



Learn Our Language: The ABCs of Working with US Army Medical Research and Materiel Command - Tools to Build a Partnership

UNCLASSIFIED

6 March 2017





U.S. Army Medical Research and Materiel Command Overview

UNCLASSIFIED

LTC John Goodrich
US Army Medical Research and Acquisition Activity
6 March 2017



Disclaimer



The views expressed in this presentation are those of the author(s) and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.



Mission and Vision











We Save Lives





Focused on materiel and knowledge-based medical solutions to:

- Increase warfighter readiness
- Improve fitness, health, protection, and resilience
- Improve downrange health delivery
- Enhance recovery, rehabilitation or reintegration



USAMRMC: Where Saving Lives Begins!



U.S.ARMY

Why is Army Medicine Involved?



Select, modify, and procure commercial medical materiel solutions when appropriate or we partner to develop.

We take the lead in R&D when:

- The issue is unique to the military
 - Blast injuries
- Industry/academia lack interest
 - Endemic diseases in specific area of responsibility (AOR)
- Military needs a timely solution
- Directed by Congress



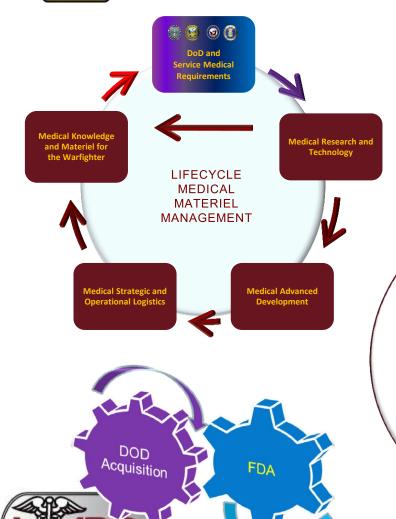






Army's Medical Lifecycle Manager





A full lifecycle command leveraging DoD, Federal, Academic, and Industry partners to advance military medicine





Threats to Service Member Readiness

Combat Injuries

Hemorrhage Head Trauma Blast Injury Lung Injury Burns

Mental & Physical Stress

Physical Performance
Musculoskeletal Injuries
Cognitive Performance
Mental Health
Post-Traumatic Stress
Suicide

Endemic Diseases

Parasitic Diseases Bacterial Diseases Viral Diseases

Battle Sequelae

Loss of limbs Loss of tissue Loss of vision Pain

Environmental Hazards

Heat and Cold Altitude Toxic Industrial Chemicals

Systems Hazards

Lasers Noise

Chemical & Biological Warfare Agents

Chemical Warfare Agents Biological Warfare Agents







Response to Threats



Combat Injuries

- Hemorrhage Control and Resuscitation devices (tourniquets), drugs, and blood products prevent leading cause of preventable death
- Joint Trauma System Clinical Practice Guidelines: evidence-based guides for Combat Casualty Care
- Diagnostic Tests for Traumatic Brain Injury: on-the-spot assessment minimizes unnecessary MEDEVAC, speeds return-to-duty

Performance (function/dysfunction)

- Musculoskeletal injury prevention guidelines and optimized training reduce the risk of musculoskeletal injuries
- Resiliency solutions enhance human performance, prevent negative behaviors, and prepare Warfighters to handle operational stressors

Systems Hazards

 Sensory Performance and Hearing Protection standards and drugs to prevent hearing loss and reduce the incidence of tinnitus in Warfighters

Battle Sequelae

- Battlefield Pain Management Drug rapidly treats severe pain without complications of opioid drugs
- Regenerative medicine technologies will restore form and function to severely injured Warfighters

Environmental Hazards

- Environmental Sentinel Biomonitor ensures safe drinking water
- Extreme Environments: predictive models, decision aids and countermeasures prevent or mitigate the effects of the extreme environments

Endemic Diseases

- Leishmania Rapid Test and Topical
 Drug diagnose and treat at Role 1
 without MEDEVAC or use of toxic drugs
- Intravenous Artesunate is a last-line treatment for deadly falciparum malaria

Endemic Diseases (cont'd)

- Zika vaccine will prevent illness, complications (congenital, neurological)
- Joint West Africa Research Group: build sustainable partnerships and platforms to address DoD and global health needs and prevent surprise

Chemical and Biological Threats

 Emergency Use Authorization for DoD Ebola Zaire Diagnostic Assay, Ebola vaccine clinical trials: developing safe and effective countermeasures against lethal hemorrhagic fever viruses





Program Area Directorates





Ft Detrick



PA(R&T) Fort Detrick, MD

Principal Assistant for Research & Technology

Program Area Directorates (PADs) – Functions

- Manage programs; do not execute programs (do not perform research and technology)
- Fund intramural and extramural research and technology
- Responsible for both the problem set and the solution set
- Devise a research strategy (program) and fund research and technology that fit the program
- Collaborate with industry, academia and professional societies

Medical Simulation and Information Sciences Research Program (MSISRP) – *Dr. Janet Harris*

- Medical simulation and training
- · Health informatics and mobile health
- Decision support tools and physiological models

Program Coordinating Offices

- CBRN Defense Medical Research
- DoD Blast Injury Research Program
- Joint Trauma Analysis and Prevention of Injury

Military Infectious Diseases Research Program (MIDRP) – COL Michael Kozar

- Medical Readiness
- Vaccines
- Biotechnology
- Prophylaxis/treatment drugs
- Diagnostics/prognostics
- Vector Control
- Medical 4ISR
- HIV countermeasures (congressional mandate)

Combat Casualty Care Research Program (CCCRP) – Col Todd Rasmussen

- Trauma care and resuscitation
- Traumatic brain injury care
- Blood replacement on the battlefield
- Technology to support combat medic
- Acute pain management
- Burn and acute wound management
- Combat dentistry research

Military Operational Medicine Research Program (MOMRP) – COL Dennis McGurk

- Injury prevention and reduction
- Psychological health and resilience
- Physiological health
- Environmental health and protection

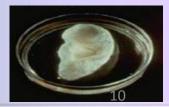
Clinical & Rehabilitative Medicine Research Program (CRMRP) – COL Teresa Brininger

- Rehabilitation of neuromusculoskeletal injuries
- Regenerative medicine and transplants
- Sensory Systems (Vision, Hearing and Balance)
- Pain management













Advanced Development Program





Ft Detrick



PAA Fort Detrick, MD

Principal Assistant for Acquisition (PAA) (Medical Milestone **Decision Authority)**

