

TIER 7 REPORT ON CRADAS AND DoD NON-DILUTIVE FUNDING

Your Company's Strategic Roadmap
to Non-Dilutive DoD Funding



Introduction

Funding opportunities for research and development of biomedical technologies are often overlooked when the source resides outside of the National Institutes of Health (NIH). The U.S. Department of Defense (DoD) has been and remains a major force in financing biomedical research to offer novel technologies that enhance the DoD's mission. Furthermore, collaborating with the DoD offers benefits not only to all parties involved, but also improves the lives of our military personnel, Veterans and their families.

Technologies for Human Weapon Systems

Through a combination of intellectual, psychological, and physical components, the human system is the most adaptive and effective weapon system available. Measures taken to promote, improve, or conserve the physical and mental well-being of Service members is known as Force Health Protection (FHP), and characterizes every Service member as a human weapon system (HWS).¹

Our country's human performance doctrine requires support and innovation in performance sustainment, optimization, and enhancement. Performance sustainment seeks to maintain performance levels while minimizing total life-cycle costs. Performance optimization aims to achieve the most efficient use of limited human resources. Performance enhancement utilizes science and technology that enables Service members to operate beyond established and sustainable performance thresholds. The performance enhancement spectrum ranges from intra-human technologies (e.g., biotechnology, pharmacology) to extra-human technologies (e.g., hardware, software, personnel protective equipment).¹

Innovating Dual-Use (DoD and Civilian) Technologies

Dual-use technologies are products or processes that satisfy military needs while also exhibiting commercial viability in the competitive marketplace.² Many technologies in early stages of development or at lower Technology Readiness Levels (TRLs) can be readily innovated to meet dual-use purposes, while those at more advanced TRL stages originally designed for civilian commercial interests can frequently be innovated or ruggedized to meet required military specifications.

Tier 7's mission is to identify and rapidly deliver dual-use technologies to our country's warfighters. Tier 7 only selects dual-use technologies that will improve healthcare, operational readiness and situational awareness for our warfighters.

DoD Strategic Roadmap Methodology

Tier 7 identifies biomedical technologies that improve the delivery of health care for our active duty personnel, Veterans, and their families, as well as human weapon systems technologies that advance operational readiness and improve situational awareness for our warfighters. We search for dual-use technologies that can be innovated, optimized, or ruggedized to enter DoD, Federal, and International marketplaces. Dual-use technologies that serve the military and civilian communities are of primary interest.

Warfighters and Civilians



The DoD is heavily invested in providing the best health care and technologies for our warfighters. There has been and continues to be an increasing effort to pursue and develop technologies that will not only enhance human performance capabilities, but also those that will assist in maintaining each Service member's optimal physical and psychological health.

Dual-use technologies have applications in both civilian and military populations. Through collaboration, these innovative technologies can be rapidly developed and put to use to improve the lives of civilians and Warfighters.





Creating long-term business opportunities via public-private hybrid relationships are critical for any biomedical and human weapon system technology to reach our warfighters. Tier 7 can assist in those processes.

DoD Support of HWS and Dual-Use Technologies

There are many DoD Commands, Subcommands, divisions, laboratories and medical treatment facilities that support research and development (R&D) of technologies to enhance and improve the capabilities available to our Human Weapon Systems (a few examples from many are listed below):

<u>Air Force</u>	<u>Army</u>	<u>Navy</u>
<p>Air Force Research Lab <u>711th Human Performance Wing (711 HPW)</u> ➤ Human Systems Integration Directorate (HP) ➤ Human Effectiveness Directorate (RH)</p>	<p>Army Research Lab <u>Human Research and Engineering Directorate (HRED)</u> ➤ Soldier Performance ➤ Human Factors Integration ➤ Simulation and Technology Training</p>	<p>Office of Naval Research <u>Code 34: Warfighter Performance Department</u> ➤ Human & Bioengineered Systems Division ➤ Warfighter Protection and Applications Division</p>
<u>Office of the Secretary of Defense (OSD)</u>		
<p>Human Performance, Training & Biosystems (HPT&B) Directorate <u>Human Systems</u> ➤ Protect & Sustainment ➤ Human Systems Integration (HSI) ➤ Social Culture Understanding ➤ Personnel & Training ➤ System Interfaces <u>Medical Research & Engineering</u></p>	<p>Force Health Protection & Readiness (FHP&R) ➤ Civil-Military Medicine ➤ Defense Medical Logistics ➤ Defense Medical Research & Development Program ➤ Deployment Technologies & Support Programs ➤ Force Readiness & Health Assurance ➤ International Health ➤ Medical Countermeasures ➤ Operational Medicine & Medical Force Readiness ➤ Psychological Health Strategic Operations</p>	

