CDC, biomedical R&D spending
South Carolina Delegation

› Senator Lindsey Graham
  ‣ Armed Services Committee, Chairman of the Armed Services Subcommittee on Personnel
  ‣ Appropriations Committee, Chairman of the Subcommittee on Defense
    ‣ These committees/subcommittees have oversight of all medical-related spending in the DoD

› Senator Tim Scott
  ‣ Senate Committee on Health, Education, Labor and Pension (oversight of all NIH spending)

› Representative Trey Gowdy
  ‣ Permanent Select Committee on Intelligence

Alabama Delegation

› Senator VACANT
  ‣ Special Election

› Senator Richard Shelby
  ‣ Appropriations Committee, Subcommittees on Defense and Labor, Health and Human Services, Education and Related Agencies

› Representative Mike Rogers
  ‣ House Armed Services Committee
Health and Life Sciences Team Profile

- **John Winston**
  - Former Chief of Research Review at the Telemedicine and Advanced Technology Research Center (TATRC) at the United State Army Medical Research and Materiel Command (USAMRMC)

- **Warren Grundfest, MD**
  - Member of the Food and Drug Administration (FDA) Science Advisory Board
  - Professor of Surgery, UCLA School of Medicine
  - Chair of the American Institute for Medical and Biological Engineering’s (AIMBE) Council of Societies
  - Former consultant to the FDA Office of Device Evaluation and Office of science and Engineering

- **J. David Gangemi, PhD**
  - Former Senior Advisor to the Assistant Secretary of Defense for Health Affairs and Special Assistant to the President for Institutional Collaborative Research, Uniformed Services University for the Health Sciences (USUHS)
  - Former Director of the Institute for Nutraceutical Research at Clemson University

- **Col. (Ret.) Dallas Hack, MD**
  - Former Director of the US Army Combat Casualty Care Research Program and Chair of the Joint Program Committee for Combat Casualty Care
  - Former DoD Brain Health/Fitness Research Program Coordinator, US Army Medical Research and Materiel Command (USAMRMC)
  - Former Senior Medical Advisor to the Principal Assistant for Research and Technology, U.S. Army Medical Research and Materiel Command (USAMRMC)

- **Charles Peterson, MD**
  - Former Director of the Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute
  - Former Chief Scientist Telemedicine and Advanced Technology Research center of the Army

- **Lucas Booth**
  - Massachusetts Institute of Technology (Langer Lab), Tufts University
Tips for Success

- DoD process starts with an idea – not necessarily a posted funding opportunity
- Socializing your research ideas ahead of Program Announcements is critical to success
  - Some program managers are willing to provide feedback on draft pre-proposals
- If they are interested, DoD program managers/scientists may point you to specific funding opportunities and encourage a submission. Often these are the same people who will be reviewing your proposal.
- Demonstrating a clear link between your research and a military need/capability is imperative.
- Technical interchange with program managers/scientists, participation in relevant conferences, as well as reviewing BAAs can inform and help shape your focus. This improves your odds of success.
"Socializing" Your Research

RELATIONSHIPS MATTER: The key to success in the DoD is building relationships with DoD scientists, clinicians, and program managers. The DoD is always interested in new strategies to address its problems. Program Managers and scientists are generally receptive to communication and will provide feedback.

Opportunities for dialogue:

- DoD-sponsored Conferences
  - Military Health System Research Symposium (MHSRS) – held annually in August (Tentative: August 15-18 2018 Kissimmee, FLA)
  - Special Operations Medicine Scientific Assembly (SOMSA) Conference – held annually (May 24-26 in Charlotte, NC)

- Discipline-specific civilian conferences (example: AABB (formerly American Association of Blood Banks) is attended by most DoD experts and Program Managers in blood/blood products)

- Conference calls and visits with DoD scientists/program managers
**White Papers** are used to provide DoD officials with introductory information about ongoing research/capabilities. They provide the groundwork for requests for agency meetings or begin the process for socializing your work with DoD subject matter experts (SMEs) before a Program Announcement is issued. We will provide a template and review/edit them.