US Army Medical Materiel Agency

COL Lynn Marm, Commander Dr. Tyler Bennett, Deputy for Acquisition

Medical Devices - Mr. Douglas Wright

Commercial and Developmental Medical Devices

Integrated Clinical Systems - Ms. Terri Pryor

- Clinical Technologies
- Image Management Systems

Medical Evacuation Mission Equipment Package – LTC Charles Cook Enterprise Information Technology Systems - Mr. Darrin Good

FDA-compliant IT Systems



US Army Medical Materiel Development Activity

COL William Geesey, Commander Ms. Kathy Berst, Deputy for Acquisition

Pharmaceutical Systems – Dr. Lawrence Lightner

- **Antiparasitic Drugs**
- Virus, Bacteria, and Parasite Vaccines
- **Blood Products**
- Infectious Disease Diagnostics
- Pain Management

Medical Support Systems - Mr. Steven Hawbecker

- Combat Casualty Care
- **Ground & Air Evacuation Systems**
- **Preventive Medicine Systems**
- Cold Chain Management Systems
- Medical Prototype Development Lab

Neurotrauma & Psychological Health - LTC Kara Schmid

- **Drug Treatment**
- Diagnostics
- **Knowledge Products**

Tissue Injury & Regenerative Medicine / Advanced Tissue Biofabrication Manufacturing – Ms. Kristy Pottol

- Cellular Therapies
- **Knowledge Products**

Hyperbaric Oxygen – CAPT Brett Hart

Knowledge Products



Procurement – US Army Medical Research and Acquisition Activity (USAMRAA)



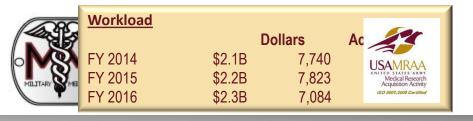
PARC Roles and Responsibilities

- Surveys performance
- Approves individual deviations to the FAR/DFARS/AFARS
- Issues command specific procurement guidance





- Senior Trained Staff Official of the Contracting function
- Carries our delegable authorities of the Head of Contracting Activity (HCA)
- USAMRAA is the contracting element of the USAMRMC
- Provides support to the Command headquarters and its worldwide network of laboratories and medical logistics organizations (e.g., Cooperative Agreements, Grants, Contracts)
- USAMRAA also supports Army-wide projects sponsored by the Army Surgeon General, and numerous Congressionally mandated programs





Tools to Build a Partnership Highlights



- » Small Business Considerations Mr.Jerome Maultsby
- Gateway to Partnering (NPI) Ms.Amanda Cecil
- Contracting and Assistance The Basics –
 Ms. Laurie Hovermale
- » CRADAs Mr. Bob Charles
- » SBIR/STTR Ms. Colleen Gibney







Resources for our Business Partners



» Office of Small Business Programs

http://www.mrmc.smallbusopps.army.mil/

» New Product Ideas Web Portal http://mrmc-npi.amedd.army.mil/



- » US Army Medical Research Acquisition Activity http://www.usamraa.army.mil/
- » US Army Medical Research and Materiel Command Office of Research and Technology Applications http://technologytransfer.amedd.army.mil/
- Small Business Innovation Research / Small Business Technology Transfer DoD

http://www.acq.osd.mil/osbp/sbir/







Office of Small Business Programs

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Mr. Jerome Maultsby Associate Director

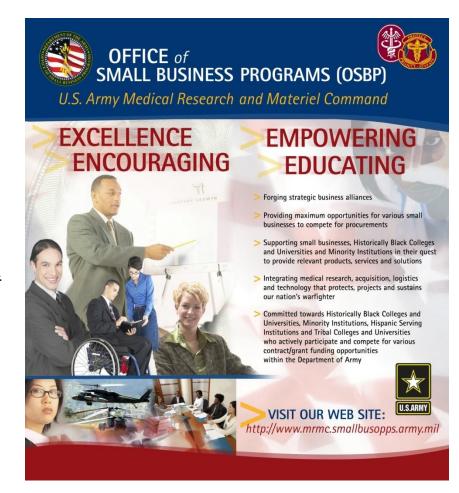
US Army Medical Research and Materiel Command 6 March 2017



Office of Small Business Programs



- Mission: Forge strategic business alliances and provide maximum opportunities for various categories of small businesses and HBCU/MI to compete for procurements as either a prime or subcontractor.
- Vision: Assure all reputable small business concerns remain a vital link to USAMRMC's ability to provide relevant and innovative business solutions in support of Department of Defense and other government agency initiatives.





It is the Law!



15 U.S.C. §631(a)

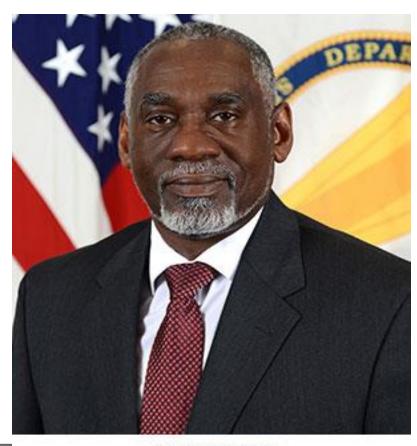
The essence of the American economic system of private enterprise is free competition. The preservation and expansion of such competition is basic not only to the economic well-being but to the security of this Nation. Such security and well-being cannot be realized unless the actual and potential capacity of small business is encouraged and developed. It is the declared policy of the Congress that the Government should aid, counsel, assist, and protect, insofar as is possible, the interests of small-business concerns in order to preserve free competitive enterprise, to insure that a fair proportion of the total purchases and contracts or subcontracts for property and services for the Government ... be placed with small business enterprises, to insure that a fair proportion of the total sales of Government property be made to such enterprises, and to maintain and strengthen the overall economy of the Nation



Director, Army Office of Small Business Programs



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Mr. Tommy Marks Director

"Our vision is to be the premier advocacy organization committed to maximizing small business opportunities in support of the Warfighter and the institutional transformation of the Army."





Educate – Change the Culture



• What is the Small Business Program?

- A Mission Enabler
- A Resource that Results in ... Competition, Affordability, Choice
- Industrial Base Development Program
 - Consisting of large and small businesses
 - Develop future sources for government requirements
 - Create strategies and requirements that generate competition
- Tools to make smart decisions
- Strategic, future competition

What the Small Business Program is not...