Cooperative Research & Development Agreements (CRADAs)

CRADAs are one of the most frequently used mechanisms for facilitating technology transfer (T2) between private industry and DoD labs. A CRADA is a written legal agreement between one or more federal laboratories and one or more non-federal parties. The purpose of this agreement is to leverage each other's resources in order to conduct collaborative R&D that is in alignment with the federal laboratory's mission.

Under a CRADA, federal laboratories may provide non-federal parties with any of the following (*but no funds will be provided from the Federal Lab via a CRADA*):

- | | | |
|-------------|--------------|-------------------------|
| ➤ Personnel | ➤ Facilities | ➤ Intellectual Property |
| ➤ Services | ➤ Equipment | ➤ Other Resources |

Collaboration



Tier 7 identifies companies with dual-use technologies of interest to the DoD and then contacts DoD principal investigators (PIs) with expertise and resources for initiating collaborative research and development (R&D) projects. Tier 7's CRADA development efforts are focused on implementation with military treatment facilities (MTF; n=208) and DoD research laboratories (n=76).

Having a CRADA in place with a military treatment or research facility can greatly increase your company's likelihood of award success when pursuing non-dilutive funding from the DoD.





Non-federal parties may provide any of the above resources in addition to funds.

Benefits to Industry

Private industry benefits from CRADA implementation by building long-term business relationships with the DoD. The CRADA is a straightforward agreement that serves as a non-disclosure agreement (NDA), material transfer agreement (MTA), data sharing agreement, and allows the private company and the DoD PI and their team to collaborate on seeking NDF from DoD and other military assisting Federal Agency sources. Under a CRADA, the non-federal party obtains a non-exclusive, paid-up, royalty-free license for any patents resulting from the collaboration and can negotiate an exclusive or non-exclusive commercial license. A CRADA also provides proprietary information protection. This form of collaboration has repeatedly and significantly increased the likelihood of award success for private industry.

Benefits to Federal Laboratories and MTFs

DoD collaborators on CRADAs benefit from access to private industry resources, expertise, knowledge base and company intellectual property for dual-use innovation purposes. The DoD also benefits from the provision of and integration of new dual-use technologies into the DoD clinical and operational armamentariums. When IP is licensed by industry from the DoD and a CRADA is implemented, the company benefits from access to DoD facilities and expertise in its efforts to bring an embodiment of the licensed invention to market. The DoD benefits from the private sector investment in DoD IP that advance the level of technology maturity.

Economic Impact

Licensing DoD technology can be a growth accelerator for your company. A 2015 study estimated the economic contribution of license agreements between DoD labs and U.S. industry. The study found that 48% of the license agreements had generated sales of products or services or other revenues, generating more than **\$20.4 billion** in total cumulative sales (includes commercial and military sales of new products and services, follow-on R&D contracts, royalties, sublicensee sales, and sales by spin-out or start-up companies). This equates to a 52% increase in total sales from a similar study conducted in 2012. Military product and service sales accounted for **\$3.4 billion**; 17% of total sales and a 162% increase from the 2012 study.³ If your company is interested in licensing DoD technology, Tier 7 can connect you to the experts at TechLink.