**Abstracts & Posters** can be submitted for presentation at military conferences. If your talk or poster is accepted, this not only demonstrates technical merit, but also guarantees some exposure and technical interchange with DoD SMEs.
Conferences

- Military Health System Research Symposium (MHSRS)
- Special Operations Medical Association (SOMSA)
- NHRA Annual Rural Health Conference
Congressional Involvement: Budget Timeline

- **February** – Congressional committees receive the Federal Budget blueprint from the President.
- **March and April** – Congressional committees begin analyzing the budget in hearings and Congressional offices accept and evaluate appropriations and authorization requests from constituents.
- **April** – All Appropriations and Authorization requests are due to the Defense Appropriations subcommittee and defense Authorization staff.
- **May** – Draft Appropriations and Authorization bills are “marked up” by the subcommittees and full Committees. Votes are taken at the subcommittee and Full committee levels.
Congressional Involvement: Budget Timeline (cont.)


- **July and August** – Appropriations and Authorization Conference begins.

- **September** – Final versions of the Defense Appropriations Bill and the National Defense Authorization Act are passed by the House and Senate and sent to the President for signature.

- **October** – Fiscal Year Begins.
U.S. Federal Contracting Process

Marketing Phase

1. Identify a requirement for your technology/research
2. Brief Government Departments/Agencies (Project Exec. Off. (PEO) and Project Manager (PM))
3. Gain Government Champion to Determine Funding Opportunities
4. Seek sole-source “Unsolicited Funding” Opportunity
5. Identify potential partners

Funding Phase

NO

Funding Available in Current Budget

- Funds must be appropriated in the following year's Budget

U.S. Congressional Appropriations Process

Contracting Phase

Funding Available in Program Office's Current Year Budget

- Present proposal of your technology/research to the US Government

Funding released

Funding Acquired by Program Office

Contract Awarded
The following report language was included in the FY18 NDAA by the House Armed Services Committee:

“The Committee is aware of research demonstrating the effectiveness of Osteopathic Manipulative Medicine (OMM) in reducing recovery time for injured athletes, and as an adjunct therapy for pain management. OMM is a non-invasive, drug-free treatment that can improve readiness and reduce the need for opioid pain medication in the armed services. The committee encourages the Department of Defense to evaluate OMM as an adjunct to manage pain and expedite recovery for warfighters.”
Navigating DoD Process

- **BAA** - Broad Agency Announcements are intended to solicit research ideas, usually without specific deadlines. Proposals are accepted on a rolling basis and are usually open for a full year; we do not generally recommend submitting proposals in response to BAAs without coordinating with us first. These announcements describe very broad areas of interest to the issuing agency and are tools for researchers to understand DoD’s interests.

- **Program Announcements** - Used especially by the DMRDP to solicit research proposals in specific military-relevant areas, these generally have specific deadlines.

- **RFIs** – The Request for Information process allows the Agency to collect information about research capabilities and assists Agency Leadership to help make decisions on what next steps to take.

- **RFPs** - Requests for Proposals are issued when funding is either programmed within the Defense Budget or Congressionally added above the budget.
Using BAAs

Use a BAA as a guide to what interests the military. For example, USAMRMC BAA 16-1 provides this guidance from the combat casualty care directorate:

“Secondary damage to organs frequently occurs after severe trauma and resuscitation. The CCCRP is interested in materiel and/or devices that can reduce acute secondary organ damage such as ischemia/reperfusion injury, cell death, general organ failure, and secondary brain/spinal cord damage. Technologies to sustain or support single and multiple organ injury and failure are also of interest to the CCCRP. These objectives include methods to reduce cellular demand for oxygen and metabolic substrates and therapeutics to modulate the immune response to traumatic injury.”
**Proposition-Based**
- Pre-Proposal or Letter of Intent
- Full proposals by invitation only
- Two-Tier Review Process (Peer and Programmatic)