Not a social welfare program, and not goals



Office of Small Business Programs



- 10 Steps To Doing Business With the U.S. Army & USAMRMC
- Step 1: Determine what you want to market/sell, and your business size
- Step 2: Register in the System for Award Management (SAM)
- Step 3: Identify which Army/DoD organizations buy your product/service or business solutions
- Step 4: Identify anticipated/current Army procurement opportunities (i.e., forecasts)
- Step 5: Become familiar with federal contracting regulations and procedures
- Step 6: Utilize the U.S. Army Small Business Programs
- Step 7: Be prepared to compete, win the contract, and perform IAW terms and conditions





Office of Small Business Programs



- 10 Steps Continued –
- Step 8: Seek additional assistance in the Defense marketplace
- Step 9: Pursue Subcontracting Opportunities (\$750K and >)
- Step 10: Investigate Federal Supply Schedules (FSS) on www.gsa.gov
- ***Be receptive to feedback from government procurement representatives.





Top NAICS Codes within USAMRMC



NAICS

334310

339112/113

541690

561111

541711/712

811219/211

541519

541990

334112

333314

Commodity

Manufacturing Computer/Electronic Products

Manufacturing, Miscellaneous

Professional Scientific and Technical Services

Technical Services, Biomedical Technician

Professional Scientific and Technical Services

Precision Equipment Repair and Maintenance

Other computer related Services

All Other Professional, Scientific, & Technical

Computer Storage Device Manufacturing

Electronic Computer Manufacturing





10%

0%

SB

Hunter/peter.j.hunter4.civ@mail.mil/(210)295-7178

FY16 Year-End Small Business Metrics





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SDVOSB

3.45%

Slide 4 of 9

7.13%

6.00%

WOSB

2 October 2016

1.00% 0.74%

HZ SB

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SDB

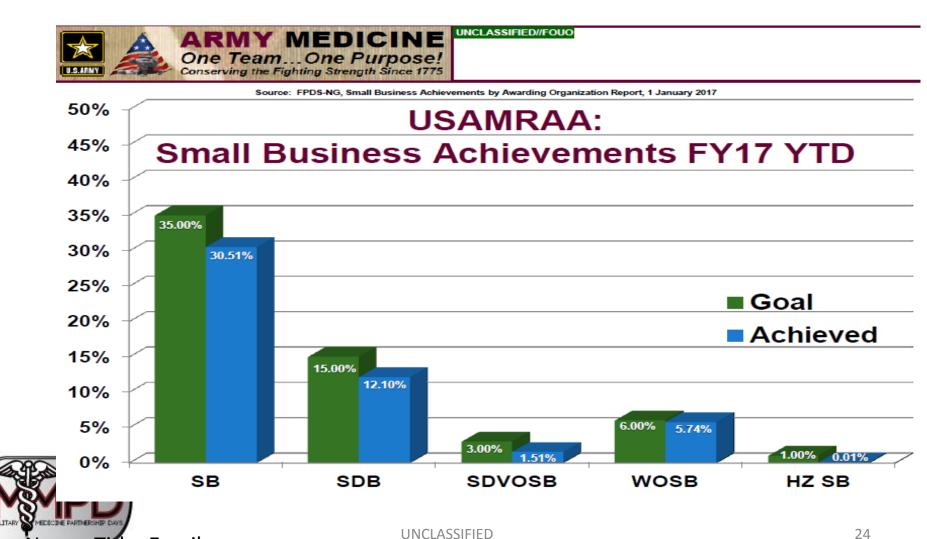
3.00%

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Small Business Achievements FY 17 YTD







DoD Office of Small Business Programs







Department of Army Office of Small Business Programs







Small Business Administration



Contracting | The U.S. Small Business Administration | SBA.gov



Search SBA.gov



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Government Contracts Overview >

Contracting

Video: Sell to the Government ▶ Qualify for Government Contracts ► Government Contracting Blogs ►

SBA.gov » Contracting

What is Government Contracting?