It is commonly assumed that large defense contractors or other large corporations are the primary DoD T2 partners. However, small businesses (i.e., those with fewer than 500 employees) were found to account for 83% of DoD license agreements which generated revenue. Furthermore, within the small business category, “very small” companies (i.e., fewer than 10 employees) constituted the largest subcategory (42%).³

DoD Non-Dilutive Funding (NDF)

Research Grants

Unlike the National Institutes of Health (NIH), National Science Foundation (NSF), and some other federal grant-awarding agencies, DoD grants are technically contracts

Creating a Competitive Edge



Tier 7’s mission is to identify and prioritize lesser-known, unique, and underutilized non-dilutive funding mechanisms to increase the likelihood of award success.

Even though the DoD has received more than twice as many SBIR and STTR applications each year than the NIH, the DoD has a consistently higher rate of award success.

Our FY16 focus areas fall into three technology areas: Personal Protective Equipment (PPE), Sensors & Internet of Things (IoT), and Traumatic Brain Injury (TBI).





– they are legally binding and therefore require a more detailed structure and offer less flexibility in how awarded funds are utilized.¹ In addition, your company’s existing track record (i.e., past performance references), as well as established relationships with DoD researchers can carry a lot of weight during the review of a grant proposal. Most DoD grants can be found on Grants.gov and FedBizOpps.gov. Typically, for most DoD funding programs there is a two-stage process: first a white paper, concept paper or pre-proposal is submitted, and the highest-rated offerors are then invited by a letter of invitation to submit a full application.

Funding Targeted for Small Businesses

RAPID INNOVATION FUND (RIF)

The goal of the DoD RIF is to “transition small business technologies into defense acquisition programs.”⁴ Over the history of the RIF program, 89% of all awards have gone to small businesses. The average award amount is \$2.1 million, with a maximum of \$3 million. There are topic components for the Army, Navy, Air Force, and Office of the Secretary of Defense (OSD). Typically, the majority of DoD RIF topics are heavily line-focused (i.e., non-medical topics), but \$250M was available in FY16.

DOD SBIR & STTR

Under the U.S. Government Small Business Innovation Research (SBIR) program, all federal agencies with extramural research budgets greater than \$100M must have a percentage of that budget reserved for contracts or grants to small businesses. For FY16, this percentage was ≥ 3.0% and will increase to ≥ 3.2% for FY17. The Small Business Technology Transfer (STTR) program is similar – it funds cooperative R&D projects with small businesses in collaboration with universities and other not-for-profit research institutions. Federal agencies with extramural budgets exceeding \$1B must reserve 0.45% of their funds allocated for advancing STTR projects.

Financial Impact

The FY16 DoD budget request recommended a 0.1% increase for Science & Technology (S&T) over the FY15 estimate- a \$12.3B budget.⁵ Human Systems is one of the current DoD S&T priorities.

FY 2015 DOD SPENDING⁶

CFDA	Service	Grants	Total
12.300 – Basic and Applied Scientific Research	Navy	4,710	\$696,359,770
12.340 – Naval Medical Research and Development	Navy	4	\$6,025,180
12.360 – Research on Chemical and Biological Defense	Army	18	\$10,772,495
12.420 – Military Medical Research and Development	Army	2,498	\$965,133,861
12.431 – Basic Scientific Research	Army	2,200	\$462,477,746
12.630 – Basic, Applied, and Advanced Research in Science and Engineering	Army	446	\$199,709,666
12.750 – Uniformed Services University Medical Research Programs	DoD	205	\$295,681,597
12.800 – Air Force Defense Research Sciences Program	Air Force	1,627	\$437,698,665
12.910 – Research and Technology Development	DARPA	468	\$204,554,433

Innovative Technologies



Biomedical areas of interest include informatics, computational biology, simulation and training; clinical and rehabilitative medicine; combat casualty care; environmental toxicology and chemical countermeasures; health information systems and technology; medical radiological defense; military infectious diseases and biological countermeasures; and military operational medicine.

Areas of interest within Human Systems includes personnel, training, and leader development; protection, sustainment, and physical performance; social, cultural, and behavioral understanding; and system interfaces and cognitive processing.