**Funding awarded to the Institution versus the Principal Investigator**
Award Mechanisms

- Grants
- Cooperative Agreements
- Contracts
- Cooperative Research and Development Agreements (CRADA) (NOTE: for collaboration, not funding)
- Commercial Test Agreements
- Small Business Technology Transfer (STTR) / Small Business Innovation Research (SBIR)
- Broad Agency Announcements
- New Products and Ideas Portal
Small Business Technology Transfer (STTR)

- Unique feature of the STTR program is the requirement for the small business to formally collaborate with a non-profit research institution (i.e. university, hospital, clinic, etc.)
- Each year, Federal agencies with extramural research and development (R&D) budgets that exceed $1 billion are required to reserve 0.3% of the extramural research budget for STTR awards to small businesses. These agencies designate R&D topics and accept proposals.
- Currently, five agencies participate in the STTR program:
  1. Department of Defense
  2. Department of Energy
  3. Department of Health and Human Services
  4. National Aeronautics and Space Administration
  5. National Science Foundation
Adapt your language to the audience – military research program managers are interested in practical application of new or novel concepts.

Remember, DoD’s primary interest is in meeting requirements and solving problems. Iterative research is important to the DoD, but it has to be placed in the context of a specific problem to be addressed.

Be sure to articulate a long-range vision for the research. DoD SMEs will want to see that you are thinking about issues such as how long development will take, what regulatory approvals would be required, etc.
ADI Federal Business Development & Legislative Workshop

- ADI has extensive experience delivering workshops whereby we create panels of experts on various departments/agencies who have research budgets and who fit in with VCOM’s research interests and/or capabilities.
- Presenters will drill down in much greater detail about specific programs, research funding trends, unique capabilities sought, etc.
- Dual focus on legislative process itself (i.e. how Congress works, congressional funding timelines, Congress’s oversight responsibilities, Federal Budget process, etc.)
- Here, we would take a look at your specific members of Congress, which committees they serve on, etc.
- Typically reserve half or full day for the workshop
- Ability to conduct remotely so that all three campuses will participate simultaneously
Contacts

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Useful Links

Armed Forces Radiobiology Research Institute: [http://www.usuhs.edu/afrrri](http://www.usuhs.edu/afrrri)
Clinical and Rehabilitative Medicine Research Program: [https://crmrp.amedd.army.mil](https://crmrp.amedd.army.mil)
Combat Casualty Care Research Program: [https://ccc.amedd.army.mil](https://ccc.amedd.army.mil)
Congressionally-Directed Medical Research Programs: [http://cdmrp.army.mil](http://cdmrp.army.mil)
DoD Hearing Center of Excellence: [http://hearing.health.mil/](http://hearing.health.mil/)
Military Infectious Disease Research Program: [https://midrp.amedd.army.mil](https://midrp.amedd.army.mil)
Useful Links, cont.

National Intrepid Center of Excellence: http://www.nicoe.capmed.mil
Office of Naval Research: http://www.onr.navy.mil
Office of the Under Secretary of Defense for Acquisition, Technology, & Logistics: http://www.acq.osd.mil
Uniformed Services University of the Health Sciences: http://www.usuhs.edu
U.S. Army Aeromedical Research Laboratory: http://www.usaarl.army.mil/
U.S. Army Institute of Surgical Research: http://usaisr.amedd.army.mil
U.S. Army Medical Research Acquisition Activity: http://www.usamraa.army.mil/
U.S. Army Medical Research and Materiel Command: http://mrmc.amedd.army.mil
U.S. Army Medical Research Institute of Infectious Diseases: http://www.usamriid.army.mil
U.S. Army Research Institute of Environmental Medicine: http://www.usariem.army.mil
U.S. Army Research Laboratory: http://www.arl.army.mil
U.S. Department of Veterans Affairs, Office of R&D: http://www.research.va.gov
U.S. Naval Research Laboratory: http://www.nrl.navy.mil
Walter Reed Army Institute of Research: http://wrair-www-army.mil
Uniformed Services University of the Health Sciences (USUHS): https://www.usuhs.edu/