Overview

SBA's Role in Contracting

Your Responsibilities as a Contractor

Contracting Regulations

Finding Government Customers

Resources for Finding Customers

Getting Started as a Contractor

Qualifying as a Small Business

Make Sure You Meet SBA Size Standards

Get a D-U-N-S Number

Determine Your NAICS code

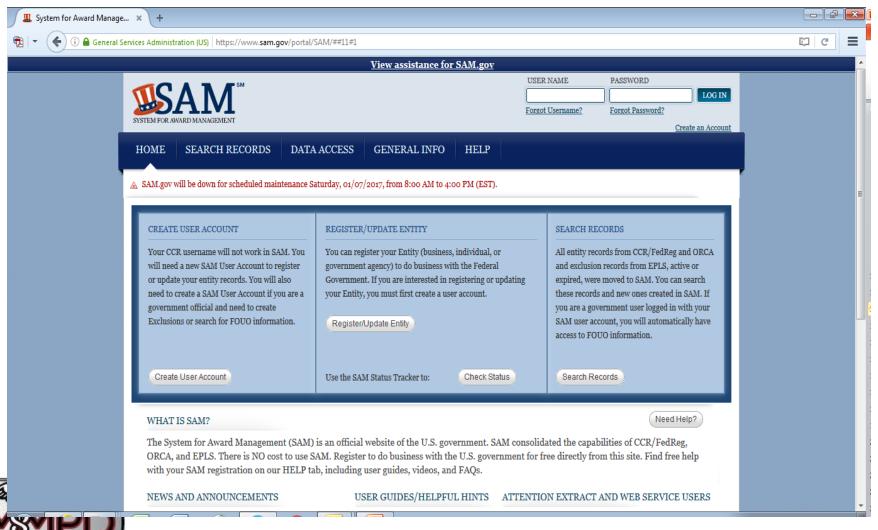
Register as a Government Contractor

Government Contracting Programs



System for Award Management

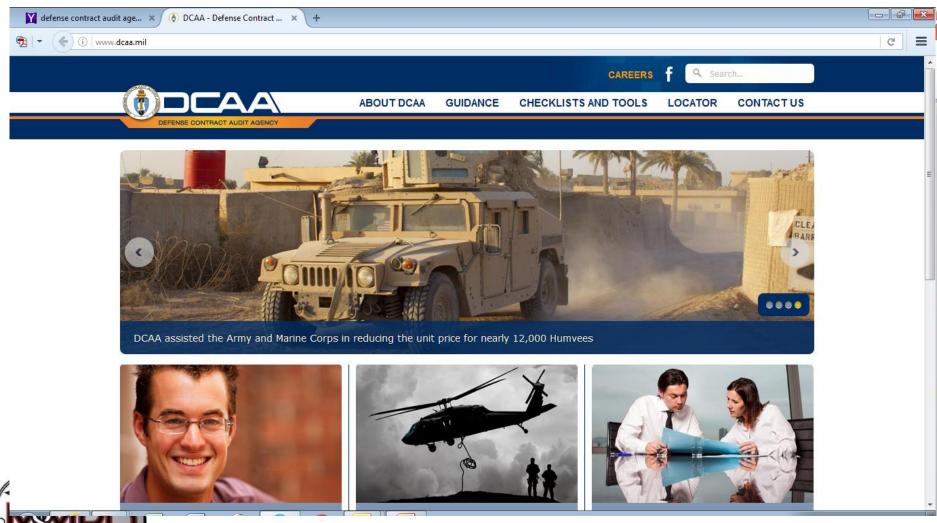






Defense Contract Audit Agency







Website - mrmc.smallbusopps.army.mil



United States Army Medical Research and Materiel Command
or /> and Fort Detrick | Office of Small Business Programs



Office of Small Business Programs

United States Army Medical Research and Materiel Command and Fort Detrick



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ABOUT OSBP | OUR CUSTOMERS | OSBP INITATIVES | CONTACT US | BUSINESS OPPORTUNITIES | SITEMAP |

Headquarters, USAMRMC

HQDA OSBP

DoD OSBP

USAMRAA

CDMRP

FedBizOpps

Expectations for OSDBU Directors

The Center for Veterans Enterprise

USACE Baltimore District

Electronic Subcontracting Reporting

System (eSRS)

Small Business Administration

USAMRMC Business Tutorial

Internship Opportunities

Contact Webmaster

iSalute

IMPORTANT LINKS

OSBP Newsletter February 2016

OSBP Newsletter May 2015

February 2015 Newsletter

New Products & Ideas (NPI)

Broad Agency Announcements (BAA)

FDBDO Closure

Newsletter

Pre-Proposal Information

STTR Information

SBIR Information

Fort Detrick Garrison

Solicitations

Government Purchase Card

Grants.Gov

HBCU / MI / HSI / TCU

FAQ's

WELCOME



A Message from the Associate Director, Office of Small Business Programs, US Army Medical Research and Materiel Command

NEWS & UPDATES



Military Medicine Partnership Conference



FY 2017 Small Business Goals



Y 16 Year-End Small Business Achievements



USAMRMC FY17 Supplemental AAF (pending)



2016 Spring Research Festival

FY 2016 Assigned Small Business Goals

Conference 19-20 April - Medical Research, Development and Acquisition

in Support of the Warfigther

USAMRMC FY16 Supplemental AAF

Expand list for older items, click here.

OSBP PROGRAM AREAS

Small Businesses

HUB Zone

Small Disadvantaged Business





Internal Stakeholder Coordination



OSBP

(Office of Small Business Programs)

Head of Contracting Activity

Contracting Office, Commanders,

Directors

Advance Acquisition Plans, PMs

SBA, DoD, and HQDA

(Small Business Administration, Department of Defense and Headquarters, Department of Army)





External Stakeholder Coordination



SYNERGISTIC APPROACH

INDUSTRY

Small & Large Businesses

(Innovative & Relevant Products, Services, & Business Solutions)

ACADEMIA

(Biomedical, Engineering Research Universities, and HBCU/MI)

Other Government Entities

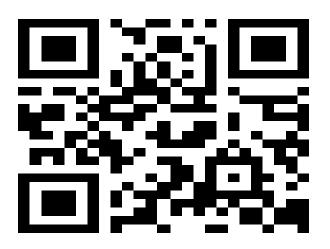
(Advanced technologies & innovative discoveries)





Organizational QR Code Office of Small Business Programs











Small business is big business

in the Army!

Department of the







New Products and Ideas (NPI) "Gateway to Partnerships"



Ms. Amanda Cecil
New Products and Ideas Administrator
Strategic Planning Office (ATC)
US Army Medical Research and Materiel Command
6 March 2017

NPI Purpose





- » NPI is a mechanism for submitters to determine MRMC interest in their new products, services, or ideas
- » It is a starting point for individuals who are not familiar with finding information or opportunities and want to raise awareness in their products/ideas
- » It is a web-based system designed to provide timely feedback to submitters





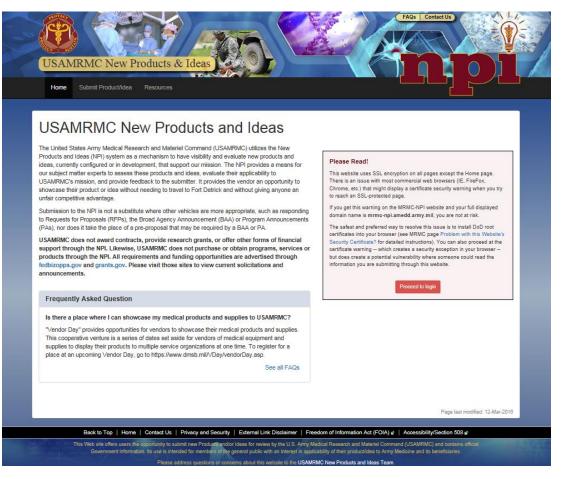


NPI Background





- The first version of NPI went "live"December 2006
- » Revamped website launched April 2016
- » Widely accessible





Link: http://mrmc-npi.amedd.army.mil/



The "Fine Print"





NPI gives the public direct access to the scientific expertise of DoD. The NPI portal is open to the public, so anyone can submit an idea or information about a new product and have it reviewed by DoD subject matter experts.

However:

- » NPI is not a substitute when the Broad Agency
 Announcement/Program Announcement (BAA/PA) or Request for
 Proposal (RFP) is a more appropriate entry portal
- » NPI is not for submission of a proposal or a pre-proposal
- » NPI does not directly award contracts, provide research grants, or offer other forms of financial support





How To Apply/Register





Visit the USAMRMC homepage and scroll down to NPI



How To Apply/Register cont'd





d Ideas

VIC) utilizes the New late new products and VPI provides a means for applicability to vendor an opportunity to vithout giving anyone an

opriate, such as responding or Program Announcements BAA or PA.

other forms of financial tain programs, services or re advertised through solicitations and

Please Read!