Key Strategic Findings

Tier 7's Competitive Position

Tier 7 is unique in providing a combination of services to include:

- Identification of DoD researchers for collaboration with private industry;
- CRADA development at no cost to private companies (focused on seed and early stage small businesses and some medium sized companies);
- Broad knowledge of lesser-known, unique and underutilized DoD NDF mechanisms;
- Knowledge of distribution, procurement and acquisition mechanisms for entering DoD and international markets.

CRADAs

CRADAs are frequently utilized by the “line” (e.g., weapon technologies) side of industry. However, CRADAs are underutilized by companies collaborating with the DoD for biomedical or operational medicine purposes. Thousands of U.S. companies with dual-use technologies could benefit from developing a CRADA relationship with one or more DoD services. However, implementing a dual-use innovation or new product development program can require company-wide change in culture, business approach, and organizational structure when entering the Federal procurement/acquisition markets. Tier 7 can provide R&D assessment and other services to enable the implementation of effective CRADAs and assist with expanding the company's market base. Tier 7 has a seven-year contracted services agreement that started in 2014 between Montana State University and its DoD non-profit partnership intermediary entity, TechLink, to provide CRADA development and implementation services. Tier 7 identifies companies with dual-use technologies of interest to the DoD and establishes CRADAs at no charge to the company.

DoD NDF

Tier 7 focuses on lesser-known, unique and underutilized DoD and other military assisting Federal Agency solicitation mechanisms. Companies have elected to engage Tier 7 for consulting purposes with or without previously developing a CRADA. Tier 7 consulting services include biomedical and DoD business development and assistance with obtaining NDF from DoD and other military assisting Federal Agencies (non-NIH). Companies receiving NDF have achieved higher rates of long-term business success. NDF consulting services are of primary interest to companies, but companies should consider pursuing the inherent value of CRADAs and that partnering with a DoD PI leads to an increased likelihood of NDF award.

Submit a White Paper

If you are developing an innovative technology in one of our focus areas, we want to hear from you. Please visit www.tier7.us/submit-white-paper/ to submit a white paper. Tier 7 does not provide marketing, sales, procurement, or acquisition services for companies interested in increasing the sales of an existing product or service to DoD or other military assisting Federal Agencies. Priority will be given to novel or incremental innovations of dual-use biomedical, operational readiness, and situational awareness technologies that can benefit our warfighters, Veterans and their families.

Roadmap to Success



Tier 7 delineates methods to innovate, optimize, or ruggedize your technologies to meet dual-use requirements. We also increase the visibility and awareness of innovative biomedical and operational technologies via demonstrations, conferences, presentations, DoD/Federal roadshows, and publications.

CRADAs with an estimated value to the DoD and Industry of over \$1.5M have been established between 2013 and 2015.

In 2015, 75% of full applications submitted by Tier 7 and Industry received awards, totaling over \$2.6M in funding.





References

1. Tvaryanas, A. P., Brown, L., & Miller, N. L. (2009). Managing the Human Weapon System: A Vision for an Air Force Human-Performance Doctrine. *Air & Space Power Journal*, 23(2), 34-41.
2. White, R. H., Bell, J. P., Hauger, J. S., Nash, M. S., Roberson, M., Tai, A., & Ziemke, C. (1996). *A Survey of Dual-Use Issues*. Defense Advanced Research Projects Agency. Alexandria, VA: Institute for Defense Analyses.
3. TechLink and University of Colorado Business Research Division. (2016). *National Economic Impacts from DoD License Agreements with U.S. Industry, 2000-2014*. U.S. Department of Defense. Retrieved from <http://techlinkcenter.org/sites/default/files/articles/node-57750-edit/attachments/2016%20DoD%20Licensing%20Study%20E-Publication.pdf>
4. *Rapid Innovation Fund (RIF) Program, Program Overview*. (2016, March). Retrieved from Defense Innovation Marketplace: http://www.defenseinnovationmarketplace.mil/resources/RIF_Overview_Mar2016.pdf
5. Vetterkind, M. (2016). Chapter 11: Department of Defense. In *The President's FY 2016 Budget*. AAAS. Retrieved from <http://www.aaas.org/fy16budget/departement-defense>
6. (2016). Retrieved July 2016, from USAspending.gov: www.usaspending.gov