This website uses SSL encryption on all pages except the Home page. There is an issue with most commercial web browsers (IE, FireFox, Chrome, etc.) that might display a certificate security warning when you try to reach an SSL-protected page.

If you get this warning on the MRMC-NPI website and your full displayed domain name is mrmc-npi.amedd.army.mil, you are not at risk.

The safest and preferred way to resolve this issue is to install DoD root certificates into your browser (see MRMC page Problem with this Website's Security Certificate? for detailed instructions). You can also proceed at the certificate warning — which creates a security exception in your browser — but does create a potential vulnerability where someone could read the information you are submitting through this website.



Click on Proceed to Login/Create new account



My Account

An MRMC-NPI account is required to submit a new product/idea through this website.

Having an account allows us to verify your contact information; it also provides a way for you to start a submission,

Use the form below to create your account. Items marked with an * are required.

* Email:	Email	
* Confirm Email:	Re-type Email	
* First Name:	First name	
* Last Name:	Last name	
* Phone Number:	Phone number	
Organization:	Select	~
Organization Type:	Select	~
Address:		
City:		
State:	Select	
Postal Code:		
Causton	Colori	~
	Create account Cancel	

Fill in blanks and create account

NPI Process/Outcomes





- » Submitter enters data into the website/form; submission routes to subject matter expert
- » Subject matter expert reviews information and provides feedback in 60 days or less
- » Submission information is archived and password protected
- » Submitters may be directed to submit to:
 - » An existing Request for Proposal (RFP)
 - » A Program Announcement (PA)
 - » The Broad Agency Announcement (BAA)
 - » Other funding opportunities, e.g. Small Business Innovation Research (SBIR) or other agencies
- Submitter may be asked to present at a Military Health System
 Vendor Day, located at Fort Detrick, MD



U.S.ARMY

Example Good News / Successful Interactions



- » Steady increase in number of NPI submissions since April 2016; average 11 submissions per month
- » Submission to NPI resulted in further collaborative ventures for multiple products in areas such as Combat Casualty Care, Pest Management, Military Operational Medicine, Casualty Care Support Systems, Infectious Diseases, Burn Treatment, and Surgery
- » NPI has gained interest from other federal entities; discussions around possible partnerships
- » Submission to NPI has led to increased communications between submitters and organizations such as US Army Medical Command, PEO Soldier, Air Force



Useful Tips





- » Due to timeout requirements, we strongly encourage you answer submission questions in a Word document in order to copy/paste into the online version
- While there is no funding associated, NPI allows for constructive feedback which may help you to tailor your submissions to the BAA/PA/SBIR
- » Familiarize yourself with USAMRMC missions and review NPI categories and definitions to identify which discipline your product or idea may fall into







Military Health System Vendor Days



- Opportunity for vendors to showcase products for the austere medical environment to the Defense Health Agency (DHA) and six medical materiel agencies under the Department of Defense (DoD)
- » Frequency held seven times per year beginning in March through November







Vendor Day Website - http://www.health.mil/VendorDay





Military Medicine Partnership Days



 Purpose of MMPD – bring together Government, academia, industry, nonprofit organizations, and other stakeholders for discussions of gap areas and issues related to medical materiel and equipment development, acquisition, and technology efforts







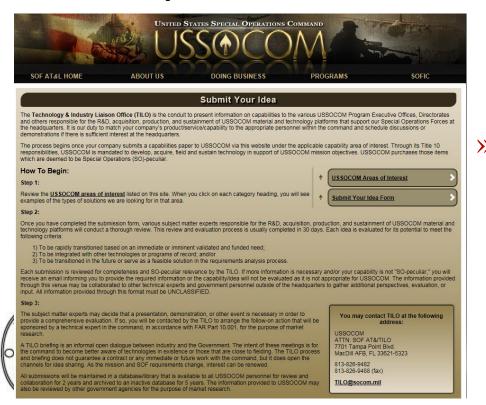


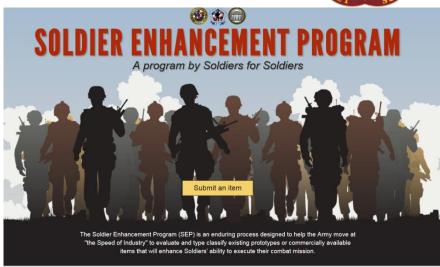


Other Resources/Systems Similar to NPI



» PEO Soldier – Soldier Enhancement Program http://www.peosoldier.army .mil/sep/





 SOCOM – Technology & Industry Liaison Office (TILO)
 http://www.socom.mil/sordac /Pages/SubmitYourldea.aspx

U.S.ARMY

For More Information



- » For NPI and how to get started All inquiries should be directed to the NPI email address at <u>usarmy.detrick.medcom-usamrmc.other.npi@mail.mil</u> or to the USAMRMC Strategic Planning Office at 301-619-1880
- » For other related resources:
 - » Visit the NPI website and USAMRMC website for more information regarding DoD programs/areas of interest and to view our "Gateway to Partnerships" brochure









Contracting and Assistance – The Basics



Ms. Laurie Hovermale
Chief, Business Operations Division
US Army Medical Research Acquisition Activity
6 March 2017

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U.S. Army Medical Research Acquisition Activity (USAMRAA)



USAMRAA is the contracting and assistance agreement element of the USAMRMC.

- ➤ Supports MRMC headquarters and its worldwide network of laboratories and medical logistics organizations (e.g. Cooperative Agreements, Grants, Contracts, Other Transactions for Prototype)
- ➤ USAMRAA also supports Joint Service Programs, Army-wide projects sponsored by the Army Surgeon General, Defense Health Agency and numerous Congressionally mandated programs.

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FY 2015

FY 2016

Dollars Actions \$2.4B 7,823 \$2.3B 7,084





USAMRAA's Home Page www.usamraa.army.mil





United States Army Medical Research Acquisition Activity USAMRAA

PRODUCTS | CUSTOMERS | ORGANIZATION | BUSINESS | REFERENCES | COMMUNITY | TOOLS | LINKS | SITEMAP |

- **7** OSBP
- **➢** Assistance Agreements
- 7 Forms
- Assistance Advisory Notices
- Procurement Advisory Notices
- 7 New Products & Idea Submissions
- 7 BAA
- Contact Webmaster
- 7 iSalute
- 7 PRWeb Help
- **MRMC**
- **MEDCOM**
- ARMY.MIL
- 7 SHARP
- National Suicide

Prevention Lifeline

IMPORTANT LINKS

Conference - Medical Research, Development and Acquisition in Support of the Warfighter.

Center of Excellence

CMRA

USAMRAA Contract Requirements Matrix

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

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 FEDBIZOPPS and ASFI

SOLICITATIONS \$15,000 TO \$25,000

Pursuant to FAR 5.101(a)(2) all solicitations issued by this activity expected to exceed \$15,000 and not expected to exceed \$25,000 will be posted on Federal Business Opportunities at https://www.fbo.gov, Choose the "Opportunities" tab, then enter "Department of the Army / U.S. Army Medical Research Acquisition Activity" in the Agency search field.

FISCAL YEAR 2016 YEAR END CUT-OFF CONTRACTING SERVICES

Memorandum: Notification of Fiscal Year 2017 (FY17) Year-End Cut-Off for Acquisition Services and CAAW Estimate Template FY17

MISSION

The US Army Medical Research Acquisition Activity provides quality, timely, and cost effective business advice and solutions for our customers.



Award Instruments and Regulatory Authority



Principal Purpose (31 U.S.C 6301-6308)

Purpose	Process	Regulation
To acquire property or services for the direct benefit or use of the US Government	Contract	 Federal Acquisition Regulation (FAR) Defense Federal Acquisition Regulation Supplement (DFARS) Service specific regulations
To stimulate or carry out a public purpose authorized by law	Grant or Cooperative Agreement	 Department of Defense Grant and Agreement Regulations (DoDGAR) 2 CFR 200

- Advertising funding opportunities
- Competition requirements
- Evaluation criteria and selection processes
- Various restrictions and limitations





Types of Instruments for Medical Research & Development Awards

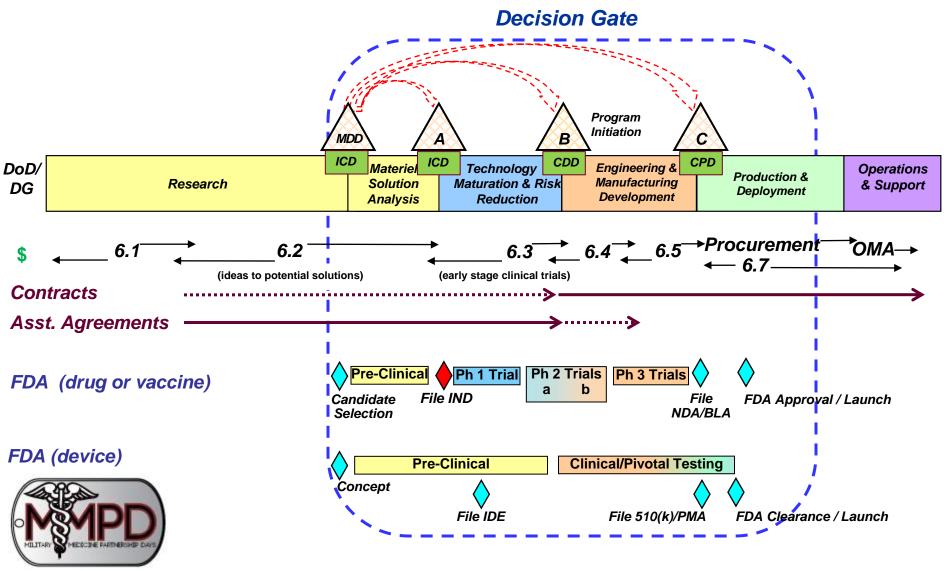


	Non-Procure	ment (Assistance)	Procurement (Acquisition)	
Areas of Difference		e Agreements R, 2 CFR 200	Contracts FAR, DFARS, AFARS	
Award Type	Grants	Cooperative Agreements	Numerous Types	
Advertised	www.grants.gov		www.fbo.gov	
Solicitation Method & Review Process	Program Announcement (PA) or Broad Agency Announcement (BAA); Peer and Programmatic Review		Request for Proposal (RFP); Source Selection Board	
Principal Purpose	The principal purpose of the activity to be carried out is to stimulate or support a public purpose, rather than the direct benefit of the US Government		The principal purpose is the acquisition of supplies and service for the direct benefit or use of the Federal Government	
Fee or Profit	DOD does not allow fee or profit		Permitted, Negotiable, For-Profit Organizations	
Termination	 (1) Recipient has the unilateral right to terminate (2) Government has the right to terminate for "material failure to comply" (3) Mutual agreement of both parties 		Government has the unilateral right to terminate at any time for its convenience and for default ("T for C" and "T for D")	
Patents	Patent rights per Bayh Dole Act. Gives recipient the right to elect title to subject inventions		Patent rights per Bayh Dole Act. Gives recipient the right to ele title to subject inventions	
Intellectual Property (Other than Patents)	Federal Purpose Rights		Procedures and clauses in place to identify, negotiate, and validate right to proprietary information (Data Rights and Copyrights)	
Other Considerations		Consortium (Large Arrangements)	Partnering with Commercial Entities Small Business Considerations	



Moving from Applied Research to Development







Synopsis of Requirements or Funding Opportunities



Type of intended award drives how the requirement is advertised and the location of synopsis.

- > Procurement Contracts
 - Synopsized on FEDBIZOPS
 - Solicitation or Request for Proposal released
- ➤ Grant or Cooperative Agreements
 - Synopsized on Grants.gov
 - Funding Opportunity Announcement released
- ➤ MRMC Broad Agency Announcement
 - Synopsized on FEDBIZOPS and Grants.gov





FEDBIZOPPS (1 of 3)



- ➤ URL is https://www.fbo.gov
- > Advertise:
 - Requests for Information
 - Pre-solicitation Notices and Solicitation/RFP
 - Requirements greater than \$15,000
 - Draft solicitations
 - Award notices





FEDBIZOPPS (2 of 3)



- > Active or archive search by:
 - Dates
 - Type of Notice
 - Solicitation or Award Number
 - Place of Performance Zip Code
 - Set-Aside Type
 - NAICS/FSC/PSC
 - Key Words
 - Agency Identify or DODAAC (W81XWH)





FEDBIZOPPS (3 of 3)



- ➤ Tip: Register for Vendor Notification Service by:
 - Specific Solicitation Number
 - Same selections as Above
 - All Notices (Caution)





Helpful Tips When Responding to Requests For Proposals (1 of 3)



> FEDBIZOPS

- Read and Respond to Requests for Information or Sources Sought Notices
- Solicitations/RFP
 - Read Entire Document
 - Pay Special Attention to:
 - Performance Work Statement / Statement of Work or Minimum Essential Characteristics (Section C)
 - Special Instructions (Section H)
 - Instructions to Offerors (Section L)
 - Evaluation Criteria (Section M)
 - Submission deadlines for questions and proposals





Helpful Tips When Responding to Requests For Proposals (2 of 3)



- Solicitations/RFP (continued)
 - Determine the type of skills and quantity of resources necessary to perform work
 - Take notes
- Questions
 - Do not make assumptions
 - Submit all questions timely
- Proposal Submission
 - Complete
 - Acknowledge all amendments
 - Proper format
 - Timely





Helpful Tips When Responding to Requests For Proposals (3 of 3)



Negotiations

- Address all weaknesses and deficiencies
- Review revised proposal before submission

> After Award

- Ask for a debriefing
- Perform the work as proposed
- Submit timely deliverables
- Monitor FEDBIZOPS for new requirements





How Long is The Process?



- ➤ Varies dependent on requirement characteristics and regulatory guidance.
 - Synopsis 15 days prior to issuance of solicitation if non-commercial
 - Response time (from date of issuance)
 - Questions approximately 10 days
 - Proposal 30 days non-commercial
 - Proposal 45 days R&D
 - Evaluations range 2 4 weeks
 - Discussions/Clarifications 2 weeks
 - Possible re-evaluation/discussion cycle -2 4 weeks
 - Final evaluation and source selection 2 4 weeks
 - Performance start date as stated in award





Be Aware of Subcontracting Opportunities



- FedBizOpps "Small Business Events" and "Vendor Collaboration" announcements https://www.fbo.gov
- ➤ **Defense.gov** >\$7M award notices https://www.defense.gov/News/Contracts
- ➤ Office of Small Business Programs
 https://www.acq.osd.mil/osbp/
- > SBA SUB-Net https://sba.gov/contracting/finding-government-customers/subcontracting/sub-net





Grants.gov (1 of 2)



- ➤ URL is http://www.grants.gov
- ➤ Common location for all Federal Funding
- Opportunity Announcements (Extramural)
- Portal for submission of all grant applications
- ➤ Ability to browse opportunities or search for specific opportunities





Grants.gov (2 of 2)



- ➤ Browse funding opportunities by:
 - Newest
 - Categories (S&T and other R&D)
 - Agencies (DoD)
 - Eligibilities (state, local gov't, non-profit w/501(c)3)
- > "Search Grants" by:
 - Key words
 - Opportunity Number
 - CFDA (12.420)





Funding Opportunity Announcements



- Format and content established by OMB and used Government wide
- > Research requirements announced on either:
 - Specific program area(s) of interest; or
 - Agency's broad areas of interest
- > Applications received through Grants.gov





Program Announcements



- > Specific to a Program's research interest
- > Application submission deadlines apply
- > Result in award of grants or cooperative agreements
- > Estimated funding amounts and number of awards
- ➤ Pre-application required, full application/proposal by invitation only
- ➤ Number of submittals typically restricted
- > Follows two-tier evaluation process





Broad Agency Announcements



Both FAR and DoDGAR include provisions for Broad Agency Announcements (BAA)

- Applicable to basic, applied and advanced research for scientific study and experimentation directed towards advancing the state of the art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution
- Targets requirements that meet budget activities 6.1 6.3 (BA 6.4 grey area)





How Long is The Process?



- ➤ Varies dependent on requirement characteristics and regulatory guidance.
 - Pre-application submission 30-45 days from posting to Grants.gov
 - Review and invitation release -30-45 days
 - Application submission 80 days
 - Peer Review 60 days
 - Programmatic Review 48 days
 - Funding approval -2-5 weeks
 - GOR pre-coordination -2-4 weeks
 - Award negotiation -90 120 days





USAMRAA's Approach to Broad Agency Announcements (1 of 3)



- > Typically contain all regulatory requirements to allow award of either a research contract, grant or cooperative agreement
- Synopsized on both FEDBIZOPPS and Grants.gov
- Agency's research interests conveyed either for an individual program area or for broadly defined areas of interest for all Agency requirements
- ➤ Note: Applications/Proposals received through Grants.gov





USAMRAA's Approach to Broad Agency

Announcements (2 of 3)



MRMC Agency BAA

- Broadly defined areas of interest of Agency
- New fiscal year BAA posted every 1 October
- No specified funding amounts or estimated number of awards
- Pre-application required, full application/proposal by invitation only
- No restriction on the number of pre-application submittals
- Follows two-tier evaluation process





USAMRAA's Approach to Broad Agency Announcements (3 of 3)



MRMC Program Specific BAA

- Narrower focus Program research interest(s)
- Caution: Application submission deadlines
- Estimated funding amounts and number of awards
- Pre-application required, full application/proposal by invitation only
- Number of submittals may or may not be restricted
- Follows two-tier evaluation process





Tips for Collaborating with the DoD



- Collaboration is encouraged!
- Pre-planning is highly recommended
- Caution: Pay special attention to budget submission requirements
 - Military facility costs must be identified separately within the budget submission
 - MRMC opportunities include special budget form "Collaborating DoD Military Budget Form"
 - Used to identify all Military facility direct and indirect costs associated with research project
 - Funding will be transferred via resource management process outside
 the contract, grant or cooperative agreement award



Key Agency Contacts



PARC, Director (301) 619-8808

Office Manager (301) 619-2183

Executive Officer (301) 619-9879

Chief of Staff (301) 619-2933

Chief Operations Division (301) 619-2180







CRADAS (Cooperative Research and Development Agreements)

UNCLASSIFIED

Mr. Robert L. Charles, J.D., LL.M., M.P.H.
Chief, Medical Research Law
US Army Medical Research and Materiel Command
6 March 2017

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What is a CRADA?





The Big Picture

 A flexible mechanism for federal laboratories to do R&D collaborations with nonfederal parties. CRADAs are used for Non-Disclosure Agreements, Material Transfer Agreements, as well as complex R&D collaborations.





". . . any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources, with or without reimbursement (but not funds to the non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research and development efforts which are consistent with the missions of the laboratory;"



U.S.ARMY

What is a CRADA? (cont'd)



...any agreement between one or more Federal laboratories and one or more non-Federal parties under which **the Government**, through its laboratories, **provides** resources **with or without reimbursement**..."

 This is stand-alone, discretionary to the lab, statutory authority to negotiate and receive reimbursement from \$0.00 up to fair market value for whatever the lab will provide or has provided



U.S.ARMY

What is a CRADA? (cont'd)



"...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to the non-Federal parties)..."

 The lab cannot provide funds, but it can direct the partner to other potential funding sources, such as grants, SBIR, state economic development funds, etc.

U.S.ARMY

What is a CRADA? (cont'd)



"...any agreement between one or more Federal laboratories and one or more non-Federal parties under which ... the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources..."





What is a CRADA? (cont'd)



All resources to be provided by the parties, including how much reimbursement goes to the lab, are

NEGOTIABLE!







SBIR and STTR Programs



- Congressionally-mandated
 Programs intended to promote technological innovation and economic growth through Federal investment
- Eleven Federal agencies participate
- The Small Business Administration (SBA) holds programmatic authority as expressed in SBIR/STTR Policy Directives







Federal Agency Participation



SBIR + STTR Programs:



Dept. of Defense



Dept. of Health and Human Services



Dept. of Energy



National Aeronautics and Space Administration



National Science Foundation

SBIR Program only:



Dept. of Agriculture



Dept. of Education



Dept. of Transportation



Environmental Protection Agency



Dept. of Homeland Security



Dept. of Commerce

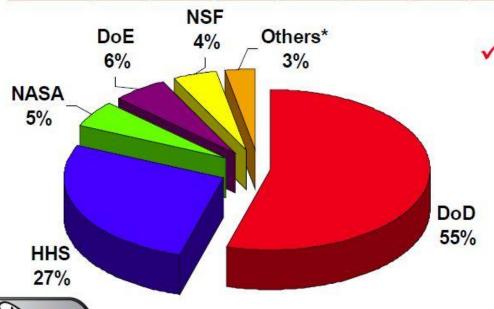




Federal Agency Participation



	DoD	NASA	DOT	EPA	DHS	USDA	DOE	NSF	DOC	DoED	HHS
SBIR	•	•	•	•	•	•	•	•	•	•	•
STTR	•	•					•				
Contract/ Grant	С	С	С	С	С	G	G	G	G/C	G/C	G/C



- ✓ Small Business Administration (SBA) oversees the federal SBIR/STTR programs
 - Policy Directives
 - Congressional Reports
 - Size Determination
 - Waivers



DoD Component Participation



SBIR + STTR Programs:



Air Force



Army



Navy



Defense Advanced Research Projects Agency



Office of the Secretary of Defense



Special
Operations
Command



Defense Health Agency



Missile Defense Agency



Joint S&T Office for Chemical and Biological Defense

SBIR Program only:



Defense Microelectronics Activity



National Geospatial Agency



Defense Threat Reduction Agency



Defense Logistics Agency





SBIR Eligibility



- For-profit; based in U.S.
- 500 employees or fewer
- 51% U.S.-owned; controlled by individuals
- Min. 2/3 of Phase I effort and 1/2 of Phase II effort performed by small business
- Principal Investigator's primary employment must be with the small business





U.S.ARMY)

SBIR Eligibility



- Same size, control, and benchmark requirements as SBIR
- Formal cooperative R&D effort
 - Min. 40% by small business
 - Min. 30% by U.S. Research Institution
- U.S. Research Institution (partner):
 - College or university
 - Federally Funded Research and Development Centers
 - Not Government-run labs







Army & DHA SBIR/STTR Process Flow



Topics

Phase I



The State of the Control of the Cont

DoD Solicitations

SBIR: YY.1, YY.2, and YY.3 STTR: YY.A, YY.B, and YY.C



Proof of Concept \$150K, 6 months

Army SBIR only: \$100K, 6 months + \$50K Option, 4 months

Phase II



Prototype
Development
\$1M, 2 years

Phase III



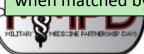
Commercialization

Transition to Government or private industry

No SBIR Funds

No funding or time limits

PH II Enhancement = \$500K SBIR funding may be committed when matched by a qualified \$500K non-SBIR investment.





DoD SBIR/STTR Solicitations



A DoD SBIR/STTR Solicitation includes:

- DoD Instructions
- Service/Component
 Unique Instructions
- Topics

SBIR 17.1 STTR 17.A

Pre-Release 30 Nov 16

Open 10 Jan 17

Close 8 Feb 17

SBIR 17.2 STTR 17.B

Pre-Release 21 Apr 17

Open 23 May 17

Close 21 Jun 17

SBIR 17.3 STTR 17.C

Pre-Release 25 Aug 17

Open 26 Sep 17

Close 25 Oct 17

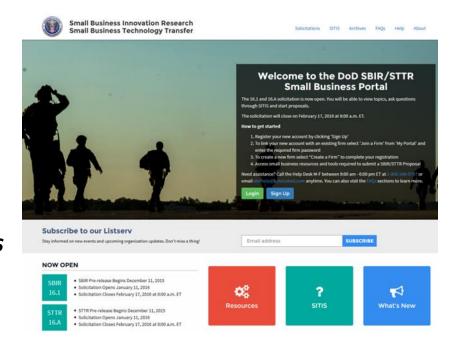




Proposal Submission



- A SBIR/STTR Phase I or Phase II
 proposal to <u>any</u> DoD Component must
 be submitted through the DoD
 Submission System
 https://sbir.defensebusiness.org
- Search topics:
 https://sbir.defensebusiness.org/topics
- Topics Q&A (SITIS): https://sbir.defensebusiness.org/sitis







SBIR/STTR Resources



DoD SBIR/STTR Resources

- Program Overview
- Current/ Past Solicitations
- Program Reports
- News
- Doing Business with DoD









SBIR/STTR Resources



SBA's SBIR/STTR Hub

Search for:

- Applicant Instructions
- Awardee Information
- Investors
- Large Businesses
- Agencies
- Policy Directives



www.sbir.gov





USAMRMC SBIR/STTR Contacts



SBIR/STTR Project Manager

(301) 619-7377

SBIR/STTR Deputy Project Manager

(301) 619-3719

MRMC SBIR/STTR Operations Manager

(301) 619-5047

DHA SBIR/STTR Program Analyst

(301) 619-5146

TBD- Army SBIR/STTR Program Analyst

TBD- Army and DHA SBIR/STTR Technical Assistance Advocate (TAA)





Questions?



For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil



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